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Embrace Treatment | Empower Prevention | Advance Innovation

ABSTRACT BOOK

Promosso da



e da

INMI, Istituto Nazionale per le Malattie Infettive
Lazzaro Spallanzani IRCCS
ISS, Istituto Superiore di Sanità
AMCLI, Associazione Microbiologi Clinici Italiani
SIICA, Società Italiana di Immunologia, Immunologia
Clinica e Allergologia

SIMaST, Società Interdisciplinare per lo Studio delle
Malattie Sessualmente Trasmissibili
SITA, Società Italiana per la Terapia Antinfettiva
Antibatterica Antivirale Antifungina
SIV-ISV, Società Italiana di Virologia - Italian Society
for Virology
ANLAIDS, Associazione Nazionale per la Lotta
contro l'AIDS ETS
ARCIGAY, Associazione LGBTQIA+ Italiana APS
ARCOBALENO Aids ODV
ASA, Associazione Solidarietà AIDS-ODV

C.I.C.A., Coordinamento Italiano delle case alloggio
per persone con HIV/AIDS ETS
EpaC, Associazione EpaC ETS
LILA, Lega Italiana per la Lotta contro l'AIDS Onlus
Mario Mieli, Circolo Cultura Omosessuale Mario
Mieli APS
Milano Checkpoint, Associazione Milano
Checkpoint ETS
NADIR, Associazione Nadir ETS
NPS Italia, Network Persone Sieropositive APS
PLUS, Rete persone LGBT+ sieropositive APS



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Index of Presenting Author

Name	page	Name	page
Lorenzo	Abbate 240	Bianca	Bruzzone 220
Francesca	Abrescia 290	Andrea	Buzzi 339
Tezete Evet	Adeola 150	Chiara	Cacace 359
Beatrice	Allegretti 336	Filippo	Calandra Buonauro 257
Tiziano Giacomo	Allice 52	Giulia Valeria	Calvino 188
Rebecca	Alpo 337	Leonardo	Calza 273, 275
Emilio	Altavilla 271	Marta	Camici 101
Lorenzo	Ansaldo 98	Giada	Canavesi 321
Michele	Antonacci 242	Caterina	Candela 236
Antonella	Antonino 200	Sara	Cannella 366
Caterina	Antonucci 44	Carla	Capasso 368
Daniele	Armenia 53	Anna Giulia	Cappagli 201
Stefania	Arsuffi 141	Anna	Carraro 107
Teresa	Asciore 308	Enrico	Caruso 35
Matteo	Augello 45	Aurelio	Castro 7, 140, 143
Alessandra	Bailoni 71	Gaia	Catalano 247
Nicholas Brian	Bana 106, 120, 216	Bianca	Catania 282
Ambra	Barco 144	Sara	Caucci 192
Francesco	Bassani 104	Eugenio Nelson	Cavallari 317
Sara	Belladonna 131	Anna	Cavallaro 178
Maria Carolina	Benvenuto 331	Albiana	Cekrezi 299
Annalisa	Bergna 21	Danilo	Cereda 80
Alessandra Maria	Bianchi 27, 124	Federica	Cerigi 330
Alice	Bilotta 14	Adriana	Cervo 17, 229
Alice	Bilotta 162	Federico	Cesanelli 253
Valentina	Bleve 237	Alice	Chinelli 61
Valeria	Bono 70	Antonio	Cianciaruso 291
Veronica	Bordoni 251	Arturo	Ciccullo 43, 74, 171
Alberto	Borghetti 314	Isabella	Ciciolla 199
Luca	Bortolani 12, 157	Tommaso	Clemente 54, 65, 121
Giuseppe Maria	Bottino 241	Viola	Cogliandro 118, 145
Giorgio	Bozzi 358	Luna	Colagrossi 315
Valeria	Brogna 238, 284	Silvia	Colaiuda 281
Luisa	Brogonzoli 212, 233	Nicola	Colavito 151
Elena	Bruzzesi 67	Gaia	Cologgi 102, 103

Index of Presenting Author

Name	page	Name	page
Anna	Colucci 182, 191, 214	Marco	Falaguasta 205
Claudia	Conti 258	Chiara	Fanelli 369
Crescenzo	Coppola 295, 322	Damiano	Farinacci 34
Maria Luisa	Cosmaro 312	Laura	Fernandez 10
Maria Vittoria	Cossu 117, 179, 267	Micol	Ferrara 78
Lorenzo	Costacurta 48	Ludovica	Ferrari 319
Lorenzo	Costacurta 279	Raffaele	Ferri 136
Gianluca	Cruschelli 109	Giovanni	Festa 56
Gianluca	Cuomo 217	Lia	Fiaschi 20
Jessica	Cusato 293	Benedetta	Fioretti 8
Giulio	D'Agati 226	Alemju	Fontu 196
Myriam	d'Amato 341	Giuseppe	Formica 123, 147
Stefano	D'Anna 55	Andrea	Forni 87
Antonella	d'Arminio Monforte 159	Giorgia	Fracca 186, 187, 202
Mario	D'Auria 269	Alessandro	Franzò 154
Sara	De Biasi 47	Nicoletta	Frattoni 208
Simone	De Giorgi 246	Francesco Maria	Fusco 311
Sara Giovanna	De Maria 165	Chiara	Fusetti 26, 213
Ludovica	De Martino 266	Roberta	Gagliardini 41, 79
Martina	De Sanctis 228	Rosario	Galipò 206
Andrea	De Vito 32, 73	Antonella	Gallicchio 252
Cristina	De Vivo 262	Giada	Garzillo 126
Melania	Degli Antoni 160	Andrea	Gasperin 161
Giulia	Del Duca 239, 298	Sonia	Generoso 232
Vito Leonardo	Del Negro 88	Andrea	Giacomelli 40, 49, 276
Carla	della Ventura 95	Laura	Gianserra 329
Elisabetta	Delmonte 175	Claudia	Gioé 19
Giacomo	Dessi 184, 305	Eugenia	Giuliani 343
Laura	Di Clemente 355, 362	Massimo	Giuliani 37
Dario	Diana 169	Marianna	Giurco 105
Stefania	Dispinseri 96	Andrea	Gizzi 155
Federica	Dominelli 243	Chiara	Grillo 256
Micaela	Donnini 97	Ilaria	Grossi 16
Maria	Dorrucci 139	Giovanni	Guaraldi 185
Josefina Maria	Faiella Marsengo 230	Mariasilvia	Guardiani 46

Index of Presenting Author

Name			page	Name			page
Marta	Guastavigna	110	Giulia	Micheli	33, 36, 114		
Miriam	Inverardi	346	Jovana	Milic	51, 69		
Valgjine	Kelmendi	280	Carola	Minet	347		
Filippo	Lagi	152, 255	Brunella	Mocci	218		
Massimiliano	Lanzafame	227	Giulia	Moi	135		
Elisabetta	Lazzari	361	Sara	Moriconi	225		
Samuel	Lazzarin	176	Manuela	Morosi	86, 100		
Alessandro	Lazzaro	92	Davide	Moschese	30, 209, 304, 335		
Martina	Leone	112	Marco	Munarini	235		
Davide	Leoni	320	Enrico	Mura	183, 193		
Sonia	Lerta	270	Elena	Muresu	203		
Gabriele	Loi	66, 77	Ilaria	Mussetto	338		
Laura	Loiacono	245	Liudmila	Nekrasova	29, 313, 324		
Francesca	Lombardi	116, 138	Gloria	Notore	211		
Miriana	Lucente	91	Ottavia	Nozza	219		
Donatella	Maddalena	325	Sara	Occhineri	82		
Luca	Maddaloni	58	Chiara	Orlandi	316		
Greta	Maffeis	303	Gian Carlo	Orofino	148, 352		
Alessia	Magnapera	260	Luciano	Pacelli	360		
Francesca	Marinacci	149	Simone	Pagano	294		
Domenico	Marrali	153	Layla	Pagnucco	261, 265, 328, 367		
Domenico	Martinelli	332	Claudia	Palazzolo	350		
Salvatore	Martini	166	Alessandra	Palomba	268		
Martina	Maruotto	24	Martina	Paoletti	296		
Giovanni	Massobrio	163	Chiara	Papalini	274		
Maddalena	Matone	174	Anna	Parodi	234		
Elena	Matteini	173	Carmelo	Parrotta	263		
Sandro	Mattioli	181, 302	Patrizia	Pasculli	342, 364		
Martina	Mazzoccoli	146	Flavia	Passini	345		
Marco	Mazzoni	130	Andrea	Pastena	310		
Valentina	Mazzotta	31, 81, 99	Michele Salvatore	Paternò Raddusa	288		
Paolo	Meli	11	Silvia	Pauciullo	93		
Marianna	Menzio	9, 18, 84	Andrea	Pedot	168		
Ilaria	Mercurio	63	Caterina	Pellegris	60		
Giuliana	Metrangolo	309	Sabrina	Penon	85		

Index of Presenting Author

Name	page	Name	page
Margherita Pernich	210	Francesco Vladimiro Segala	170
Maria Raffaella Petrara	6	Tosca Semenzin	180
Giovanna Picchi	307	Lorenzo Serroni	156
Lorenzo Piermatteo	356	Francesco Siviero	340
Luigi Pisano	318	Flavia Smoquina	363, 365
Pierluca Piselli	13, 108, 113	Alessandro Soria	25
Francesca Pratavia	122	Serena Spampinato	222, 254, 259
Lucia Pugliese	189	Vito Speciale	158
Giulia Quartini	283	Nicola Squillace	75, 286, 289
Angelo Roberto Raccagni	223, 301, 333, 334	Rossana Starace	292
Laura Amelia Rachele Rancilio	177	Federica Stefanelli	128, 132, 133
Nadia Randazzo	357	Rebecca Jo Steiner	39
Alice Ranzani	306	Marco Stizioli	190
Stefano Rapino	195, 354	Marta Stracuzzi	272, 353
Vincenza Regine	64	Chiara Taibi	224
Anna Repishti	125	Maciej Stanislaw Tarkowski	349
Semela Resuli	231	Gianluca Bruno Tassone	127
Michela Rigoni	323	Paolo Marco Testoni	62
Diego Ripamonti	72, 167, 250	Marianna Ticozzelli	244
Annunziata Ilenia Ritacco	348	Giorgio Tiecco	90
Agostino Riva	142	Golnaz Torkjazi	50
Salvatore Giuseppe Rizzello	287	Caterina Tramontozzi	23
Annunziata Romeo	207	Marcello Trizzino	285
Roberto Rossotti	57, 326	Eleonora Vania	119
Gabriella Rozera	22	Serena Venturelli	89, 300
Antonio Russo	28, 94, 197	Alessandra Vergori	42, 115
Daria Russo	204	Francesca Vignale	172
Valentina Sala	83	Alex Viguerie	134
Lorenzo Salmoni	15, 249, 277	Simone Villa	137
Federica Salvati	344	Serena Vita	194, 248
Martina Salvi	278, 327	Drieda Zace	111
Pierluigi Francesco Salvo	68, 76	Emanuela Zappulo	38
Paola Sammarco	215	Maria Antonella Zingaropoli	59, 129
Valentina Santoiemma	164	Alberto Zuppioli	264
Daniela Segala	198, 221, 297, 351		

Aging with HIV: survival is not enough

OC 1 COMPREHENSIVE AGING PROFILE IN ELDERLY PEOPLE LIVING WITH HIV

M.R. Petrara¹, S. Pavanello², L. Sasset³, E. Ruffoni¹, L. Cannella², F. Carmona¹, M. Morello¹, L. Calandrino³, S. Cancian³, E. Masetto⁴, M. Campisi², S. De Vidi², A. De Rossi⁵, S. Giunco⁵, A.M. Cattelan³

¹Immunology and Diagnostic Molecular Oncology Unit, Veneto Institute of Oncology IOV – IRCCS, Padova, Italy, ²Department of Cardiac, Thoracic, and Vascular Sciences and Public Health, University of Padova, Padua, Italy; Occupational Medicine Unit, University Hospital of Padua, Padova, Italy, ³Infectious and Tropical Diseases Unit, Padova University Hospital, Padova, Italy, ⁴Clinical Trials and Biostatistics Unit, Veneto Institute of Oncology IOV–IRCCS, Padova, Italy, ⁵Oncology and Immunology Section, Department of Surgery, Oncology and Gastroenterology, University of Padova, Italy

Background: There is growing global concern about the increasing proportion of elderly people living with HIV (EP-LWH). Compared with the general population, EP-LWH have a higher risk of developing age-related diseases, including malignancies. However, comprehensive biomarkers defining the aging profile in this population are still lacking. The identification of reliable aging biomarkers is critical for optimizing routine clinical monitoring and management of this high-risk population.

Patients and Methods: 58 EP-LWH (median [interquartile range-IQR] age 70 [67-74] years, median time of infection 21 [14-23] years, and median time on ART 20 [13-24] years) were included in the study and compared with 28 age-matched (71 [66-77] years) HIV-negative elderly controls (EP-NoLWH). The immune aging profile (including activated, exhausted and senescent CD4 and CD8 T-cell subsets) was analyzed by flow cytometry. Relative telomere length and HIV-DNA in PBMC were measured by multiplex real-time PCR and ddPCR, respectively. Circulating denervation biomarkers NCAM-1 (neural cell adhesion molecule 1) and CAF (C-terminal Agrin Fragment), associated with aging and sarcopenia, were assessed by ELISA. DNA methylation age (DNAmAge) was determined using the 5-CpG epigenetic clock panel by pyrosequencing. Statistical analyses were performed using RStudio software and data were adjusted by age.

Results: EP-LWH had significantly higher percentages of activated, exhausted and senescent CD4 and CD8 T cells, higher circulating levels of CAF and NCAM-1 and shorter telomeres compared to EP-NoLWH (Table 1). Moreover, EP-LWH exhibited a significantly higher DNAmAge than EP-NoLWH, consistent with an accelerated epigenetic aging profile (Table 1). The overall percentage of reported cancers did not significantly differ (26% vs 21%) between the two groups; however, EP-LWH developed cancer at a younger chronological age than EP-NoLWH (mean age 61 vs 67 years).

Conclusion: Overall, these results indicate that, despite long-term antiretroviral therapy, the lifelong persistence of HIV, likely through chronic immune activation, induces an accelerated and multidimensional aging profile compared with the general elderly population, and may contribute to an earlier onset of cancer.

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Aging with HIV: survival is not enough

OC 2 MAPPING OF PSYCHOSOCIAL AND RELATIONAL DETERMINANTS OF HEALTHY AGING IN PEOPLE LIVING WITH HIV: THE ITALIAN HEALTHY AGING SURVEY

A. Castro², G. Giupponi³, P. Meli⁴, M. Farinella⁵, F. Von Schloesser⁶, S. Patrucco⁷, D. Masci⁸, M. Stagnitta⁹, M. Cernuschi¹⁰, L. Butini¹¹, A. Moznich¹², S. Cecere¹³, H. Gebdo¹⁴, G. Guaraldi¹

¹University di Modena e Reggio Emilia, Modena, Italy, ²University di Milano Bicocca, Milan, Italy, ³LILA Naz Como Italy, ⁴CICA, Milano, Italy, ⁵Circolo di Cultura Omosessuale Mario Mieli Roma, Italy, ⁶NADIR Roma Italy, ⁷Arcobaleno Aids Torino Italy, ⁸Fondazione Villa Maraini Roma Italy, ⁹CNCA Roma Italy, ¹⁰ASA Milano Italy, ¹¹Anlaids Roma Italy, ¹²NPS Italia Milan Italy, ¹³Plus-rete Persone LGBT+ Sieropositivo Bologna Italy, ¹⁴CDCP Trieste Italy

Background: The progressive ageing of people living with HIV (PWH) represents one of the major transformations of the epidemic in Italy. However, national data integrating quality of life, psychosocial wellbeing, stigma, intimacy, and satisfaction with health and welfare systems remain limited. The Ministerial Project “Healthy Aging in People with HIV” aimed to map, at a national level, the multidimensional needs of PWH aged ≥50 years and to operationalize the concept of healthy aging.

Materials and Methods: This study reports the results of the Italian Ministerial Project “Healthy Aging in People with HIV”, conducted in collaboration between the Azienda Ospedaliero-Universitaria Policlinico di Modena and 12 Italian HIV community-based associations.

In February 2026, a national quali-quantitative survey was administered via Qualtrics to PWH aged ≥50 years across Italy. All individuals aged ≥50 years were eligible. Participants were stratified into two age groups: 50–64 years and ≥65 years.

The survey was developed from prior focus groups and included validated instruments assessing: health-related quality of life (EQ-5D-5L), attitudes toward aging, loneliness, HIV-related stigma, satisfaction with healthcare services and welfare systems, affective/sexual satisfaction, housing preferences, and bio-psycho-social-legal needs.

Results: The sample included N= 472 (139 women, 331 men, 2 non-binary; mean age 59.3±8 years; mean duration of HIV infection 23.9±12 years) people.

Participants aged ≥65 years reported significantly lower health-related quality of life compared to those aged 50–64 and were more likely to perceive aging as a “time of loss”.

Loneliness showed a strong positive association with perceiving aging as loss and a negative association with perceiving aging as growth ($R^2=-0.23$, $p<0.001$) or change. Longer duration of HIV infection was modestly associated with both perceiving aging as loss and growth, suggesting a complex adaptation trajectory.

Regarding intimacy, affective satisfaction was reported more frequently than sexual satisfaction (52.2% vs 41%). Difficulties in finding sexual partners were reported by 34.2% of participants, while 27.8% reported difficulties in establishing emotional relationships. Only 30.2% felt comfortable disclosing their HIV status to partners and 32.3% felt at ease in intimate communication. Nearly one-third reported having reduced or avoided emotional (29%) and/or sexual (25%) relationships.

Conclusions: This first national mapping of psychosocial and relational needs among older PWH in Italy highlights loneliness, stigma, and intimacy challenges as key determinants of healthy aging. In the HIV context, healthy aging emerges as a multidimensional construct integrating physical health, psychological wellbeing, relational fulfillment, and system-level support. These findings provide an evidence base to inform person-centered care models, community empowerment strategies, and tailored policy reforms.

Aging with HIV: survival is not enough

OC 3 POLYPHARMACY AND GENDER-SPECIFIC VULNERABILITY TO COGNITIVE AND PHYSICAL FUNCTION AMONG OLDER PEOPLE LIVING WITH HIV: DATA FROM GEPPPO COHORT

B. Fioretti¹, S. Calza², A. Salvini³, S. Arsuffi¹, C. Candela⁴, B.M. Celesia⁵, P. Bonfanti⁶, M. Ferrara⁷, A. Cattelan⁸, G. Madeddu⁹, G. De Socio¹⁰, G. Orofino¹¹, A. Calcagno¹², G. Guaraldi¹³, A. Marengoni³, E. Foca¹

¹Division of Infectious and Tropical Diseases, Department of Clinical and Experimental Sciences, University of Brescia and ASST Spedali Civili of Brescia, Brescia, Italy,

²Unit of Biostatistics and Bioinformatics, Department of Molecular and Translational Medicine, University of Brescia, Brescia, Italy, ³Division of Geriatric Medicine, Department of Clinical and Experimental Sciences, University of Brescia and ASST Spedali Civili of Brescia, Brescia, Italy, ⁴Clinic of Infectious Diseases, San Raffaele Scientific Institute, Milano, Italy, ⁵ARNAS 'Garibaldi' UOC Malattie Infettive Catania, Catania, Italy, ⁶Clinic of Infectious Diseases, IRCCS San Gerardo dei Tintori, ALA Milano Onlus and School of Medicine, University of Milan-Bicocca, Monza, Italy, ⁷Unit of Infectious Diseases, Department of Medical Sciences, Amedeo di Savoia Hospital, University of Torino, Italy, ⁸Infectious and Tropical Diseases Unit, Padua University Hospital, Padova, Italy, ⁹Unit of Infectious Diseases, Department of Medical, Surgical and Experimental Science, University of Sassari, Sassari, Italy, ¹⁰Department of Medicine, Clinic of Infectious Diseases, University of Perugia, Perugia, Italy, ¹¹Unit of Infectious Diseases, «Division A», Ospedale Amedeo di Savoia, Turin, Italy, ¹²Division of Infectious Diseases, Department of Translational medicine, UPO - Università del Piemonte Orientale, Novara, Italy, ¹³Department of Surgical, Medical, Dental and Morphological Sciences, University of Modena and Reggio Emilia, Modena, Italy

Background: People living with HIV (PLWH) aged ≥ 65 years is rapidly increasing. Despite durable virological suppression, persistent immune activation, multimorbidity, and long-term antiretroviral exposure contribute to high rates of polypharmacy, which may negatively affect cognitive and physical performance. However, whether the impact of polypharmacy differs by sex, particularly on cognitive function, remains poorly understood.

Methods: We conducted a cross-sectional analysis within the Italian multicenter GEPPPO cohort including 1,668 PLWH aged 65–95 years. Polypharmacy was defined as ≥ 5 non-ART drugs. Outcomes included cognitive performance (Mini-ACE), depressive symptoms (CES-D), anxiety (HAM-A), physical performance (SPPB), physical activity (IPAQ-E), handgrip strength, and pegboard test. Associations of polypharmacy, sex, and their interaction with outcomes were evaluated using generalized linear models (GLM) with appropriate link functions according to outcome distribution. Models were adjusted for age and relevant clinical covariates.

Results: The cohort included 293 women and 1,375 men, with comparable age (70.1 ± 5.2 vs 69.8 ± 4.6 years; $p=0.3$). Polypharmacy prevalence was 10% in women and 15% in men ($p=0.039$).

Sex differences at univariable level: women showed a less favorable neuropsychological and functional profile, with higher depressive symptom scores (CES-D 17.7 ± 11.3 vs 13.2 ± 9.7 ; $p=0.044$), lower cognitive performance (Mini-ACE 18.5 ± 6.9 vs 24.4 ± 3.7 ; $p=0.019$), lower physical activity levels (IPAQ-E; $p=0.004$), and a markedly higher prevalence of weak handgrip strength (84% vs 13%; $p<0.001$).

Multivariable analyses: male sex was independently associated with better cognitive performance (Mini-ACE $\beta=1.022$; 95% CI 0.365–1.680; $p<0.01$) and higher odds of normal handgrip strength (OR 40.68; 95% CI 15.14–126.66; $p<0.001$) (Figure 1). Polypharmacy was not independently associated with Mini-ACE ($\beta=-0.572$; $p=0.331$), CES-D ($\beta=0.234$; $p=0.363$), handgrip strength (OR 0.54; $p=0.586$), or pegboard performance ($p=0.561$) (Figure 1).

Sex-stratified patterns: Despite the lack of statistically significant interaction terms (all $p>0.2$), women exposed to polypharmacy consistently showed lower cognitive and affective scores compared with men with polypharmacy, suggesting a potential sex-specific vulnerability in cognitive domains.

Conclusions: Among older OPLWH, marked sex differences exist in cognitive and physical domains. While polypharmacy was not independently associated with performance decline in the overall sample, its impact appears clinically more relevant in women, particularly in cognitive and affective domains. These findings support sex-sensitive medication review strategies and multidimensional geriatric assessment in aging PLWH particularly focused on older women.

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Aging with HIV: survival is not enough

OC 4 SEMAGLUTIDE IN PEOPLE WITH HIV: A METABOLIC HEALTH INTERVENTION TOWARD THE FOURTH 90%

M. Menozzi¹, J. Milic², G. Cuomo¹, A. Cervo¹, G. Mancini¹, C. Mussini², G. Guaraldi²

¹Infectious Disease Clinic, Azienda Ospedaliero-Universitaria Policlinico di Modena - Modena HIV Metabolic Clinic, Modena, Italy, ²Infectious Disease Clinic, University of Modena and Reggio Emilia, Modena HIV Metabolic Clinic, Modena Italy

Background: Health-related quality of life (HRQoL) is the fourth 90% target in HIV care, yet remains largely unmet. Antiretroviral therapy (ART) is the only pharmacological intervention consistently shown to improve HRQoL in people with HIV (PWH), while additional gains have mainly been demonstrated through psychosocial or lifestyle interventions. In the general population, glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are associated with modest but significant improvements in HRQoL, particularly in physical and weight-related domains. However, no evidence exists regarding their impact on HRQoL in PWH, who face a disproportionate burden of metabolic comorbidities. We aimed to assess whether GLP-1 therapy may improve HRQoL in this population, alongside metabolic benefits.

Methods: This prospective study included 25 PWH with metabolic complications prescribed semaglutide at the Modena HIV Metabolic Clinic, Italy, from January 2020 to September 2025. Baseline was GLP-1 initiation; follow-up was the latest available visit (≥ 6 months) and included demographics, HIV history, anthropometric and metabolic parameters, liver elastography, lipids, glycemic profile, and cardiovascular risk scores. HRQoL was assessed with EQ-5D-5L and EQ-VAS. Linear regression explored associations between weight loss and HRQoL improvement. We also evaluated the proportion achieving optimal HRQoL ($>90\%$ EQ-5D-5L index).

Results: Participants were mostly male (88%), median age 60 years, median HIV duration 28 years, and with high comorbidity burden (68% diabetes, 56% hypertension). Median follow-up was 388 days. Significant improvements were observed in weight, BMI and visceral adipose tissue, total and LDL cholesterol and CAP (Table1). HRQoL significantly improved: EQ-5D-5L index increased from 0.857 to 0.910 ($\Delta +0.031$; $p < 0.01$). Improvements were evident in pain/discomfort domains and self-rated health (Figure 1). At baseline, 8 patients (32%) had HRQoL $>90\%$. At follow-up, 15 patients (60%) achieved this threshold, a net gain of 28%.

Conclusions: GLP-1 therapy in PWH was associated with improvements in HRQoL, beyond its metabolic benefits. This may represent one of the first pharmacologic interventions after ART to demonstrate a measurable impact on quality of life in this population. These findings suggest GLP-1s could contribute to achieving the fourth 90% UNAIDS target, historically reached mainly through psychosocial approaches.

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Reaching the unreachable: community strategies for HIV testing and care

OC 5 LEVERAGING HARMONISED AND DISAGGREGATED DATA FOR STRONGER COMMUNITY-BASED TESTING RESPONSES: INSIGHTS FROM THE COBATEST NETWORK

L. Fernández-López^{1,2,3}, M. Gogishvili^{1,2}, M. Alarcón^{1,2}, P. Piselli⁴, J. Aceitón^{1,2}, C. Folch^{1,2,3}, and COBATEST Network

¹Centre of Epidemiological Studies of HIV/AIDS and STI of Catalonia (CEEISCAT), Health Department, Generalitat de Catalunya, Badalona, Spain, ²Institute for Health Science Research Germans Trias i Pujol (IGTP), Badalona, Spain, ³CIBER Epidemiología y Salud Pública (CIBERESP), Madrid, Spain, ⁴INMI L. Spallanzani IRCCS, Clinical Epidemiology & Biostatistics Unit - Department of Epidemiology and Preclinical Research, Rome, Italy

Background: The COBATEST Network brings together community-based testing services across Europe, enabling the systematic collection of harmonised and disaggregated data on HIV, viral hepatitis, and sexually transmitted infections. Comprehensive, comparable, and multidimensional data are essential for understanding epidemiological patterns, identifying disparities across key populations, and monitoring the performance of community-based testing services. The recent updates to the COBATEST data collection system—through the EU-funded projects BOOST and CORE—primarily aim to strengthen the network's capacity to capture high quality, standardised information across gender identities, age groups, and overlapping key population categories.

Material and Methods: This analysis includes all 2024 testing visits reported through the COBATEST online data collection tool. Standardised indicators were analysed across HIV, HCV, HBV, and syphilis testing, with results disaggregated by gender, age, and key population. Additional variables on drug use patterns and social vulnerabilities were also examined. Integrated testing practices and intersectionalities between key population were analysed using Venn diagrams.

Results: In 2024, 22,994 testing visits were registered from 73 CBVCT services in 10 European countries. The availability of harmonised, disaggregated data enabled comparisons across demographic and behavioural dimensions. Men who have sex with men, migrants, and people who use drugs were the most frequently tested groups, with notable overlaps between key population categories (Figure 1). Reactivity patterns varied substantially across gender identities and population subgroups, being transgender women and people who inject drugs those consistently showing the highest positivity rates across infections (Table 1). Integrated testing was widely implemented, with nearly 20% of visits including rapid tests for all four infections (Figure 1). Newly introduced variables on drug use provided granular insight into consumption routes, frequency, material sharing, opioid agonist treatment, and homelessness—critical factors for understanding vulnerability and guiding harm reduction strategies.

Conclusions: The 2024 COBATEST dataset demonstrates the value of collecting harmonised, disaggregated information to support evidence-based decision-making in community-based testing. Such data illuminate disparities across populations, uncover intersectional vulnerabilities, and enable cross-country comparability—ultimately strengthening prevention, early diagnosis, and linkage-to-care strategies. Expanding the adoption of standardised tools across to diverse community-based testing services, including harm-reduction services, and further improving completeness of disaggregated data will be key to advancing equitable and integrated infectious disease responses in Europe.

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Reaching the unreachable: community strategies for HIV testing and care

OC 6 THE VALUE OF PROMOTING HEPATITIS AND HIV SCREENING IN HIGH-PREVALENCE POPULATIONS: THE "TEST IN THE CITY" PROJECT

P. Meli¹, I. Mercurio¹, V. Gotti¹, C. Pellegris¹, F. Gritti¹, E. Zanetti¹, F. Maggiolo¹, R. Carissoli², L. Comi³, S. Venturelli³ on behalf of 'Test in the City' Working Group composed by 14 Italian Fast-Track Cities*

¹Cooperativa Don Giuseppe Monticelli/Bergamo Fast-track City Network, Bergamo, Italy, ²Arcigay Bergamo Cives/Bergamo Fast-track City Network, Bergamo, Italy,

³ASST Papa Giovanni XXIII, Bergamo, Italy

*Ancona, Bari, Bergamo, Cremona, Brescia, Firenze, Genova, Milano, Latina, Legnano, Padova, Palermo, Sanremo, Torino

Background: Test in the City involved 14 Italian Fast-Track Cities and addressed high-risk populations: migrants, DU and people over 55. The goal was to implement a screening campaign for hepatitis and HIV, supporting the health system in identifying and taking charge of undiagnosed patients. The tests used are antibody tests for HIV and HCV, and HBsAg for HBV. The project, funded by Gilead Sciences, ran in 2025 and involved third sector organisations, healthcare facilities and institutions.

Materials and Methods: We established a network to share strategies and best practices through monthly meetings. A dedicated website and multilingual communication tools were developed, as well as a data collection method based on a shortened version of the COBATEST questionnaire. Each city identified procedures for referring people with reactive tests to healthcare facilities for confirmatory testing and treatment and promoted screening actions by identifying the best contexts and opportunities at the local level including CPIA, CAS, low-threshold services, embassies, addiction services and community gathering places.

Results: During 2025, 5,572 people were tested, of whom 5,020 were in the target group (Table 1): 84.34% were foreigners (127 countries), 16.4% having been homeless in the last year, 12.71% reported drug use, 11.67% reported not having access to the National Health Service, 63% were male, and the distribution across different age groups was homogeneous, with 14% over 55.

The results show significant incidences for all infections, especially new diagnoses for HBV, in addition to a certain number of people with already known diagnoses (Table 2). Analysis of the characteristics of people tested highlights further significant elements. Being male correlates with reactive tests, particularly for HBV and HCV. Considering age, HBV infection is distributed across all age groups, with a significant incidence in under 44 years; for HCV there is a significant incidence in the 45-54 age group, while for HIV in the 35-54 age group. Not having access to the healthcare system or being homeless correlates significantly with all three infections. The use of psychoactive substances is significant for HIV and HCV. Correlations with geographical origin are widely confirmed (Table 3).

In general, significant indications emerge regarding the relevance of age, origin and the eight of health determinants, largely confirming the hypotheses on which the project was based.

Conclusions: This project points to the most efficient way to achieve the WHO's 2030 goals. The road ahead is certainly difficult, because the populations with the highest prevalence of these infections are difficult to reach. Collaboration between healthcare institutions and the third sector, with targeted approaches, is not only desirable, but absolutely necessary. The findings identify those most at risk and highlight where and how efficiently address undiagnosed cases. The project continues, but it cannot become structural without adequate public financial support.

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Reaching the unreachable: community strategies for HIV testing and care

OC 7 FROM REGULATION TO IMPLEMENTATION: A CROSS-COUNTRY ECOLOGICAL ANALYSIS OF HIV TESTING FRAMEWORKS AND LATE DIAGNOSIS IN EUROPE

L. Bortolani, A. Lazzaro, F. Alessi, M. Ridolfi, E. Altavilla, V. Bleve, G. Ceccarelli, C.M. Mastroianni, G. d'Ettorre

Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy

Background: Rate of new HIV diagnoses in recent years has remained stable across Europe and proportion of late presentation at diagnosis continues to be high, as highlighted by latest ECDC report. Despite longstanding recommendations to expand routine and community-based testing, cross-country evidence linking national testing frameworks to late diagnosis remains limited. We aimed to assess whether structural and legal characteristics of HIV testing systems are associated with late presentation rates.

Methods: We conducted an ecological cross-sectional study including countries from WHO European Region. Two composite indices were developed a priori: an HIV Test Legal Stringency Index, capturing HIV-specific regulatory requirements (explicit legal mention, HIV-specific consent procedures, written consent, mandatory pre-test counselling), and an HIV Testing Accessibility Index, reflecting structural facilitation (routine offer, indicator-condition guidelines, community testing, self-testing availability, integrated models). Higher scores indicated greater procedural regulation and structural normalization, respectively. Index components were identified through structured review of national legislation and official public health documents in the local language for each country. AI-assisted search tools supported systematic document retrieval, with manual verification of extracted information. Components were coded as binary and summed without weighting. Variables were assessed as of 2024 to ensure temporal alignment. Primary outcome was the country-level proportion of new HIV diagnoses with CD4 <350 cells/mm³, extracted from the ECDC HIV/AIDS Surveillance in Europe 2025 (2024 data). Countries without complete late presentation data were excluded, yielding 42 countries for analysis.

Results: In multivariable models adjusted for geographic macro-area and national HIV incidence rates, higher HIV Testing Accessibility Index scores were independently associated with lower late presentation rates ($p = 0.01$). Each one-point increase in the accessibility score was associated with approximately a 6% lower late presentation rate. In contrast, the legal stringency index was not significantly associated with late diagnosis (Figure 1). Results remained consistent in sensitivity analyses adjusting for testing rates, restricted to the 24 countries with available data.

Conclusions: Our findings suggest that the degree of legal stringency alone may not represent the primary structural barrier to timely HIV diagnosis. Rather, greater accessibility to HIV testing appears to be associated with lower rates of late presentation. These results reinforce need for structured implementation policies aimed at normalizing HIV testing within routine healthcare settings and expanding low-threshold access models. Coordinated advocacy efforts involving clinicians, public health authorities, and policy-makers are essential to translate these findings into scalable testing strategies.

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Reaching the unreachable: community strategies for HIV testing and care

OC 8 CHARACTERISTICS OF INDIVIDUALS TESTED FOR HIV WITHIN COMMUNITY-BASED VOLUNTARY COUNSELLING AND TESTING (CBVCT) ACTIVITIES IN ITALY (2019-2025)

P. Piselli¹, E. Gennaro¹, C. Cimaglia¹, G. Giupponi², L. Fernández-López³, L. Cosmaro⁴, M. Cernuschi⁵, P. Mell⁶, S. Mattioli⁷, N. Frattini⁸, M. Farinella⁹, L. Rancilio¹⁰, I. Pennini¹¹, S. Patrucco¹², A. Camposeragna¹³, D. Masci¹⁴, G. Moi¹⁵, C. Nicoara¹⁶, L. del Negro¹⁷, M. Gogishvili³, A. Caioli¹, S. Leone¹, A. Navarra¹, A. Caraglia¹⁸, E. Girardi¹, for the Working Group of the project "Contribution of the Association to the continuum of care of persons living with HIV and AIDS"

¹INMI L. Spallanzani, Rome, Italy, ²LILA Como, Como, Italy, ³Centre of Epidemiological Studies of HIV/AIDS and STI of Catalonia (CEEISCAT), Health Department, Generalitat de Catalunya, BADALONA, Spain, ⁴LILA Milano, Milan, Italy, ⁵Milano Checkpoint, Milan, Italy, ⁶CICA, Bergamo, Italy, ⁷PLUS, Bologna, Italy, ⁸Associazione Solidarietà AIDS (ASA), Milan, Italy, ⁹Circolo di Cultura Omosessuale "Mario Mieli", Rome, Italy, ¹⁰CARITAS Ambrosiana, Milan, Italy, ¹¹Arcigay, Padua, Italy, ¹²Arcobaleno AIDS, Turin, Italy, ¹³CNCA, Rome, Italy, ¹⁴Fondazione Villa Maraini, Rome, Italy, ¹⁵Movimento Omosessuale Sardo (MOS), Sassari, Italy, ¹⁶Network Persone Sieropositive (NPS) Italia, Milan, Italy, ¹⁷Checkpoint PLUS Roma, Rome, Italy, ¹⁸Ministero della Salute, Rome, Italy

Background and Objectives: The activity of testing for HIV in the context of community-based voluntary counselling and testing (CBVCT) services run by Non-governmental organizations (NGOs) rapidly increased. Our aim was to characterize the number and characteristics of people accessing HIV-testing and the reactivity in the last years (2019 -2025).

Material and Methods: We collect disaggregated data collected from several NGOs offering HIV screening during the period of study (Jan2019-Dec2025). Given the non-standardization of data collection procedures and structure of dataset, in this analysis we consider those variables universally collected which included gender, age, nationality, reason for testing and preliminary result. The number of people to be tested to find one HIV-positive individuals (Number needed to test, NNT) was calculated according to sexual orientation, age and nationality dividing the number of strata-specific tested individuals by the number of reactive tests.

Results: Data from 41 single organizations mainly participating to the COBATEST network from all over Italy were included. Overall 60039 testers were considered, with an increasing number of tests performed starting from 4297 in 2019 up to 12568 tests in 2025 with a minimum of 2946 tests in 2020. The majority were males (66.4%) than females (31.4%), with an overall median age at test of 29 years (interquartile range, IQR: 24-37). Overall, 344 (0.57%) testers resulted HIV-reactive. Persons with a reactive test were older than those with a non-reactive result (33 vs 29, $p < 0.001$). According to gender, females showed a lower prevalence (0.25%), while 0.67% in males (0.85% in MSM/Bisexual males) and higher in transgender persons (6/286, 2.97%) (Table 1). In a subgroup 53276 tests (88.7%) where among other information on nationality those referring a previous test (which overall represent 57.9% of all testers), prevalence was higher in foreigners vs. Italians (1.20% vs 0.47%, $p < 0.001$), and in those referring a previous HIV-test (0.67% vs. 0.45%, $p < 0.001$). Considering the trend of NNT according to sexual orientation MSM/Bisexual male showed a lower number of NNT than Heterosexual that for both groups increased over time up to 2021, while decreasing thereafter (Figure 1). For Italians there was no evident trend over time of NNT change, while the NNT for non-Italian increased over time (Figure 1). NNT was higher for younger individuals and progressively lower in older testers, with no clear trend over time (Figure 1).

Conclusions: NGOs were able to provide an increasing number of testing opportunity for HIV. Sharing data among NGOs with different experiences, target and geographical distribution can provide a more comprehensive and detailed figure able to show data on key-populations and hard to reach groups, often underrepresented in the surveillance data. *Project supported and financed by Italian Ministry of Health: General Direction for Health prevention (ref 4023).

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Evolving liver care in people with and without HIV: prevention, innovation, and long term outcome

OC 9 HIGH DIAGNOSTIC YIELD OF REPEATED HCV SCREENING IN ADDICTION SERVICES: COMPARED FINDINGS FROM TWO LARGE-SCALE CAMPAIGNS IN 2023 AND 2025

A. Bilotta¹, E. Princi¹, S. Babudieri¹, G. Madeddu¹, G. Seu², P. Milia², I. Maida¹

¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ²Azienda Sanitaria Locale (ASL) di Sassari, Sassari, Italy

Background: Addiction Services (SERD) represent a strategic setting for hepatitis C (HCV) screening and early case identification. Screening campaigns performed in 2023 and 2025 provide an opportunity to evaluate changes in the target population, screening performance, and the potential for identifying undiagnosed infections. This study compares the two campaigns to assess how population dynamics and screening coverage influence the detection of new HCV cases.

Materials and Methods: We retrospectively analysed aggregated data from three SERDs in Northern Sardinia. In 2023, anti-HCV screening was universally offered to all patients in care. In 2025, screening targeted only individuals who had been HCV-negative or not previously screened in 2023. Key indicators included overall population size, proportion of patients on opioid substitution therapy, screening coverage, and positivity rates among those tested.

Results: The SERD population increased from 1107 individuals in 2023 to 1474 in 2025 (+32.8%). The proportion of patients receiving opioid substitution therapy (OST) rose from 55.9% (619/1107) to 61.4% (905/1474), corresponding to a 9.8% relative increase and indicating a progressively more complex case-mix (Figure 1).

Screening performance differed between the two campaigns. In 2023, 849 of 1107 patients were screened (coverage 76.7%). In 2025, among 378 individuals eligible for screening, 248 were tested (coverage 65.6%) (Figure 2), suggesting that the growing and more heterogeneous population was increasingly difficult to reach. Despite this, anti-HCV positivity among newly screened individuals in 2025 remained high: 106 of 248 subjects (42.7%). This confirms the presence of a substantial reservoir of previously undiagnosed infection.

The apparent reduction in seroprevalence observed between the two campaigns - from approximately 80% in 2023 to 42.8% in 2025 (Figures 3, 4) - does not reflect a true epidemiological improvement. Rather, it results from the substantial expansion of the SERD population, which now includes a large proportion of individuals whose HCV status is either negative or simply unknown due to lack of testing. As a consequence, the relative weight of known anti-HCV-positive patients decreases within a much larger denominator, leading to an artefactual decline in calculated seroprevalence. The underlying burden of HCV infection within the SERD population therefore remains significant, as demonstrated by the high positivity rate (42.7%) among newly screened individuals in 2025.

Conclusions: Comparison of the 2023 and 2025 screening campaigns highlights major changes in population size and complexity within SERDs, accompanied by a reduction in screening coverage. The persistently high proportion of positive tests among newly screened individuals in 2025 demonstrates the ongoing presence of hidden HCV infection. These findings reinforce the importance of repeated, structured screening initiatives to ensure the emergence of undiagnosed cases and to support HCV elimination efforts within addiction care settings.

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Evolving liver care in people with and without HIV: prevention, innovation, and long term outcome

OC 10 VITAMIN D STATUS AND HEPATIC STEATOSIS IN PEOPLE WITH HIV: EVIDENCE FROM PAIRED MEASUREMENTS

J. Milic^{1,2}, L. Salmoni³, S. Kaleci², L. Gozzi⁴, F. Cinque⁵, T. Albano⁴, M. Ricciardetto⁴, I. Avanzini⁴, E. Delmonte⁴, M. Menozzi⁴, G. Cuomo⁴, G. Mancini⁴, R. Lombardi⁵, C. Mussini^{1,2,4}, G. Sebastiani⁶, G. Guaraldi^{1,2,4}

¹Modena HIV Metabolic Clinic, University of Modena and Reggio Emilia, Modena, Italy, ²Department of Surgical, Medical, Dental and Morphological Sciences, University of Modena and Reggio Emilia, Modena, Italy, ³Department of Mental Health and Public Medicine, Section of Infectious Diseases, University of Campania Luigi Vanvitelli, Naples, Italy, ⁴Clinic for Infectious Diseases, University Hospital of Modena, Modena, Italy, ⁵Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy, ⁶Division of Gastroenterology and Hepatology, and Chronic Viral Illness Service, McGill University Health Centre, Montreal, Canada

Background: Vitamin D insufficiency and metabolic dysfunction-associated steatotic liver disease (MASLD) are highly prevalent in people with HIV (PWH). Evidence suggests vitamin D may modulate hepatic fat accumulation, but data in HIV are limited. We assessed the relationship between serum 25-hydroxyvitamin D [25(OH)D] and hepatic steatosis severity in a prospective cohort with paired transient elastography (TE) and vitamin D measurements.

Methods: We included all clinical observations from the Modena HIV Metabolic Clinic, Italy, where TE (liver stiffness measurement [LSM] and controlled attenuation parameter [CAP]) and serum 25(OH)D were measured concurrently. Demographic, anthropometric, metabolic, and HIV-related data were collected at the same visit. Steatosis was graded by CAP (S0: <248 dB/m, S1: 248–268, S2: 269–279, S3: ≥280). Multivariable mixed-effects linear regression was applied with CAP as the dependent variable, adjusting for age, sex, BMI, waist circumference, diabetes, CD4 count, HIV suppression, and ART class.

Results: A total of 6579 observations from 1614 PWH were analyzed (median age 56 years; 72% male). Baseline characteristics are shown in Table 1. Median follow-up time was 4.10 (Q1, Q3: 1.23, 5.56) years. Among 1614 PWH, liver steatosis was distributed as following: 974 (60.3%) in S0, 199 (12.3%) in S1, 93 (5.8%) in S2, and 348 (21.6%) in S3. A progressive worsening of cardiometabolic profile was observed from S0 to S3 (Table 1). Median BMI and waist circumference increased stepwise (both $p < 0.001$), paralleled by higher prevalence of sedentary lifestyle ($p < 0.001$). HDL cholesterol decreased, while triglycerides, HOMA-IR, and HbA1c increased significantly across groups (all $p < 0.001$), whereas total and LDL cholesterol did not differ significantly. The prevalence of diabetes and hypertension rose progressively (both $p < 0.001$), as did estimated cardiovascular risk by SCORE-2 ($p < 0.001$) (Table 1). In a linear mixed-effects model, higher BMI, larger waist circumference, and lower 25(OH)D levels were independently associated with higher outcome values, while higher CD4 count was associated with lower outcome values (all $p < 0.001$). Age, sex, diabetes, HIV RNA status, and antiretroviral regimen (PI, NNRTI, or INSTI use) were not significantly associated with the outcome (Table 2).

Conclusions: In this large prospective cohort of PWH, vitamin D deficiency was strongly and independently associated with hepatic steatosis severity, even in a setting where supplementation is systematically recommended. These findings support a potential protective role of vitamin D in liver health and underscore the importance of monitoring vitamin D as part of metabolic and hepatic risk assessment in HIV care. Longitudinal and interventional studies are needed to determine whether correcting deficiency can modify MASLD progression in this population.

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Evolving liver care in people with and without HIV: prevention, innovation, and long term outcome

OC 11 CHRONIC HDV INFECTION IS CHARACTERIZED BY DISTINCT PROFILES OF HBSAG ISOFORMS UNDERLYING DIFFERENT DISEASE STAGES

I. Grossi¹, C. Tramontozzi¹, A. Magnapera¹, S. D'Anna¹, E. Dileo², A. Olivero², L. Piermatteo¹, G. Mengozzi², A. Ciancio², A. Loglio³, M. Viganò³, S. Fagioli^{3,4}, P. Colombatto⁵, B. Coco⁵, M.R. Brunetto⁵, D. Angrisani⁶, A. Galeota Lanza⁶, C. Magni⁷, G. Rizzardini⁷, V. Messina⁸, M. Milella⁹, A. Saracino⁹, L. Marinaro¹⁰, G. Cariti¹⁰, V. Cossiga¹¹, F. Morisco¹¹, S. Cretella¹², G. Verucchi¹³, E. Biliotti¹⁴, G. D'Offizi¹⁴, M. Feasi¹⁵, E. Pontali¹⁵, C. Coppola¹⁶, R. Rapetti¹⁷, M. Pirisi¹⁷, A. Izzi¹⁸, T. Santantonio¹⁹, V. Di Marco²⁰, A. Marrone²¹, N. Coppola²², M. Rizzi²³, A.M. Cattelan²⁴, G.A. Niro²⁵, P. Toniutto²⁶, F.R. Ponziani²⁷, L.S. Belli²⁸, A. Federico²⁹, G. Bertino³⁰, M. Barone³¹, M. Puoti³², A. Civolani³³, M. Distefano³⁴, L.A. Surace³⁵, R. Cozzolongo³⁶, E.M. Cela³⁷, E. Teti³⁸, P. Lampertico^{39,40}, T. Stroffolini⁴¹, R. Salpini¹, V. Svicher¹, M. Rizzetto², G.P. Caviglia²

¹Department of Biology, University of Rome Tor Vergata, Rome, Italy, ²Department of Medical Sciences, University of Torino, Turin, Italy, ³Division of Gastroenterology, Hepatology and Transplantation, ASST Papa Giovanni XXIII, Bergamo, Italy, ⁴Gastroenterology, Department of Medicine, University of Milan Bicocca, Milan, Italy, ⁵Department of Clinical and Experimental Medicine, Hepatology and Liver Physiopathology Laboratory and Internal Medicine Unit, University of Pisa, Pisa, Italy, ⁶Hepatology Unit, AORN A. Cardarelli, Naples, Italy, ⁷Division of Infectious Diseases, ASST-FBF-Sacco, Milan, Italy, ⁸Infectious Diseases Unit, AORN Sant'Anna e San Sebastiano, Caserta, Italy, ⁹Clinic of Infectious Diseases, Department of Precision and Regenerative Medicine and Ionian Area, University of Bari "Aldo Moro", Bari, Italy, ¹⁰Clinica Malattie Infettive UniTo, "Ospedale Amedeo di Savoia", Turin, Italy, ¹¹Department of Clinical Medicine and Surgery, Liver and Biliary Diseases Unit, University of Naples "Federico II", Naples, Italy, ¹²Infectious Diseases Unit, Department for Integrated Infectious Risk Management, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy, ¹³Infectious Diseases Unit, Department of Medical and Surgical Sciences, University of Bologna, Bologna, Italy, ¹⁴Infectious Diseases and Hepatology Unit, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ¹⁵Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ¹⁶Unit of Hepatology and Interventional Ultrasonography, Department of Internal Medicine, OORR Area Stabiese, Gragnano, Italy, ¹⁷Internal Medicine, Azienda Ospedaliero-Universitaria "Maggiore Della Carità", Department of Translational Medicine (DiMeT), Università del Piemonte Orientale, Novara, Italy, ¹⁸UOC di malattie infettive emergenti e ad alta contagiosità, Ospedale Cotugno, Naples, Italy, ¹⁹Department of Medical and Surgical Sciences, Infectious Diseases Unit, University of Foggia, Foggia, Italy, ²⁰Section of Gastroenterology and Hepatology, Dipartimento Di Promozione Della Salute, Materno Infantile, Medicina Interna e Specialistica di Eccellenza (PROMISE), University of Palermo, Palermo, Italy, ²¹Department of Advanced Medical and Surgical Sciences, University of Campania "Luigi Vanvitelli", Naples, Italy, ²²Infectious Diseases Unit, Department of Mental Health and Public Medicine, University of Campania "Luigi Vanvitelli", Naples, Italy, ²³SC Infectious Diseases, ASST Papa Giovanni XXIII, Bergamo, Italy, ²⁴Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ²⁵Gastroenterology Unit, Fondazione Casa Sollievo Della Sofferenza IRCCS, San Giovanni Rotondo, Italy, ²⁶Hepatology and Liver Transplant Unit, Azienda Sanitaria Universitaria Integrata di Udine, Udine, Italy, ²⁷Liver Unit, Centro Malattie dell'Apparato Digerente (CEMAD), Medicina Interna e Gastroenterologia, Fondazione Policlinico Universitario Gemelli IRCCS, Rome, Italy, ²⁸Hepatology and Gastroenterology Unit, ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ²⁹Department of Precision Medicine, University of Campania "Luigi Vanvitelli", Naples, Italy, ³⁰Hepatology Unit, University Hospital Policlinico "G. Rodolico - San Marco", Department of Clinical and Experimental Medicine, University of Catania, Catania, Italy, ³¹Gastroenterology Unit, Department of Precision and Regenerative Medicine—Jonian Area—(DiMePre-J), University of Bari "Aldo Moro", Policlinic University Hospital, Bari, Italy, ³²Division of Infectious Diseases, ASST Grande Ospedale Metropolitano Niguarda; Department of Medicine, University of Milan Bicocca, Milan, Italy, ³³Teaching Hospital "Dulio Casula", Azienda Ospedaliero-Universitaria di Cagliari, Cagliari, Italy, ³⁴UOSD Hepatology, Ospedale Umberto I^o, ASP 8 Siracusa, Siracusa, Italy, ³⁵Dipartimento Di Prevenzione, Azienda Sanitaria Provinciale di Catanzaro, Centro di Medicina del Viaggiatore e delle Migrazioni, P. O. Giovanni Paolo II, Lamezia Terme, Italy, ³⁶Gastroenterology Unit, IRCCS "S. De Bellis", Castellana Grotte, Italy, ³⁷Gastroenterology Unit, Riuniti Polyclinic of Foggia, Foggia, Italy, ³⁸Infectious Disease Unit, Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy, ³⁹Division of Gastroenterology and Hepatology, Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ⁴⁰CRC "A. M. and A. Migliavacca" Center for Liver Disease, Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy, ⁴¹Department of Tropical and Infectious Diseases, Policlinico Umberto I, Rome, Italy

Background: Hepatitis B surface antigen (HBsAg) circulates in three isoforms, small (S)-, medium (M)-, and large (L)-HBsAg, which reflect specific steps of HBV life cycle and particle morphogenesis. In the setting of HBV/HDV co-infection, we assessed how HBsAg isoforms relate to markers of viral activity and liver injury in HDV-RNA-positive patients according to different clinical phenotypes.

Methods: This study included 366 viremic patients (n = 229 [62.6%] males; median age 56, IQR 46–62 years; n = 216 [59.0%] native Italians) from the HDV Describe study cohort. Serum S-, M-, and L-HBsAg levels were quantified by ELISA (Beacle Inc., Kyoto, Japan) and correlated with HDV-RNA (Robogene v2, Roboscreen GmbH, Leipzig, Germany), HBcrAg (Fujirebio, Tokyo, Japan), ALT, and liver stiffness measurement (LSM) (Fibroscan, Echosens, Paris, France). Patients' clinical phenotypes included liver cirrhosis, chronic hepatitis D (CHD; HDV-RNA ≥ 3 Log IU/mL), and inactive/mild disease (HDV-RNA < 3 log IU/mL), as previously defined in Caviglia et al. Liver Int 2025.

Results: Median (IQR) HDV-RNA was 5.1 (3.4–6.0) log IU/mL and total HBsAg was 3331 (675–9055) ng/mL, while median (IQR) levels of S-, M-, L-HBsAg were 2686 (483–7234), 538 (92–1467) and 0.75 (0.10–4.50) ng/mL, respectively. Total, S-, M-, L-HBsAg showed positive correlations with HDV-RNA (rs=0.47, 0.47, 0.47, and 0.42, respectively; all p<0.001) and HBcrAg (rs=0.57, 0.56, 0.57, and 0.44, respectively; all p<0.001). Furthermore, total, S-, M-, and L-HBsAg levels were significantly higher in patients with ALT >40U/L compared to those with ALT ≤40 U/L (all p<0.001), whereas only L-HBsAg showed a correlation (albeit modest) with LSM (rs=0.16; p=0.007).

Total, S, M-, L-HBsAg levels varied according to patients' clinical phenotype, with the highest levels observed in high-viremic CHD, followed by cirrhosis and low-viremic CHD. Notably, in multivariate analysis, higher S-HBsAg levels were significantly associated with high-viremic CHD (OR=1.58, 95% CI 1.16–2.15; p=0.003), higher M-HBsAg with liver cirrhosis (OR=1.78, 95% CI 1.04–3.03; p=0.035), while lower L-HBsAg levels were associated with low-viremic CHD (OR=0.38, 95% CI 0.25–0.58; p<0.001).

Conclusions: Total HBsAg levels and HBsAg isoforms correlated with the extent of HDV replication and cytolytic activity. Notably, HBsAg isoforms showed distinct associations across clinical phenotypes, suggesting a differential regulation of HBV envelope proteins in HDV-driven liver disease.

Evolving liver care in people with and without HIV: prevention, innovation, and long term outcome

OC 12 LONG-TERM OUTCOMES IN LIVER TRANSPLANT RECIPIENTS: COMPARISON BETWEEN PATIENTS LIVING WITH AND WITHOUT HIV INFECTION

A. Cervo¹, M. Albertini^{1,2}, F. Casari^{1,2}, J. Milic^{1,2}, B. Catellani³, P. Magistri^{2,3}, E. Franceschini^{1,2}, G.P. Guerrini³, C. Mussini^{1,2}, F. Di Benedetto^{2,3}, G. Guaraldi^{1,2}

¹Clinic of Infectious Diseases, University Hospital of Modena, Modena, Italy, ²Surgical, Medical and Dental Department of Morphological Sciences related to Transplant, Oncology and Regenerative Medicine, University of Modena and Reggio Emilia, Italy, ³Hepato-Pancreato-Biliary Surgery and Liver Transplantation Unit, University Hospital of Modena, Modena, Italy

Background: Liver transplantation (LT) is nowadays increasingly feasible in people with HIV, yet knowledge on long-term outcomes is limited. This study aims to provide a two-decade experience on people with HIV undergoing LT compared to non-HIV recipients.

Methods: Retrospective matched case-control study including all recipients with HIV (RWH) who consecutively underwent LT at the University Hospital of Modena between 2003 and 2024. Each RWH was matched 1:3 with non-HIV recipients using a propensity-score model based on age, sex, MELD, presence of hepatocellular carcinoma (HCC) at transplant, HBV and/or HCV co-infection, and donor age. Long-term graft and recipients' survival, occurrence of acute rejection (AR) and HCC recurrence were evaluated using Kaplan-Meier curves. Predictors of AR were explored using logistic regression.

Results: Eighty-seven liver RWH were included: 88% with history of drug injections, 20% with previous opportunistic infections and a median HIV duration of 25 years (IQR 20-31); at transplant, 95.4% had undetectable HIV RNA with CD4 cell count of 278 cell/mm³ (IQR 201-405). RWH were matched with 261 non-HIV recipients. Baseline characteristics were comparable (median age 53 years, IQR 47-58; 17% females) except for higher prevalence of HCV co-infection among RWH versus non-HIV recipients (93.1% vs 66.7%, $p < 0.01$). Ten-year and 15-year graft survival was 78.7% and 60.1% in RWH vs 81.6% and 72.6% in non-HIV recipients, respectively (Figure 1a); the overall recipients' survival was also comparable both at 10 years (59.6% vs 66.7%) and 15 years (48.9% vs 53.1%) (Figure 1b). HCC recurred in 10% of cases in both groups, with a post-transplant IR of 1.8 (95% CI 1.0-3.5) in HIV vs 1.4 (95% CI 1.0-2.1) in non-HIV per 100 PYFU ($p = 0.519$), although time to recurrence tended to be longer in HIV recipients [2.4 (IQR 1.2-6.7) vs 0.8 (IQR 0.6-1.6) years, $p = 0.06$]. Recurrent HCC reduced significantly survival compared ($p < 0.001$), without difference according to HIV serostatus ($p = 0.426$) (Figure 2a-b).

The incidence rate (IR) of AR was 5.5 (95% CI 3.3-9.3) in RWH vs 0.8 (95% CI 0.5-1.2) in non-HIV per 100 PYFU. Among transplants performed after 2015, 1-year rejection IR decreased to 1.1 (95% CI 0.3-4.6) in RWH vs 0.9 (95% CI 0.2-3.9) in non-HIV recipients per 100 PYFU (Figure 3 a-b). Predictors of rejection were HIV infection (aOR 2.43, 95%CI 1.10-5.32), CMV infection/reactivation (aOR 3.25, 95%CI 1.25-8.47), and active HCV infection (aOR 2.40, 95%CI 1.10-5.24); after 2015, only CMV infection/reactivation was associated to rejection (Table 1).

Conclusion: LT in HIV achieves good long-term outcomes comparable to non-HIV recipients. After 2015, thanks to the advent of effective anti-HCV treatment and the disuse of protease inhibitors, HIV infection was no more associated to higher risk of rejection. HCC recurred in about 10%, without any difference between HIV and non-HIV, though impacting on survival even after HCV eradication.

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Virological insights shaping antiviral treatment

OC 13 ELIGIBILITY FOR REGIMENS CONTAINING ISLATRAVIR IN THE ARCA COHORT IN VIROLOGICALLY SUPPRESSED PEOPLE LIVING WITH HIV

M. Menozzi¹, M. Sambo², M.M. Santoro³, A. Bezenchek^{4,5}, O. El Khalili³, I. Giovannelli⁶, G. Massobrio⁷, W. Gennari⁸, A. Giacomelli⁹, C. Mussini¹⁰, V. Micheli¹¹, V. Ricucci¹², B. Rossetti¹³, F. Ceccherini-Silberstein³, A. De Vito¹⁴, D. Armenia¹⁵

¹Clinic of Infectious Diseases, Azienda-Ospedaliero Universitaria Policlinico di Modena, Modena, Italy, ²Infectious and Tropical Diseases Unit, Azienda Ospedaliero-Universitaria Senese, Siena, Italy, ³Department of Experimental Medicine, University of Rome "Tor Vergata", Rome, Italy, ⁴IPRO-InformaPRO S.r.l., Rome, Italy, ⁵EuResist Network GEIE, Rome, Italy, ⁶Clinical Immunology, Allergy and Advanced Biotechnologies Unit, AUSL - IRCCS Reggio Emilia, Reggio Emilia, Italy, ⁷Infection disease Unit, IRCCS - Policlinico San Martino Hospital, Genoa, Italy, ⁸Microbiology and Virology Division, University Hospital of Modena – University of Modena and Reggio Emilia, Modena, Italy, ⁹Department of Biomedicine and Clinical Sciences, Università degli studi di Milano - Department of infectious diseases, asst Fatebenefratelli Sacco, Milan, Italy, ¹⁰Clinic of Infectious Diseases, University Hospital of Modena – University of Modena and Reggio Emilia, Modena, Italy, ¹¹Clinical Microbiology, Virology and Bioemergency Diagnostics, ASST Fatebenefratelli Sacco, Luigi Sacco Hospital, Milan, Italy, ¹²Hygiene Unit, IRCCS - Policlinico San Martino Hospital, Genoa, Italy, ¹³Infectious Diseases Unit, USL Sud-Est Toscana, Ospedale Misericordia, Grosseto, Italy, ¹⁴Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ¹⁵UniCamillus, Saint Camillus International University of Health Sciences, Rome, Italy

Background: Islatravir (ISL) has shown sustained activity against multiple HIV-1 subtypes and high potency even in the presence of several NRTI resistance-associated mutations (RAMs). However, in vitro data indicate reduced susceptibility to ISL in viral strains harboring M184I/V alone or in combination with other mutations such as V90I, A114S, I142V, T165R or at least ≥ 1 thymidine analogue mutation (TAM). We therefore estimated the proportion of virologically suppressed people living with HIV with experience of combined antiretroviral therapy (Exp-PLWH) in the ARCA cohort who might be eligible for ISL, based on the prevalence of mutation patterns known to modify ISL susceptibility.

Methods: We performed a cross-sectional study including virologically suppressed Exp-PLWH in the ARCA cohort who were on stable ART, had active follow-up in 2024 and had ≥ 1 available genotypic resistance test (GRT). Mutations patterns associated with ISL-reduced susceptibility were evaluated. ISL activity was explored according to the following definitions: (1) absence of any ISL RAM; (2) absence of the combination M184V plus ≥ 1 TAM. As Doravirine is currently being evaluated as a companion drug for ISL-based regimens, its genotypic susceptibility was also assessed through Stanford Algorithm version 10.1. Logistic regression models were built to identify predictors of ISL preserved activity according to the two resistance patterns.

Results: Overall, 1,809 virologically suppressed Exp-PLWH were included: 67.8% were males, with median age 58 years (IQR: 49-63), a median follow-up 20 years (IQR 12-31) and a median duration of viral suppression of 11 years (IQR 7-16) (Table 1).

ISL RAMs were observed in 37.3% of PLWH (Figure 1). Specifically, the M184I/V mutation was found as follows: alone in 21.7% of individuals; in combination with ≥ 1 TAM in 14.7%; with K65R in 1.1%; no subjects harbored the M184I/V with V90I, A114S or I142V+T165R. Compared with others, individuals with ISL RAMs were older, with a lower CD4+ cell count nadir, longer follow-up, and a more prolonged and extensive antiretroviral exposure (Table 1). Multivariable analysis showed that antiretroviral initiation in more recent calendar years and a lower cumulative antiretroviral exposure were independently associated with the absence of any of the ISL resistance mutations (Table 2).

According to the historical genotypic susceptibility score, 82.8% of subjects had full susceptibility to Doravirine.

Conclusions: In this of virologically suppressed Exp-PLWH receiving stable ART, the predicted activity of ISL was generally high, reflecting the absence of key ISL RAMs and the relatively low prevalence of NRTI mutations known to reduce ISL susceptibility. However, individuals with a long treatment history and extensive antiretroviral exposure may require careful resistance assessment prior to ISL initiation.

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Virological insights shaping antiviral treatment

OC 14 TIMING OF FIRST VIRAL BLIPS ACROSS MODERN ANTIRETROVIRAL REGIMENS: A RETROSPECTIVE ANALYSIS

C. Gioè¹, M. Trizzino¹, L. Pipitò^{1,2}, C. Mascarella^{2,3}, D. Graceffa^{2,3}, C. Bonura^{2,3}, G. Giammanco^{2,3}, A. Cascio^{1,2}

¹Infectious and Tropical Diseases Unit, Sicilian Regional Reference Center for the Fight Against AIDS, AOU Policlinico "P. Giaccone", Palermo, Italy, ²Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G D'Alessandro", University of Palermo, Palermo, Italy, ³Microbiology and Virology Unit, AOU Policlinico "P. Giaccone", Palermo, Italy

Background: Viral blips (50–1000 copies/mL) are a common and often transient occurrence in people with HIV (PWH) on suppressive antiretroviral therapy (ART). With the widespread adoption of Two-Drug Regimens (2DR) and modern integrase inhibitor-based triple therapies, characterizing the temporal dynamics of these virological events is essential. We aimed to evaluate the timing of the first viral blip across different ART regimens to better understand their specific virological profiles.

Material and Methods: Retrospective study of 286 virologically suppressed PWH with 378 documented blips identified from 9,157 viral load measurements (2020–2025, Infectious Diseases Unit, AOU Policlinico Paolo Giaccone, Palermo). The timing of the first viral blip was calculated as the number of days from the initiation of the current ART regimen. The median time to the first blip (67.5 days) was used as a cut-off to categorize events as "Early" (≤ 67.5 days) or "Late" (> 67.5 days). Associations between blip timing, therapeutic regimens (2DR, DTG/3TC, BIC-based), and baseline clinical characteristics were assessed using Pearson's Chi-square and Fisher's exact tests.

Results: The cohort (median age 54 years, 78% male) was treated primarily with 2DRs (43.7%, including DTG/3TC at 24.5%) and BIC-based regimens (38.8%). Baseline clinical severity included a CD4 nadir < 100 cells/ μ L in 24.5% of patients and prior virologic failure in 15%. The overall median time to the 1st viral blip was 67.5 days. Bivariate analysis indicated that the first blip tended to occur earlier in patients receiving 2DRs (62.4% early vs 37.6% late, $p < 0.001$), including the DTG/3TC subgroup (61.4% early, $p = 0.017$). Conversely, blips during BIC-based regimens were more frequently observed later in the treatment course (36.9% early, $p < 0.001$). To evaluate potential confounders, baseline severe immunosuppression (CD4 nadir < 100) and regimen complexity (multi-pill burden) were analyzed. Neither factor showed a significant impact on early blips globally ($p = 0.099$ and $p = 0.246$, respectively). When analyzing only the 2DR subgroup ($n=125$), neither CD4 nadir < 100 ($p = 0.519$) nor pill burden ($p = 0.325$) significantly influenced blip timing.

Conclusions: Different ART regimens may exhibit distinct virological kinetics. In our cohort, the first viral blip occurred earlier after initiation of 2DRs (such as DTG/3TC) compared to BIC-based triple therapies, independent of baseline immune status or pill burden. These findings highlight different temporal distributions of low-level viremia rather than differences in long-term clinical efficacy. This study is limited by its retrospective design and the lack of adherence data and unmeasured pharmacological interactions, which could influence transient viral fluctuations. Further prospective investigations with adherence monitoring are required to fully interpret the virological dynamics underlying these early blip events.

Table 1, Table 2

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Virological insights shaping antiviral treatment

OC 15 MULTIDISCIPLINARY ASSESSMENT OF THE HIV-1 RESERVOIR AFTER SWITCHING FROM TRIPLE TO DUAL ANTIRETROVIRAL THERAPY IN VIROLOGICALLY SUPPRESSED INDIVIDUALS, A PROSPECTIVE OBSERVATIONAL PILOT STUDY

L. Fiaschi¹, N. Bartolini¹, M. Compagno², L. Benedetti², O. El Khalil², C. Biba¹, C. Paletti¹, I. Varasi¹, M. Iannetta², V. Malagnino², M. Santoro², R. Salpini², V. Svicher², F. Ceccherini-Silberstein², L. Sarmati², F. Saladini¹, M. Zazzi¹, I. Vicenti^{1,3}

¹University of Siena, Siena, Italy, ²University of Rome Tor Vergata, Rome, Italy, ³Saint Camillus International University of Health Sciences, Rome, Italy

Background: Two-drug regimens (2-DRs) are increasingly used in people with HIV (PWH) with sustained virological suppression, demonstrating non-inferior efficacy compared with triple therapy (3-DRs). Since their long-term impact on the HIV-1 reservoir and its tissue distribution remain unclear, we evaluated longitudinal changes in blood reservoir markers after switching from 3-DR to 2-DR and explored their relationship with gut-associated lymphoid tissue (GALT).

Materials and Methods: Sixty-seven virosuppressed PWH were enrolled, 32 continued 3-DR and 35 switched to 2-DR. Peripheral blood was collected at baseline (T0) and after 18 months (T1). CD4+ T-cells were isolated and total HIV-1 DNA (CAD), intact proviral DNA (IP) and cell-associated HIV-1 RNA (CAR) were quantified by digital PCR. In a subset of people undergoing rectal biopsy, CAD (n=19) and IP (n=18) were measured in GALT at T0 and T1. Inter-group differences were assessed by Mann-Whitney U test, longitudinal changes by Wilcoxon signed-rank test, correlations by Spearman's rank test, and predictors of reservoir dynamics by linear regression analysis.

Results: At T0, the two groups were comparable for sex, CD4+ count, zenith viral load and duration of ART, whereas the 2-DR group had lower age and higher nadir CD4+ (Tab.1).

In blood CD4+ T-cells, CAD, IP and CAR did not differ between groups at T0 (Tab.2) and only CAD and CAR were correlated in the whole dataset ($Rho=0.653$, $p<0.001$). Intra-group analyses over time showed decreased CAR in the 3-DR group ($p=0.023$), increased CAD ($p=0.003$) and decreased IP ($p=0.039$) in the 2-DR group. When comparing changes between groups, ΔIP (T1-T0) was the only marker with a significant difference (median [IQR] of 0.5 [9.0] in 3DR vs. -6.5 [14.3] in 2DR, $p=0.035$) (Fig.1). In a model controlling for age, zenith VL, ART duration, nadir CD4+, baseline CD4+, and treatment group, T0 CAD predicted ΔCAD ($B=0.499$, $p<0.001$), baseline IP and CAR predicted ΔIP ($B=-0.792$, $p<0.001$; and $B=2.821$, $p=0.011$; respectively) and baseline CAR predicted ΔCAR ($B=-0.418$, $p=0.001$) (Tab.3), suggesting baseline-dependent reservoir kinetics.

In GALT, CAD and IP values were not strongly correlated with the paired blood CD4+ T-cell values, and only a mild correlation of CD4+ T0 IP and GALT T0 CAD ($Rho=0.608$, $p=0.012$) emerged. CAD and IP did not change over time and were comparable between the 2DR and 3DR groups.

Conclusions: Treatment simplification was not associated with measurable expansion of the HIV-1 reservoir after 18 months, supporting the virological safety of 2-DR strategies. The lack of concordance between blood and GALT measurements suggests that peripheral blood may not fully recapitulate the reservoir dynamics and advises for expanding investigation of the lymphoid tissue.

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Virological insights shaping antiviral treatment

OC 16 CHARACTERISATION OF HIV-1 RESERVOIR IN SUBJECTS ON LONG-ACTING THERAPY

A. Bergna¹, C. della Ventura², I. Serravalli², M. Liturri², C. Mauro², E. Marinosci², M.V. Cossu¹, C. Gervasoni¹, S. Antinori^{1,2}, A. Riva^{1,2}, G. Zehender², A. Lai²

¹Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ²Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy

Introduction: Data on HIV-1 reservoir dynamics of HIV during treatment with long-acting cabotegravir and rilpivirine (LA CAB/RPV) remain limited. This study aimed to investigate intra-patient viral evolution and the persistence of transcriptionally active proviruses, providing insights into reservoir stability and the impact of long-term LA CAB/RPV therapy.

Methods: Six people living with HIV initiating LA CAB/RPV at our centre were enrolled. Samples were collected at three different time points: before the first injection (T1), at the fourth injection (T4) and at the seventh injection (T7). The numbers of HIV-1-infected cells and the transcriptional activity were assessed by measuring cell-associated HIV-1 DNA (CAD) and cell-associated HIV-1 RNA (CAR) levels using digital PCR (dPCR) targeting three genomic regions (DNA: LTR-GAG-TREX1 and RT-GAG-TREX1; RNA: GAG-TAT-POLYA). Whole genome sequencing was performed at all time points. Two additional subjects experiencing virological failure on LA CAB/RPV were included as a comparator group.

Results: All participants were males, Italian born, with a median age of 47 years (interquartile range, IQR: 39–50 years) and a median duration of antiretroviral therapy of 13.95 years (IQR: 12–14 years). All subjects were MSM; 5 carried B and 1 CRF02_AG subtypes. At T7, integrase resistance-associated mutations were detected in one subject. About failing subjects, resistance-associated mutations were observed in one case while no resistance mutations were detected in the second subject at viral rebound. Off-target mutation analysis in gag and env genes revealed several variations, with the highest mutation burden in subjects with virological failure; only one gag mutation was consistently detected across all individuals.

dPCR analyses showed a progressive decrease in quantification of single positive targets, both in DNA and RNA overtime. In contrast, for double and triple positive targets, the decrease was less pronounced, except for the DNA triplex with gag-trex1-rt targets. In the RNA triplex, with the tat-gag-poly-A targets, the levels at T1 and T4 were comparable, while at T7 a more marked reduction was observed. Subjects with virological failure showed higher CAD and CAR levels, although differences were not statistically significant. Triplex analyses were largely comparable between the two groups.

Conclusion: During the first year of treatment, LA CAB/RPV regimen significantly impacts the HIV-1 reservoir. CAD and CAR measurements showed concordant trends, with most participants showing zero long transcripts and intact proviruses. Whole genome analysis revealed previously undetected DNA mutations suggesting a certain dynamism in viral mutations even under effective long-acting treatment.

Virological insights shaping antiviral treatment

OC 17 HUMAN AND HCMV-ENCODED MICRORNAS IN CEREBROSPINAL FLUID (CSF) OF ART-TREATED PEOPLE WITH HIV (PWH): CORRELATION WITH HIV-1 REPLICATION AND INFLAMMATORY MARKERS

G. Rozera, E. Lazzari, E. Cimini, F. Cristofanelli, E. Tartaglia, F. Smoquina, F. Forbici, G. Berno, L. Fabeni, C. Pinnetti, V. Mazzotta, A. Antinori, F. Maggi, I. Abbate

National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy

Background: MicroRNAs (miRNAs) are small non-coding RNA molecules that regulate gene expression in various biological fluids. The aim of our study was to characterize the expression profile, in CSF, of several human (hsa) and HCMV-encoded miRNAs, primarily involved in the regulation of vascular inflammation, and to compare these profiles with their expression in plasma. Correlation with CSF and plasma levels of IL-1 β , IL-6, IL-8 and TNF- α was also investigated.

Methods: Ten paired CSF-plasma samples from ART-treated PWH, co-infected with HCMV, were analyzed for the expression of 8 human miRNAs and 14 HCMV-encoded miRNAs, using miRCURY LNA RT Kit and UniSp6 spike-in. Quantitative PCR was then performed using specific miRCURY miRNA PCR primers. MiRNA expression levels were calculated using ΔC_t , with UniSp6 Ct as reference. CSF and plasma levels of IL-1 β , IL-6, IL-8 and TNF- α were quantified by ELISA, with 5 plasma samples from healthy donors (HD) as controls.

Results: The subjects were 9 males and 1 female, with a median (IQR) age of 51.5 (46.0-67.8). Median (IQR) HIV-1 RNA were 2.87 (1.39-3.69) and 1.95 (1.46-4.59) Log copies/ml in CSF and plasma, respectively. HCMV DNA was detected in 1 CSF and in 4 plasma samples. All human miRNAs were more highly expressed in plasma than CSF, and 5 out of 8 were highly expressed in the plasma of PWH compared to HD (Table 1A). Hsa-miR20b-5p was detected in only 2 CSF samples, while hsa-150-3p and hsa-155-5p only in 3 CSF. Among HCMV-encoded miRNAs, hcmv-US33-5p and hcmv-UL-70-3p were consistently expressed. Hcmv-UL22A-5p was detected in all plasma and only in 1 CSF samples. Other HCMV-encoded miRNAs were variably expressed, with hcmv-UL148D more frequently detected. In a subject with HCMV-related encephalitis, all HCMV-encoded miRNAs, except hcmv-miR-US4-5p, were found in CSF. Plasma cytokine levels were higher in PWH compared to HD. IL-8 and TNF- α were predominantly expressed at higher levels in CSF and plasma, respectively. IL-1 β was also significantly higher in plasma than in CSF (Table 1B). IL-8 showed a statistically significant positive correlation with all human miRNAs, while TNF- α showed a statistically significant negative correlation. IL-1 β levels were negatively correlated with 7 out of 8 human miRNAs. Conversely, HCMV-encoded hcmv-US33-5p and hcmv-UL-70-3p showed a significant positive correlation with IL-1 β and TNF- α (Table 1C). No correlations were observed between overall miRNAs, cytokines and HIV-1 RNA levels, calculated by combining the two compartments.

Conclusion: Human and HCMV-encoded miRNAs display distinct expression patterns in plasma and CSF of ART-treated PWH, and show differential associations with inflammatory cytokines. These preliminary findings suggest a potential interplay between host and viral miRNAs in the inflammatory milieu of treated HIV infection. Larger studies are needed to confirm these observations, and clarify their clinical significance.

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Virological insights shaping antiviral treatment

OC 18 CMV-RNA KINETICS IN ALLO-HSCT PATIENTS: OPTIMIZING VIRAL SURVEILLANCE DURING AND AFTER LETERMORVIR PROPHYLAXIS

C. Tramontozzi¹, L. Piermatteo¹, G. Torre¹, P. Paba², B. Mariotti³, V. Malagnino⁴, L. Campogiani⁴, A. Bertoli², S. D'Anna¹, I. Grossi¹, A. Magnapera¹, G. De Angelis³, G. Ciangola³, S. Grelli², L. Sarmati⁴, R. Cerretti³, A. Venditti^{3,5}, R. Salpini¹, V. Svicher¹

¹Department of Biology, University of Rome Tor Vergata, Rome, Italy, ²AOU Policlinico Tor Vergata, Rome, Italy, ³Department of Onco-Hematology, Policlinico Tor Vergata Foundation, Rome, Italy, ⁴Infectious Diseases Unit, Policlinico Tor Vergata Foundation, Rome, Italy, ⁵Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy

Background: Cytomegalovirus (CMV) infection continues to be a significant contributor to morbidity and mortality among recipients of allogeneic hematopoietic stem cell transplantation (allo HSCT). The introduction of Letermovir (LTV) prophylaxis, which blocks the viral terminase complex and consequently prevents the processing of CMV genomic concatemers, has markedly lowered the incidence of CMV infection and reactivation. Despite this progress, the most appropriate strategy for virological surveillance remains uncertain. CMV DNA has been so far the only virological marker, even if there is increasing evidence that its quantification in plasma mainly reflects CMV genomic fragments or concatemers. CMV RNA, targeting UL21.5 mRNA packaged within virions, has recently emerged as a potential tool to better reflect the real burden of virions. On this basis, the present study investigates the kinetics of CMV RNA and CMV DNA during and following LTV prophylaxis.

Methods: We enrolled 42 onco-hematological patients (pts) undergoing allo-HSCT and receiving LTV prophylaxis for at least 2 months: 30 (71.4%) were monitored after LTV for a median time of 87 [IQR 71–134] days. In total, 464 plasma samples were collected longitudinally and analyzed for CMV DNA and CMV RNA levels using the Elitech assays, with limits of quantification of 112 IU/mL and 30 IU/mL, respectively.

Results: During LTV prophylaxis, 5 pts (11.9%) exhibited CMV DNA >112 IU/mL (median[IQR]: 296[194–1258]), mostly presenting as single or recurrent blips. None of these individuals showed detectable CMV RNA, suggesting absence of virion production and the release of CMV-DNA concatemers. After discontinuation of LTV, 16 of 30 pts (53.3%) developed CMV DNA >112 IU/mL (median[IQR]: 536[314–3908]); CMV RNA was positive in 5/16 (31.2%). CMV-RNA positivity was associated with higher levels of plasma CMV-DNA (median[IQR]: 12196 [9194–29729] IU/mL in pts with CMV-RNA+ vs 787 [493–2392] IU/mL in pts with CMV-RNA-, $p=0.0005$) and also with a markedly prolonged duration of CMV DNA detectability (median[IQR]: 129[53–159] days in CMV RNA+ vs 10[7–20] days in CMV RNA-, $p<0.0001$). This reinforces that transient and low level rises of CMV-DNA do not reflect virion production. Kinetic evaluation during anti CMV treatment revealed a more rapid decline and earlier clearance of CMV RNA, consistent with ongoing release of CMV DNA fragments despite effective suppression of viral particle production.

Conclusions: CMV RNA offers a more refined interpretation of virological monitoring by differentiating active viral replication from residual genomic material. Its incorporation into clinical practice may support more responsible anti CMV treatment stewardship, reducing overtreatment and mitigating the burden of drug associated toxicity.

Lives, stigma and risk: social realities of sexual health and prevention

OC 19 HIV CARE TRAJECTORIES AMONG TRANSGENDER AND CISGENDER MIGRANTS IN A SETTING WITH STRONG COMMUNITY SUPPORT: A 10-YEAR MONOCENTRIC STUDY IN TUSCANY, ITALY

M. Maruotto², S. Trevisan², C. Malcontenti¹, M. Trotta¹, V. Donini¹, B. Borchì¹, P. Corsi¹, M. Pozzi¹, C. Fiorelli¹, A. Farese¹, I. Campolmi¹, G. Sterrantino², A. Bartoloni², F. Lagi¹

¹Infectious and Tropical Diseases Unit, Careggi University Hospital, Florence, Italy, ²Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy

Background: Transgender migrants (TM) often present with distinct social and clinical profiles. The extent to which HIV care trajectories are driven by gender identity per se or by underlying structural vulnerabilities may vary across healthcare settings. We aimed to describe the profile of TM living with HIV and to investigate determinants of linkage to care and loss to follow-up (LTFU) compared with cisgender migrants (CM) in a real-world care setting with established third-sector organizations providing general support to migrant populations, including outreach, health system navigation, and linkage to HIV care.

Methods: This retrospective study included all migrants living with HIV taken into care at the Infectious and Tropical Diseases Unit of a tertiary teaching hospital in Florence, Italy, between 1 January 2014 and 1 March 2025, with data censored on 28 February 2026. Time to linkage to care was defined as the interval from arrival in Italy to linkage for ART-experienced individuals, and from first HIV-positive test to linkage for ART-naïve individuals. Early linkage was defined as linkage within 3 months, while LTFU was defined as absence from care for ≥ 12 months without documented transfer.

Determinants of linkage to care and LTFU were assessed using Cox regression models.

Results: Among 308 migrants (217 CM, 91 TM), TM were almost exclusively Latin American transgender women (98.9%), with higher out-of-status rates than CM (82.4% vs 23.9%, $p < 0.001$) and sex work prevalence increasing from pre- to post-migration (47.2% to 75.8%, $p < 0.001$) (Table 1) TM consistently accounted for nearly one third of new linkages to care over the study period.

In multivariable analysis with an interaction between ART experience and administrative status, out-of-status condition was associated with earlier linkage to care among ART-naïve migrants (HR 1.65, 95% CI 1.01–2.69; $p = 0.048$), while ART-experienced migrants with regular status were less likely to link early (HR 0.26, 95% CI 0.14–0.47; $p < 0.001$). This effect was attenuated among ART-experienced out-of-status individuals (HR 0.60, 95% CI 0.35–1.02; $p = 0.057$).

Transgender identity and age were not associated with linkage timing (Table 2).

During 2101.7 person-years of follow-up, the incidence rate of LTFU was 4.1 per 100 person-years (95% CI 3.3–5.1), with no differences between TM and CM (Figure 1). In multivariable analysis, administrative vulnerability was the only factor independently associated with LTFU (HR 2.25, 95% CI 1.28–3.94) (Table 3).

Conclusions: In our setting HIV care trajectories among migrants appear to be shaped primarily by structural and legal vulnerability rather than gender identity. Administrative vulnerability facilitates early linkage mainly at diagnosis and represents the main driver of loss to follow-up regardless of prior ART experience, highlighting the potential role of integrated community–healthcare models in mitigating HIV care disparities.

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Lives, stigma and risk: social realities of sexual health and prevention

OC 20 "NARRATING TO TRANSFORM": STIGMA, COPING, AND THE RESHAPING OF LIFE TRAJECTORIES FROM DIAGNOSIS TO DISCLOSURE AMONG WOMEN WITH HIV

S. Bergamo¹, F. Ferrami¹, F. Sabbatini², G. Giupponi³, V. Cogliandro², N. Squillace², P. Bonfanti⁴, F. Gaspani¹, A. Soria²

¹Department of Sociology and Social Research, University of Milano-Bicocca, Milan, Italy, ²Clinic of Infectious Diseases, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy, ³LILA, Como, Italy, ⁴School of Medicine and Surgery, University of Milano-Bicocca, Monza, Italy

Background: Despite biomedical advances, women with HIV (WWH) still face stigma, moralised guilty narratives, and structural inequalities. Diagnosis and disclosure may represent critical biographical turning points that disrupt identity and relations, but could also activate processes of agency, coping, and identity reconstruction that impact well-being. However, how women negotiate diagnosis and disclosure in everyday life and how these processes shape patient-reported outcomes (PROs) is poorly explored, especially from a sociological perspective.

Material and Methods: We conducted a qualitative study based on semi-structured interviews with WWH. Using a participatory research perspective, clinicians and people with HIV (PWH) were involved in the study design, recruitment, and interpretation of results. The project involved LILA Como, the Infectious Diseases Unit of IRCCS San Gerardo (Monza), and the Department of Sociology and Social Research of the University of Milano-Bicocca. Participants were recruited through clinical and community networks. Interviews, lasting approximately 1 hour each, explored diagnosis, disclosure, stigma, relationships, coping strategies, and healthcare experiences. The study received Ethics Committee approval.

Results: Fifteen WWH, aged 35 to 75, were interviewed. Thematic analysis showed that diagnosis is narrated as a biographical rupture of taken-for-granted identities and future imaginaries. Through biographical reconstruction and agency-oriented coping, participants engaged in active meaning-making to restore continuity. Strategies included cognitive reframing of HIV as a chronic and manageable condition, emotional regulation, information-seeking, and reorganisation of life priorities. Disclosure emerged as a relational practice rather than a single event: WWH calibrated timing, audience, and narrative framing according to anticipated stigma, gender norms, and power asymmetries. Boundary-setting in intimate and family relationships acted as protection, while selective openness preserved social belonging. Peer networks fostered collective coping, reinforcing self-efficacy and resilience. Although stigma—often moralised around sexuality and responsibility—affected self-perception and mental well-being, coping practices mitigated its impact by supporting identity renegotiation, empowerment, and perceived control over life trajectories. Supportive clinical relationships further enhanced adherence and positively influenced self-reported quality of life.

Conclusions: Women's experiences of HIV highlight the dynamic interplay between stigma and agency, showing how diagnosis and disclosure function as socially embedded turning points that require active processes of biographical and identity reconstruction. Integrating PROs into HIV care from a social sciences perspective could empower women as active agents in their health trajectories, thus complementing biomedical advances.

Lives, stigma and risk: social realities of sexual health and prevention

OC 21 CHEMSEX PRACTICES AND BEHAVIORAL DETERMINANTS AMONG PREP USERS IN THE ITALIAN PRIDE COHORT

C. Fusetti¹, D. Moschese¹, G. Frate², G. Micheli², E. Caruso³, A.M. Lucchini⁴, A.R. Raccagni⁵, C. Tincati⁶, S. Lazzarin¹, D. Farinacci², M. Cernuschi³, S. Nozza⁵, V. Mazzotta²

¹Department of Infectious Diseases, Luigi Sacco University Hospital, Milan, Italy, ²National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ³Milano Checkpoint ETS, Milan, Italy, ⁴CeMuSS (Multidisciplinary Sexual Health Center), ASL Città di Torino, Turin, Italy, ⁵Infectious Diseases Unit, Vita Salute San Raffaele University, Milan, Italy, ⁶Clinic of Infectious Diseases and Tropical Medicine, ASST Santi Paolo e Carlo, Milan, Italy

Background: Chemsex refers to the intentional use of psychoactive substances in sexual contexts, predominantly among MSM in order to prolong and intensify sexual experiences. Substances commonly associated with chemsex include GHB/GBL, synthetic cathinones, and crystal methamphetamine, often in combination with other drugs. Through sexual disinhibition and prolonged encounters, chemsex may amplify exposure to HIV and other sexually transmitted infections (STIs).

Our study aims to evaluate the frequency of chemsex and its associated factors within Prevention ICONA Dedicated Ensemble (PrIDE), the largest nationwide Italian PrEP cohort.

Methods: Information on substance use, chemsex practices, and sexual behaviors was collected through anonymous self-administered questionnaires in 2025 and linked to clinical data from medical records, including demographics, history of STIs, prior post-exposure prophylaxis (PEP), sex work, and doxycycline post-exposure prophylaxis (doxy-PEP).

Continuous variables are presented as medians with interquartile ranges (IQR); categorical variables as counts and percentages. Group comparisons used Wilcoxon rank-sum, chi-squared, or Fisher's exact tests as appropriate. Multivariable logistic regression identified factors independently associated with chemsex engagement.

Results: Among 2,180 PrEP users included in the analysis (Table 1), 279 (13.0%) reported chemsex engagement. Prevalence was comparable across macro-regions (13.2% in northern vs 11.5% in central-southern Italy). The substances most frequently reported were mephedrone (60.6%), GHB/GBL (41.9%), and cocaine (40.5%). Ketamine use was also substantial, reported by 69 participants (24.7%), as well as crack cocaine (56; 20.1%), MDPV (56; 20.1%), and crystal methamphetamine (40; 14.3%) (Table 2).

In adjusted analyses, chemsex was positively associated with transgender/non-binary identity (OR 3.90; 95% CI 1.60–8.99), fisting (OR 3.30; 95% CI 2.36–4.60), group sex (OR 2.86; 95% CI 1.91–4.37), doxy-PEP use (OR 1.80; 95% CI 1.15–2.78), and prior STI diagnosis (OR 1.51; 95% CI 1.13–2.02). Condom use (OR 0.38; 95% CI 0.26–0.68) and age >50 years (OR 0.51; 95% CI 0.30–0.89) were inversely associated.

Conclusions: In this large Italian PrEP cohort, 13% of participants reported chemsex. The strong associations with high-risk sexual practices and prior STI history underscore the need for integrated models of care within PrEP services. Harm-reduction counseling, substance-use assessment, and strategies that can support adherence should be incorporated into routine practice.

Although the number of transgender and non-binary participants was limited, the association with chemsex engagement highlights the importance of gender-affirming and structurally sensitive prevention programs.

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Lives, stigma and risk: social realities of sexual health and prevention

OC 22 CHEMSEX AND MDPV: ASSESSING NEEDS RELATED PROBLEMATIC CHEMSEX TO PROVIDE COMPREHENSIVE SERVICES

A. Bianchi¹, P.L. Vinti¹, A. Antonino¹, C. Soligo¹, P.M. Testoni¹, M. Manfredini¹, G. Fracca¹, D. Zagato¹, M. Cernuschi^{1,2}

¹ASA ODV, Milano, Italy, ²San Raffaele Hospital, Milano, Italy

Background: Since 2017 we offer community-based services to address problematic chemsex, including group and individual therapy sessions. Since 2023, MDPV use and related requests for support sharply increased. This required scaling up service delivery, setting up a network with local facility-based addiction services, providing training and supervision to addiction services with knowledge gaps about chemsex. We assessed needs related to problematic chemsex to guide future activities and advocacy.

Methods: Sociodemographic characteristics of clients, characteristics of their requests and themes emerging from their first interview were collected between February 2025 and February 2026. First interviews were semi-structured and included discussion of: behavioural and socio-psychological aspects of drug use, motivations for requesting help, history of drug use, history of pharmacological or psychological treatment, HIV status, condom use. We used descriptive statistics and thematic analysis.

Results: We received 63 requests for support, with characteristics described in Table 1. Clients were mostly male (96%), gay (87%), university graduates or higher (65%), aged 31-40 (44%), employees (59%), born in Northern Italy (43%), living in Milano (50%). Clients predominantly reached out to us because they felt they had lost control on drug use (53%), were severely scared by a specific episode (34%), and asking for help to quit chemsex (82%). Characteristics of clients' drug use are presented in Table 2. 98% used stimulant drugs, most frequently MDPV (77%). While clients most frequently practiced chemsex weekly (41%), 24% did it daily. 40% of clients practiced chemsex with occasional partners, 36% also alone. 36% first started chemsex due to traumatic events or loneliness, 48% to emulate their partners, 16% to reduce sexual inhibitions. 62% had been practicing chemsex for more than one year. 49% never used drugs before starting chemsex. 52% were not currently able to have sober sex. Clients' history of treatment is presented in Table 3. 32% had been hospitalized or accessed the ER at least once to treat chemsex-related issues. 61% had previously accessed another health service for problematic chemsex, while 50% of them felt their issue was not understood there, 33% felt welcome and supported. Only 14% never had psychotherapy previously. 95% reported never using condoms in the previous 3 months, and 29% were neither on ART or PrEP.

Conclusions: Clients who reached out to our service reported increasingly complex and severe cases, both for mental and sexual health. Networks between facility- and community-based services are needed to provide comprehensive care to them. To this end, providing supervision and training on psychological aspects of chemsex and long-acting ART/PrEP formulations to local addiction services are needed. All addiction services should receive training to address problematic chemsex, also considering its increasing geographical spread.

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Expanding PrEP horizons: gender, age and community engagement in HIV prevention

OC 23 PREP BEYOND 50: BASELINE PROFILE AND PREP STRATEGIES OF OLDER USERS IN THE ITALIAN PRIDE COHORT

A. Russo^{1,2}, R. Lolatto³, A. Giacinta⁴, G. Bozzi⁵, E. Caruso⁶, A.R. Raccagni⁷, R.F. Del Vecchio⁸, C. Fusetti⁹, A. Guida¹⁰, A.M. Lucchini¹¹, A. Renzani¹², G. Ancona¹³, S. Cerere¹⁴, P. Vassalini¹⁵, V.L. Del Negro¹⁶, A. Cattelan¹⁷, M. Cernuschi¹⁸, V. Mazzotta¹⁹, S. Nozza^{7,20}

¹Link Campus University, Rome, Italy, ²Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy, ³Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy, ⁴National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ⁵Infectious Diseases Unit, Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ⁶Milano Checkpoint ETS, Milan, Italy, ⁷Infectious Diseases Unit, Vita-Salute San Raffaele University, Milan, Italy, ⁸UOC Malattie infettive, PO Umberto I ASP Siracusa, Siracusa, Italy, ⁹Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ¹⁰PO Cotugno, AORN dei Colli, Naples, Italy, ¹¹Azienda Sanitaria Locale "Città di Torino", Turin, Italy, ¹²S.C. Malattie Infettive, IRCCS San Gerardo dei Tintori, Monza, Italy, ¹³Clinic of Infectious Diseases, Department of Health Sciences, ASST Santi Paolo e Carlo, University of Milan, Italy, ¹⁴BLQ Checkpoint, Bologna, Italy, ¹⁵Infectious Disease Unit, Sant'Andrea Hospital, Sapienza University of Rome, Rome, Italy, ¹⁶Checkpoint Plus Roma, Rome, Italy, ¹⁷Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy Project and Clinical Research Unit, Padua University Hospital, Padua, Italy, ¹⁸A.S.A. Onlus - Association of Solidarity AIDS, Milan, Italy, ¹⁹Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases Lazzaro Spallanzani, IRCCS, Rome, Italy, ²⁰Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: In daily practice, an increasing number of individuals aged ≥ 50 years are requesting HIV pre-exposure prophylaxis (PrEP); however, real-world data on this population remain limited and often underreported.

Methods: We conducted a cross-sectional analysis using baseline data from the PRIDE cohort (enrolled in 2025). Participants were stratified into three age groups: <50 , 50–65, and >65 years. We described and compared demographics, anthropometrics, sexual behaviour, PrEP regimen and dosing strategy, and history of sexually transmitted infections (STIs) across the three age categories. χ^2 /Fisher's exact and Kruskal–Wallis test were used as appropriate.

Results: Overall, 5,604 PrEP users were included; 4,685 (83.6%) were aged <50 years, 862 (15.4%) were 50–65 years, and 57 (1.0%) were >65 years. Most participants were male at birth (98.5%). Compared with those <50 , older participants had a higher body mass index (median BMI 23.44 kg/m² in <50 vs 24.66 in 50–65 and 24.49 in >65 ; $p=0.001$). Reporting partners of both sexes was more common in the older groups (8.1% in <50 vs 11.0% in 50–65 and 22.8% in >65 ; $p=0.001$). Italian nationality was highly prevalent across all age groups and reached 98.3% among those >65 . At enrolment, PrEP was mainly based on tenofovir disoproxil fumarate/emtricitabine in all age groups. Long-acting cabotegravir was used more often with increasing age (9.8% in <50 , 11.5% in 50–65, 18.8% in >65). On-demand PrEP was widely used and was particularly frequent among participants aged >65 years (48.8% in <50 vs 67.6% in >65). A previous history of STIs was very common and overall similar across ages (68.8% in <50 , 70.4% in 50–65, 61.5% in >65 ; $p=0.343$), but the distribution of specific infections differed across age groups: syphilis was reported more often in older participants (24.1% in those aged <50 years vs 36.5% in 50–65 years and 28.9% in >65 years; $p=0.001$), whereas rectal gonorrhoea decreased with age (17.8% vs 11.7% and 3.9%; $p=0.001$). A history of hepatitis A increased markedly with age (2.3% in <50 years vs 5.8% in 50–65 years and 15.4% in >65 years; $p=0.001$), and hepatitis B was also more frequent in older groups, particularly among participants aged 50–65 years (1.1% in <50 years vs 6.6% in 50–65 years and 3.9% in >65 years; $p=0.001$).

Conclusions: In the PRIDE cohort, people aged ≥ 50 years account for a non-negligible proportion of PrEP users and display distinct clinical and behavioural characteristics compared with younger participants. Differences in PrEP strategy (greater use of long-acting and on-demand regimens) and in the distribution of STIs suggest that prevention approaches should be adapted for older adults rather than extrapolated from younger. Tailored counselling and targeted screening strategies may improve prevention outcomes and counter the misconception that older adults are a lower-priority population for HIV prevention.

Table 1, figure 1

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Expanding PrEP horizons: gender, age and community engagement in HIV prevention

OC 24 CUMULATIVE HIV VULNERABILITY AND PREP ENGAGEMENT AMONG CISGENDER WOMEN ACCESSING A COMMUNITY-BASED TESTING SERVICE

L. Nekrasova¹, L. Cavallero¹, E. Caruso¹, D. Zagato¹, R. Repossi¹, I. Gotti¹, P. Russo¹, P. Vinti¹, D. Moschese^{1,2}, V. Iannone^{1,2}, R. Rossotti^{1,5}, M. Cernuschi^{1,4}, N. Frattini¹

¹Milano Checkpoint ETS, Milan, Italy, ²ASST Fatebenefratelli-Sacco, Milan, Italy, ³ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ⁴San Raffaele Scientific Institute, Milan, Italy, ⁵ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy

Background: Cisgender women remain underrepresented in PrEP programs despite global HIV&AIDS statistics showing women accounting for 45% of all new infections in 2024. This study aims to investigate the interplay between behavioral vulnerability, PrEP awareness and engagement in a cisgender female population in a community-based setting.

Materials and Methods: We performed a cross-sectional analysis including cisgender women accessing a community-based HIV/STI testing service from April to December 2025. Data were collected during peer-led pre-test counseling using the COBATEST platform and a structured ad-hoc survey. A cumulative HIV risk score (0–8) was constructed based on sexually transmitted infections (STIs) diagnosis, ≥ 2 partners per year, group sex, recreational drug use, irregular STI testing, inconsistent condom use, sex work, sex with cisgender male partners in the previous 12 months, and categorized as 0–1, 2, and ≥ 3 indicators. Potential PrEP indication was defined according to international guidelines (e.g. CDC, EACS, BHIVA/BASHH) as ≥ 1 of the following: STI diagnosis, ≥ 2 partners, group sex, recreational drug use, inconsistent condom use, or sex work in the previous 12 months. PrEP awareness and interest were assessed. Associations were evaluated using chi-square tests. Multivariable binary logistic regression examined independent associations between risk indicators and PrEP interest.

Results: The study included 250 cisgender women. Overall, 94.4% reported ≥ 1 guideline-based potential PrEP indication. Based on the cumulative risk score, 3.6% reported 0–1 indicators, 23.6% reported 2, and 72.8% reported ≥ 3 concurrent indicators (Table 1). PrEP awareness did not significantly differ across cumulative risk categories (77.8%, 69.5%, and 64.3%, respectively; $p=0.572$). Similarly, PrEP interest was not associated with cumulative vulnerability (11.1%, 22.0%, and 23.1%, respectively; $p=0.7$). Age distribution did not significantly differ across risk categories ($p=0.568$), and PrEP interest was not significantly associated with age ($p=0.12$), despite a descriptive increase in interest among older women. In multivariable analysis, no individual behavioral risk indicator was independently associated with PrEP interest (all $p>0.05$; McFadden $R^2=0.027$).

Conclusions: Cisgender women accessing a community-based testing service reported a high cumulative burden of HIV-related behavioral risks, with most meeting at least one guideline-based indication for PrEP use. However, a higher vulnerability was not associated with increased awareness or interest in PrEP. These findings suggest that current prevention strategies may not adequately reach women with higher likelihood of HIV exposure, underlining the need to strengthen PrEP integration within this population.

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Expanding PrEP horizons: gender, age and community engagement in HIV prevention

OC 25 IDENTIFYING THE ELIGIBILITY GAP FOR LONG-ACTING INJECTABLE PREP IN THE ITALIAN PRIDE COHORT

D. Moschese¹, S. Nozza², S. Leone³, S. Cecere⁴, E. Caruso⁵, G.C. Marchetti⁶, R. Esvan⁷, A.R. Raccagni², G. Frate³, M. Tutone⁸, M. Cernuschi⁹, A. Gori¹, A. Antinori⁷, A. Castagna², V. Mazzotta⁷

¹Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ²San Raffaele Vita-Salute University, Milan, Italy, ³Fondazione ICONA, Milan, Italy, ⁴Plus Onlus, Bologna, Italy, ⁵Milano Checkpoint ETS, ⁶Università degli Studi di Milano, Milan, Italy, ⁷Lazzaro Spallanzani National Institute for Infectious Diseases, Rome, Italy, ⁸ASL Città di Torino, ⁹ASA Milano, Milan, Italy

Background: Long-acting cabotegravir (CAB-LA) is a key addition to HIV prevention but requires more resources than oral PrEP. To guide sustainable use, we estimated the proportion of users in Italy who may truly need CAB-LA.

Methods: We analyzed PrEP users from the Italian PrIDE cohort, a nationwide observational study. Participants were enrolled July 2024-August 2025 in 14 hospital and 3 community sites. The “active oral PrEP” population excluded definitive discontinuation, CAB-experience, and those lost to follow-up (no visit ≥ 6 months). Observation spanned from first post-enrolment visit to last visit plus 90 days.

Eligibility criteria (≥ 1 for inclusion): renal impairment (eGFR ≤ 60 mL/min/1.73m², contraindicated if < 60), proximal tubular dysfunction, proteinuria, or decline > 20 mL/min; poor self-reported adherence, defined as $< 60\%$ on a 0–100 visual analog scale for daily users or “sometimes/never” correct 2+1+1 on-demand (including chemsex-induced); drug intolerance required both side effects and ≥ 1 suspension for adverse events (excluding intermediate suspensions); psychiatric comorbidities; malabsorption syndromes; and being a cis or transgender women. Renal decline was assessed over ≥ 6 months. Time on PrEP was described but not modeled to avoid time-dependent bias. Predictors were tested with logistic regression and Cox models (censoring at last visit plus 90 days).

Results: Among 2,368 PrEP users, 337 (14.2%) met ≥ 1 one strict eligibility criterion. Specifically, 156 (6.6%) reported poor adherence, 61 (2.6%) psychiatric comorbidities, 38 (1.6%) suboptimal renal function, 32 (1.4%) drug intolerance, 27 (1.1%) malabsorption, and 23 (1.0%) were cisgender or transgender women (Table 1). In univariable logistic regression, higher education was linked with lower odds of eligibility (OR 0.60; 95% CI 0.39–0.93). In the multivariable logistic model, receiving care in a community-based setting was significantly associated with a lower risk of LA-PrEP eligibility (OR 0.65; 95%CI: 0.47 – 0.88; $p=0.007$), likely due to referral of complex PrEP cases to hospitals.

Conclusions: In our nationally representative cohort, 14.2% of oral PrEP users met strict clinical or behavioral criteria for CAB-LA. Only a minority would therefore require LA PrEP, supporting a targeted rather than universal rollout. Restricting access to those with clear needs would increase feasibility and sustainability while directing resources to those most likely to benefit.

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Expanding PrEP horizons: gender, age and community engagement in HIV prevention

OC 26 PROPORTION OF DAYS COVERED BY LONG-ACTING CABOTEGRAVIR VERSUS ORAL PREP IN THE ITALIAN PRIDE COHORT

V. Mazzotta¹, S. Nozza², S. Leone¹, G. Frate³, D. Farinacci¹, E. Caruso⁴, A.R. Raccagn², A. Lucchini⁵, G.C. Marchetti⁶, A.M. Cattelan⁷, M. Tutone⁵, V.L. del Negro⁸, R. Rossotti, C. Tincati⁶, C. Mussini¹⁰, M. Cernuschi⁴, A. Gori¹¹, A. Castagna², A. Antinori¹, D. Moschese¹¹

¹INMI L. Spallanzani IRCCS- Roma, Italy, ²Ospedale San Raffaele, Università Vita-Salute - Clinica Malattie Infettive - Milano, Italy, ³Fondazione ICONA, Italy, ⁴Milano Checkpoint, Italy, ⁵Azienda Sanitaria Locale "Città di Torino", Torino, Italy, ⁶ASST Santi Paolo e Carlo, Milan, Italy, ⁷University Hospital of Padova, Padua, Italy, ⁸PLUS Roma, Italy, ⁹ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ¹⁰Azienda Ospedaliero-Universitaria, Policlinico of Modena, Modena, Italy, ¹¹Luigi Sacco Hospital, ASST Fatebenefratelli Sacco, Milan, Italy

Background: The impact of oral PrEP with tenofovir disoproxil fumarate/emtricitabine (F/TDF) can be limited by poor adherence. Long-acting cabotegravir (CAB-LA) may overcome adherence challenges and enhance prevention coverage, yet real-world evidence from Europe is lacking. We described Italian CAB-LA use in the Italian PrIDE cohort, compared proportion of days covered (PDC) between CAB-LA and F/TDF, and explored predictors of low PDC.

Methods: All PrEP users enrolled in the PrIDE cohort from December 2024 (CAB availability) to December 2025 (database cut-off) were included.

PrEP coverage was measured as the proportion of days covered (PDC) from the first injection or refill through the follow-up period and was compared between the CAB-LA and F/TDF groups using the Wilcoxon rank-sum test. Predictors of poor coverage (defined as >4 weeks delay from target CAB injection and <4 pills/week for F/TDF) were assessed by a multivariable logistic regression. For CAB-LA, injections were classified as on time (within ± 7 days from the target date), delayed (>7 days), or interrupted; discontinuations were categorised by reason.

Results: Among 4,105 users, 487 (12%) received CAB-LA and 3,618 (88%) oral PrEP. Overall, participants were mostly Italian (87.3%) and male (98.5%), with a median age of 37 years (IQR 31–45) (Table 1).

Median PDC was 100.0 (IQR 100.0–100.0) with CAB-LA and 87.6 (71.4–100.0) with oral PrEP ($p < 0.001$) (Figure 1A).

Poor coverage occurred in 37/487 (7.6%) CAB-LA and 338/3,618 (9.3%) oral users ($p = 0.21$).

In oral PrEP, poor coverage was less likely in community-based vs hospital settings (aOR 0.69, 95%CI 0.51–0.94; $p = 0.021$) and more likely in Centre/South/Islands vs North (aOR 1.33, 1.05–1.70; $p = 0.020$). No predictors of low PDC were identified in the CAB-LA group.

Overall, 94.1% of injections were on time, with on-time proportions remaining ~92–93% from the 4th to the 8th injection (Figure 1B). CAB-LA discontinuations occurred in 35 users (7.2%): 20 switched to oral PrEP and 15 discontinued definitively. The most frequent reasons for discontinuation were perceived reduction of sexual exposure risk (23%), injection-site reactions (23%) and logistical barriers (17%) (Table 2).

Conclusions: In the Italian experience of the PrIDE cohort, CAB-LA was feasible and achieved higher prevention coverage than oral F/TDF, with high injection timeliness, supporting its role to mitigate adherence barriers in real-world settings. Oral PrEP coverage gaps clustered by care setting and geography, suggesting targets for tailored adherence support.

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Expanding PrEP horizons: gender, age and community engagement in HIV prevention

OC 27 MISSED OPPORTUNITIES FOR DOXY-PEP USE AMONG INDIVIDUALS AT RISK: A CROSS-SECTIONAL STUDY WITHIN THE PRIDE COHORT

A. De Vito¹, R. Lolatto², E. Caruso³, G. Micheli⁴, A.R. Raccagnì⁵, D. Tesoro⁶, A.M. Lucchini⁶, A. Gizzi⁷, L.V. Del Negro⁸, J. Testa⁹, M. Menozzi¹⁰, L. Pipitò¹¹, A.M. Cattelan¹², S. Cerere¹³, M. Merelli¹⁴, G. Ancona⁶, D. Moschese¹⁵, M. Cernuschi¹⁶, V. Mazzotta⁴, S. Nozza¹⁷, R. Rossotti¹⁸

¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ²PRIDE Cohort, Italy, ³Associazione Milano Check Point – Milano, Italy, ⁴U.O.C. Immunodeficienze Virali e IST, INMI “L. Spallanzani” IRCCS – Roma, Italy, ⁵Ospedale San Raffaele, Università Vita-Salute – Clinica Malattie Infettive – Milano, Italy, ⁶U.O.C. di Malattie Infettive e Tropicali, Presidio San Paolo – ASST Santi Paolo e Carlo – Milano, Italy, ⁷Unit of Infectious Diseases, A.R. N.A.S. Civico, Palermo, Italy, ⁸Roma Check Point – Roma, Italy, ⁹Unità Complessa di Malattie Infettive, ASST Valle Olona, Busto Arsizio, Italy, ¹⁰Università degli Studi di Modena e Reggio Emilia, Modena – Clinica di Malattie Infettive e Tropicali – Modena, Italy, ¹¹Unit of Infectious Diseases, Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties, University of Palermo, Palermo, Italy, ¹²Azienda Ospedaliera di Padova – U.O.C. Malattie Infettive – Padova, Italy, ¹³BLQ Check Point – Bologna, Italy, ¹⁴Infectious Diseases Clinica, ASU FC, Udine, Italy, ¹⁵Dipartimento Malattie Infettive – ASST Fatebenefratelli Sacco – Ospedale Luigi Sacco – Milano, Italy, ¹⁶Associazione Milano Check Point – Milano, Italy, ¹⁷Clinica Malattie Infettive – Ospedale San Raffaele, Università Vita-Salute – Milano, Italy, ¹⁸S.C. Malattie Infettive – ASST Grande Ospedale Metropolitano Niguarda – Milano, Italy

Background: Doxycycline post-exposure prophylaxis (doxy-PEP) is an emerging strategy to reduce sexually transmitted infections (STIs) among individuals at high risk. Despite growing evidence of its effectiveness, uptake remains limited and heterogeneous. Identifying missed opportunities (MO) for doxy-PEP use in the presence of risk factors is crucial to optimize prevention strategies. Within the PRIDE cohort, we aimed to quantify MO and identify factors associated with non-use, including the role of counselling.

Methods: We conducted a cross-sectional analysis of visits within the PRIDE cohort, including people with at least one predefined STI risk factor: chemsex, group sex, >50 sexual partners in the previous 3 months, or sex work. Missed opportunities were defined as non-use of doxy-PEP in the presence of at least one risk factor in the prior 3 months. Demographic, behavioral, and clinical variables were analyzed. Logistic regression models with robust standard errors clustered by participant ID were used to account for repeated visits within individuals and to identify factors associated with MO.

Results: We included 1,387 people for a total of 2,390 visits, including 909 doxy-PEP use and 1,481 MO (Table 1). Participants were predominantly cisgender men (92.1%), with a mean age of 40.5 (±9.7) years. MO were more frequent among individuals with shorter time on PrEP and lower educational levels, and among transgender individuals. In addition, MO remained frequent across individuals reporting chemsex (227/420, 54.0%), group sex (1,216/2,067, 58.8%), and sex work (217/268, 81.0%).

In multivariable analysis, longer time on PrEP was associated with lower odds of MO (OR 0.80, 95% CI 0.75–0.85), whereas female cisgender (OR 11.9, 95% CI 1.76–80.85) and transgender individuals (OR 8.97, 95% CI 3.20–25.15) had higher odds of non-use (Table 2). Behavioural factors associated with a lower likelihood of MO included a high level of education (OR 0.64, 95% CI 0.49 – 0.83), chemsex use (OR 0.56, 95% CI 0.42–0.74) and group sex (OR 0.12, 95% CI 0.05–0.26), as well as higher numbers of sexual partners. Conversely, MenB vaccination was associated with increased odds of MO (OR 1.84, 95% CI 1.38–2.45).

Among individuals with MO, prior doxy-PEP use was associated with longer time on PrEP, higher likelihood of counselling, and higher prevalence of high-risk behaviours, including sex work and a higher number of sexual partners (Table 3). Counselling was strongly associated with doxy-PEP use, both at the current visit and in previous visits.

Conclusion: Missed opportunities for doxy-PEP use remain frequent among individuals at high risk for STIs in the PRIDE cohort. Uptake is influenced by demographic, behavioral, and structural factors, including time on PrEP, gender identity, education, and counselling exposure. Targeted interventions, particularly improved and systematic counselling, may reduce disparities and increase doxy-PEP uptake among underserved populations.

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Expanding PrEP horizons: gender, age and community engagement in HIV prevention

OC 28 CHARACTERISTICS OF CISGENDER AND TRANSGENDER WOMEN IN PRIDE COHORT, RISK BEHAVIOURS AND STIGMA

G. Micheli¹, D. Farinacci¹, R. Lolatto², C. Fusetti³, E. Caruso⁴, E. Bruzzese⁵, A. Lucchini⁶, D. Tesoro⁷, L. Taramasso⁸, A. Raimondi⁹, A.M. Cattelan¹⁰, E. Milano¹¹, E. Zappulo¹², F. Conti¹³, S. Venturilli¹⁴, A. De Bona⁷, A. Antinori¹, D. Moschese³, S. Nozza², V. Mazzotta¹

¹National Institute "Lazzaro Spallanzani" IRCCS, Rome, Italy, ²IRCCS Ospedale San Raffaele, Infectious Diseases Unit, Milan, Italy, ³Department of Infectious Diseases, Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ⁴Milano Checkpoint, Milano, Italy, ⁵Infectious Diseases Unit, Vita-Salute San Raffaele University, Milan, Italy, ⁶"Amedeo di Savoia" Hospital, Unit of Infectious Diseases, Turin, Italy, ⁷Infectious Diseases Unit, ASST Santi Paolo e Carlo, University of Milan, Milan, Italy, ⁸Infectious Diseases, San Martino Hospital Genoa, University of Genoa, Genoa, Italy, ⁹Department of Infectious Diseases, ASST Grande Ospedale Metropolitano Niguarda, School of Medicine and Surgery, Milan, Italy, ¹⁰Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ¹¹Clinic of Infectious Diseases, Department of Precision and Regenerative Medicine and Ionian Area, Polyclinic of Bari, University Hospital Polyclinic, University of Bari, Bari, Italy, ¹²Department of Clinical Medicine and Surgery, Infectious Diseases Unit, University of Naples Federico II, Naples, Italy, ¹³Infectious Diseases Unit, ASST Lecco, Lecco, Italy, ¹⁴Infectious Diseases Unit, ASST "Papa Giovanni XXIII", Bergamo, Italy

Background: While HIV-PrEP scale-up has expanded in several settings, key-populations at ongoing risk, particularly women, remain underrepresented among PrEP users.

The limited clinical and epidemiological data available on cisgender and transgender women (CW/TW) underscores persistent structural, stigma and gender-related barriers to access and continuity of care.

In the context of the ICONA PrIDE cohort, comparative analyses of CW/TW vs gay and bisexual men who have sex with men (GBMSM) may clarify behavioral and stigma related determinants of PrEP use.

Methods: We conducted an analysis within the PrIDE cohort including CW/TW initiating PrEP, matched 1:2 with GBMSM using nearest-neighbor propensity score matching adjusting for age, education, employment, and relationship status. We compared demographics, lifestyle habits, sexually transmitted infections (STI) history, HIV post-exposure prophylaxis (PEP) experience, PrEP schedule, and responses to questionnaires on sexual behaviors, and stigma. Categorical variables were compared using chi-square or Fisher's exact test, and continuous variables using Wilcoxon rank-sum test.

Results: Among 219 matched participants (68 CW, 5 TW and 146 GBMSM), baseline characteristics were comparable (Table 1). CW/TW were more likely to initiate daily rather than on-demand regimens (58.9% vs 39.7%, $p < 0.001$), consistent with recently extended recommendations regarding on-demand PrEP use in CW. Knowledge of DoxyPEP was lower among CW/TW (27.4% vs 43.2%, $p = 0.036$), whereas no differences were observed in previous PEP experience. No differences emerged in tobacco, alcohol, drugs, or physical enhancers use.

Regarding questionnaire, CW/TW more frequently reported receptive condomless intercourse in the last three months (19.2% vs 13.0%, $p = 0.033$) and sharing of sex toys with partners (8.2% vs 4.7%, $p = 0.024$). Sexual behaviors were similar, with no differences in number of partners (16.4% vs 23.3%, $p = 0.089$), history of condomless intercourse ($p = 0.144$), or chemsex use ($p = 0.625$). However, GBMSM more frequently reported a diagnosis of at least one STI (62.3% vs 47.9%, $p = 0.005$). Both groups reported high confidence in correct adherence, minimal changes in sexual habits after PrEP initiation, and low interference of PrEP with daily life. No differences were observed in reduction of condom use ($p = 0.788$) or group sex ($p = 0.706$).

Following an STI diagnosis, GBMSM more frequently reported feelings of stigma (9.6% vs 0%, $p = 0.003$), whereas no differences were found in stigma related to PrEP use (1.4% vs 1.4%, $p = 0.583$). Similarly, no differences emerged in self-reported depressive (2.7% vs 0%, $p = 0.414$) or anxiety symptoms (1.4% vs 0.7%, $p > 0.999$).

Conclusions: CW/TW demonstrated behavioral risk profiles comparable to GBMSM. This suggests that engagement strategies and educational policies should be implemented in order to ensure CW/TW can access to equitable, tailored, and gender-aligned PrEP services.

Table 1, figure 1

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PrEP, doxyPEP and beyond: the new challenges of STI prevention

OC 29 INCIDENCE AND PREDICTORS OF FIRST AND SUBSEQUENT BACTERIAL SEXUALLY TRANSMITTED INFECTIONS (STIS) AMONG PREP USERS IN THE ITALIAN PRIDE COHORT

D. Farinacci¹, P. Stolfi¹, R. Esvan¹, G. Frate¹, A.R. Raccagni², C. Fusetti³, S. Lazzarin³, A. Lucchini⁴, M. Augello⁵, V.L. Del Negro⁶, A.M. Cattelan⁷, S. Cerere⁸, M. Menozzi⁹, F.M. Fusco¹⁰, M. Tutone¹¹, A. Antinori¹, M. Cernuschi¹², S. Nozza², D. Moschese³, V. Mazzotta¹

¹National Institute "Lazzaro Spallanzani" IRCCS, Rome, Italy, ²Infectious Diseases Unit, Vita-Salute San Raffaele University, Milan, Italy, ³Department of Infectious Diseases, Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ⁴Unit of Infectious Diseases, Department of Medical Sciences, University of Turin, Turin, Italy, ⁵Clinic of Infectious Diseases and Tropical Medicine, Department of Health Sciences, San Paolo Hospital, ASST Santi Paolo E Carlo, University of Milan, Milan, Italy, ⁶Roma Checkpoint, Rome, Italy, ⁷Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ⁸PLUS aps (BLQ Checkpoint), Bologna, Italy, ⁹Clinic of Infectious Diseases, University Hospital of Modena, University of Modena and Reggio Emilia, Modena, Italy, ¹⁰UOC Infezioni sistemiche e dell'Immunodepresso, PO "D. Cotugno", AO dei Colli, Napoli, Italy, ¹¹Ce.Mu.S.S., Department of Prevention - ASL Città di Torino, Turin, Italy, ¹²Milano Checkpoint, Milan, Italy

Background: Pre-exposure prophylaxis (PrEP) is a cornerstone of HIV prevention, but PrEP users remain at substantial risk for bacterial STIs and risk compensation has been suggested as a potential contributor to this burden. Previous data from Italian cohort reported incidence rates (IR) of around 24, 23 and 13 per 100 PYFU for gonorrhoea (NG), chlamydia (CT) and syphilis (TP), respectively, with frequent subsequent infections. We assessed IRs of first and subsequent STIs in the PrIDE cohort and identified predictors of recurrent infections, to flag individuals at persistently high STI risk despite counselling and inform targeted prevention strategies.

Methods: We included PrEP users enrolled in the PrIDE cohort up to December [VM1.1][VM1.2]2025. Demographic, behavioural and clinical data were collected. STI prevalence at enrolment was assessed using samples collected within 28 days. IR of TP, NG and CT and of subsequent STI events were calculated per 100 person-years of follow-up. Time to first STI and to first subsequent event (defined at least 60 days after a previous positive test) was estimated using Kaplan–Meier (KM) analysis, stratified by symptomatic vs asymptomatic presentation when available.

Predictors of STI occurrence and recurrence were assessed by a penalised Cox model, including doxyPEP use as a covariate.

Results: A total of 5.759 participants were included in the analysis. Most were male (5.674, 98.5%) with a median age of 37 years (IQR 31-45), and 65% had a university degree.

Baseline prevalence was 8.2% for CT, 9.4% for NG and 3.4% for TP.

IR/100 PYFU were 20.0 (17.9, 22.2) for CT, 25.0 (22.7, 27.4) for NG and 7.8 (6.5, 9.2) for TP.

When stratified by symptomatic events, IRs were higher for symptomatic individuals: 48.8 (32.9, 69.6) for CT, 60.2 (42.3, 82.9) for NG and 30.9 (18.1, 48.2) for TP.

Overall, 693 first events and 138 second events were observed over a median follow-up of 191 days. KM analysis showed a progressive increase in the probability of a first STI, mostly within the first year of follow-up. Symptomatic individuals exhibited a steeper early increase in cumulative incidence compared with asymptomatic individuals (Figure 1). The cumulative incidence of a second STI increased more gradually over time (Figure 2).

A higher number of sexual partners in the last 3 months and student status were the strongest predictors of incident STI (Figure 3).

Conclusions: In the PrIDE cohort, bacterial STIs remain frequent among PrEP users, with a substantial burden of early and recurrent events, particularly within the first year of follow-up and among symptomatic presentations. A higher number of recent sexual partners and student status emerged as key predictors of incident STIs. These findings highlight the need for intensified, risk-tailored prevention strategies focused on individuals at persistently elevated risk.

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PrEP, doxyPEP and beyond: the new challenges of STI prevention

OC 30 DOXYPEP REMAINS UNDERUTILISED TO EXERT ITS FULL PROTECTION: DATA FROM A COHORT OF PREP USERS

E. Caruso¹, C. Muccini^{1,2}, P. Russo¹, A. De Bona^{1,3}, D. Moschese^{1,4}, N. Frattini¹, L. Nekrasova¹, D. Tesoro^{1,3}, V. Iannone^{1,4}, P. Vinti¹, M. Cernuschi¹, R. Rossotti^{1,5}

¹Milano Checkpoint ETS, Milan, Italy, ²San Raffaele Scientific Institute, Milan, Italy, ³ASST Santi Paolo e Carlo, Milan, Italy, ⁴ASST Fatebenefratelli-Sacco, Milan, Italy, ⁵ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy

Background: DoxyPEP has demonstrated high effectiveness against bacterial sexually transmitted infections (bSTI); however, its utilisation among PrEP users in everyday clinical practice remains unclear. Aims of this study were to: (i) describe the characteristics of individuals who chose to use doxyPEP, (ii) explore the contexts in which it is most frequently used, and (iii) describe its real-life safety, tolerability, and efficacy.

Methods: This retrospective analysis included all individuals with at least two visits between January 2024 and September 2025 to a community-based service providing free medical assistance to PrEP users. Participants were prescribed doxyPEP, with recommendations for its use specifically during sexual exposures involving a high number of partners within a short timeframe. Descriptive and nonparametric statistics were used to characterise the study population. Logistic regression was applied to identify individual and behavioural factors associated with doxyPEP uptake. Poisson regression was used to evaluate its effect on bSTI incidence.

Results: The study included 975 individuals, representing a total of 4,187 visits; 382 of these individuals reported using doxyPEP at least once (Table 1). The median number of doses administered between visits was 2 (IQR 1-3). The majority (92.9%) adhered to the prescribed schedule. Factors associated with doxyPEP use were chemsex (aOR 2.18, 95%CI 1.63-2.90), years on PrEP (aOR 1.17, 95%CI 1.12-1.23), and a higher number of sexual intercours (aOR 1.06 per 10 more, 95%CI 1.03-1.08). DoxyPEP was primarily used during groupsex (57.1%) and when attending cruising venues (48.6%). Adverse events were uncommon (13.9%), predominantly gastrointestinal (93.0%). After adjusting for age, chemsex use, and number of sexual intercours, the effect of doxyPEP on the risk of bSTIs acquisition was not protective (IRR 1.15, 95%CI 1.05-1.26).

Discussion: In our population, doxyPEP was utilised by individuals at significant risk of exposure for a limited number of sexual encounters. Although employed in high-risk contexts, it did not demonstrate a protective effect, likely due to the infrequent use and to risk compensation issues. Substantial efforts regarding counselling and prescription are required to achieve a significant protective effect at both the individual and population levels.

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PrEP, doxyPEP and beyond: the new challenges of STI prevention

OC 31 AWARENESS OF KEY PREVENTION TOOLS IN SEXUAL HEALTH: COMPARISON OF KEY GROUPS FROM A CROSS-SECTIONAL SURVEY DURING EUROPEAN TESTING WEEK IN ROME (LET'S TEST! STUDY)

G. Micheli, R. Esvan, G. Frate, V. Barchi, F. Cannone, D. Farinacci, R. Speranza, R.J. Steiner, O. Bruzzi, A. Giacinta, S. Onori, A. Antinori, V. Mazzotta

National Institute for Infectious Diseases "Lazzaro Spallanzani"- IRCCS, Rome, Italy

Background: Dissemination of sexual health prevention knowledge and implementation of tools such as PrEP, PEP, and HIV testing are still scarce in key vulnerable populations at-risk of acquiring HIV infection, such as young people and women. Large-scale initiatives like European Testing Week (ETW) may help identify missing key populations not reached by current preventive campaigns and interventions.

Material and Methods: A cross-sectional survey was conducted in Rome during the ETW campaign in 2024 (with LGBTI and gender-violence advocacy organisations) and 2025 (with family counselling clinics). Sociodemographic characteristics, risk behaviors, HIV prevention knowledge of the key HIV-prevention concepts (PrEP, PEP, and U=U), and reasons for testing were collected through a standardised assessment. Baseline HIV and syphilis prevalence were determined using rapid POC tests. Logistic regression and multivariable mixed-effects logistic regression models were fitted to estimate the overall and topic-specific appropriate knowledge.

Results: Of 397 individuals enrolled (290 in 2024, 107 in 2025), participants in 2025 were younger, more often cis women, and less often university-educated (all p-values <0.001; Table 1). A previous STI was reported in 29.9% of cases overall (36.8% in 2024 vs 10.2% in 2025; p<0.001).

First-ever HIV testing occurred in 43.3% overall and was higher in those observed in 2025 (72.0% vs 32.8%; p<0.001). The main reason for testing was personal willingness (82.8%; 97.1% vs 77.6%), followed by recent at-risk exposure (11.4%, mainly 2024) (p<0.001). Rapid testing identified 2 reactive HIV results (0.5%), both in people tested in 2024.

Knowledge of prevention tools was limited overall and lower in the population accessing in 2025. (Figure 1). Awareness of doxycycline PEP was rare (4.0%), precluding regression analyses. In multivariable analysis, older age was independently associated with greater overall knowledge of prevention tools (35-44 years: aOR 2.89, 95%CI 1.10-7.58, p 0.03, 45-59 years: aOR 7.962, 95%CI 2.319, 27.333, p <0.001). Table 2 shows predictors of knowledge of each HIV prevention topic.

Conclusions: The ETW campaign may reach underserved populations and identify many first-time testers, particularly younger individuals. Knowledge gaps were evident among younger people and in groups with lower educational levels, highlighting the need to expand sexual health education and develop tailored prevention strategies integrated within testing initiatives. Different outreach settings engaged distinct profiles, reinforcing the value of combining rapid testing with setting-specific education.

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PrEP, doxyPEP and beyond: the new challenges of STI prevention

OC 32 HIV BURDEN AND TESTING PATTERNS AMONG PATIENTS WITH SEXUALLY TRANSMITTED INFECTIONS: A 30-YEAR REAL-WORLD ANALYSIS

M. Giuliani¹, C. Stingone¹, L. Gianserra¹, M. Zaccarelli¹, F. Pimpinelli², M. G. Donà¹, E. Giuliani¹, F. Di Tullio¹, A. Latini¹

¹STI/HIV Unit, San Gallicano Dermatological Institute IRCCS, Rome, Italy, ²Microbiology and Virology, San Gallicano Dermatological Institute, IRCCS, Rome, Italy

Background: Sexually transmitted infections (STIs) are important markers of HIV acquisition risk and provide key opportunities for HIV testing and diagnosis. However, real-world data describing HIV serostatus, testing coverage, newly diagnosed and known HIV infection across specific STI diagnoses remain scarce.

Material and Methods: We conducted a retrospective analysis of all STI cases diagnosed at an urban referral centre over three decades. For each STI case, the known HIV-positive status at presentation, HIV test result at time of STI diagnosis, and newly identified HIV infection were available.

Results: From January 1991 to December 2023, 17,771 STI cases were recorded. Overall, an HIV test result was available for 8,299 (46.7%) patients; 829 of these were previously known to be people living with HIV (PLWH), and 7,470 underwent HIV testing at the time of STI diagnosis. The proportion of cases with known HIV infection at presentation varied substantially by STI, ranging from 33.3% for lymphogranuloma venereum, 16.0% for infectious syphilis (primary, secondary and early latent) and 14.6% for late latent syphilis, to 1.4% for anogenital warts and <1.0% for non-gonococcal non-chlamydial urethritis and vaginitis. Overall, HIV period prevalence was 12.3% (1,023/8,299; 95% CI: 11.6–13.0) and differed markedly across STIs: from 45.5% (5/11; 95% CI: 19.8–70.2) in lymphogranuloma venereum, 25.1% (136/542; 95% CI: 21.4–28.7), in latent syphilis, 22.3% (472/2,121; 95% CI: 20.5–24.9) in infectious syphilis, to 6.2% (196/3,238; 95% CI: 5.4–7.0) in anogenital warts, 3.8% (22/584; 95% CI: 2.2–5.3) in genital herpes, 3.0% (6/202; 95% CI: 0.6–5.3) in non-gonococcal non-chlamydial urethritis, and 1.6% (3/190; 95% CI: undetermined) in non-gonococcal non-chlamydial vaginitis. Among cases tested at the time of STI diagnosis, the highest proportions of new HIV diagnoses were observed in latent syphilis (4.9%). HIV testing coverage varied widely across STIs, with higher coverage in syphilis, gonorrhoea, lymphogranuloma venereum, and genital herpes (median tested: 72.9%; IQR 69.0–73.3), and lower coverage in anogenital warts and molluscum contagiosum (median tested 28.1%; IQR 23.9–30.2).

Conclusions: STI diagnoses are associated with a heterogeneous yet often substantial HIV burden, partly driven by a high proportion of PLWH within STI case series. Although HIV testing coverage is higher for STIs most strongly linked to HIV acquisition risk, a considerable proportion of patients remain unaware of their serostatus at the time of STI diagnosis, representing missed opportunities for timely HIV detection. These findings are consistent with data from the Italian STI Sentinel Surveillance System and likely reflect a broader, system-level gap rather than a local anomaly. In line with recommendations from other European settings, opt-out HIV testing should be systematically implemented for all STI diagnoses, including those traditionally considered to be at lower risk.

PrEP, doxyPEP and beyond: the new challenges of STI prevention

OC 33 INCIDENT SYPHILIS AND IMMUNOVIROLOGICAL PERTURBATIONS IN VIRALLY SUPPRESSED PEOPLE LIVING WITH HIV: A REAL-WORLD SELF-CONTROLLED COHORT STUDY

E. Zappulo, G. Di Filippo, S. Mercinelli, M. Cotugno, S. Candilio, M. D'Amato, M.A. Landri, M. Silvitelli, I. Gentile

Department of Clinical Medicine and Surgery, Infectious Diseases Unit, University of Naples Federico II, Naples, Italy

Background: Syphilis and other STIs are resurging among PLWH. In the ART era, syphilis may transiently perturb immune markers and trigger low-level HIV-RNA detectability, but determinants and real-world impact on durable suppression remain uncertain.

Methods: We analysed our PLWH cohort in care (N=677) at the Infectious Diseases Division, AOU Federico II, Naples, to describe temporal trends and predictors of first incident syphilis after centre entry (Cox model; censoring at last visit). Separately, we performed a self-controlled episode analysis of incident syphilis occurring on ART with documented pre-event HIV-RNA <200 cp/mL. For each episode we extracted CD4, CD8, CD4/CD8 ratio and lymphocytes at T-1 (median 116 days before diagnosis), T0 (diagnosis) and T+1 (median 126 days after). Paired changes were tested (Wilcoxon). Mixed models (random intercept per patient) explored predictors of Δ ratio. Virological outcomes were detectable HIV-RNA at T0 (≥ 50 cp/mL, DETECT50), BLIP (50–199 with pre/post <50) and confirmed viraemia (≥ 200 at T0 and post). DETECT50 predictors were assessed by GEE (clustered by patient).

Results: Over 6,706 person-years, 101/677 patients developed incident syphilis after entry (1.49/100 PY). In multivariable Cox analysis, MSM (aHR 6.24, 95%CI 3.13–12.45) and male sex (aHR 3.75, 1.25–11.29) predicted incident syphilis, while CDC stage did not. Episode incidence increased from 1.30/100 PY (2010–2015) to 3.02/100 PY (2020–2025) (Fig.1); calendar year was associated with higher incidence (IRR 1.056/year, $p=0.009$; +5.6%/year). Median pre-episode CD4 was 702 (IQR 497–884) cells/mm³. From T-1 to T0, CD4 and CD8 showed no significant change (median Δ CD4 +7, $p=0.237$; Δ CD8 0, $p=0.864$), while CD4/CD8 ratio increased modestly (+0.033; $p=0.014$) (Table 1). Post-episode, CD4 and total lymphocytes increased (Δ T0→T+1 +46; $p=0.036$ and +75, $p=0.044$, respectively). At syphilis diagnosis, HIV-RNA was ≥ 50 cp/mL in 32/149 episodes (21.5%); BLIP occurred in 4/149 (2.7%), confirmed ≥ 200 cp/mL in 3/149 (2%). Baseline CD4/CD8 ratio <0.5 strongly predicted DETECT50 (aOR 10.33, 95%CI 2.47–43.20, $p=0.001$), independently from RPR titre, early syphilis, reinfection and CDC stage. At T0, detectable HIV-RNA occurred more frequently in episodes on PI-based ART (22.2% vs 7.8%). In GEE models, PI use was associated with DETECT50 in univariable analysis (OR 3.04, 95% CI 1.00–9.20, $p=0.049$), but not after adjustment for per baseline immune status. Higher RPR ($\geq 1:64$) was associated with larger Δ ratio (β +0.185, $p=0.043$).

Conclusions: In real-world, virally suppressed PLWH, incident syphilis is increasingly diagnosed and is associated with modest, largely reversible immunological changes and frequent low-level HIV-RNA detectability (one in five episodes, 21.5%) without loss of overall suppression. A low pre-event CD4/CD8 ratio identifies individuals at higher risk of virological perturbation, supporting intensified monitoring around syphilis episodes.

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PrEP, doxyPEP and beyond: the new challenges of STI prevention

OC 34 CHANGES IN MPOX CLINICAL PRESENTATION ACROSS EPIDEMIC PHASES: A SINGLE-CENTRE COHORT STUDY IN ITALY, 2022-2026

R.J. Steiner¹, P. Stolfi², V. Barchi¹, G. Frate¹, D. Farinacci¹, R. Esvan¹, L. Bordi¹, G. Micheli¹, A. Giacinta¹, R. Schiavone¹, N. Braccialarghe¹, G. De Carli³, F. Vairo³, F. Maggi¹, A. Antinori^{1,4}, V. Mazzotta¹

¹National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy, Regional AIDS Reference Center, Rome, Italy, ²Institute for Applied Mathematics "Mauro Picone", National Research Council, Rome, Italy, ³SERESMI, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ⁴Health Direction, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Background: The 2022–2023 mpox outbreak in Europe was characterized by a distinct clinical phenotype, predominantly affecting gay and bisexual men who have sex with men (GBMSM) and generally presenting with mild-to-moderate disease. After a decline in incidence, despite increasing population immunity due to vaccination policies, a resurgence occurred in 2025–2026. Whether the clinical presentation and disease course changed over time remains unclear. Here we describe and compare epidemiological and clinical features of mpox cases diagnosed at a single Italian referral centre across epidemic phases.

Methods: We conducted a single-centre retrospective analysis (May 2022–January 2026), comparing the 2022–2023 and 2025–2026 periods. Interepidemic cases were not included. Clinical and epidemiological characteristics were compared using logistic regression models. Adjusted models included age, HIV status, CD4 T-cell count at mpox diagnosis, and any smallpox vaccination (2nd or 3rd generation).

Adjusted Odds ratios (aORs) with 95% confidence intervals (CI) were estimated by maximum likelihood and represented as forest plots. Hospitalisation was defined as admission due to clinical need, not for isolation purposes. Disease severity was defined as the presence of ≥ 1 of the following: ocular involvement, pharyngitis, proctitis, hospitalisation, and > 20 lesions.

Results: Overall, 162 cases were recorded (136 in the 2022–2023 vs 26 in the 2025–2026). Median age was 40 years (IQR 33–46) and all cases were male at birth; 92.0% identified as GBMSM and 45.1% were people with HIV (97.2% on ART; median CD4 644 cells/mm³ [IQR 457–843]). Any smallpox/mpox vaccination was reported in 11.7%. MPXV clade Ib was detected only in 2025–2026 (23.1%) (Table 1).

In multivariable logistic regression adjusted for age, HIV status, CD4 count at diagnosis and vaccination, the 2025–2026 phase was associated with markedly lower odds of hospitalization due to clinical need (aOR 0.08, 95% CI 0.01–0.64; $p=0.017$) and concurrent STIs (aOR 0.21, 95% CI 0.06–0.81; $p=0.023$).

No evidence for a difference in disease severity was observed. Disease duration ≥ 28 days showed a non-significant trend toward higher odds in 2025–2026 with wide confidence intervals (aOR 2.13, 95% CI 0.49–9.22; $p=0.313$) (Figure 1).

Conclusions: In this single-centre cohort, the 2025–2026 resurgence was associated with substantially fewer hospitalisations and lower risk of concurrent STIs, independent of measured potential confounders. Overall disease severity did not differ between phases and estimates for other outcomes—including disease duration—were imprecise due to the limited sample size. Larger, multicentre studies integrating immunological and virological data are needed to clarify the determinants of this evolving epidemic pattern.

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Real World Evidence: insights from Italian Cohorts

OC 35 VIROLOGICAL AND CLINICAL OUTCOMES OF PWH WITH AND WITHOUT ADVANCED HIV DISEASE AND VERY HIGH HIV-RNA AT ART INITIATION: DATA FROM THE ICONA FOUNDATION COHORT

A. Giacomelli^{1,2}, N. Lentini³, A. Tavelli^{4,5}, A. Mondì⁶, L. Taramasso⁷, G. D'Ettore⁸, G.F. Pellicano⁹, G. Madeddu¹⁰, A. Di Biagio^{7,11}, E. Bruzzesi¹², V. Mazzotta⁶, A. Antinori⁶, S. Lo Caputo¹³, C.F. Perno¹⁴, A. d'Arminio Monforte⁴, on behalf of ICONA Foundation Study Group - ICONA cohort

¹Department of Infectious Diseases, ASST Fatebenefratelli Sacco, Luigi Sacco Hospital, Milan, Italy, ²Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milan, Italy, ³Department of Life Sciences and Public Health, Section of Hygiene, Università Cattolica del Sacro Cuore, Rome, Italy, ⁴ICONA Foundation, Milan, Italy, ⁵Department of Public Health, Experimental and Forensic Medicine, National PhD Programme in One Health Approaches to Infectious Diseases and Life Science Research, University of Pavia, Pavia, Italy, ⁶Clinical Infectious Diseases Department, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ⁷Infectious Disease Clinic, IRCCS Ospedale Policlinico San Martino, Genova, Italy, ⁸Department of Public Health and Infectious Diseases, Sapienza Università di Roma, Rome, Italy, ⁹Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, AOU Policlinico G. Martino, Messina, Italy, ¹⁰Unit of Infectious Diseases, Department of Medicine, Surgery, and Pharmacy, University of Sassari, Sassari, Italy, ¹¹Department of Health Sciences, University of Genoa, Genoa, Italy, ¹²Infectious Diseases Unit, Vita-Salute San Raffaele University, Milan, Italy, ¹³Clinic of Infectious Diseases, Department of Medical and Surgical Sciences, University of Foggia, 71122 Foggia, Italy, ¹⁴Microbiology and Diagnostics of Immunology Unit, Multimodal Research Area, IRCCS Bambino Gesù Pediatric Hospital, Rome, Italy

Background: Uncertainties persist regarding virological and clinical outcomes of people with HIV (PWH) across different HIV-RNA levels, particularly among those presenting with very high viral loads. We aimed to assess time to virological suppression (VS) and clinical outcomes among PWH initiating their first ART according to baseline HIV-RNA strata and advanced HIV disease (AHD) status.

Methods: We included all ART-naïve PWH enrolled in the ICONA cohort between 2018 and 2024 who initiated an integrase inhibitor-based regimen. Individuals with acute/recent HIV infection (negative test <12 months before enrolment) were excluded. Baseline HIV-RNA was stratified as <100,000, 100,000–499,999, and ≥500,000 copies/mL. AHD was defined as CD4 <200 cells/mm³ and/or AIDS. Baseline characteristics were summarized according to AHD status. Kaplan–Meier curves were used to estimate time to (1) first VS (HIV-RNA <50 copies/mL) and (2) a composite clinical endpoint (new AIDS events, major cardiovascular events, cancer, or death), according to HIV-RNA strata and AHD status. Cox regression models assessed the effect of AHD within each HIV-RNA stratum on virological and clinical outcomes, adjusting for sex assigned at birth, age, laboratory assay, mode of HIV acquisition, and country of origin.

Results: A total of 3,798 PWH were included, of whom 1,582 had AHD (539 [34.1%] with AIDS defining conditions). Compared with those without AHD, individuals with AHD were older (45 [IQR 36–55] vs 38 [30–49] years, $p<0.001$) and more frequently presented with HIV-RNA ≥500,000 copies/mL (41.2% vs 13.6%, $p<0.001$). Median CD4 count was 64 cells/mm³ (IQR 28–136) in PWH with AHD versus 424 cells/mm³ (IQR 313–581) in those without AHD ($p<0.001$) (Table 1).

Overall, PWH with AHD achieved VS more slowly than those without AHD. The longest time to VS was observed among PWH with HIV-RNA ≥500,000 copies/mL, particularly in those with AHD, who achieved VS after a median of 7.1 months (95% CI 6.6–7.8), compared with 5.8 months (95% CI 5.1–6.6) in those without AHD. The corresponding probabilities of VS at 12 and 24 months were 70.1% vs 77.2% and 87.4% vs 90.4%, respectively (Figure 1A,B,C and 2).

After adjustment, PWH with AHD had a consistently lower likelihood of achieving VS across all HIV-RNA strata (<100,000 copies/mL: aHR 0.85 [95% CI 0.75–0.96]; 100,000–499,999: aHR 0.85 [95% CI 0.75–0.96]; ≥500,000: aHR 0.84 [95% CI 0.72–0.98]). After adjustment, PWH with AHD showed a progressively higher risk of the composite clinical endpoint with increasing HIV-RNA levels: <100,000 copies/mL aHR 4.70 (95% CI 3.07–7.21); 100,000–499,999 aHR 5.23 (95% CI 2.82–9.69); and ≥500,000 aHR 6.15 (95% CI 2.99–12.63).

Conclusion: PWH with AHD had a consistently lower probability of achieving virological suppression, regardless of baseline HIV-RNA levels. Moreover, the risk of adverse clinical outcomes among individuals with AHD increased progressively with higher HIV-RNA levels at ART initiation.

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Real World Evidence: insights from Italian Cohorts

OC 36 DURABILITY OF BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE VS DOLUTEGRAVIR-BASED SINGLE TABLET REGIMENS IN A LARGE COHORT OF EXPERIENCED PWH: THE BIC-LASTING STUDY

R. Gagliardini¹, A. Cozzi-Lepri², A. Tavelli^{3,4}, A. Saracino⁵, V. Iannone⁶, F. Conti⁷, R. Corsini⁸, V. Mazzotta¹, M.C. Polisenò⁵, L. Albinì⁹, G. Forcina⁹, A. Gori¹⁰, A. Castagna¹¹, A. Antinori¹, A. d'Arminio Monforte³, on behalf of the Icona Foundation Cohort

¹National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ²Centre for Clinical Research, Epidemiology, Modelling and Evaluation (CREME), Institute for Global Health, UCL, London, UK, ³ICONA Foundation, Milan, Italy, ⁴National PhD Programme in One Health approaches to infectious diseases and life science research, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy, ⁵Clinic of Infectious Diseases, Department of Precision Medicine and Jonian Area (DiMePre-J), University of Bari "Aldo Moro", Bari, Italy, ⁶ASST Fatebenefratelli-Sacco, DIBIC Luigi Sacco, Milan, Italy, ⁷Infectious Diseases Unit, Alessandro Manzoni Hospital, Lecco, Italy, ⁸Infectious Disease Unit, Azienda USL-IRCCS di Reggio Emilia, Italy, ⁹Gilead Sciences Srl, Italy, ¹⁰II Infectious Diseases Unit, ASST Fatebenefratelli Sacco, Department of Biomedical and Clinical Sciences L. Sacco, Centre for Multidisciplinary Research in Health Science (MACH), University of Milan, Milan, Italy, ¹¹Department of Infectious Diseases, IRCCS San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Milan, Italy

Background: Large real-world data about the durability of bicittegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) vs. dolutegravir (DTG)-based single tablet regimens (STR) on treatment failure-related discontinuations are limited.

Methods: BIC-LASTING (GS-IT-380-7317, sponsored by Gilead Sciences) is a retrospective analysis on people with HIV (PWH) enrolled in the ICONA cohort who initiated BIC/FTC/TAF or a DTG-STR (both two-drug regimens-2DR- and 3DR) with HIV-RNA $\leq$ 50 cp/mL after Jan-2019 (baseline). PWH of the DTG-STR group who were previously on the same non-STR regimen were excluded. Baseline characteristics were compared by treatment group. Main reasons for treatment discontinuations (TD) as reported by the treating physician were collected. The primary endpoint was time to VF/AEs-related TDs, i.e. TD due to virological failure (VF) or toxicity. VF/AEs-related TDs were compared between groups using Kaplan-Meier (KM) curves and Cox regression models adjusted for selected covariates. Secondary endpoints: time to TD regardless of the reason (including simplification) overall and after excluding the switch from abacavir (ABC)/lamivudine(3TC)/DTG to DTG/3TC.

Results: We included 4,520 PWH; 2,332 who started BIC/FTC/TAF (52%) vs. 2,188 DTG-STR (48%), mainly DTG/3TC (75%), followed by DTG/rilpivirine (18.7%) and DTG/3TC/ABC (6.2%). Median age was 48 years (interquartile range, IQR:39-56), 19% females, CD4 count of 726 cells/mm³ (528-954). NRTI backbone of the previous regimen was the most imbalanced factor between groups (in DTG-STR mainly with ABC/3TC (50%) while only 38% used TAF/FTC, $p<0.001$), followed by calendar year of baseline (2021 for DTG vs 2020, $p<0.001$). Over a median follow-up of 39 months (22-52), 210 VF/AEs-related TDs were observed (42 VF and 168 AEs). The 2-year risk of VF/AEs-related TD was 3.7% (95% CI 2.9–4.5) with BIC/FTC/TAF vs 3.9% (3.0–4.8) with DTG-STR ($p=0.164$). After controlling for confounders, no evidence for a difference between the 2 groups in the primary endpoint was observed in the adjusted Cox regression model (BIC vs DTG-STR: adjusted Hazard Ratio (aHR): 0.77, 95% CI 0.55-1.07) (Table 1). For the secondary endpoint of TD for any reason, additional discontinuations were counted as events: 585 for simplification, 45 for PWH's decision and 193 for other reasons. No evidence for differences among the 2 groups was found in the risk of TD for any reason overall (BIC vs DTG-STR: aHR 0.89, 95% CI 0.76-1.04) and after excluding the switch from ABC/3TC/DTG to DTG/3TC (BIC vs DTG-STR: aHR 1.14, 95% CI 0.97-1.35) (Tables 2-3).

Conclusions: In virologically suppressed PWH, no evidence for a difference in treatment failure was observed in those switching to BIC/FTC/TAF compared to DTG based STR, including 2DR in 94% of cases. These data support the favourable long-term efficacy and safety profile of BIC/FTC/TAF in clinical practice. Immortal time bias, and the possibility of unmeasured confounding cannot be excluded.

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Real World Evidence: insights from Italian Cohorts

OC 37 LEGACY ART IN THE MODERN ERA: WHO STILL RECEIVES OUTDATED REGIMENS?

A. Vergori¹, A. Tavelli^{2,3}, A. Giacomelli⁴, S. Rusconi⁵, S. Nozza⁶, A. Costantini⁷, G. Lapadula⁸, S. Bonora⁹, G. Madeddu¹⁰, R. Gagliardini¹¹, A. Antinori¹¹, A. d'Arminio Monforte², S. Lo Caputo¹

¹Infectious Diseases Unit, Department of Clinical and Surgical Sciences, University of Foggia, Foggia, Italy, ²ICONA Foundation, Milan, Italy, ³National PhD Programme in One Health approaches to infectious diseases and life science research, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy, ⁴III Infectious Diseases Unit, ASST Fatebenefratelli-Sacco, DIBIC Luigi Sacco, Università degli Studi di Milano, Milan, ⁵Infectious Diseases Unit, Ospedale Civile di Legnano, ASST Ovest Milanese, and DIBIC, Università degli Studi di Milano, Milan, ⁶Department of Infectious Diseases, IRCCS San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Milan, Italy, ⁷Clinical Immunology Unit, Azienda Ospedaliero Universitaria delle Marche - Università Politecnica delle Marche, Ancona, Italy, ⁸Department of Infectious Diseases, IRCCS San Gerardo dei Tintori, University of Milano-Bicocca, Monza, Italy, ⁹Unit of Infectious Diseases, Department of Medical Sciences, University of Turin, Amedeo di Savoia Hospital, Turin, Italy, ¹⁰Unit of Infectious Disease, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ¹¹Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy

Background: In the INSTI-based antiretroviral therapy (ART) era a number of people with HIV (PWH) is still on guidelines (GLs)-outdated or alternative regimens. We aimed to characterize PWH on such regimens and the related features in clinical centers.

Methods: Cross-sectional analysis in 50 centers of the ICONA cohort including PWH with a last visit in 2024-2025. Regimens were classified as recommended (RecR), outdated (OutR) and alternative (AltR) according to the most recent EACS GLs: OutR were no longer recommended, AltR were considered as alternative to RecR in selected settings (ABC-based regimens, DRV/b+3TC, TDF/F/RPV). Adjusted logistic mixed-effects models including a random intercept for clinical center were used to assess PWH-level and center-level factors associated with use of OutR; center factors were also analyzed for AltR use.

Results: In total, 10,859 (94.9%) of 11,444 PWH were receiving RecR, 2.7% OutR, and 2.4% AltR. Compared with RecR, PWH on OutR were older [median 57.0 (IQR 47.0–63.0) vs 50.0 (40.0–58.0)], more frequently female (33.0% vs 18.8%), and PWID (15.2% vs 7.7%). PWH on OutR showed a longer treatment-experienced profile, with longer ART exposure [13.1y (8.2-21.2) vs 8.0 (3.1-12.0)], higher prevalence of prior AIDS (18.4% vs 14.4%), and of VF on ART (23.6% vs 9.0%), higher number of ART lines [4 (2-6) vs 3 (1-4)], lower median CD4 count at ART start [290.0 (109.0–446.0) vs 329.0 (164.0–490.0) cells/mm³] (Table 1). Higher median total cholesterol and glucose levels were observed in AltR vs RecR. The detailed breakdown of OutR is shown in Figure 1.

In the mixed adjusted models, older age (aOR per 10 y 1.14, 95%CI 1.01-1.29) and longer ART duration (aOR per y 1.09, 95%CI 1.07-1.11) and female sex (aOR 1.40, 95%CI 1.04-1.89) were independently associated with OutR use. MSM showed significantly lower odds (aOR 0.66, 95% CI 0.48–0.91), whereas unemployment was associated with an increased risk (aOR 1.50, 95% CI 1.07-2.10). In contrast, higher total cholesterol levels were associated with only a modest increase in odds (aOR per +10 mg/dL: 1.03, 95% CI 1.00-1.06). In the center-level model, neither center size nor HIV care model were associated with OutR and AltR use (Table 2). Between-center variation accounted for 19.9% of the variance in use of AltR regimens compared to only 8.0% for OutR, indicating greater standardization across centers in avoiding outdated treatments, but less for AltR.

Conclusions: OutR use appears primarily driven by patient complexity rather than center organization, supporting the need for targeted ART optimization strategies. Notably, OutR and AltR accounted for 5.1% of cases overall. These findings should be interpreted with caution considering the cross-sectional design, potential survivor bias and limited availability of personal and clinical factors influencing the regimen choice. Therefore, the appropriateness of some prescriptions cannot be excluded.

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Real World Evidence: insights from Italian Cohorts

OC 38 LONG-TERM EFFECTIVENESS AND TOLERABILITY OF CABOTEGRAVIR PLUS RILPIVIRINE AS A SWITCH STRATEGY IN A MULTICENTER ITALIAN REAL-WORLD COHORT

A. Ciccullo¹, G. Balducci², A. Cervo³, M.V. Cossu⁴, S. Trevisan⁵, A. De Vito⁶, M. Fabbiani⁷, E. Altavilla⁸, E. Delmonte³, M. Matone⁴, F. Lagi⁵, F. Bassani⁹, P.F. Salvo², G. Madeddu⁶, A. Borghetti¹⁰, S. Rusconi⁹, A. Giacomelli³, C. Mussini³, S. Di Giambenedetto^{2,11}

¹Infectious Diseases Unit, Ospedale San Salvatore, L'Aquila, Italy, ²Infectious Diseases Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, ³Department of Infectious Diseases, Azienda Ospedaliero-Universitaria di Modena, Modena, Italy, ⁴Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ⁵Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy, ⁶Infectious Diseases Unit, University of Sassari, Sassari, Italy, ⁷Department of Medical Sciences, Infectious and Tropical Diseases Unit, University Hospital of Siena, Siena, Italy, ⁸Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ⁹Infectious Diseases Unit, ASST Ovest Milanese, Legnano, Italy, ¹⁰Infectious Diseases Unit, Department of Clinical and Experimental Medicine, Azienda Ospedaliera Universitaria Pisana, Pisa, Italy, ¹¹Catholic University of the Sacred Heart, Rome, Italy

Background: We assessed long-term virological and immunological effectiveness and tolerability of CAB+RPV as a switch strategy in clinical practice.

Material and Methods: This observational study enrolled virologically suppressed people with HIV (PWH) switching to CAB+RPV within the ODOACRE multicenter cohort. Clinical and virological data were collected. Kaplan–Meier analysis evaluated time to virological failure (VF) and treatment discontinuation (TD). VF was primarily defined according to a Delphi-like criterion as two consecutive HIV-RNA ≥ 200 copies/mL or a single ≥ 1000 copies/mL (CVF-200). A more stringent sensitivity definition was also applied (two consecutive HIV-RNA ≥ 50 copies/mL or a single ≥ 1000 copies/mL; CVF-50). Predictors of VF were assessed using Cox regression based on CVF-200 with parallel sensitivity analyses using CVF-50.

Results: Overall, 490 PWH were included: 398 (81.2%) were males, with a median age of 52 years (IQR 43-59). Full population characteristics are shown in Table 1.

During 809.8 PYFU (median follow-up of 1.85 years), 5 CVF-200 occurred (0.62/100 PYFU); using the stringent definition, 15 CVF-50 were observed (1.85/100 PYFU). Freedom from VF was 98.9% and 98.5% at weeks 48 and 144 using the CVF-200 definition and 97.5% and 95.1% using the CVF-50 definition.

In Cox models, previous VF on NNRTI-based ART was associated with higher risk of VF using CVF-50 (aHR 28.3, 95%CI 2.5-322.8, $p=0.007$), after adjusting for viral subtype and BMI. With CVF-200, only a non-significant trend was observed for subtype A1/A6 (aHR 13.7, 95%CI 0.8-232.5, $p=0.070$).

Regarding tolerability, during 815.2 PYFU we observed 69 TD (8.46/100 PYFU). Main reasons were injection-site reactions (24, 4.9% of total population), treatment intensification (17, 3.5%), CNS toxicity (7, 1.4%), PWH request (6, 1.2%), other toxicity (3, 0.6%), pregnancy (3, 0.6%), death (3, 0.6%), other/unknown (6, 1.2%). Estimated probability of maintaining CAB+RPV was 89.5% at week 48 and 80.2% at week 144.

CD4+ count and CD4/CD8 ratio progressively improved, with significant increases at weeks 96 (both) and 144 (CD4/CD8). CD4+ gain was greater in PWH with lower baseline CD4 (per +10 cell/mm³: B -2.3, $p=0.001$) and in women (B -97.0, $p=0.014$) after adjusting for age, CD4+ cell nadir and number of previous ARV lines. Women also showed greater improvement in CD4/CD8 ratio (B -0.15, $p=0.011$). No clinically relevant changes in BMI or SCORE-2 were observed, while HDL showed a modest but significant increase during follow-up.

Conclusions: In this large real-world cohort, CAB+RPV showed durable effectiveness and good tolerability through 144 weeks. However, the markedly increased risk of VF observed in PWH with prior NNRTI failure suggests that this switch strategy should be used with caution and generally avoided in this population. Continued immunological improvement supports the robustness of CAB+RPV in appropriately selected patients.

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Immuno and inflammomology markers in translational research

OC 39 A 3D AIRWAY EPITHELIUM-MONOCYTE CO-CULTURE MODEL TO ASSESS THE IMPACT OF CCR2 AND CCR5 INHIBITION ON SARS-COV-2 REPLICATION AND INFLAMMATORY RESPONSES

C. Antonucci, M. Andreotti, Z. Micheli, C.M. Galluzzo, R. Amici, A. Eramo, G. Castelli, S. Lo Cicero, A.M. Cerio, S. Cecchetti, F. Spadaro, R. Bona, M.C. Gauzzi, L. Fantuzzi

Istituto Superiore di Sanità, Rome, Italy

Background: Current evidence indicates that a monocyte/macrophage-driven cytokine storm is a major pathogenic event in severe COVID-19. Excessive chemokine release promotes monocyte recruitment to the lungs, leading to hyper-inflammation, tissue damage, acute respiratory distress syndrome and multi-organ failure. Among the key pathways involved are CCL2/CCR2 and CCR5 ligands, which regulate monocyte/macrophage migration and infiltration. This study assessed the impact of CCR2 and CCR5 blockade during SARS-CoV-2 infection using a 3D co-culture model of fully differentiated primary human airway epithelium and primary monocytes.

Materials and Methods: Primary bronchial conditionally reprogrammed cells (CRC) were seeded onto transwell inserts and cultured at air-liquid interface (ALI) for 5 weeks to generate a differentiated, polarized epithelium (CRC-ALI). Cultures were apically infected with SARS-CoV-2 (BetaCov/Italy/CDG1/2020). Twenty-four hours post-infection, cells were treated with the antibodies plozalizumab (anti-CCR2) or PRO-140 (anti-CCR5). In selected experiments, freshly isolated primary monocytes ($3 \times 10^5/100 \mu\text{L}/\text{well}$) were added to the apical surface of infected CRC-ALI cultures in the presence or absence of the antibodies. After 4 hours at 37°C , the apical medium was removed and cultures were maintained under ALI culture conditions. Every 24 hours up to 96 hours post-infection, apical washes and cell lysates were collected for RT-qPCR quantification of the SARS-CoV-2 N gene. Surface phenotypic and activation markers were analyzed by flow cytometry.

Results: Basal expression of CCR2 and CCR5 in CRC-ALI cultures was low; infection induced a slight increase in CCR5 expression. Treatment of infected cultures with plozalizumab or PRO-140 inhibited viral replication with distinct kinetics and a more pronounced and sustained effect observed with CCR2 blockade. Both antibodies modulated epithelial activation, as indicated by changes in HLA-DR expression. Notably, addition of primary monocytes to infected CRC-ALI cultures determined a reduction of viral replication, suggesting an active role of recruited monocytes in controlling infection within this model. Experiments are in progress to assess the effect of CCR2 and CCR5 blockade in infected co-cultures of CRC-ALI and monocytes.

Conclusions: CCR2 and CCR5 blockade modulates SARS-CoV-2 replication and epithelial activation in a 3D airway model. These findings support a dual role for chemokine receptor pathways in regulating viral replication and inflammatory responses and provide experimental evidence for targeting CCR2/CCR5 axes to modulate host responses in severe COVID-19.

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Immuno and inflammomology markers in translational research

OC 40 ULTRA-LOW LEVEL SOLUBLE P24 PRODUCTION IDENTIFIES AN IP-10-DOMINANT INFLAMMATORY SIGNATURE LINKED TO PHYSIOLOGIC FRAILTY AND MORTALITY RISK IN VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV

M. Augello¹, A. Mingione², C. Orlandi³, R. Rovito¹, V. Bono¹, V. Sala¹, C. Tincati¹, F. Martinelli Boneschi², A. Casabianca³, G. Marchetti¹

¹Clinic of Infectious Diseases and Tropical Medicine, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy,

²Clinic of Neurology, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ³Department of Biomolecular Sciences, University of Urbino "Carlo Bo", Urbino, Italy

Background: Despite virologically suppressive ART, residual inflammation persists in people with HIV (PWH), thus driving higher risk of serious non-AIDS events (SNAEs) and mortality. Circulating HIV proteins have been detected in some suppressed PWH, as an expression of the persistence of the translation-competent reservoir. We therefore seek to investigate whether peripheral inflammation is associated with p24 production in this population.

Methods: PWH on suppressive ART and age/sex-matched healthy controls without HIV were enrolled. Ultra-low level serum p24 was cross-sectionally (baseline) and longitudinally (6 and 12 months) quantified by Simoa following immune complexes acid dissociation. In addition, the following were cross-sectionally measured at baseline: plasma biomarkers of inflammaging (Luminex/ELISA), CD38+CD8+ T-cells (flow cytometry), cell-associated (CA) total/unintegrated/integrated HIV DNA and RNA (qPCR). VACS Index 2.0 was computed to estimate physiologic frailty and mortality risk. In vitro experiments tested whether p24 modulates IP-10 secretion by PBMCs.

Results: 120 PWH and 20 controls were recruited. PWH (83.3% males) had a median age of 54 (IQR 47–59) years, and were on ART for 10 (6–19) years, with a current CD4 T-cell count of 725 (504–908) cells/μL. PWH exhibited a distinct inflammaging profile characterised by higher IP-10, TNF-α, IL-17A, IL-8, sCD14, sCD163, TIMP-1, and GDF-15 than controls. Several biomarkers were associated with the VACS Index 2.0 in univariable analyses, but only IP-10 and GDF-15 remained independently associated in multivariable modelling. By setting the p24 positivity cut-off at 0.025 pg/mL based on the mean+3SD of controls, soluble p24 was detectable in 25/120 (20.8%) PWH at baseline (median: 0.0516 pg/mL; range: 0.0264–0.8280 pg/mL) (Fig.1A). p24 detectability was associated with male sex yet not with immunological parameters, ART duration/regimen, or CA HIV DNA and RNA. Among inflammaging biomarkers, p24 was associated exclusively with higher plasma IP-10, both as categorical and continuous variable, even after adjustment for sex, age, CD4 T-cell count, and ART duration (Fig.1B–C). Longitudinal analyses in a subset of 30 PWH revealed dynamic p24 patterns, with persistently p24-positive PWH [8/30 (26.7%)] exhibiting the highest baseline IP-10 levels (Fig.1D–E). In vitro, p24 alone did not induce IP-10 secretion by PBMCs, but in the presence of IFN-γ+TNF-α, it produced a modest yet significant increase, supporting a context-dependent proinflammatory effect (Fig.1F).

Conclusions: These findings demonstrate that a subset (~21%) of virologically suppressed PWH produce detectable levels of soluble p24, and that this residual HIV protein expression is selectively associated with an IP-10–dominant inflammatory profile. Given the positive association between IP-10 and VACS Index 2.0, these data suggest that p24-driven inflammation may contribute to SNAEs and mortality in virologically suppressed PWH.

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Immuno and inflammomology markers in translational research

OC 41 LONG-TERM FOLLOW-UP TO 96 WEEKS OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE: SUSTAINED REDUCTION OF IMMUNE ACTIVATION AND SENESCENCE IN PEOPLE LIVING WITH HIV AND CMV CO-INFECTION

M. Guardiani³, F. Dominelli¹, E. Tortellini¹, A. Carraro¹, L. Ansaldo², M.A. Zingaropoli¹, M. Proietti¹, M. Antonacci¹, F. Mengoni¹, G. Mancarella², A. Gasperin², M. De Masi², S. Vita³, C.M. Mastroianni¹, R. Marocco², C. Del Borgo², M. Lichtner³

¹Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ²Infectious Diseases Unit, SM Goretti Hospital, Sapienza University of Rome, Latina, Italy, ³Department of Neurosciences, Mental Health, and Sense Organs, NESMOS, Sapienza University of Rome, Rome, Italy

Introduction: Despite the effectiveness of combined antiretroviral therapy (ART), HIV infection remains a chronic condition characterized by persistent residual inflammation and immune activation, partly associated with HIV persistence and co-factors such as cytomegalovirus (CMV) coinfection. Evidence comparing the long-term immunological impact of different ART regimens remains limited and controversial. Long-acting (LA) injectable formulations may modulate the chronic immunoinflammatory state associated with HIV. We evaluated the dynamic changes in lymphoid immune activation and senescence markers in people with HIV(PWH) switching to long-acting cabotegravir/rilpivirine (CAB/RPV-LA), compared with PWH continuing oral ART, extending follow-up to 96 weeks.

Methods: T-cell immune activation(CD38⁺HLA-DR⁺) and senescence(CD28⁺CD57⁺) were assessed at baseline (T0), and at weeks 4 (T4), 28 (T28), 48 (T48), 72 (T72), and, when available, 96 (T96) after switching to CAB/RPV-LA. A control group (CG) on daily oral ART was evaluated at T0 and T48. CMV-specific cellular and humoral immune responses were also measured.

Results: Thirty-eight PWH switching to CAB/RPV-LA and nine PWH-CG were enrolled. Up to week 72, total CD4 levels remained stable, while CD8 levels decreased significantly at T72 versus T0 and T4. The CD4/CD8 ratio remained stable in both groups. Immune activation progressively declined in PWH-LA, with significant reductions in CD4 activation at T48 and T72 versus earlier time points and in CD8 activation at T72 versus T0 and T4. Immune senescence decreased in both compartments, with a significant reduction in CD8 senescence at T28, T48 and T72 compared to earlier time-points. Delta analysis confirmed a greater reduction in immune activation and senescence in PWH-LA compared to PWH-CG. CMV-specific responses showed a transient increase at T28 before returning to baseline at T48 and T72.

At 96 weeks (n=15), total CD4 and CD8 counts, as well as the CD4/CD8 ratio, were increased compared with previous time points, improving trend observed at T72. CD4 activation and senescence and CD8 senescence were significantly reduced at T96 compared to T0, T4, T28, and T48, remaining stable relative to T72, which had already shown a marked decline. Polyfunctional CD4 and CD8 T cells, as well as total responding CD4 T cells, confirmed at T96 the favourable trend observed at T72. Notably, responding CD8 T cells further increased at T96 compared to T72 and all preceding time points. Plasma HIV-RNA and CMV-DNA remained undetectable in all subjects at all time points.

Conclusions: Switching to CAB/RPV-LA is associated with a sustained and progressive reduction of T-cell activation and senescence up to 96 weeks. These findings suggest a durable restoration of immune homeostasis beyond viral suppression. However, CMV coinfection remains a relevant contributor to residual immune dysregulation.

Table

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Immuno and inflammomology markers in translational research

OC 42 IMMUNOMETABOLIC REMODELING, NOT RESPONSE MAGNITUDE, DISTINGUISHES ACUTE FROM CHRONIC HIV INFECTION

D. Lo Tartaro¹, E. Santacroce¹, N. Paschalidis², A.L. Ciobanu¹, E. Serattini¹, L. Gibellini¹, M. Menozzi³, C. Mussini³, A. Cossarizza^{1,4}, S. De Biasi¹

¹Department of Medical and Surgical Sciences for Children and Adults, University of Modena and Reggio Emilia School of Medicine, Modena, Italy, ²Biomedical Research Foundation Academy of Athens, Athens, Greece, ³Department of Surgical, Medical, Dental and Morphological Sciences, University of Modena and Reggio Emilia, Modena, Italy, ⁴National Institute for Cardiovascular Research, Bologna, Italy

Background: HIV infection induces persistent immune activation and dysfunction that are not fully reflected by measurements of antigen-specific cell frequency alone. Immunometabolic programming plays a key role in regulating lymphocyte differentiation, function, and fate, but how metabolic states evolve from acute to chronic HIV infection remains unclear.

Aim: To determine whether acute and chronic HIV infection differentially shape the immunometabolic and functional profiles of antigen-specific T and B cells, and whether disease stage influences the magnitude, quality, or metabolic programming of HIV-specific responses.

Methods: Peripheral blood mononuclear cells (PBMC) from individuals with acute (n=12) or chronic (n=18) HIV infection were stimulated with peptide pools spanning GAG, POL, and ENV. Antigen-specific CD4⁺ and CD8⁺ T cells were identified by activation markers and analyzed using 45-parameter single-cell mass cytometry-based metabolic profiling (scMEP), combined with FlowSOM clustering and UMAP dimensionality reduction. B-cell immunometabolic landscapes were analyzed using the same approach, with HIV-specific cells identified by gp140 expression. Functional capacity was assessed by intracellular cytokine staining to evaluate cytokine production, degranulation, and polyfunctionality.

Results: Frequencies of antigen-specific CD4⁺ and CD8⁺ T cells were similar between acute and chronic infection, indicating comparable response magnitude. However, clear differences emerged at the immunometabolic level. Acute infection was enriched in highly metabolically active and transitional memory subsets, including POL-specific CD4⁺ T cells with coordinated activation of glycolytic, mitochondrial, and biosynthetic pathways, and fewer metabolically quiescent effector memory cells. Chronic infection was characterized by more differentiated and metabolically restrained populations.

The B-cell compartment was extensively remodeled in both stages and dominated by glycolytic atypical memory-like subsets. Acute infection showed higher proportions of metabolically active transitional and DN2/age-associated B cells. Rare gp140-specific B cells displayed strong metabolic activation across disease stages.

Despite metabolic differences, cytokine production and overall polyfunctionality of antigen-specific T cells were largely comparable between acute and chronic infection, although responses to ENV were consistently lower than those to GAG.

Conclusion: HIV uncouples the magnitude of antigen-specific responses from their metabolic and qualitative features. Acute infection imprints highly activated metabolic states that evolve into stable, metabolically constrained programs during chronic disease. Early immunometabolic programming may represent a key determinant of long-term immune trajectory and a critical dimension of HIV-associated immune dysregulation.

Success comes at a cost: weight, lipids and metabolic risks in HIV

OC 43 THE CHOICE OF FIRST-LINE ART CLASS IS NOT ASSOCIATED WITH DIFFERENTIAL WEIGHT GAIN IN PEOPLE WHO ARE ALREADY OBESE OR OVERWEIGHT

L. Costacurta¹, L. Taramasso², E. Ricci³, N. Squillace⁴, G. Orofino⁵, G.F. Pellicano⁶, G.V. De Socio⁷, B. Menzaghi⁸, S. Ferrara⁹, P. Maggi¹⁰, P. Bonfanti⁴, A. Di Biagio^{1,2}, on behalf of CISAI Study Group

¹Department of Health's Sciences, University of Genoa, Genoa, Italy, ²Infectious Diseases Clinic, IRCCS Azienda Ospedaliera Metropolitana, Genoa, Italy, ³Fondazione ASIA Onlus, Buccinasco (MI), Italy, ⁴Infectious Disease Unit, Fondazione IRCCS San Gerardo dei Tintori, Monza, University of Milano-Bicocca, Monza, Italy, ⁵Division of Infectious and Tropical Diseases, ASL Città di Torino, Italy, ⁶Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, AOU Policlinico G. Martino, Messina, Italy, ⁷Clinic of Infectious Diseases, Department of Medicine and Surgery, University of Perugia, Italy, ⁸Unit of Infectious Diseases, ASST della Valle Olona – Busto Arsizio (VA), Italy, ⁹Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy, ¹⁰Infectious Diseases Unit, AORN Sant'Anna e San Sebastiano, Caserta, Italy

Background: The impact of antiretroviral therapy (ART)-associated weight gain in people with HIV (PWH) who are already obese or overweight still needs to be clarified.

Materials and Methods: This multicentre, prospective study analysed overweight and obese PWH who were ART-naïve in the Italian SCOLTA observational cohort, after they started their first antiretroviral treatment. Weight change was analysed using a linear model adjusted for potentially associated variables.

Results: A total of 239 people with HIV (PWH) were selected in this study. Of the participants, 198 (82.8%) were overweight and 41 (17.2%) were obese. The mean age was 42.9 years (SD $\pm$ 11.7) and 186 (77.8%) were male. The median CD4+T-cell count at enrolment was 370 cells/mm³ (interquartile range, IQR, 206-514). The study population is further characterized in Table 1. During a median follow-up of 24 months (IQR 15-39) the mean weight change observed in this cohort was +0.11 kg/month in overweight individuals (95% CI 0.06; 0.17, p = 0.0001) and +0.12 kg/month in obese PWH (95%CI 0.01-0.24, p = 0.025). At the multivariate analysis, a significant weight gain, compared to baseline, was shown in people younger than 50 years (+0.16 kg/month, 95%CI 0.03-0.30), of non-Caucasian origin (+0.20 kg/month, 95%CI 0.04-0.35) and in those who were diagnosed with hypertension (+0.20 kg/month, 95%CI 0.04-0.36). However, the change from baseline was not significantly different from that observed in their counterparts, namely in people older than 50 years (p = 0.39), in Caucasian participants (p = 0.09) and in those without hypertension (p = 0.08), as detailed in Table 2. Regarding risk factor for HIV acquisition, weight gain resulted significant in people who acquired HIV through sexual exposure (+0.08 kg/month, 95%CI 0.11-0.28) or for other/unknown risk factor (+ 0.20 kg/month, 95%CI 0.00-0.38), but not in those who reported intravenous drug use (IVDU), without significant differences among weight trends in the three groups (p = 0.39). In univariate analysis, weight change seemed significant in all the types of ART regimens that were studied, except NNRTI. However, after multivariable adjustment, the weight resulted not significantly different compared to baseline in each of the drug regimens explored, nor resulted different in the inter-group comparisons among regimens. See Table 2 for details.

Conclusions: We observed modest weight changes in overweight and obese PWH who initiated ART, with no influence of different ART classes on the association with weight gain.

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Success comes at a cost: weight, lipids and metabolic risks in HIV

OC 44 OBESITY AT ANTIRETROVIRAL THERAPY INITIATION AND LONG-TERM RISK OF CARDIOVASCULAR DISEASE, CANCER, OR DEATH IN PEOPLE WITH HIV: A PROSPECTIVE COHORT STUDY

C. Mussini¹, A. Giacomelli^{2,3}, G. Lapadula^{4,5}, A. Di Biagio^{6,7}, A. Gori^{2,3}, G. Orofino⁸, E. Quiros-Roldan⁹, A. Cingolani¹⁰, G. Madeddu¹¹, V. Mazzotta¹², R. Rossotti¹³, S. Lo Caputo¹⁴, G. Marchetti¹⁵, J. Chester¹⁶, A. d'Arminio Monforte¹⁷, G. Guaraldi¹, A. Cozzi-Lepri¹⁸, on behalf of the ICONA Foundation Study Group - ICONA cohort

¹Infectious Diseases Unit, Azienda Ospedaliero-Universitaria Policlinico di Modena; University of Modena and Reggio Emilia, School of Medicine, Modena, Italy, ²Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milano, Italy, ³Department of Infectious Diseases, ASST Fatebenefratelli Sacco, "L. Sacco" University Hospital, Milan, Italy, ⁴Infectious Diseases Unit, IRCCS San Gerardo dei Tintori, Monza, Italy, ⁵University of Milano-Bicocca, Monza, Italy, ⁶Infectious Diseases Unit, IRCCS Ospedale Policlinico San Martino, Genoa, Italy, ⁷Department of Health Sciences (DISSAL), University of Genoa, Genoa, Italy, ⁸Division I of Infectious and Tropical Diseases, ASL Città di Torino, Torino, Italy, ⁹Department of Clinical and Experimental Sciences, Unit of Infectious and Tropical Diseases, University of Brescia and ASST Ospedali Civili di Brescia, Brescia, Italy, ¹⁰Unit of Infectious Diseases, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Department of Safety and Bioethics, Università Cattolica del Sacro Cuore, Rome, Italy, ¹¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ¹²Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy, ¹³Clinic of Infectious Diseases, University of Verona, Verona, Italy, ¹⁴Clinic of Infectious Diseases, Department of Medical and Surgical Sciences, University of Foggia, Foggia, Italy, ¹⁵Clinic of Infectious Diseases and Tropical Medicine, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ¹⁶Department of Surgical, Medical, Dental and Morphological Sciences Related to Transplant Oncology and Regenerative Medicine, University of Modena and Reggio Emilia, Modena, Italy, ¹⁷Icona Foundation, Milan, Italy, ¹⁸Centre for Clinical Research, Epidemiology, Modelling and Evaluation (CREME), Institute for Global Health, UCL, London, UK

Background: Altered adipose tissue biology plays a key role in the development of cardiovascular disease (CVD) and cancer and contributes to mortality. We assessed the effect of obesity in people with HIV (PWH) at antiretroviral treatment (ART) initiation on the risk of clinical events.

Methods: We included PWH from the Icona study who, at ART initiation, were free from AIDS, CVD and cancer. PWH were grouped by BMI at ART initiation as non-obese (BMI 18.5-29.9) or obese (BMI ≥30). Underweight PWH were excluded. We performed a standard survival analysis with time-fixed covariates at baseline with a composite outcome of CVD/cancer/death. We hypothesized that age may be an effect measure modifier: results are presented after stratification by age (young [18-30], middle aged [31-60] and older [≥60 years]).

Results: A total of 11,652 PWH (20.7% females, median age 38 years [IQR: 31, 46]) were included: 11,005 (94.4%) were non-obese and 647 (5.6%) obese (Table 1). A total of 837 events were recorded: 122 CVD, 374 cancers and 341 deaths.

By 15 years from ART initiation, the risk of CVD/cancer/death was 19.1% in obese (95% CI: 14.1-24.9%) vs. 12.4% in non-obese (95% CI: 11.3-13.4%, log-rank p=0.006) (Figure 1A,B). After controlling for confounding, the difference was attenuated (adjusted hazard ratio [aHR] 1.28 [95% CI: 0.98-1.67], p=0.073) (Table 2). Although we did not find evidence for interaction (p-value=0.758) there was a clear trend for a larger effect in younger PWH: young (aHR 1.83 [95% CI 0.74, 4.56]), middle aged (aHR 1.49 [95% CI 1.11, 2.00]) and older (aHR 1.20 [95% CI 0.60, 2.41]).

Conclusions: Obesity at ART initiation is associated with an increased risk of CVD/cancer/death and the effect size was larger for PWH younger than 60 years. Addressing obesity in PWH from ART initiation should be integrated into an overall strategy towards improving PWH prognosis.

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Success comes at a cost: weight, lipids and metabolic risks in HIV

OC 45 STATIN THERAPY FOR PRIMARY AND SECONDARY PREVENTION IN PEOPLE WITH HIV: GAPS AND ACHIEVEMENTS IN A REAL-LIFE SETTING

G. Torkjazi^{1,2}, R. Papaioannu Borjesson¹, N. Capra¹, R. Lolatto¹, C. Muccini¹, S. Nozza^{1,2}, D. Canetti¹, T. Clemente¹, E. Bruzzesi¹, H. Hasson¹, A. Castagna^{1,2}, V. Spagnuolo^{1,2}

¹IRCCS San Raffaele Scientific Institute, Infectious Diseases Department, Milan, Italy, ²Vita-Salute San Raffaele University, Milan, Italy

Background: Following publication of the REPRIEVE trial, international guidelines have broadened the indications for statin use in primary prevention among people with HIV (PWH). However, the extent of real-life implementation remains uncertain.

This study aimed to evaluate the “cascade of care” for statin therapy - prevalence of statin eligibility, treatment initiation, and achievement of low-density lipoprotein cholesterol (LDL-c) goals - in an Italian cohort after the 2023 guidelines update.

Methods: This is a cross-sectional study including PWH aged ≥ 40 years followed at IRCCS San Raffaele, Milan, fulfilling at least one of the following criteria: last LDL-C measurement of >100 mg/dL in the past year, undergoing statin therapy, SCORE-2 $>5\%$, or prior major adverse cardiovascular event (MACE).

We considered LDL-c target achieved when ≤ 100 mg/dL in PWH without prior MACE, <55 mg/dL in individuals with a history of prior MACE. Evaluation was performed on the date of the last available LDL-C. Data were reported as median (IQR) or frequency (%).

Results: Among 5019 PWH actually followed at our center, 3540 (68.2%) were eligible for statin therapy. Of these, 1924 (54.4%) were receiving lipid-lowering therapy: 60.7% were on statin alone, and 39.3% on a combination therapy. The cascade of care is reported in Figure1.

Overall, at evaluation the median age was 59.4 (52.6-64.1) years, and 80.9% of PWH were males. The median CD4 T-cell count was 790 (600-1020) cells/ μ L, and 94.7% of individuals had a HIVRNA <50 cp/mL.

Among individuals without a history of prior MACE (3266, 92.3%), 1696 (51.9%) were on statins; of these, 1453 (85.7%) received moderate-intensity regimens, with 61.5% achieving LDL-C targets, overall.

Among 1570 PWH not in therapy but who met criteria, 218 (13.9%) were previously exposed to statins, but currently untreated; discontinuation was mainly due to patient decision (39.4%) or toxicity (38.1%).

Among PWH with documented history of MACE, 228 (83.2%) were treated, and 31.3% of treated patients achieved targets. High-intensity regimens were more frequently used in secondary vs primary prevention (40.8% vs 12.8%; p-value $<.0001$).

Conclusions: In our cohort, major gaps persisted in statin initiation for primary and secondary prevention and in LDL-c goal achievement despite treatment. These findings underscore missed opportunities for guideline-concordant care and suggest key priorities, such as systematic risk assessment and proactive management of statin intolerance.

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Success comes at a cost: weight, lipids and metabolic risks in HIV

OC 46 IMPACT OF ROSUVASTATIN VS. ATORVASTATIN ON INSULIN RESISTANCE AND DIABETES MELLITUS IN PEOPLE WITH HIV

J. Milic¹, A. Carobbio², M. Menozzi^{1,3}, M. Manicardi⁴, G. Cuomo³, G. Mancini³, M. Belli¹, T. Albano¹, M. Ricciardetto¹, I. Avanzini¹, E. Delmonte¹, L. Gozzi¹, P. Raggi⁵, C. Mussini^{1,3}, G. Guaraldi^{1,3}

¹Modena HIV Metabolic Clinic, University of Modena and Reggio Emilia, Modena, Italy, ²Department of Medical and Surgical Sciences for Children and Adults, University of Modena and Reggio Emilia, Modena, Italy, ³Infectious Diseases Clinic, Azienda Ospedaliero-Universitaria, Policlinico of Modena, Modena, Italy, ⁴Cardiology Division, Azienda Ospedaliero-Universitaria, Policlinico of Modena, Modena, Italy, ⁵Department of Medicine and Division of Cardiology, University of Alberta, Edmonton, Alberta, Canada

Background: Statins are proven to reduce cardiovascular risk in people with HIV (PWH), but the comparative impact of hydrophilic versus lipophilic statins on metabolic complications remains uncertain. The primary objective of this study was to compare longitudinal changes in Homeostatic Model Assessment for insulin resistance (HOMA-IR) among PWH treated with rosuvastatin vs. atorvastatin. The secondary objectives were to evaluate baseline HOMA-IR in participants without IR and to determine the incidence of new-onset IR and diabetes mellitus among PWH.

Methods: This was a longitudinal observational study including PWH ≥ 40 years attending Modena HIV Metabolic Clinic, Italy, from 2004 to 2024 who initiated atorvastatin or rosuvastatin and had available HOMA-IR within ± 6 months of initiation. PWH with pre-existing DM, missing HOMA-IR, or use of statins other than atorvastatin or rosuvastatin were excluded. Insulin resistance (IR) was defined as HOMA-IR ≥ 2.5 . Baseline was defined as the earliest statin initiation with complete available data, while follow-up as time from statin initiation to IR, DM onset, or last available visit. Linear mixed models (LMMs) were used to compare HOMA-IR trends overall and among those without baseline IR.

Results: We included 627 PWH (median age 55, 76% male, median CD4: 673 cells/microL, median time since HIV diagnosis 22 years, median HOMA-IR: 2.5, 48% with baseline IR. Atorvastatin was started in 235 and rosuvastatin in 285 patients, with 62 and 45 crossovers, respectively, during a median follow-up of 1.9 years. No major baseline differences were observed. During follow-up, 96 patients developed IR with no significant difference between treatments (13.9 vs 14.3 per 100 PY; $p=0.92$; IRR=1.03) (Figure 1) and 10 developed DM (1.03 vs 1.04 per 100 PY; $p=0.88$). In unadjusted and adjusted LMM, statin use was not associated with higher overall HOMA-IR (Figure 2) or higher HOMA-IR in those without baseline IR (Figure 3). Similarly, adjusted LMM showed no significant differences between the two statins in overall HOMA-IR or among PWH without baseline IR (Table 1).

Conclusions: Rosuvastatin and atorvastatin showed comparable effects on HOMA-IR trajectories and on the risk of new-onset IR or diabetes. The modest increase in insulin resistance over time appears more related to underlying metabolic status and HIV-associated risk factors than to the specific statin used. These findings support the overall metabolic safety of both statins in PWH and provide reassurance for their use in cardiovascular risk management.

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Next Generation Sequencing (NGS): redefining management of chronic viral infections

OC 47 EVALUATION OF A NGS ASSAY FOR DETECTING HIV1 PROVIRAL DRUG RESISTANCE MUTATIONS: ASSOCIATION WITH TOTAL HIV-1 DNA LEVELS AND WITH HISTORICAL GENOTYPE RESISTANCE TEST

T. Allice, F. Cerutti, G. Gregori, M.G. Milia, E. Burdino, B. Simoncelli, S. Monteleone, M. Cazzadore, A. Bottoni, E. Scuccimarra, V. Ghisetti

Laboratory of Microbiology and Virology, ASL Città di Torino, Torino, Italy

Introduction: The long-acting injectable dual therapy cabotegravir + rilpivirine improves quality of life and adherence in virologically suppressed person living with HIV (PLWH). However, risks for virological failure include HIV subtype and resistance mutations in HIV RNA or DNA. When subtype and genotypic history are incomplete, HIV DNA sequencing is recommended and increasingly performed in antiretroviral therapy (ART) experienced individuals. While plasma HIV RNA viremia predicts sequencing success, the relationship between HIV DNA levels and next generation sequencing (NGS) amplification performance remains unclear.

Objective: To evaluate a homebrew NGS genotypic resistance test (GRT) for detecting drug resistance mutations (DRMs) in protease (PR), reverse transcriptase (RT), and integrase (INT) regions of proviral HIV-1 DNA.

Materials and Methods: We analyzed 142 PBMC samples from 142 PLWH using an in-house NGS assay. PR, RT, and INT regions were amplified by nested PCR and sequenced using DNA Library Prep on the iSeq100 instrument (Illumina). DRMs and susceptibility were interpreted with Stanford HIVdb v9.8 at 10% and 20% detection thresholds. Total HIV-1 DNA was quantified in 55 samples using the HIV-1 DNA Test PRO (Diateva) processed with the Elite InGenius platform (Elitech). Historical plasma GRT was available for 54 cases.

Results: HIV1 subtype was assigned in 122/142 samples: 62.3% were subtype B and 37.7% non B. Sequencing success rates were 84% for PR, 84% for RT, and 75% for INT. HIV-1 DNA levels strongly correlated with sequencing outcome: mean 365 copies/10⁶ cells in successful samples vs 37.3 copies/10⁶ in failed ones ($p = 0.0002$). ROC analysis identified a success threshold of 55 copies/10⁶ PBMC. Major DRMs were detected in 29/122 (23,8%) individuals: 26 at frequencies above 20% and 3 at frequencies below 20%. Comparison of GRT DNA with historical RNA genotypes showed 70.4% of concordance (38/54). Among 16 discordant cases, 6 were linked to APOBEC related changes, 6 to higher DRM detection in HIV DNA, and 4 to higher DRM detection in historical RNA.

Conclusions: The NGS-based GRT-DNA assay provided reliable resistance profiles, with sequencing success of 84% (PR/RT) and 75% (INT). Sequencing performance correlated with total HIV-1 DNA, with a threshold of 55 copies/10⁶ PBMC. The assay effectively detected both major and low frequency DRMs. Discordances with historical plasma genotypes were largely due to APOBEC editing or low frequency DRMs identified only with GRT-DNA assay. GRT-DNA is a valuable tool for resistance assessment in PLWH, lacking complete genotypic histories.

Next Generation Sequencing (NGS): redefining management of chronic viral infections

OC 48 COMPARISON BETWEEN NEXT-GENERATION SEQUENCING AND HISTORICAL GENOTYPIC RESISTANCE TESTING AT VIROLOGICAL FAILURE IN ART-EXPERIENCED INDIVIDUALS: DATA FROM THE ARCA COHORT AND THE ITALIAN NGS NETWORK

D. Armenia¹, V. Michel², V. Ricucci³, A. De Vito⁴, M. Sambo⁵, A. Bezenchek^{6,7}, O. El Khalili⁸, B. Bruzzone³, W. Gennari⁹, E.G. Arosio¹⁰, I. Giovannelli¹¹, G. Massobrio¹², M. Menozzi¹³, B. Rossetti¹⁴, F. Ceccherini-Silberstein⁸, M.M. Santoro⁸

¹UniCamillus, Saint Camillus International University of Health Sciences, Rome, Italy, ²Clinical Microbiology, Virology and Bioemergency Diagnostics, ASST Fatebenefratelli Sacco, Luigi Sacco Hospital, Milan, Italy, ³Hygiene Unit, IRCCS Azienda Ospedaliera Metropolitana - Genova, Italy, ⁴Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ⁵Infectious and Tropical Diseases Unit, Azienda Ospedaliero-Universitaria Senese, Siena, Italy, ⁶IPRO-InformaPRO S.r.l., Rome, Italy, ⁷EuResist Network GEIE, Rome, Italy, ⁸Department of Experimental Medicine, University of Rome "Tor Vergata", Rome, Italy, ⁹Molecular Microbiology and Virology Unit, Azienda Ospedaliero-Universitaria di Modena, Modena, ¹⁰Microbiology and Virology Unit, ASST Papa Giovanni XXIII, Bergamo, ¹¹Clinical Immunology, Allergy and Advanced Biotechnologies Unit, AUSL - IRCCS Reggio Emilia, Reggio Emilia, Italy, ¹²Infection disease Unit, IRCCS - Policlinico San Martino Hospital, Genoa, Italy, ¹³Clinic of Infectious Diseases, University of Modena and Reggio Emilia, Modena, Italy, ¹⁴Infectious Diseases Unit, Azienda USL Toscana sud-est, Ospedale Misericordia, Grosseto, Italy

Background: Next-generation sequencing (NGS) increases sensitivity for detecting HIV-1 drug resistance mutations, including minority variants, but its real added value may depend on clinical scenarios.

Materials and Methods: We conducted a cross-sectional analysis within the ARCA cohort and Italian NGS Network, including adult people with HIV (PWH) who failed an antiretroviral regimen between 2022 and 2025 and for whom genotypic resistance testing by NGS (NGS-GRT) on plasma samples at the time of virological failure and historical Sanger-GRT (hGRT) were available. hGRTs were compared with NGS-GRT at detection thresholds of 5–20% (minority variants) and $\geq 20\%$ (high-frequency variants). Major resistance mutations (MRMs) were assessed according to the Stanford HIVdb algorithm v.10.1.

Results: We included 54 PWH; all had prior PR/RT hGRT, while integrase sequences were available for 31 PWH. Participants had a median treatment history of 14 (IQR: 9–18) years and a median of 4 (IQR: 2–8) prior regimens. At the time of NGS-GRT, median HIV-RNA was 3.9 (IQR: 3.0–4.8) log₁₀ copies/mL. PWH were receiving bictegravir/dolutegravir-based (37.0%), raltegravir/elvitegravir-based (22.2%), protease inhibitor-based (29.6%), and NNRTI-based (11.1%) regimens, for a median duration of 5 (IQR: 3–7) years.

Overall, mutation patterns were heterogeneous, combining newly emerging and historically re-detected MRMs. At a 5% threshold, 63.0% of PWH harbored ≥ 1 MRM, decreasing to 48.1% at $\geq 20\%$. MRMs exclusively detected in hGRT were observed in 11.1% of individuals.

Historical MRMs were re-detected in 16 individuals (29.6%), with complete re-detection in only eight (14.8%). New MRMs detected exclusively by NGS were observed in 40.7% and 25.9% of individuals at 5% and $\geq 20\%$ thresholds, respectively.

MRMs in hGRT and/or NGS-GRT were observed in 10 (18.5%), 25 (46.3%) and 27 (50.0%) individuals for PIs, NRTIs and NNRTIs, respectively. Historical MRMs not detected by NGS were considerable ($>25\%$) for NRTIs and NNRTIs, while modest ($<12\%$) for PIs and INSTIs (Figure 1). NGS re-detected historical RTIs resistance in a modest proportion of individuals ($<20\%$) while re-detection was poor for PIs or INSTIs resistance with a minimal contribution of minority variants (1.8% for PI MRMs). Emergent resistance was observed across all drug classes, mainly as high-frequency variants (PIs: 3.7%; NRTIs: 13.1%; NNRTIs: 9.3%; INSTIs: 12.9%).

Emerging mutations were consistent with regimen-specific selective pressure (Figure 2). MRMs were also identified in 4 individuals without prior integrase hGRT.

Conclusion: NGS performed at virological failure effectively identifies emerging resistance, with a moderate contribution of low-frequency variants. However, its ability to fully recover previously documented resistance is limited. Therefore, integration of virological failure history and historical resistance data remain crucial for appropriate treatment tailoring in PWH experiencing virological failure.

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Next Generation Sequencing (NGS): redefining management of chronic viral infections

OC 49 ADDED VALUE OF RNA-BASED WHOLE GENOME SEQUENCING IN VIREMIC PEOPLE WITH 4-CLASS DRUG-RESISTANT HIV: INSIGHTS FROM THE PRESTIGIO REGISTRY

T. Clemente¹, S. Sisti^{2,3}, B. Menzaghi⁴, M. Feasi⁵, M. Fabbiani⁶, R. Lolatto¹, M. Sampaolo³, L. Calza⁷, R. Gagliardini⁸, S. Bonora⁹, M.M. Santoro¹⁰, M. Zazzi¹¹, V. Spagnuolo^{1,2}, N. Clementi^{2,3}, on behalf of the PRESTIGIO Study Group

¹Infectious Diseases, IRCCS San Raffaele Scientific Institute, Milan, Italy, ²Vita-Salute San Raffaele University, Milan, Italy, ³Laboratory of Microbiology and Virology, IRCCS San Raffaele Scientific Institute, Milan, Italy, ⁴Unit of Infectious Diseases, ASST Della Valle Olona-Busto Arsizio, Busto Arsizio, Italy, ⁵Department of Infectious Diseases, E.O. Ospedali Galliera, Genoa, Italy, ⁶Department of Medical Biotechnologies, Infectious and Tropical Diseases Unit, Azienda Ospedaliero-Universitaria Senese, University of Siena, Siena, Italy, ⁷Infectious Diseases Unit, IRCCS Policlinico di Sant'Orsola, Alma Mater Studiorum University of Bologna, Bologna, Italy, ⁸Clinical and Research Department, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ⁹Unit of Infectious Diseases, Amedeo di Savoia Hospital, Department of Medical Sciences, University of Turin, Turin, Italy, ¹⁰Department of Experimental Medicine, University of Rome Tor Vergata, Rome, Italy, ¹¹Department of Medical Biotechnology, University of Siena, Siena, Italy

Background: Our aim was to assess the added value of whole genome sequencing (WGS) in viremic people with 4-class drug-resistant HIV (4DR-PWH), comparing resistance-associated mutations (RAMs) detected by WGS and Sanger sequencing.

Methods: Laboratory-based, cross-sectional study on 4DR-PWH from the PRESTIGIO Registry with ≥ 1 cryopreserved plasma sample at HIVRNA ≥ 500 copies/mL. Extracted HIVRNA underwent both Sanger and WGS. Primary and accessory RAMs in reverse transcriptase, protease, and integrase were compared between methods. RAMs detected by WGS were also compared with those recorded in the cumulative RNA-based Sanger genotype.

Results: Thirty-nine viremic 4DR-PWH were included (Table 1).

At the $\geq 20\%$ variant detection threshold, Sanger sequencing detected ≥ 1 RAM not reliably identified by WGS in 16/39 (41.0%) samples. Additionally, in 3/39 (7.7%), both methods detected a RAM at the same position with different amino-acid substitutions. Conversely, WGS identified ≥ 1 RAM not detected by Sanger in 29/39 (74.4%) samples (Figure 1). After accounting for the cumulative Sanger genotype, complete detection of all historical RAMs by WGS occurred in only 3/39 (7.7%) cases, but WGS identified ≥ 1 new RAM in 21/39 (53.8%) (Figure 1).

At the $\geq 5\%$ threshold, Sanger sequencing detected ≥ 1 RAM not reliably identified by WGS in 12/39 (30.8%) samples. Of these discrepancies, 3 were attributable to low coverage and 5 to variants $< 5\%$; only 4 samples showed potentially meaningful discordance. In an additional 5/39 (12.8%) samples, both methods detected a RAM at the same position with different amino-acid substitutions, consistent with variants $< 5\%$. Conversely, WGS identified ≥ 1 RAM not detected by Sanger in 33/39 (84.6%) samples (Figure 1). Considering the cumulative Sanger genotype, full detection of historical RAMs by WGS occurred in 4/39 (10.3%) cases, but ≥ 1 new RAM was identified in 25/39 (64.1%) (Figure 1).

Outside pol, WGS at the $\geq 5\%$ threshold detected ≥ 1 lenacapavir RAM in 7/39 (17.9%) samples [6/7 (85.7%) without prior lenacapavir exposure] and ≥ 1 temsavir RAM in 16/39 (41.0%) [12/16 (75.0%) without prior fostemsavir exposure]. Mutations in the nucleocapsid and envelope regions potentially involved in integrase inhibitor resistance were identified in 11/39 (28.2%) and 34/39 (87.2%) samples, respectively.

Conclusions: RNA-based WGS identified additional, previously unrecognized RAMs, including variants affecting emerging antiretroviral targets beyond pol, in individuals with multidrug-resistant HIV, thereby expanding the resistance landscape captured by conventional genotyping. Despite methodological limitations, including the incomplete reconstruction of cumulative resistance history from prior RNA-based Sanger genotypes, these findings highlight the potential of WGS to deepen and broaden resistance profiling and support its role as a valuable complementary approach for comprehensive resistance characterization in populations with high mutational burden.

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Next Generation Sequencing (NGS): redefining management of chronic viral infections

OC 50 GENETIC DIVERSITY IN HEPATITIS DELTA ANTIGEN AND RIBOZYME IS ASSOCIATED WITH ALTERED VIROLOGICAL AND BIOCHEMICAL MARKERS AND COULD HELP IDENTIFY NOVEL THERAPEUTIC TARGETS

S. D'Anna¹, A. Magnapera¹, L. Piermatteo¹, T. Annamammedova¹, L. Fabeni², G. Torre¹, L. Carioti¹, E.L. Lebomo Etogo³, A. Bertoli^{1,4}, P. Paba⁴, A. Olivero⁵, E. Teti⁶, A. Di Lorenzo⁶, V. Malagnino⁶, M. Iannetta⁶, L. Baiocchi⁷, S. Francioso⁷, I. Lenci⁷, M. Arosio⁸, M. Totaro⁸, T. Santantonio⁹, N. Randazzo¹⁰, B. Bruzzone¹⁰, U. Cillo¹¹, A. Vitale¹¹, G. Brancaccio¹², G.B. Gaeta¹³, A. Ciancio⁵, F. Ceccherini-Silberstein¹, S. Grelli^{1,4}, L. Sarmati⁶, P. Lampertico¹⁴, M. Rizzetto⁵, G.P. Caviglia⁵, R. Salpini¹, V. Svicher¹

¹University of Rome "Tor Vergata", Rome, Italy, ²National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy, ³Douala Gyneco-Obstetric and Pediatric Hospital, Douala, Cameroon, ⁴Policlinico Universitario Tor Vergata, Rome, Italy, ⁵University of Turin, Turin, Italy, ⁶Infectious Disease Clinic, Policlinico Universitario Tor Vergata, Rome, Italy, ⁷Hepatology Unit, Policlinico Universitario Tor Vergata, Rome, Italy, ⁸Microbiology and Virology Unit, ASST "Papa Giovanni XXIII", Bergamo, Italy, ⁹Infectious Diseases Unit, University of Foggia, Foggia, Italy, ¹⁰University of Genoa, Genoa, Italy, ¹¹Hepatobiliary Surgery and Liver Transplantation Unit, Oncology and Gastroenterology, University of Padova, Padua, Italy, ¹²Link Campus University Rome, Rome, Italy, ¹³Infectious Disease Unit, University L. Vanvitelli, Naples, Italy, ¹⁴Division of Gastroenterology and Hepatology, Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy

Background: Current knowledge about genetic diversification within the HDV ribozyme (critical for viral replication) and HDAg domains, which drive replication and contain cytotoxic T lymphocyte epitopes (CTLEs), remains limited. We examined the degree of genetic conservation in HDV ribozyme and HDAg regions and evaluated their relationship with virological and biochemical markers.

Material and Methods: 178 individuals with chronic HDV infection were enrolled. Full-length HDV genomes were sequenced by Illumina (median [IQR] reads/patient: 69,282 [38,127–181,165]). Genotypes (Gt) were assigned by phylogeny. Nucleotides and amino acids were considered conserved if not mutated in ≥99% of sequences. HDAg domains and CTLEs (N=18) were defined according to Pascarella 2010 and Kohsar 2021.

Results: Individuals were 58% males, median age 51 (37-59) years, mainly Italians (ITs, 43.7%), followed by Eastern Europeans (EEs, 34.8%) and Africans (AFs, 21.5%). Median HDV-RNA and ALT levels were 5.4 (4.5-6.1) logIU/ml and 94 (62-151) U/l. The most prevalent Gts were 1e (57.8%) and 1c (20.8%), followed by 1b (9.5%), 1a (7.8%), 5 (2.2%), 7 (1.1%) and 6 (0.5%). Gt 1e was predominant in ITs (64%, P<0.001), 1c in EEs (81%, P<0.001), while 1a, 1b, 5, 6, and 7 were found only in AFs.

HDV ribozyme showed 100% nucleotide conservation whereas HDAg exhibited marked variability: conservation was lower in N-terminal (aa1-107) than in C-terminal domains (aa108-214, known to be crucial for HDAg activity) (14.7% vs 32.2%, P<0.005). CTLE conservation ranged from 0% in CTLEaa26-34 and CTLEaa43-51 to 50% in CTLEaa140-149.

In Gt 1e, the aa conservation was significantly reduced in individuals >40 years (68.2% vs 30.8%, P<0.0001), particularly within 6 CTLEs. The N12G mutation (median intra-patient prevalence 99%) correlated with higher ALT (101[63-152] vs 86 [69-174] U/l, P=0.01) and was enriched in individuals with 2xULN ALT (77% vs 50%, P=0.005), suggesting enhanced cytolytic activity.

Conversely, T180A (median intra-patient prevalence 63%) correlated with lower HDV-RNA and HBsAg levels (4.9 vs 5.6 logIU/ml, P=0.04 and 3.7 vs 3.9 logIU/ml, P=0.03), indicating impaired viral fitness.

Conclusions: HDAg exhibits conspicuous genetic diversification, particularly in N-terminal domains and CTLEs, with progressive enrichment in older individuals, suggesting ongoing antigenic drift. Specific mutations may modulate viral fitness and HDV-driven cytolytic activity, warranting further in vitro studies. The highly conserved ribozyme represents a promising target for RNA interference-based therapeutic strategies.

Exploring the unseen: Low-Level Viremia, Immune activation and ART outcomes

OC 51 PERSISTENT LOW-LEVEL VIREMIA IS NOT ASSOCIATED WITH INCREASED RISK OF SERIOUS CLINICAL OUTCOMES IN THE CONTEMPORARY INSTI ERA: A TIME-UPDATED ANALYSIS

G. Festa¹, R. Patanè¹, N. Capra², R. Lolatto², G. Loi¹, G. Torkjazi¹, G. Catalano¹, H. Hasson², S. Nozza^{1,2}, A. Castagna^{1,2}, V. Spagnuolo^{1,2}, T. Clemente²

¹Vita-Salute San Raffaele University, Milan, Italy, ²Infectious Diseases, IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: The clinical impact of persistent low-level viremia (LLV) during antiretroviral therapy (ART) remains unclear. We aimed to investigate the association between LLV and the risk of first serious clinical event or all-cause mortality in the contemporary INSTI-based ART era.

Methods: Cohort study with prospectively collected data analyzed retrospectively, including people with HIV (PWH) followed at IRCCS San Raffaele who initiated ART between January 2008 and January 2024 and had ≥ 3 viral loads (VLs) after 1 year on ART. Individuals were classified according to VL strata: virological suppression (VS; < 50 copies/mL), LLV (≥ 2 consecutive VLs 50-199 copies/mL), and virological failure (VF; ≥ 2 consecutive VLs ≥ 200 copies/mL or ≥ 1 VL ≥ 1000 copies/mL). Blips between 50-999 copies/mL were categorized as VS or LLV according to the previous and subsequent VLs. In line with previous reports, a time-updated measure of VL was used, reclassifying PWH if they experienced LLV or VF during follow-up; reclassification was done only to higher VL strata. Follow-up accrued from the first VL after 1 year on ART (baseline) until the first serious clinical event, death, or last visit.

The primary endpoint was the first serious clinical event (including major adverse cardiovascular events, non-AIDS-defining cancers, AIDS-defining events) or death. Univariable and multivariable Cox regression estimated the risk of first serious clinical event or death according to VL strata.

Sensitivity analyses assessed the first serious non-AIDS-defining event or death and the first AIDS-defining event or death using cause-specific Cox proportional hazards models, censoring individuals at the time of competing events.

Results: Overall, 2358 PWH were included in the analysis: 1789 (75.8%) had stable VS, 263 (11.1%) had LLV as worst category, and 306 (12.9%) had VF (Figure 1). Baseline characteristics reported in Table 1.

During a median follow-up of 8.8 (interquartile range=5.4-12.1) years, 185 PWH developed ≥ 1 serious clinical event or death: 128/1789 (7.2%) on stable VS, 15/263 (5.7%) with LLV, and 42/306 (13.7%) with VF (Figure 2). Compared with VS, the risk of first serious clinical event or death was not significantly increased in the LLV group, whereas it was more than doubled in the VF group at both univariable and multivariable analyses (Table 2).

When stratified by serious non-AIDS-defining events or death, results were consistent (Table 2). When stratified by AIDS-defining events or death, the risk of first event was non-significantly higher in the LLV group and markedly higher in the VF group (Table 2).

Conclusions: In our cohort of PWH initiating ART in the INSTI era, persistent LLV was not associated with an increased risk of serious clinical outcomes, particularly non-AIDS-defining conditions, compared with sustained suppression. These findings overall suggest no clear evidence of excess clinical risk associated with LLV in the contemporary ART era.

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Exploring the unseen: Low-Level Viremia, Immune activation and ART outcomes

OC 52 GREENWOOD STUDY: VIROLOGIC CONTROL ACHIEVEMENT SWITCHING FROM 2DRS TO 3DRS

R. Rossotti¹, N.B. Bana¹, M.C. Moio¹, F. D'Amico¹, G. Cavazza^{1,2}, E. Di Gennaro^{1,2}, A. Forni^{1,2}, L. Luzi^{1,2}, G.J. Burastero¹, L.F. Rezzonico¹, F. Peracchi^{1,2}, M. Puoti^{1,2}

¹ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ²School of Medicine and Surgery, University of Milano-Bicocca, Milan, Italy

Background: Maintaining good adherence to combined antiretroviral therapy is essential for retaining virologic success. Low adherence is a common condition in clinical practice, and one possible way to deal with this issue is to switch poorly adherent individuals to triple regimens with a high genetic barrier and a favourable forgiveness profile to reduce failure. The present study aimed to describe the rate of virologic success when people with HIV (PWH) who are poorly adherent are switched from 2DR to 3DR.

Methods: This retrospective, monocentric study enrolled all individuals with low adherence, defined as at least two detectable viral loads in the previous 18 months, from 2018 to 2025. Participants were stratified according to the treatment decided by the physicians in (i) remaining in 3DR (control group); (ii) remaining in 2DR; and (iii) switching to 3DR regimens with high genetic barrier and forgiveness. Descriptive and nonparametric statistics were used to describe study population, while bivariate logistic regression analysis was used to assess the effect of the regimen on the achievement of virologic control, defined as >90% of the follow-up time spent with an undetectable viral load. Standard survival analyses were used to estimate the risk of virologic failure (i.e., two consecutive values >200 cp/mL or one value >1,000 co/mL).

Results: Of the 2,485 PWH who attended our clinic during the study period, 548 presented with poor adherence (22.1%). They were mainly men (77.7%), with a median age of 50 (IQR 42-58) years, and GBMSM (42.5%); however, the proportions of IVDU and foreign-born PWH were relevant (17.9% and 33.6%, respectively). The majority remained with their ongoing regimens (3DR in 53.4% and 2DR in 34.1%); only 13.5% switched to a 3DR with a high genetic barrier and forgiveness (BIC-based in 59.5% of cases, mostly IVDUs and foreign-born, and with a higher baseline viral load). The rate of PWH who remained for >90% of the time with an undetectable viral load was higher with 2DR (32.6 %) than with switching (23.0%) or remaining in 3DR (22.7%) at the limit of statistical significance. After adjusting for age, risk of exposure, Italian birth, and baseline viral load, switching was not associated with an increased odds of achieving virologic success (aOR 0.32, 95%CI 0.48-1.67). We registered 66 virologic failures (12.0%; Figure 1). Adjusted Cox regression analysis did not find a protective effect when switching (aHR 1.20, 95%CI 0.61-2.36).

Discussion: Poor adherence is a common condition affecting frequently IVDUs and foreign-born PWH. Switching from 2DR to 3DR with high genetic barrier and forgiveness did not lead to increased virologic success and reduced virologic failure. These results should be interpreted cautiously because the individuals who switched were characterised by more detrimental conditions that could not be compensated by the treatment change alone.

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Exploring the unseen: Low-Level Viremia, Immune activation and ART outcomes

OC 53 LONG-ACTING CABOTEGRAVIR/RILPIVIRINE BEYOND VIRAL SUPPRESSION: EFFECTS ON HIV RESERVOIR, IMMUNE ACTIVATION AND SENESCENCE

L. Maddaloni¹, L. De Martino², Z. Michelini³, G. Bugani², L. Santinelli², C. Falvino², A. Lazzaro², R. Donà², L. Bortolani², M. Andreotti³, G. Antonelli¹, C. Mastroianni², C. Scagnolari¹, G. d'Ettore²

¹Department of Molecular Medicine, University of Rome La Sapienza, Rome, Italy, ²Department of Public Health and Infectious Diseases, University of Rome La Sapienza, Rome, Italy, ³National Center for Global Health, Istituto Superiore di Sanità, Rome, Italy

Background: Although long-acting cabotegravir/rilpivirine (LA CAB/RPV) injections have demonstrated great adherence, broad safety and efficacy comparable to oral antiretroviral therapy (ART), limited data regarding its impact on the HIV viral reservoir and immune system status are available. Here, we investigated HIV-DNA levels, immune activation and senescence on peripheral blood mononuclear cells (PBMCs) of PLWH at baseline and after 48 weeks of LA-ART.

Methods: Blood samples were collected from 17 PLWH attending Umberto I hospital of Rome at baseline (T0) and 48 weeks following CAB/RPV LA treatment (T1) and 8 matched HIV-negative volunteers. Virological and clinical parameters were collected from medical records. DNA was extracted from PBMCs to evaluate HIV-DNA levels by quantitative RealTime-PCR. Phenotypes, immune activation and senescence were evaluated by multiparametric flow cytometry on PBMCs by the following monoclonal antibodies: CD3-PerCP, CD4-APC-Vio770, CD8-FITC, CD45RO-PE-Vio770, CD27-VioBlue, CD38-APC, HLA-DR-PE, CD56-PE-Vio770 and CD57-APC. Gating strategies and data analysis were performed using the software CytExpert. Statistical analyses were performed using GraphPad Prism and $p < 0.05$ were considered statistically significant.

Results: HIV-RNA < 200 copies/mL was maintained in all PLWH for the entire study period, but two individuals were returned to oral therapy as a preventive measure due to HIV-RNA blips. In one of them, a mutation associated with resistance to RPV was found, while the other experienced a dramatic increase in BMI, which could have been responsible for alterations of CAB/RPV concentration in plasma. After 48 weeks of CAB/RPV LA, PLWH showed a significant reduction in HIV-DNA levels from baseline ($p = 0.002$). Compared to HIV- individuals, PLWH showed at both T0 and T1 higher CD38 expression on almost all CD4+ T cell subsets ($p < 0.05$). However, PLWH had lower expression of CD38 on central memory CD4+CD38+ T cells and reduced frequency of effector memory CD4+CD38+HLA-DR+ T cell at T1 compared to T0 ($p = 0.008$ and $p = 0.017$, respectively). Moreover, PLWH showed increased frequency of CD8+CD57+ T cells at T0 compared to T1 ($p = 0.0005$) and to HIV- controls ($p = 0.0009$), while comparable values were observed between these latter ($p > 0.05$). Similarly, CD57+ NK cell frequency was higher in PLWH at T0 compared to T1 and to HIV- volunteers ($p = 0.0003$ and $p = 0.0008$, respectively), but their value at T1 was still higher than HIV- controls ($p = 0.019$).

Conclusion: CAB/RPV LA is a valid therapeutic strategy to maintain virological suppression and to reduce the HIV-DNA levels, suggesting a potential impact on the viral reservoir. In addition, this new treatment seems to partially improve the activation and senescence of the immune system that chronically characterize PLWH. Nevertheless, careful monitoring HIV drug resistance, as well as anthropometric factors such as BMI, is necessary to ensure the effectiveness of CAB/RPV injections.

Exploring the unseen: Low-Level Viremia, Immune activation and ART outcomes

OC 54 TWO-YEAR IMMUNOLOGICAL AND NEUROINFLAMMATORY OUTCOMES OF SWITCHING TO LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN PLWH

M.A. Zingaropoli^{1,2}, M. Guardiani¹, A. Carraro¹, F. Dominelli¹, M. Antonacci¹, M. Proietti¹, C. Del Borgo³, E. Tortellini¹, R. Marocco³, G. Mancarella¹, L. Ansaldo³, O. Turriziani¹, M.R. Ciardi¹, C.M. Mastroianni¹, M. Lichtner¹

¹Sapienza University of Rome, Rome, Italy, ²University Hospital Policlinico Umberto I, Sapienza University of Rome, Rome, Italy, ³SM Goretti Hospital, Sapienza University of Rome, Latina, Italy

Background: Long-acting injectable cabotegravir plus rilpivirine (LA-CAB/RPV) represents a paradigm shift in HIV management. This single-center study conducted an in-depth longitudinal immunological evaluation of PLWH switching to long-acting injectable cabotegravir plus rilpivirine (LA-CAB/RPV).

Material and Methods: Three time points were considered: before LA-CAB/RPV (T0), after 12 (T12) and 24 months (T24). Plasma HIV-1 RNA and total cell-associated HIV-1 DNA levels were evaluated. T-cell and monocyte/macrophage subsets were analyzed by flow cytometry. Plasma biomarkers of neuronal (NfL) and astrocyte (GFAP) damage, monocyte/macrophage activation (sCD163, sCD14), and BBB permeability (MMP-9, TIMP-1) were investigated using microfluidic next-generation ELISA. Each time point was compared to healthy donors (HD).

Results: Twenty-six ART-experienced, aviremic PWH and 32 HDs were enrolled. At each time points, PLWH had higher intermediate monocyte counts compared to HD. Lower pDC and slanDC counts were observed compared to HD as well as higher sCD163, sCD14, NfL and GFAP plasma levels. No differences in MMP-9 and TIMP-1 plasma levels were found (see Table).

The longitudinal evaluation revealed no virological failure, nor any differences in the total cell-associated HIV-1 DNA levels. At T12, significant increases in pDC and classical monocyte counts were observed. Conversely, significant decreases were observed in non-classical monocyte counts, as well as in the NfL plasma levels compared to T0. At T24, significant increases in pDC counts were observed. Conversely, significant decreases were observed in intermediate monocyte counts, as well as in the sCD14 plasma levels compared to T0.

Positive correlations were found between non-classical monocyte counts and plasma levels of NfL ($p=0.3819$, $p=0.0096$) and GFAP ($p=0.3869$, $p=0.0087$) as well as between sCD163 and NfL plasma levels ($p=0.4081$, $p=0.0040$), sCD14 and NfL plasma levels ($p=0.4488$, $p=0.0014$). No correlations were found between total cell-associated HIV-1 DNA and monocyte/macrophage subsets nor with CNS inflammation/damage blood biomarkers.

Conclusions: Switching to LA-CAB/RPV maintains virological suppression and HIV-DNA stability over 24 months. The significant reduction in plasma NfL levels, paralleled by decreased monocyte activation, suggests a potential attenuation of subclinical neuronal damage. This highlights a possible neuroprotective effect linked to immunomodulation of the monocyte-CNS axis. LA-CAB/RPV may thus offer benefits beyond adherence, potentially mitigating HIV-associated neuroinflammation and long-term CNS comorbidities. These findings support the safety of LA regimens regarding immune reconstitution and CNS health, warranting further longitudinal investigation.

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Stigma, knowledge and behaviours in the era of HIV prevention

OC 55 KNOWLEDGE REDUCES STIGMA: THE RESULTS OF THE #CHIVUOLECONOSCERE PROJECT

C. Pellegris¹, P. Meli¹, I. Mercurio¹, V. Gotti¹, F. Gritti¹, E. Zanetti¹, F. Maggiolo¹, I. Fontana²

¹Cooperativa Don Giuseppe Monticelli/Bergamo Fast-track City Network, Bergamo, Italy, ²Ufficio scolastico provinciale di Bergamo/Bergamo Fast-track City Network, Bergamo, Italy

Background: The #cHIVuoleconoscere project has, over its 6 years, reached more than 13,000 high school students in Bergamo and its province, offering training programs on HIV and STIs to foster reflection on sexual health, and to fight against stigma and prejudice. The proposal includes two to three sessions per class, each lasting two hours, using a participatory and dialogical approach. The sessions focus not only on prevention but also on mutual respect, consent, personal responsibility in sexual decision-making, and the use of clear, inclusive language.

Materials and Methods: A survey was administered to participating students both before and at the conclusion of the program. The questionnaire investigates both knowledge (9 items) and perceptions and stigma toward people with HIV (5 items). Based on the analysis of these questionnaires, two indices were constructed — one relating to knowledge and one to stigma - and the possible correlations between these indices were explored. The knowledge index ranges from 1 to 23, where 1 is the minimum value of knowledge and 23 is the maximum. The stigma index ranges from 5 to 50, with 5 representing minimum stigma and 50 representing maximum stigma.

Results: The analysis was conducted on questionnaires completed by 11,079 students. The sample comprises 4,859 individuals who identify as female, 6,135 who identify as male, and 17 transgender individuals, 5,155 students from Prep high schools, 4,556 from technical schools, and 1,368 from vocational schools. 9,993 students are Italian, and 1,368 are foreign nationals. On average, the students surveyed demonstrated a robust baseline of knowledge prior to the interventions, with a mean score of approximately 16.5 out of 23. Furthermore, the data indicate that students with higher knowledge scores exhibit lower levels of stigma; conversely, those with lower knowledge indices present higher stigma scores (Table 1). These two variables are inversely proportional.

A strong performance in the knowledge index is significantly correlated with being female, of Italian nationality, and attending a technical school. Interestingly, the level of knowledge does not appear to be influenced as much by the current grade level (class) as by the year of birth, suggesting a downward trend among younger generations (Table 2).

Both knowledge and stigma indices showed significant improvement in the post-intervention questionnaires (Table 3).

Conclusion: Recent generations are increasingly less exposed to discourse regarding HIV. The decline in knowledge among young people suggested by the data is not only concerning for their ability to protect themselves, but also regarding stigma and prejudice, as these two variables are inversely proportional. Educational interventions that foster a holistic reflection on sexual health and address the prevention of Sexually Transmitted Infections (STIs) within school settings are effective in both enhancing knowledge and mitigating social stigma.

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Stigma, knowledge and behaviours in the era of HIV prevention

OC 56 EFFECTIVENESS AND SUSTAINABILITY OF ORGANISATIONAL MODELS FOR DELIVERING COMPREHENSIVE SEXUALITY EDUCATION IN ITALIAN SECONDARY SCHOOLS: A TWO-YEAR ANALYSIS, 2023-2025

A. Chinelli¹, G. Paparatto¹, P. Giangrande², M. Farinella³, C. Celata⁴, M. Ubbiali⁵, D. Martinelli⁶, L. Tavošchi¹

¹Department of Translational Research and New Medical and Surgical Technologies, University of Pisa, Pisa, Italy, ²Department of clinical and experimental medicine, University of Pisa, Pisa, Italy, ³Italian National Association for the Fight Against Aids (ANLAIDS), Rome, Italy, ⁴Department of Prevention, General Directorate of Welfare, Regione Lombardia, Milan, Italy, ⁵Department of Human Sciences, University of Verona, Verona, Italy, ⁶Department of Medical and Surgical Sciences, University of Foggia, Foggia, Italy

Background: Comprehensive sexuality education (CSE) is a priority area for health promotion in adolescence and a key strategy to prevent STIs, including HIV/AIDS. Scaling up effective interventions requires long-term sustainability and transferability to heterogeneous contexts. This study explores the feasibility of a CSE intervention (EduForIST) conducted in lower (LSS) and upper secondary schools (USS) in seven Italian regions during 2023/2024 and 2024/2025 school years, developed and implemented through a multi-sectoral collaboration.

Methods: The intervention consists of five two-hour sessions conducted by two educators. For each participating class, the composition of the educational team (Local Health Authority – LHA, Civil Society Organisations – CSO, teachers) and the context (e.g. type of school, location, deprivation) were collected. The intervention was evaluated using pre and post questionnaires to measure students' knowledge (28-30 items) and satisfaction (19 items). An online survey investigating programme sustainability (P-SAT) was disseminated to adult stakeholders. Multilevel regression analyses explored the association between the team composition and the outcomes of the intervention. For each domain of the P-SAT questionnaire, a score was calculated as the arithmetic mean of the corresponding items.

Results:

Knowledge

In two years, the programme involved 2094 students. Overall, knowledge increased in all domains investigated, in particular STIs prevention. In LSS, post-test scores remained consistent across team compositions, with no statistically significant differences observed ($p = 0.085$). Conversely, USS results reported higher overall scores and significant variation based on team ($p = 0.009$), showing that students taught by mixed teams performed better than those taught by a single-sector team.

Satisfaction

Overall, students reported a high level of appreciation of the intervention (>80%). Both school levels showed a clear preference for external providers, while preference for own teachers as educators was higher when teachers were part of the educational team.

Sustainability

Among the project adult stakeholders, 26 completed the P-SAT, 9 of which had a managerial role. Perceived sustainability capacity was moderate (overall mean score 5.08). Programme adaptation scored higher (5.8), while funding stability scored lower (3.4).

Conclusions: The results of the study suggest that the integration of multi-sectoral, local health and educational expertise is a distinctive strength of the intervention. The improved performance, in USS, of mixed teams suggests that a multidisciplinary approach enhances knowledge acquisition. The capacity for program adaptation might help to mitigate resource shortages and improve its transferability across different local contexts. To ensure long-term impact, efforts must address the weakness in funding stability to allow the transition from a pilot study to a standardised public health practice.

Stigma, knowledge and behaviours in the era of HIV prevention

OC 57 COMPREHENSIVE SEXUALITY EDUCATION IN SECONDARY SCHOOLS 2025-2026

P. Testoni¹, C. Soligo¹, P. Vinti¹, F. Rossi¹, A. Bianchi¹, D. Zagato¹, M. Cernuschi²

¹ASA Associazione Solidarietà AIDS ODV, Milano, Italy, ²San Raffaele Hospital, Milano, Italy

Background: Prevention efforts targeting adolescents are crucial for increasing awareness about HIV in the general population. Since 2015 we have implemented a community-led programme for comprehensive sexuality education in secondary schools in the metropolitan area of Milan.

Methods: Before and after educational sessions, students are invited to complete an anonymous online survey assessing knowledge of HIV and STIs using standardized pre- and post-intervention questionnaires (10 questions; score range 0–1). We conducted a pre–post observational study based on completed questionnaires.

Improvement analyses included only students completing both questionnaires and not achieving maximum baseline score. Knowledge gain was calculated as the difference between post- and pre-intervention scores. Multivariable linear regression identified determinants of knowledge improvement, while multivariable logistic regression assessed factors associated with questionnaire completion.

Independent variables included age, gender, school year, type of school, perceived interest and importance of the intervention, prior exposure to similar interventions, and sources of sexual health information.

Results: We delivered 25 educational sessions and reached nearly 600 students across 3 schools between Dec. '25 and Mar. '26. A total of 548 students completed at least the pre-intervention questionnaire and 391 completed both. Mean knowledge score increased from 0.60 (95% CI: 0.58–0.62) at baseline to 0.69 (95% CI: 0.67–0.71) post-intervention, corresponding to an absolute mean difference of 0.093 (95% CI: 0.074–0.111; $p < 0.001$). The multivariable linear regression model showed limited explanatory power ($n = 391$; $R^2 = 0.136$; global $p = 0.058$). A neutral perception of the intervention's importance was significantly associated with lower knowledge gains ($\beta = -0.117$; $p < 0.001$), as also prior participation in similar educational interventions ($\beta = -0.116$; $p = 0.018$). Demographic variables (age, gender, school year) were not significantly associated with knowledge gains. In logistic regression, school type emerged as the main determinant of questionnaire completion ($n = 548$; pseudo $R^2 \approx 0.19$; $p < 0.001$). Students attending high schools (OR 4.93; 95% CI: 2.47–9.86; $p < 0.001$) and technical institutes (OR 2.44; 95% CI: 1.35–4.39; $p = 0.003$) were significantly more likely to complete both questionnaires than students attending vocational/professional schools. No significant associations were observed for age or gender.

Conclusions: Knowledge improvement following school-based HIV/STI education was modest but significant and only partially explained by socio-demographic factors, while it was more strongly associated with students' perceived relevance of the intervention. Questionnaire completion was primarily associated with school type. These findings highlight the importance of motivational engagement strategies and school-level factors to maximize the effectiveness of HIV/STI educational programmes for adolescents.

Stigma, knowledge and behaviours in the era of HIV prevention

OC 58 BEYOND DIVERSITY: THE IMPACT OF A MULTI-STAKEHOLDER NETWORK ON THE RIGHT TO HEALTH

I. Mercurio¹, P. Meli¹, V. Gotti¹, F. Gritti¹, C. Pellegris¹, E. Zanetti¹, R. Carissoli², M. Rizzi³, M. Beretta³, F. Maggiolo⁴, S. Venturelli⁵, L. Comi⁵, M. Deghi⁶, C. Castell⁶

¹Cooperativa Don Giuseppe Monticelli/Bergamo FTC Network, Bergamo, Italy, ²Arcigay Bergamo Cives/Bergamo FTC Network, Bergamo, Italy, ³Croce Rossa Italiana – Comitato di Bergamo, Bergamo, Italy, ⁴Bergamo Fast Track City, Bergamo, Italy, ⁵ASST Papa Giovanni XXIII, Bergamo, Italy, ⁶CICA, Milano, Italy

Background: Bergamo FTC was established in 2019, bringing together NPOs, public institutions and healthcare providers. The goal was to link and strengthen both screening and support services for PWH and 2025 marked a year of peak operational performance across both fronts. Screening for HIV, HCV, HBV, and Syphilis is offered at the community check-point, through outreach activities and via proximity services that reach key populations. Support activities for PWH include three residential houses, a listening service, a peer support group and actions to facilitate linkage and retention in care in collaboration with hospital. The aim is to guarantee the right to health ensuring access, particularly for the most vulnerable groups. Another significant action concerns the sexual health project aimed at high schools in Bergamo and its cohort, which also impacts public awareness and information.

Material and Methods: This work analyzes 2025 data sourced from the Cobatest database, ISTAT records, partner organizations' and #cHIVuoleconoscere project reports.

Results: In 2025 3,486 people were tested (Table 1).

39% are 18-25 (1.4% of young residents VS 0.24% of the over 25); 64% of these were reached at high schools and universities. Through #cHIVuoleconoscere project 2,813 students of 23 institutes were trained and test was offered in 7 of these.

35.5% are migrants (0.8% of foreign residents VS 0.20% of the Italian-origin population): 65% were met in Italian language schools and 14% in dedicated migrant reception contexts.

15% of the total identify as MSM: 58% were tested at the city check-point and 11% during events dedicated to the LGBTQI+ community.

16.7% are people with social vulnerabilities tested in reception or harm reduction services. Among those tested in harm reduction services (64% of the vulnerable group), 20% reported being homeless and 50% are DU.

Data shows 64 new positive tests (Table 2), all were linked to the hospital; 52 required accompaniment by the network for their care pathway. The incidence of reactive tests is significantly higher among key populations.

Additionally, 38 PWH (74% men, 26% foreign) were hosted in three residential houses; 2 PWH were supported with medication pickup and delivery; 9 people attended the peer support group and 8 were re-engaged in treatment (5 for HIV and 1 for each of the other STIs). 100% of these requested support from the network for their care pathway (Figure 1).

Conclusions: The proximity model of the Bergamo FTC proves effective in reaching different target of populations, promoting sexual health, identifying undiagnosed cases through diversified and personalized screening opportunities and fostering linkage and retention in care for the most fragile populations. The strength of the project lies in the continuity of the care pathway and the quality of the network, which involves both organizations dedicated to HIV/STIs and those focused on specific KPs. The initiatives represent effective public health interventions and, therefore, require more substantial public financial support.

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Living longer, facing more: cancer and the persistent burden of late HIV diagnosis

OC 59 TRENDS AND RISK FACTORS FOR LATE HIV DIAGNOSIS IN ITALY FROM 2012 TO 2024

V. Regine, L. Pugliese, B. Suligoi

Department of Infectious Diseases, National Institute of Health, Rome, Italy

Background: Late HIV diagnosis remains an ongoing and important problem in the public health. In 2024 in the countries of the European Union, almost half of the newly diagnosed HIV people were diagnosed several years post-infection, suggested by a CD4 count below 350 cells/mm³ and one third of people with advanced HIV infection (CD4 count below 200 cells/mm³) (1). In the same year in Italy the proportion of late HIV diagnosis was 60% and 25% of all new diagnoses were AIDS presenters (2). The aim of this study is to analyze the trends and the factors associated with being diagnosed late among persons with a new HIV diagnosis in Italy from 2012 to 2024.

Material and Methods: Data on new HIV diagnoses reported by the HIV surveillance system between 2012 and 2024 was used. Late diagnosis (LD) is defined as a CD4 cell count < 350 cells/mm³ or AIDS presenter at first HIV diagnosis, unless there is evidence of recent infection (3). We then used a binary logistic regression model to assess risk factors for late HIV diagnosis, including year of diagnosis, age group at HIV diagnosis, mode of transmission, nationality, and reporting area (Northern, Central, Southern Italy).

Results: Between 2012 and 2024 38,909 HIV diagnoses were reported to the Italian Surveillance System. Out of them, 32,966 (84,7%) had data on CD4 cell counts. Late diagnoses (LD) accounted for 54.4%. The proportion of LD shows a slow and gradual increase over time until 2019 (52.7% in 2012; 54.5% in 2019) and more pronounced in the last three years (54.9% in 2022; 56.6% in 2024). The median age of LD was 43 years (IQR 34-52), the highest proportions of LD were among people older than 50 years of age (70.5%), heterosexual males (65.5%), heterosexual females (57.7%), and people diagnosed in Southern Italy (56%). At multivariate analysis, the risk of LD increased with age: 25-39 ys OR = 1.85 (95% CI 1.69-2.17); 40-49ys OR=3.23 (95% CI 2.94-3.54); older than 50ys OR=5.16 (95% CI 4.68-5.69), compared to less than 25 ys. At multivariate analysis, factors significantly associated with LD were: having been diagnosed in Central or Southern Italy vs. Northern Italy OR = 1.22 (95% CI 1.15-1.29); being non-national vs Italian, OR 1.43 (95% CI 1.36-1.52); heterosexual transmission (male) OR = 1.96 (95% CI 1.85-2.08), heterosexual transmission (female) OR = 1.56 (95% CI 1.46-1.66), IDU transmission OR = 1.30 (95% CI 1.16-1.45) compared to MSM transmission.

Conclusions: The proportion of LD continuously increased in the study period, especially in the last three years. Older people, heterosexual males, non-Italians and people diagnosed in Central or Southern Italy showed a higher risk of LD. It is crucial to promote initiatives to reduce late HIV diagnosis, by facilitating and expanding access to test, promoting opt-out testing in various settings, and contrasting stigma.

Living longer, facing more: cancer and the persistent burden of late HIV diagnosis

OC 60 MORE THAN DOUBLED RISK OF VIRUS-RELATED NON-AIDS-DEFINING CANCERS IN PEOPLE WITH MULTIDRUG-RESISTANT HIV: A MATCHED MULTICOHORT ANALYSIS

T. Clemente¹, N. Capra¹, L. Oreni², R. Lolatto¹, G. Pozza², S. Di Giambenedetto^{3,4}, C. Fornabaio⁵, E. Fronti⁶, D. Distefano⁷, M. Matone², F. Lagi⁸, A. Cervo⁹, V. Spagnuolo^{1,7}, A. Giacomelli^{2,10}, on behalf of the PRESTIGIO Study Group

¹Infectious Diseases, IRCCS San Raffaele Scientific Institute, Milan, Italy, ²Department of infectious diseases, ASST Fatebenefratelli Sacco, Milan, Italy, ³Infectious Diseases Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, ⁴Catholic University of the Sacred Heart, Rome, Italy, ⁵Infectious Diseases Unit, ASST Cremona, Cremona, Italy, ⁶Unit of Infectious Diseases, AO-Universitaria, Parma, Italy, ⁷Vita-Salute San Raffaele University, Milan, Italy, ⁸Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy, ⁹Department of Infectious Diseases, Azienda Ospedaliero-Universitaria di Modena, Policlinico di Modena, Modena, Italy, ¹⁰Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milan, Italy

Background: HIV multidrug resistance is associated with a high disease burden, but data on cancer risk are limited. We aimed to explore the risk of non-AIDS-defining cancers in people with 4-class drug-resistant HIV (4DR-PWH).

Methods: Matched cohort study including PWH on antiretroviral therapy (ART) without prior non-AIDS-defining cancers, classified as: i) 4DR (exposed), from the PRESTIGIO Registry; ii) non-4DR (unexposed), from ASST FbF Sacco and IRCCS San Raffaele. Groups were matched by age (± 5 years), sex, and ART duration (± 5 years), with a 1:3 ratio.

Baseline was defined as the date of first 4DR evidence for exposed participants and as the date of the nearest visit (± 6 months) for unexposed PWH. Follow-up accrued from baseline until the first non-AIDS-defining cancer, last visit, or death.

The primary endpoint was the first non-AIDS-defining cancer (excluding non-melanoma skin cancers); the secondary was the first virus-related non-AIDS-defining cancer.

Cumulative incidence functions estimated the cumulative probabilities of the primary (using death as a competing risk) and the secondary endpoints (using death and non-virus-related non-AIDS-defining cancers as competing risks). Poisson regression modelled incidence rates (IRs), 95% confidence intervals (95%CI), and incidence rate ratios (IRRs). Multivariable Fine-Gray models were adjusted for smoking habit, HCV serostatus, and CD4+ nadir.

Analyses were repeated using multiple imputation to handle missing data.

Results: Overall, 236 4DR- and 708 non-4DR-PWH included: characteristics reported in Table 1.

During a median follow-up of 7.9 (interquartile range=3.9-11.2) years [7275 person-years (PY)], 28/236 (11.9%) 4DR- and 64/708 (9.0%) non-4DR-PWH developed a non-AIDS-defining cancer, corresponding to IRs of 1.42 (95%CI=0.94-2.06)/100 PY and 1.21 (95%CI=0.93-1.54)/100 PY; IRR 1.18 (95%CI=0.76-1.84; $p=0.466$). The cumulative probability of non-AIDS-defining cancers is shown in Figure 1. No statistically significant association was observed between 4DR status and the risk of non-AIDS-defining cancer (Table 2).

Restricting to virus-related non-AIDS-defining cancers, 16 4DR- and 21 non-4DR-PWH developed the event, corresponding to IRs of 0.81 (95%CI=0.46-1.32)/100 PY and 0.40 (95%CI=0.24-0.60)/100 PY; IRR 2.05 (1.07-3.94; $p=0.027$). People with 4DR HIV had a more than doubled risk of virus-related non-AIDS-defining cancer compared to non-4DR-PWH (Figure 2; Table 2). The distribution of first virus-related non-AIDS-defining cancer differed significantly according to 4DR status ($p=0.036$): anal cancer predominated among 4DR-PWH, hepatocellular carcinoma among non-4DR-PWH (Figure 3).

Results were consistent after multiple imputation analyses.

Conclusions: Among non-AIDS-defining cancers, 4DR status was associated with an increased risk of virus-related malignancies, particularly anal cancer. These findings support the need for enhanced, targeted screening and prevention strategies in this population.

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Living longer, facing more: cancer and the persistent burden of late HIV diagnosis

OC 61 TRENDS IN AGE AT CANCER DIAGNOSIS AND CANCER TYPE DISTRIBUTION IN PEOPLE WITH HIV FROM 2008 TO 2025

G. Loi¹, N. Capra², R. Lolatto², E. Bruzzesi², H. Hasson², S. Bossolasco², V. Spagnuolo^{1,2}, S. Nozza^{1,2}, A. Castagna^{1,2}, C. Muccini²

¹Vita-Salute San Raffaele University, Milan, Italy, ²IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: The improved survival of people with HIV (PWH) in the antiretroviral therapy era has led to progressive population ageing, with relevant implications for cancer epidemiology. This study aimed to investigate temporal trends in age at first cancer diagnosis (AFCD) and changes in the distribution of cancer types in an Italian cohort of PWH.

Methods: We included PWH who were diagnosed with a first malignancy during consecutive triennia between 2008 and 2025 (T1–T6). Individuals with a cancer diagnosis prior to 2008 or diagnosed before or within 30 days of HIV diagnosis were excluded. Primary outcomes were mean AFCD and the distribution of cancer diagnoses by type. Analyses were conducted overall and stratified by assigned sex at birth and by virus-related (VRC; including anal and invasive cervical cancer, hepatocellular carcinoma [HCC], Kaposi sarcoma [KS], Hodgkin lymphoma [HL] and non-Hodgkin lymphoma [NHL]) vs non-virus-related (NVRC). Mean AFCD and 95% confidence intervals (95% CI) were estimated using generalized linear models adjusted for years since HIV diagnosis. Temporal trends were assessed using p-trend tests.

Results: A total of 602 PWH with a first cancer diagnosis were included (characteristics in Table 1). In the overall population, a significant and consistent increase in AFCD was observed over time, rising from 48.4 years (95%CI 46;50.6) in T1 to 58.1 years (55.7;60.5) in T6 (p-trend <0.0001). A similar pattern was observed among men, with AFCD increasing from 48.5 years (45.9;51.1) in T1 to 58.9 years (56.0;61.7) in T6 (p-trend <0.0001). Among women, although AFCD significantly increased over time, a decline was observed between T5 and T6 (from 58.4 years [55.5;61.3] to 56.1 years [52.2;60.1]). When stratified, both VRC and NVRC showed a significant increase in AFCD over time (all p-trend ≤0.005 except for VRC in males). Trends in AFCD are shown in Figure 1.

The distribution of cancer diagnoses changed substantially over time. Among VRC, NHL was the most frequent diagnosis in T1 (34.9%), followed by cutaneous KS (22.2%) and HL (17.5%). In contrast, in T6 the most frequent VRC were anal cancer (53.3%), NHL (26.7%) and HCC (13.3%). A distribution shift was also observed among NVRC: in T2, the most common cancers were breast and colorectal cancer (both 14.3%), followed by lung cancer (10.2%), whereas in T6 prostate cancer predominated (32.1%), followed by lung, colorectal and oral carcinoma (each 8.9%).

Conclusions: In our cohort, AFCD increased by nearly a decade over an 18-year period. However, a recent decline in AFCD among women, particularly for NVRC, was observed. Moreover, the spectrum of both VRC and NVRC has shifted over time, underscoring the need for tailored cancer prevention and screening strategies in ageing PWH populations.

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Living longer, facing more: cancer and the persistent burden of late HIV diagnosis

OC 62 REAL-WORLD IMPACT OF IANS RECOMMENDATIONS ON ANAL CANCER SCREENING PRACTICES

E. Bruzzesi¹, N. Capra¹, R. Lolatto¹, C. Candela², A.R. Raccagni², G. Ponta¹, T. Clemente¹, A.M. Tamburini³, A. Castagna^{1,2}, S. Nozza^{1,2}

¹Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy, ²Vita-Salute San Raffaele University, Milan, Italy, ³Gastrointestinal Surgery Unit, San Raffaele Scientific Institute, Milan, Italy

Background: People with HIV (PWH) are at increased risk of anal cancer compared with the general population. The International Anal Neoplasia Society (IANS) recently published guidelines to standardize anal cancer screening and identify populations at risk. Aim of the study was to assess the impact of the IANS consensus guidelines release on anal cancer screening uptake in a real-life cohort of people with and without HIV and to evaluate concordance between clinical practice and recommendations.

Methods: Cohort study with retrospective analysis of prospectively collected routine clinical data from people with and without HIV, followed at the Infectious Diseases Unit of San Raffaele Hospital, Milan, Italy.

Eligible participants were those who had received anal cancer screening during one of two study periods: before the release of the IANS Guidelines (1st January 2023–31st June 2024) and after their release (1st July 2024–31st December 2025). A six-month lag period was included to account for waiting-list delays.

Demographic, clinical, and laboratory data were collected from the CSL-HIV Cohort database. Baseline characteristics between the two periods were compared using the Wilcoxon rank-sum test for continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate.

Results: A total of 446 and 624 individuals were screened in the first and second periods, respectively, corresponding to 455 and 647 screening examinations, indicating increased uptake. Participants screened in the first period were significantly younger. Among PWH, immunovirological characteristics were comparable between groups in terms of CD4 nadir, viral suppression, and prior AIDS diagnosis; however, immunological parameters were modestly improved in the second period.

After guideline release, a higher proportion of women (4.8% of those screened) and heterosexual individuals underwent screening. In contrast, pre-exposure prophylaxis (PrEP) users and individuals with a history of sexually transmitted infections were more frequently screened in the first period. Individuals with prior anal condylomata and those previously tested for HPV were more commonly screened in the second period (Table 1).

Overall, concordance with screening recommendations significantly improved following guideline release. In the first period, 367/446 individuals (82.3%) met the recommended indications, compared with 586/624 (93.9%) in the second period ($p < 0.0001$). MSM with HIV represented the most frequently screened population in both periods (Figure 1).

Conclusions: Our findings provide real-world evidence of the impact of the IANS recommendation publication, demonstrating rapid implementation in clinical practice alongside a parallel increase in screening uptake, which plausibly reflect increased clinician awareness and sensitization to the indication, particularly given that no additional appointment capacity was made available within the service.

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Connecting the dots: cardiovascular, renal and metabolic risk in HIV

OC 63 INDEPENDENT PREDICTORS OF MAJOR CARDIOVASCULAR EVENTS (MACEs) IN PEOPLE LIVING WITH HIV (PLWH) BEFORE AND AFTER 2015: A MATCHED CASE-CONTROL ANALYSIS

P.F. Salvo^{1,2}, F. Lombardi^{1,2}, A. Carbone^{1,2}, G. Baladin^{1,2}, G. Lenzi², C. De Vivo², S. Colaiuda², F. La Fata², G. Cucinotta², C. Torti^{1,2}, S. Di Giambenedetto^{1,2}

¹Dipartimento di Scienze Mediche e Chirurgiche, UOC Malattie Infettive, Fondazione Policlinico Universitario "A. Gemelli" IRCCS, Roma, Italy, ²Dipartimento di Sicurezza e Bioetica, sezione Malattie Infettive, Università Cattolica del Sacro Cuore, Roma, Italy

Background: People living with HIV (PLWH) remain at increased risk of major cardiovascular events (MACEs). Whether conventional cardiovascular risk algorithms adequately capture HIV-related determinants in the contemporary antiretroviral therapy (ART) era remains debated. In particular, the widespread introduction of second-generation integrase strand transfer inhibitors (INSTIs) after 2015 has substantially modified treatment strategies, toxicity profiles, and long-term metabolic exposure. We aimed to identify independent predictors of MACEs in PLWH and to assess whether risk determinants differed before and after the modern INSTI-based ART era.

Methods: We conducted a retrospective matched case-control study including PLWH with MACEs and controls individually matched 1:1 for duration of HIV infection to ensure comparable cumulative exposure to HIV-related risk. Cardiovascular risk was assessed using the SCORE2/SCORE2-OP algorithm, as appropriate. Multivariable conditional logistic regression identified independent predictors. A pre-specified sensitivity analysis restricted to individuals with baseline after 2015—corresponding to the widespread implementation of second-generation INSTI-based regimens—was performed to evaluate determinants in the modern ART era.

Results: Overall, 670 PLWH were included, 335 cases with MACEs and 335 matched controls. Among cases, events included myocardial infarction (n=241), ischemic stroke (n=80), and hemorrhagic stroke (n=14). Median age was 52 yrs, and 73% were male. Cases had significantly higher median SCORE2 compared with controls (7.1 vs 4.3, p<0.005). However, 60% of MACEs occurred in individuals with SCORE2 <10%, indicating potential underestimation by conventional algorithms.

In multivariable conditional logistic regression, HCV seropositivity (OR 6.55, 95% CI 1.52–28.31, p=0.012), cumulative ART exposure (OR 2.16, 95% CI 1.39–3.37, p<0.005), and ART polytherapy (OR 2.83, 95% CI 1.03–7.82, p=0.044) were independently associated with MACEs.

The post-2015 subgroup included 262 PLWH (131 cases and 131 matched controls). In this modern ART-era population, HCV seropositivity was no longer significantly associated with MACEs (OR 2.01, p=0.321). Conversely, cumulative ART exposure (OR 2.31, 95% CI 1.10–4.88, p=0.028) and polytherapy (OR 8.18, 95% CI 2.20–30.39, p=0.002) remained independently associated with events. Lower HDL-c also emerged as a significant predictor (OR 0.92 per mg/dL increase, 95% CI 0.85–0.99, p=0.045).

Conclusions: In PLWH, cardiovascular risk appears partially underestimated by standard algorithms. While HCV coinfection was associated with MACEs in the overall cohort, its impact attenuated after 2015, possibly reflecting the effect of DAA-mediated HCV eradication. Conversely, cumulative treatment exposure and metabolic alterations emerged as key determinants in the modern ART era, suggesting an evolution of cardiovascular risk drivers in contemporary HIV care.

Table 1

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Connecting the dots: cardiovascular, renal and metabolic risk in HIV

OC 64 PREVALENCE AND LONG-TERM TRANSITIONS OF CARDIOVASCULAR-KIDNEY-METABOLIC SYNDROME STAGES IN PWH

J. Milic¹, C. Puzzolante², L. Gozzi², M. Menozzi², F. Cinque³, G. Cuomo², G. Mancini², R. Lombardi³, C. Mussini^{1,2}, G. Sebastiani⁴, G. Guaraldi^{1,2}

¹Clinic for Infectious Diseases, University Hospital of Modena, Modena, Italy, ²Modena HIV Metabolic Clinic, University of Modena and Reggio Emilia, Modena, Italy, ³Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy, ⁴Division of Gastroenterology and Hepatology, and Chronic Viral Illness Service, McGill University Health Centre, Montreal, Canada

Background: The cardiovascular–kidney–metabolic (CKM) framework links cardiometabolic risk, kidney disease, and metabolic health in a patient-centered model. The aim of this study was to determine the prevalence of CKM stages, to characterize stage-to-stage transitions over the period 2005–2025, and to identify clinical and metabolic factors associated with progression and reversion across CKM stages among people with HIV (PWH).

Methods: This was a longitudinal observational study including PWH attending Modena HIV Metabolic Clinic from 2005 to 2025 divided into three time periods 2005–2015, 2016–2020 and 2021–2025. CKM stages 0–4 criteria are shown in Table 1. Transitions across CKM stages and death were modelled using Markov models, accounting for patient age at the time of each transition. Stage 4 CKM and death were considered as irreversible states. Sex, age, duration of HIV infection, physical activity, INSTI, PI and statin use were included as covariates to weight relative risks of progression and reversion across CKM stages.

Results: Among 31,232 observations, 3,838 PWH had at least two CKM assessments during the study period. Median follow-up was 6.36 years (Q1–Q3: 2.03–12.2), during which 171 deaths occurred. Across CKM stages 0–4 at the last available observation, participants with more advanced stages were older (median age increasing from 42 to 56 years, $p < 0.001$) and more likely to be male (53% to 84%, $p < 0.001$). Sedentary lifestyle and smoking differed significantly across stages ($p < 0.05$). HIV duration increased with higher CKM stage ($p < 0.001$), and nadir CD4 count progressively declined ($p < 0.001$). Figures 1 and 2 summarize population characteristics, prevalence and CKM stage transitions over time. In Markov models of CKM stage transitions, physical activity was associated with regression from stage 1 to stage 0 (HR 1.48, 95% CI 1.06–2.06). From stage 1, male sex and longer HIV duration were consistently associated with progression to stages 2 and 3, while higher physical activity was protective against progression to stage 2 (HR 0.76, 95% CI 0.66–0.88). Older age and longer HIV duration were strong predictors of progression from stage 2 to stage 3. Mortality risk increased with advancing age, particularly from stages 1–4. INSTI use was associated with a lower risk of regression from stage 2 to stage 1 (HR 0.61, 95% CI 0.49–0.76). PI use was associated with a lower risk of regression from stage 3 to stage 2 (HR 0.77, 95% CI 0.63–0.94).

Conclusions: In a large and well-characterized cohort, PWH show a rising prevalence of advanced CKM stages over time. Both HIV-related and traditional modifiable risk factors were associated with progression and regression across CKM stages. The CKM framework offers a patient-centered model to characterize cardiometabolic and renal disease progression in PWH, enabling longitudinal risk stratification and supporting the development of targeted, integrated strategies to preserve metabolic health.

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Connecting the dots: cardiovascular, renal and metabolic risk in HIV

OC 65 ENDOCRINE AND METABOLIC ALTERATIONS IN AGING PLWH WITH LOW BONE MINERAL DENSITY

V. Bono¹, C. Tincati¹, M. Augello¹, R. Rovito¹, A.M. Previtera², V. Sala¹, F. Monti¹, M. Cozzolino³, P. Ciceri³, G. Marchetti¹

¹Clinic of Infectious Diseases and Tropical Medicine, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ²Rehabilitation Unit, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ³Renal Division, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy

Background: Bone fragility is a highly prevalent non-AIDS comorbidity in people living with HIV (PLWH), even in the setting of sustained virological suppression. Accelerated aging, persistent immune activation, and antiretroviral therapy exposure contribute to reduced bone mineral density (BMD); however, the endocrine and metabolic mechanisms underlying this process remain poorly defined. Emerging regulators such as leptin and FGF23 play key roles in bone metabolism in the general population, but their contribution to bone loss in PLWH has not yet been clarified.

Methods: We enrolled 104 viro-suppressed PLWH, classified by BMD as normal (T-score ≥ -1 ; n=55) or low (T-score < -1 , including osteopenia, n=39 and osteoporosis, n=10). Plasma levels of adrenocorticotrophic hormone (ACTH), leptin, FGF23, Dickkopf-1 (DKK1), TNF- α , osteoprotegerin (OPG), osteocalcin (OC), osteopontin (OPN), sclerostin (SOST) and parathyroid hormone (PTH) were quantified using Luminex assay. Mann-Whitney, Kruskal-Wallis, and Dunn's multiple comparison tests were used, and Spearman correlations with immunological parameters were assessed.

Results: The majority of PLWH were older than 50 years of age (67/104; 64%). PLWH with low BMD were older than those with normal BMD (table 1; p=0.01). Plasma levels of DKK1, TNF- α , OPG, OC, OPN, SOST and PTH did not differ between groups. In contrast, PLWH with low BMD displayed significantly lower ACTH (8.2 vs 17.8 pg/mL, p=0.02; fig. 1A), leptin (10.3 vs 15.5 ng/mL, p=0.03; fig. 1B), and FGF23 (36.4 vs 56.3 pg/mL, p=0.02; fig. 1C) compared to PLWH with normal BMD.

When stratifying PLWH with low BMD into osteopenic and osteoporotic groups, no significant differences were observed in the analyzed markers between the two subgroups. However, leptin levels were significantly lower in osteopenic individuals compared to PLWH with normal BMD (9.7 ng/mL vs 15.5 ng/mL, p=0.02), while ACTH and FGF23 levels showed a trend toward reduction in the osteopenic group compared to those with normal bone density (p=0.08 and p=0.07, respectively).

Finally, age was negatively correlated with leptin (r = -0.2; p = 0.01) and positively correlated with FGF23 (r = 0.2; p = 0.05; fig. 1D-E), whereas neither current nor nadir CD4+ T-cell counts were significantly associated with any of the analyzed biomarkers.

Conclusions: Our findings indicate that endocrine and metabolic dysregulation may play a key role in HIV-associated bone fragility. PLWH with low BMD exhibited reduced ACTH, leptin, and FGF23 levels, reflecting an imbalance of the HPA axis, energy metabolism, and FGF23-mediated phosphate/vitamin D homeostasis, which may contribute to impaired bone remodeling and skeletal vulnerability.

The correlation between age and these hormonal markers further highlights the interplay between HIV, aging, and bone loss. Overall, assessment of endocrine and metabolic biomarkers may help identify PLWH at higher risk of bone fragility and guide early preventive and therapeutic strategies.

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Connecting the dots: cardiovascular, renal and metabolic risk in HIV

OC 66 STATIN USE AND TOLERABILITY IN A MULTICENTER ITALIAN COHORT OF PEOPLE WITH HIV

A. Bailoni^{1,2}, G. Carrozzo³, A. Cervo⁴, B. Rossetti⁵, F. Lagi⁶, M. Sambo^{1,2}, B. Caloni³, M. Ricciardetto⁴, C. Nencioni⁵, V. Donini⁷, A. Gori^{3,8}, M. Tumbarello^{1,2}, A. Giacomelli^{3,8}, M. Fabbiani^{1,2}

¹University of Siena, Siena, Italy, ²Azienda Ospedaliero-Universitaria Senese, Siena, Italy, ³ASST Fatebenefratelli Sacco, Milan, Italy, ⁴University Hospital of Modena, Modena, Italy, ⁵Misericordia Hospital, Grosseto, Italy, ⁶Azienda Ospedaliero-Universitaria Careggi, Florence, Italy, ⁷University of Florence, Florence, Italy, ⁸University of Milan, Milan, Italy

Background: Based on recent guidelines, people with HIV (PWH) aged ≥ 40 years are candidates for statins. However, updated data on statin use and tolerability in this population are scarce.

Material and Methods: Retrospective, observational study involving PWH aged ≥ 40 years at 5 clinical centers in Italy. PWH were followed from baseline (BL, first visit after release of DHHS recommendations on statins in February 2024) until the last available visit [follow-up (FU) truncated after 18 months]. SCORE2 was used to estimate the 10-year cardiovascular disease risk. We explored rates of statin recommendation (SR) by physicians, statin acceptability among PWH, statin discontinuation (SD), and their predictors using Cox regression models. Furthermore, variables associated with achieving the LDL target (defined according to ESC/EAS) were studied.

Results: A total of 1,390 PWH were included (72.1% males, median age 58 years, 93.1% with HIV-RNA < 50 copies/mL, median CD4 737 cells/ μ L, 57% with a SCORE2 $\geq 5\%$). Statin use and achievement of LDL target, stratified by cardiovascular risk, are detailed in figure. At BL, 461 (33.2%) PWH were already taking a statin. Among those not on statin at BL and without previous intolerance ($n=879$), only 36.5% ($n=321$) (27% vs 46.1% with SCORE2 $< 5\%$ vs $\geq 5\%$, $p < 0.001$) were offered a statin during FU; older age (aHR 1.24 per +10 years, $p=0.017$), higher LDL (aHR 1.16 per +10 mg/dL, $p < 0.001$) and a SCORE2 $\geq 5\%$ (aHR 1.52, $p=0.010$) were independent predictors of SR by physicians. Among PWH who were offered a statin, 222 (69.2%) accepted the therapy. During FU, 14 (6.3%) PWH discontinued statin (mainly for myalgias), with an estimated SD rate of 10.6% at 12 months: protease inhibitors (PI) use was an independent predictor of SD (aHR 15.48, $p=0.015$). In statin-treated PWH with available FU, LDL target was reached by only 167/604 PWH (27.6%) (44.6% vs 19.2% with SCORE2 $< 5\%$ vs $\geq 5\%$, $p < 0.001$). Injecting drug use (aHR 0.52, $p=0.046$), PI use (aHR 0.41, $p=0.024$), higher LDL at BL (aHR 0.82 per +10 mg/dL, $p < 0.001$) and a SCORE2 $\geq 5\%$ (aHR 0.18, $p < 0.001$) were associated to a lower probability of reaching LDL target.

Conclusions: In our multicenter cohort, statin use is increasing but statin recommendation by physicians is still suboptimal, especially in PWH with SCORE2 $\geq 5\%$. Counselling should be strengthened to improve patient acceptance of statins. Statin tolerability was good with low discontinuation rates. Lipid-lowering therapy adjustments should be pursued during follow-up to improve LDL target achievement.

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Switch for a Long-Term Success

OC 67 REASONS FOR DISCONTINUATION OF SINGLE-TABLET REGIMEN RILPIVIRINE/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (RPV/FTC/TAF) IN THE ERA OF 2ND-GENERATION INSTIS

D. Ripamonti¹, L. Comi¹, D. Valenti², A. Cargnelutti³, M.V. Cossu⁴, A. Poloni⁴, A. Giacomelli^{4,5}, G. Lapadula⁶, L. Mezzadri⁶, P. Bonfanti⁶, M. Mazzitelli⁷, A. Cattelan⁷, R. Gulminetti⁸, L. Pagnucco⁸, A. Celsi⁸, S. Rapino⁹, B. Fioretti⁹, A. Francavilla², E. Foca⁹

¹Infectious Diseases Unit, ASST Papa Giovanni XXIII, Bergamo, Italy, ²FROM-Fondazione per la Ricerca Ospedale di Bergamo-ETS, Bergamo, Italy, ³School of Medicine and Surgery, University of Milan, Milan, Italy, ⁴Department of Infectious Diseases, ASST Fatebenefratelli Sacco, Milano, Italy, ⁵Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milan, Italy, ⁶IRCCS Fondazione San Gerardo dei Tintori, University of Milano Bicocca, Monza, Italy, ⁷Infectious and Tropical Diseases Unit, Department of Molecular Medicine, Padua University Hospital, Padova, Italy, ⁸Department of Medical Science and Infectious Diseases, Fondazione IRCCS Policlinico San Matteo, University of Pavia, Pavia, Italy, ⁹Department of Infectious and Tropical Diseases, University of Brescia, Brescia, Italy

Background: The triple regimen of RPV/FTC/TAF was recommended in the past both as initial and switch strategies in people living with HIV (PWH) and largely adopted in clinical practice due to its safety, tolerability, efficacy and convenience. We report on the durability of this single tablet regimen and the reasons for treatment discontinuation (TD) in the INSTI era.

Methods: Retrospective and observational study in PWH consecutively enrolled on RPV/FTC/TAF in 6 large HIV clinics, in Northern Italy. The primary composite endpoint was TD defined as any reason of discontinuation (including virological failure (VF), as confirmed HIV RNA >50 copies/mL or any values followed by a switch). Survival analysis with Kaplan-Meier estimator was used to assess the probability of treatment discontinuation over time.

Results: A total of 2658 PWH were included in the study, 75% were males, 45% heterosexual, 36% MSM, and 80% were born in Italy. Median nadir (IQR) CD4 count was 308 (183-453) cells/ml and 20% had AIDS. At study entry, median age (IQR) was 48 (40-45) years, median CD4 count (IQR) was 660 (481-870) cells/ml and 68% had received 3 or less treatment lines. Overall, 82% of PWH had switched from other effective regimens (NNRTI-, PI- and INSTI-based triple options in 86%, 3% and 2.4%, respectively). A total of 1497 (56.3%) of subjects discontinued this regimen. The major reasons for stopping were simplification to 2-drug regimens (51.5%), drug interactions (16%), toxicity (5.6 %), lost to follow-up (4.6%), side effects (3.2%) and pregnancy (2.6%), while VF occurred in 4.4% of individuals. A total of 2.3% of individuals died during the follow-up. Among those who discontinued, 57.4% were switched to 2-drug INSTI-based regimens (i.e. DTG/3TC, DTG/RPV and CABO/RPV LA for 49.7%, 33% and 9.1%, respectively), while the remaining subjects mostly switched to 3-drug INSTI-based regimens (27%). For those continuing on RPV/FTC/TAF, median (IQR) follow-up since this regimen initiation was 6 (5-7) years.

Conclusions: RPV/FTC/TAF demonstrated a high virological efficacy and durability as switch strategy in the real life. TD was largely driven by simplification to 2-drug regimens or shift to a regimen with a higher barrier to resistance, while virological failure was infrequent.

Switch for a Long-Term Success

OC 68 CLINICAL OUTCOMES IN PWH SWITCHING FROM ORAL COMBINATIONS WITH DOLUTEGRAVIR (DTG) + LAMIVUDINE (3TC) OR RILPIVIRINE (RPV) TO BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (B/F/TAF): DATA FROM THE ITALIAN ICONA FOUNDATION COHORT (OPTIMIZE-BIC ANALYSIS)

A. De Vito¹, A. Tavelli^{2,3}, A. Giacomelli^{4,5}, V. Mazzotta⁶, G. Orofino⁷, R. Serraino⁸, R. Marocco⁹, R. Rossotti¹⁰, S. Nozza¹¹, L. Albini¹², G. Forcina¹², A. Vergori¹³, A. Di Biagio^{14,15}, A. d'Arminio Monforte², G. Madeddu¹

¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ²Fondazione ICONA, Milan, Italy, ³National PhD Programme in One Health Approaches to Infectious Diseases and Life Science Research, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy, ⁴Department of Infectious Diseases, Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ⁵Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy, ⁶U.O.C. Immunodeficienze Virali e IST, INMI "L. Spallanzani" IRCCS – Roma, Italy, ⁷Unit of Infectious Diseases, "Divisione A", ASL "Città di Torino", Torino, Italy, ⁸Dipartimento di Sicurezza e Bioetica - Sezione di Malattie Infettive, Università Cattolica del Sacro Cuore, Rome, Italy, ⁹Infectious Diseases Unit, SM Goretti Hospital, Latina, Italy, ¹⁰S.C. Malattie Infettive – ASST Grande Ospedale Metropolitano Niguarda – Milano, Italy, ¹¹Clinica Malattie Infettive - Ospedale San Raffaele, Università Vita-Salute – Milano, Italy, ¹²Gilead Sciences Srl, Italy, ¹³Infectious Diseases Unit, Department of Medical and Surgical Sciences, University of Foggia, Foggia, Italy, ¹⁴Department of Health Sciences, University of Genoa, Genoa, Italy, ¹⁵Infectious Disease Unit, IRCCS Ospedale Policlinico San Martino, Genoa, Italy

Background: Data on the effectiveness and durability of B/F/TAF in people with HIV (PWH) switching from DTG-based two-drug oral regimens (2DR) are limited. We aimed to characterize treatment-experienced PWH switching from DTG-based 2DR to B/F/TAF and to evaluate virological, immunological, and metabolic outcomes.

Methods: OPTIMIZE-BIC (GS-IT-380-7670) is a retrospective analysis including PWH from the ICONA cohort who switched from DTG+3TC or DTG+RPV (single- or multi-tablet regimens) to B/F/TAF, between Jul-2019 and Apr -2025, regardless of HIV-RNA at switch. We included only PWH with ≥ 1 HIV-RNA measurement post-switch. Participants were stratified by HIV-RNA at switch: < 50 copies/ml (uVL) or ≥ 50 copies/ml (dVL). The primary endpoint was virological suppression (HIV-RNA < 50 copies/ml) at the last follow-up. Secondary endpoints included time to: - virological failure (VF, 2 consecutive HIV-RNA > 50 or single > 1000 copies/ml followed by ART-change) among uVL; - virological suppression (VS) among dVL; - treatment discontinuation (TD) for any reason and for toxicity. Changes in CD4 count, CD4/CD8 ratio, liver enzymes, and lipid profile were assessed. Kaplan–Meier methods and mixed linear regression models were used.

Results: Eighty-three PWH were included; median age 48 years (IQR 38–58), 69.9% male, and median ART exposure of 7.7 years (IQR 3.6–11.4). At switch, 47 (56.6%) were in the uVL group and 36 (43.4%) in the dVL group (Table1). After a median follow-up of 1.4 years (IQR 0.6–2.6), overall 74/83 PWH (89.2%, 95%CI 80.4–94.9) had HIV-RNA < 50 copies/mL at last observation.

In the dVL group, 83.3% (95%CI 67.2–93.6) had HIV-RNA < 50 cps/ml at last assessment. Median time to suppression was 3.5 months (95%CI 2.8–5.3), with 81.8% (95%CI 67.2–92.6) of PWH reaching VS by 1-year (Figure 1A).

In the uVL group, HIV-RNA was < 50 cps/ml at last measurement in 93.6% (95%CI 82.5–98.7). Only 1 VF occurred with a probability of 3.1% at 1 year (95%CI 0.45–20.2, Figure1B).

17 PWH discontinued B/F/TAF during follow-up. The cumulative probability of TD for any reason was 10.1% (95% CI 5.0–20.2, Figure1C) at 1 year, with no significant differences between dVL and uVL ($p=0.498$). Discontinuations were mainly driven by treatment simplification ($n=7$, 6.4%), lack of virological control ($n=3$, 3.6%) and toxicity ($n=3$, 3.6%). At 1-year the probability of TD for toxicity was 3.2% (95%CI 0.8–11.6, Figure1D).

The CD4/CD8 ratio significantly increased in both groups. Among dVL, CD4 counts increased significantly at 12 months (Figure2). Liver enzymes and lipid parameters remained stable, with a modest increase in HDL cholesterol (Figure3).

Conclusions: In this real-world cohort, switching from DTG-based 2DR to B/F/TAF resulted in high rates of virological suppression, rapid viral control in viremic PWH, low virological failure, and good treatment durability, with favorable immunological trends and a neutral metabolic profile.

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Switch for a Long-Term Success

OC 69 TOLERABILITY AND CARDIOVASCULAR SAFETY OF DOR/3TC/TDF AS A SWITCH REGIMEN AFTER 144 WEEKS OF OBSERVATION IN THE DOROTEA STUDY COHORT

A. Ciccullo¹, G. Balzin², A. Tommasi³, A. Cervo⁴, G. Formica⁵, V. Iannone⁶, M. Fabbiani⁷, E. Altavilla⁸, M. Menozzi⁴, G. Madeddu⁹, S. Colaiuda¹⁰, F. Lagi⁵, C. Papalini³, D. Moschese⁶, S. Di Giambenedetto^{2,10}

¹Infectious Diseases Unit, Ospedale San Salvatore, L'Aquila, Italy, ²Infectious Diseases Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, ³Department of Medicine and Surgery, Section of Infectious Diseases, University of Perugia, Perugia, Italy, ⁴Department of Infectious Diseases, Azienda Ospedaliero-Universitaria di Modena, Modena, Italy, ⁵Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy, ⁶Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ⁷Department of Medical Sciences, Infectious and Tropical Diseases Unit, University Hospital of Siena, Siena, Italy, ⁸Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ⁹Infectious Diseases Unit, University of Sassari, Sassari, Italy, ¹⁰Catholic University of the Sacred Heart, Rome, Italy

Background: We aim to analyze the tolerability and cardiovascular safety of DOR/3TC/TDF after 144 weeks of observation in a multicenter cohort.

Methods: This was an observational study enrolling virologically suppressed people with HIV (PWH) switching to DOR/3TC/TDF in our multicenter cohort; we collected their clinical history as well as laboratory parameters. For a subgroup, SCORE-2 and METS-IR metabolic scores were available. We performed Kaplan–Meier survival analysis to evaluate time to treatment discontinuation (TD), Cox regression to identify predictors of TD, and linear mixed-effects models to assess changes in metabolic parameters over time.

Results: We analyzed data from 439 PWH: 314 (71.5%) were males, with a median age of 51 years (IQR 43–58). Full population characteristics are shown in Table 1.

During 1256.5 PYFU, we observed 150 TD (11.9 per 100 PYFU), mainly driven by switches to long-acting regimens rather than toxicity or clinical failure. In particular, reasons for TD were: switch to a LA regimen (37, 8.4% of total population), toxicity (34, 7.7%), treatment intensification (16, 3.6%), pregnancy (7, 1.4%), death (no AIDS-related, 7, 1.4%), other/unknown (49, 11.2%). Estimated probabilities of maintaining DOR/3TC/TDF were 89.7% (SD±1.5) at 48 weeks and 70.8% (SD±1.3) at 144 weeks. In our regression analysis, we found no predictors of TD.

Analyzing cardiovascular (CV) risk scores, we observed a significant overall reduction in METS-IR over time, reaching statistical significance at week 144 ($p=0.009$). The reduction was more pronounced in PWH with a higher baseline score ($B\ 0.17$, $p=0.035$) and those with a longer time from HIV diagnosis ($B\ -0.28$, $p=0.047$) while it was less pronounced in PWH with a longer exposure to ARV treatment ($B\ 0.40$, $p=0.020$), after adjusting for age and sex at birth.

SCORE-2 trends were overall stable over time. A statistically significant increase was observed among women at week 144 ($p=0.009$); however, the absolute change was small and of uncertain clinical relevance, particularly in light of the limited female sample size.

In subgroup analyses, previous exposure to TAF was associated with significant reduction in SCORE-2 at week 144 ($p=0.024$) and in METS-IR at both week 48 ($p=0.034$) and 144 ($p=0.012$), whereas no significant changes were observed among those without prior TAF exposure. These metabolic improvements occurred without significant changes in Body Mass Index. Consistently, we observed significant improvements in total cholesterol, triglycerides, and LDL cholesterol at week 48 and 144 ($p<0.001$ for all).

Conclusions: In this large real-world cohort, DOR/3TC/TDF showed high durability and was associated with significant improvements in lipid profile and insulin resistance without weight gain. Cardiovascular risk remained overall stable, with evidence of metabolic benefit among individuals switching from TAF. These findings support the long-term metabolic safety of this regimen in clinical practice.

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Switch for a Long-Term Success

OC 70 SWITCHING ANTIRETROVIRAL THERAPY AFTER WEIGHT GAIN: PRO AND CONS FROM THE ICONA FOUNDATION COHORT

L. Taramasso¹, M. Muccio¹, N. Squillace², A. De Vito³, M. Guastavigna⁴, E. Quiros Roldan⁵, C. Tincati⁶, M. Fabbiani⁷, N. Gianotti⁸, M. Puoti⁹, A. Cozzi-Lepri¹⁰, G. Guaraldi¹¹, A. Di Biagio^{1,12}, on behalf of ICONA Foundation Study Group - ICONA cohort

¹Infectious Diseases Clinic, IRCCS Azienda Ospedaliera Metropolitana, Genova, Italy, ²Infectious Disease Unit, Fondazione IRCCS San Gerardo dei Tintori, Monza - University of Milano-Bicocca, Monza, Italy, ³Unit of Infectious Disease, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ⁴S.C. Malattie Infettive e Tropicali I, ASL Città di Torino, Amedeo di Savoia Hospital, Turin, Italy, ⁵Department of Clinical and Experimental Sciences, Unit of Infectious and Tropical Diseases, University of Brescia and ASST Spedali Civili di Brescia, Brescia, Italy, ⁶Clinic of Infectious Diseases, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ⁷Infectious and Tropical Diseases Unit, Azienda Ospedaliero-Universitaria Senese, Siena, Italy, ⁸Icona Foundation, Milan, Italy, ⁹Department of Infectious Diseases, ASST Grande Ospedale Metropolitano Niguarda, University of Milano-Bicocca, Milan, Italy, ¹⁰Centre for Clinical Research, Epidemiology, Modelling and Evaluation (CREME), Institute for Global Health, UCL, London, UK, ¹¹Department of Infectious Diseases, Azienda Ospedaliero-Universitaria di Modena, Policlinico di Modena, University of Modena and Reggio Emilia, Modena, Italy, ¹²Department of Health Sciences (DISSAL), University of Genoa, Genoa, Italy

Background: Antiretroviral therapy (ART)-associated weight gain is a frequent phenomenon after ART initiation, whose occurrence is sometimes reported as a reason for switching in observational and randomised studies. The aim of the present study is to describe the durability of the regimen after switching due to weight gain, the probability of virological failure and the weight trajectories across different post-switch ART regimens.

Material and Methods: This is a prospective observational multicentre study conducted within the ICONA (Italian Cohort Naïve to Antiretrovirals) Foundation cohort, between 1 January 2008 and 30 April 2025. Participants with undetectable HIV RNA (<50 copies/mL) whose reason to switch ART was weight gain, as reported by treating physician, were included. PWH were excluded if they had a diagnosis of a new malignancy, were pregnant, or had received GLP-1 agonists.

Kaplan–Meier curves were used to describe ART durability and virological failure by two years after switching ART. Virological failure was defined as a single HIV RNA > 200 copies/mL or a confirmed HIV RNA > 50 copies/mL.

The trajectories of weight change were modelled using linear mixed models with repeated measures.

Results: A total of 56 people living with HIV (PWH) were included, 30.4% were women, with 19.6% reporting an AIDS-defining event in their medical history (Table 1). On average, they had gained 14.6% of their body weight in the two years preceding the switch.

Most participants switched from regimens containing INSTI (82%) to NNRTI- (60%) or PI-based regimens (20%). TAF was the most prevalent backbone before the switch (66%), whereas TDF became the most prevalent after the switch (41%).

Two years after switching, the probability of discontinuing the ongoing ART regimen was 24.5% (95%CI: 14.6%–39.3%), while the probability of virological failure was 12.7% (95%CI: 5.9%–26.3%), as shown in Figure 1.

After switching, a significant overall reduction in body weight of -1.9 (95%CI: -3.3– -0.6) kg per year was observed ($p = 0.007$): the change per year was -2.5 (95%CI: -4.4–0.6), -1.7 (95%CI: -4.2–0.8) and 0.7 (95%CI: -3.7–2.3) kg in people switched to NNRTIs, to INSTIs and to PIs respectively, without significant differences across regimens ($p = 0.61$ for comparison between INSTI vs NNRTI; $p = 0.32$ for comparison bPI vs NNRTI). Similarly, with regard to backbone drug, in the post-switch period, weight change was -3.8 (95%CI: -6.8 – -0.9) kg per year in PWH switched to TAF, -1.8 (95%CI: -3.9–0.3) kg per year in those switched to TDF, and -1.0 (95%CI: -3.1–1.8) kg per year in those on other backbones, without significant differences between TDF and TAF ($p = 0.264$) or between other ART drugs and TAF ($p = 0.12$), see Figure 2.

Conclusions: In ICONA, switches for weight gain have been burdened by a high rate of discontinuation and virological failure. Although PWH lost weight after switching, their weight trajectories were similar in people remaining in INSTI or TAF and in those who switched to other regimens.

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Long-Acting Cabotegravir/Rilpivirine from different perspectives

OC 71 SCALING LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN ROUTINE HIV CARE: 48-WEEK IMPLEMENTATION OUTCOMES FROM THE PROGRESS MODEL

S. Di Giambenedetto^{1,2}, P.F. Salvo^{1,2}, A. Carbone^{1,2}, G. Cucinotta¹, F. Lombardi^{1,2}, E. Visconti², E. Tamburrini^{1,2}, G. Baldin², F. Pellegrini³, A. De Belvis⁴, C. Torti^{1,2}

¹Dipartimento di Scienze Mediche e Chirurgiche, UOC Malattie Infettive, Fondazione Policlinico Universitario "A.Gemelli" IRCCS, Roma, Italy, ²Dipartimento di Sicurezza e Bioetica, Sezione Malattie Infettive, Università Cattolica del Sacro Cuore, Roma, Italy, ³Dipartimento Scienze della Vita e Sanità Pubblica, Igiene e Medicina Preventiva, Università Cattolica del Sacro Cuore, Roma, Italy, ⁴UOC Percorsi Clinici e Valutazione degli Outcome, Fondazione Policlinico Universitario "A. Gemelli" IRCCS, Roma, Italy

LA-ART integration into routine HIV care remains constrained by organizational barriers. Italian data have shown heterogeneous uptake across centers, driven by structural limitations. In March 2025, our clinic implemented PROGRESS, a structured clinical care pathway designed to optimize delivery of LA-ART through organizational redesign. We evaluated early implementation outcomes during the first 48w.

Methods: We conducted a single-center pre-post observational implementation study. The pre-implementation period spanned from October 2022 to February 2025. PROGRESS included: a dedicated nurse care manager coordinating injection scheduling; a centralized triage desk serving as access point; protected agendas and dedicated clinical spaces; and a reminder system to ensure adherence to schedule.

Guided by the Proctor implementation outcomes framework, we evaluated predefined implementation outcomes. Adoption was defined as the rate of new PWH initiating CAB/RPV over time. Penetration was defined as the proportion of eligible patients receiving LA-ART. Timeliness referred to the interval between treatment proposal and first injection. Fidelity was defined as adherence to the recommended 56 ± 7 -day dosing window. Treatment discontinuation was assessed as incidence rate per 100PYFU. Service throughput was defined as the number of injections/month.

Penetration was calculated relative to two previously estimated eligible populations at our center: 1,205/1,752 (68.8%) based on clinical criteria, and 923/1,752 (52.7%) when restricting to patients with available GRT and no RAMs.

Results: The n of patients receiving CAB/RPV increased from 80 to 218, corresponding to an increase in the monthly initiation rate from 2.76 to 19.82 PWH/month.

Penetration increased from 5.0–6.5% to 18.3–23.8%, representing a 3- to 4-fold relative increase in access among eligible PWH.

Service throughput improved: administered injections increased from a mean of 18/month (510 injections over 29 months) to approximately 80/month (874 injections).

Timeliness improved, with median time from treatment proposal to first injection decreasing from 7 days (IQR 3–14) to 3 days (IQR 2–6).

Treatment discontinuation decreased from 23/80 patients (28.8%; 11.9 per 100 PYFU) to 6/218 patients (2.8%; 3.0 per 100PYFU). All 874 injections administered post-implementation were delivered within the recommended 56 ± 7 -day dosing window, whereas two delayed administrations occurred during the pre-implementation period.

Conclusions: Implementation of the PROGRESS multicomponent care pathway was associated with substantial improvements in adoption, penetration, timeliness, fidelity, treatment retention, and service capacity for CAB/RPV LA delivery. Organizational redesign incorporating centralized access, dedicated care coordination, and protected injection capacity significantly enhanced scalability of long-acting ART within a publicly funded healthcare system without compromising virological effectiveness.

Table 1, figure 1

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Long-Acting Cabotegravir/Rilpivirine from different perspectives

OC 72 CLINICAL COMPLEXITY IN PEOPLE WITH HIV SWITCHING TO CAB/RPV VERSUS ORAL INTEGRASE INHIBITOR-BASED THERAPY

G. Loi¹, N. Capra², R. Lolatto², S. Bagaglio², D. Zandonà², D. Canetti², V. Spagnuolo^{1,2}, S. Nozza^{1,2}, A. Castagna^{1,2}, C. Muccini²

¹Vita-Salute San Raffaele University, Milan, Italy, ²Department of Infectious Diseases, IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: The introduction of cabotegravir/rilpivirine (CAB/RPV) into HIV care has raised questions about equitable access, particularly for people with HIV (PWH) with multiple comorbidities and concomitant medications. This study aimed to assess whether the characteristics of PWH who switched to CAB/RPV differed from those of PWH who switched to oral integrase inhibitor (INSTI)-based therapy.

Material and Methods: Observational cohort study conducted among PWH eligible for CAB/RPV (virologically suppressed, without hepatitis B coinfection, and with no documented resistance to CAB or RPV) who switched between July 2022 and April 2025 to CAB/RPV or an oral INSTI-based regimen, including dolutegravir/lamivudine, dolutegravir/RPV and bicitegravir/emtricitabine/tenofovir alafenamide.

Continuous variables were reported as median (IQR) and categorical variables as number (%). Differences between groups were assessed using the Wilcoxon rank-sum test for continuous variables and the chi-square test or Fisher's exact test for categorical variables. Comparisons included non-antiretroviral drugs, comorbidities, and anticholinergic burden measured by the ACB score. Due to baseline imbalances in age and gender, a sensitivity analysis using 1:1 matching was performed (exact matching for gender and ± 5 years for age).

Results: Overall, 464 PLWH were switched to CAB/RPV and 401 to oral therapy. Participants receiving CAB/RPV were younger [48.9 (39.6-56.4) vs. 54.6 (45.5-60.5) years, $p < 0.0001$] and more frequently male [424 (91.4%) vs. 317 (79.1%), $p < 0.0001$]. Compared to PWH switching to oral therapy, those on CAB/RPV used fewer non-antiretroviral drugs [1 (1-2) vs. 2 (1-4), $p < 0.0001$], had dyslipidemia less often [266 (57.3%) vs. 266 (66.3%), $p = 0.007$], and a lower anticholinergic burden [ACB ≥ 3 : 8 (1.7%) vs. 20 (5%), $p = 0.001$] (Panel 1). Participants who switched to oral therapy appeared to have more cases of chronic obstructive pulmonary disease [6 (1.5%) vs. 1 (0.2%), $p = 0.054$] and diabetes [25 (6.1%) vs. 16 (3.5%), $p = 0.055$], with marginal statistical significance (Panel 1).

Once individuals had been matched by gender and age, we included 338 PWH for each of the two groups, with a median age of 52 years and 89% of the population being male. Following the sensitivity analysis, no differences emerged in the participants' characteristics between those who switched to CAB/RPV or oral therapy, either in terms of polypharmacy, comorbidity, or anticholinergic burden (Panel 2).

Conclusions: In this cohort, individuals who switched to CAB/RPV were younger and appeared to have a lower clinical complexity. However, after matching for age and gender, no significant differences were observed between the two groups in comorbidities, polypharmacy, or anticholinergic burden, suggesting that access to CAB/RPV was not limited by a more challenging medical history.

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Long-Acting Cabotegravir/Rilpivirine from different perspectives

OC 73 INTRACELLULAR PHARMACOKINETICS AND INHIBITORY QUOTIENT OF LONG ACTING CABOTEGRAVIR AND RILPIVIRINE IN THE CLINICAL SETTING

M. Ferrara¹, V. Maccario¹, C. Lipani¹, M. Tettoni¹, L. Trentini¹, G. Orofino², E. Martina³, E. Barnini³, S. Soloperto³, A. De Nicolò³, A. D'Avolio³, S. Bonora¹

¹Unit of Infectious Diseases, Department of Medical Sciences, University of Torino, Torino, Italy, ²Unit of Infectious Diseases, Amedeo di Savoia Hospital, ASL Città di Torino, Italy, ³Laboratory of Clinical Pharmacology and Pharmacogenetics, Department of Medical Sciences, University of Torino, Torino, Italy

Background: Few data on plasma exposure and no data on intracellular (IC, intra-PBMC) accumulation of long-acting cabotegravir and rilpivirine (CAB/RPV LA) administered intramuscularly are currently available. Therefore, our aim was to evaluate CAB and RPV plasma and IC pharmacokinetics (PK), including the intracellular inhibitory quotient (IQ), and to explore the potential role of PK parameters on virological efficacy during an almost 3-year follow-up (FU).

Methods: Participants receiving CAB/RPV every two months were enrolled after informed consent. Plasma and IC CAB and RPV trough concentrations (C_{trough}) were quantified using a validated UHPLC-MS/MS method at the end of each dosing interval, every two months from month 1 to month 31 (M1–M31). The intracellular inhibitory quotient (IQ) was defined as the ratio between IC concentration and the protein-adjusted inhibitory concentration 90% (PA-IC₉₀), established in literature as 12 ng/mL for RPV and 166 ng/mL for CAB. An IQ value above 1 is considered necessary to ensure optimal antiviral activity and adequate intracellular penetration in PBMCs. Virological assessment was performed at each timepoint. PK parameters were expressed as geometric mean (95%CI). Comparisons were performed using Mann-Whitney and Spearman tests.

Results: Overall, 703 IC determinations from 148 participants were included; 86.3% were male, median age was 51 years (49–52) and BMI 24.5 kg/m² (23.9–25.0); in 90.3% of IC, VL was <20 copies/mL. Study population characteristics are summarized in Table 1. Across 703 IC determinations, the overall mean IQ was 26.2 (24.5–27.9) for RPV and 0.97 (0.91–1.03) for CAB. CAB and RPV IQ parameters during FU are reported in Figure 1. No significant correlation was observed between IQ values and virological suppression for either drug. The IQ for both drugs remained stable over time, with no significant differences. Strong and significant correlations were observed between plasma and IC concentrations at all follow-up timepoints (p<0.001).

Conclusions: Our study provides the first longitudinal characterization of intracellular exposure and inhibitory quotient (IQ) of long-acting CAB and RPV. RPV achieved intracellular concentrations approximately 20-fold above the IQ efficacy threshold, despite greater variability in plasma exposure, indicating substantial intracellular accumulation. In contrast, CAB intracellular concentrations remained close to the target IQ value of approximately 1, even in the presence of higher and more stable plasma levels. No association between IQ and virological failure was observed. Furthermore, no intracellular determination showed IQ values below the predefined cut-off for both drugs simultaneously. These findings support the long-term pharmacological robustness of CAB/RPV LA and emphasize the importance of intracellular PK assessment to better characterize antiviral efficacy and interindividual variability.

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Long-Acting Cabotegravir/Rilpivirine from different perspectives

OC 74 OUTCOMES OF CABOTEGRAVIR-RILPIVIRINE IN KEY GROUPS OF PEOPLE WITH HIV (PWH): DATA FROM THE ICONA COHORT

R. Gagliardini¹, A. Tavelli^{2,3}, A. Giacomelli^{4,5}, A.R. Raccagni^{6,7}, V. Mazzotta¹, L. Pipitò⁸, L. Brescini⁹, S. De Benedittis², C. Muccini^{6,7}, A. Cingolani¹⁰, G. Marchetti¹¹, A. Antinori¹, A. d'Arminio Monforte² on behalf of the Icona Foundation Cohort

¹National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ²ICONA Foundation, Milan, Italy, ³National PhD Programme in One Health approaches to infectious diseases and life science research, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy,

⁴Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milan, Italy, ⁵Department of Infectious Diseases, ASST Fatebenefratelli Sacco, "L. Sacco" University Hospital, Milan, Italy, ⁶Infectious Diseases, Vita-Salute San Raffaele University, Milano, Italy, ⁷Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milano, Italy, ⁸Infectious and Tropical Diseases Unit, Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G D'Alessandro," University of Palermo, Palermo, Italy, ⁹Department of Biomedical Sciences & Public Health, Polytechnic University of Marche, Ancona, Italy, ¹⁰UOC Malattie Infettive, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Dipartimento di Sicurezza e Bioetica, Università Cattolica del Sacro Cuore, Rome, Italy, ¹¹Clinic of Infectious Diseases, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy

Background: The widespread adoption of cabotegravir (CAB)/rilpivirine (RPV) long-acting (LA) in clinical practice may be limited not only by organizational challenges but also by clinical uncertainties due to limited real-world evidence in selected key-subgroups of people with HIV (PWH).

Methods: PWH enrolled in the Icona Cohort who started CAB/RPV with HIV-RNA < 50 cp/ml and with ≥1 follow-up (FU) were included. Aim: to estimate the risk of treatment failure (TF, defined as CAB/RPV discontinuation for any cause, TD, or virological failure, VF50, 2 HIV-RNA >50 cp/ml or a single >1000 cp/ml followed by ART change), according to selected exposures of interest: PWH aged ≥60 years (vs <60), females (vs males), migrants (vs Italy-born), PWH without availability of genotype resistance test (GRT) before CAB/RPV start, PWH with previous HBV infection (HBcAb pos vs HBcAb neg), body mass index (BMI) ≥30kg/m² (vs <30kg/m²).

TF was compared across exposure groups using standard survival analysis (Kaplan-Meier (KM) curves) and multivariable Cox regression models stratified by center. Covariate adjustment for each exposure was guided by a directed acyclic graph. Secondary analysis of TD and VF50 were also performed, VF was also evaluated as 2 HIV-RNA >200 cp/ml or one >1000 cp/ml followed by ART change (VF200).

Results: Overall, 920 PWH started CAB/RPV LA (Table 1): 11.6% females, 10.8% ≥60 years, 7.4% with BMI ≥30 kg/m², 11.7% non-Italians, 17.9% anti-HBc pos and 8.7% without previous GRT available (% excludes missing data). In a median FU of 21 months (interquartile range, IQR, 10-30) 104 TF occurred (12 VF50 and 92 TD); the estimated cumulative probability of TF was 9.2% (95% CI 7.4-11.4%) at 1-yr and 12.4% (10.2%-15.0%) at 2-yrs.

KM curves showed comparable cumulative probabilities of TF across the selected exposures (Figure 1). In the adjusted Cox regression model, no evidence for a difference between the groups in TF was observed (females vs males, adjusted hazard rate, aHR, 1.02, 95% CI 0.52-1.99; migrants vs Italian-born, 0.90, 0.47-1.69; obese vs BMI<30 kg/m², 1.33, 0.65-2.74; previous GRT available vs not, 0.49, 0.21-1.16; age ≥ 60 ys vs < 60, 0.82; 0.41-1.64; AntiHBc pos vs AntiHBc neg, 1.14, 0.66-1.97) (Table 2).

Estimated cumulative probability of TD, mainly driven by toxicity/adverse events (69.3%), was 9.2% (7.4-11.4%) at 1-yr and 12.2% (10.0-14.8%) at 2-yrs. Similarly, no evidence for a difference in aHR of TD was detected.

Estimated cumulative probability of VF50 was 1.5% (0.8-2.6%) at 1-yr and 11/12 VF occurred <1yr from CAB/RPV start. The estimated 1-yr probability of VF200 was 0.7% (0.3-1.6%).

Conclusions: In this real-world Italian study, rate of TF of CAB/RPV was 12.4% at 2 years, with no evidence of differences across the key groups evaluated, supporting a broader use of this strategy across heterogeneous groups, while acknowledging the low prevalence of key exposures; residual confounding and potential selection bias cannot be excluded.

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Vaccine response and public health impact in PWH

OC 75 FROM MONITORING TO IMPACT: INCREASED VACCINATION COVERAGE IN 2025 VS 2024 AMONG PEOPLE LIVING WITH HIV IN THE LOMBARDY REGION AFTER IMPLEMENTATION OF A VACCINATION COVERAGE MONITORING SYSTEM

D. Cereda^{1,2}, M. Maffeo^{1,2}, G. del Castillo^{1,2}, M.C. Moiola⁴, G. Marchetti^{5,19}, M.V. Cossu^{6,2}, S. Rusconi^{7,19}, N. Gemignani⁸, F. Crippa⁹, E. Focà^{10,11}, C. Fornabaio¹², B. Menzaghi¹³, L. Pagnucco^{14,2}, B. Mariani¹⁵, N. Squillace¹⁶, D. Canetti^{17,18}, M. Melazzini¹

¹Directorate General for Health - Lombardy Region, Milan, Italy, ²Regional Center for Infectious Diseases – CEREMI - Lombardy Region, Milan, Italy, ³Department Biomedical Sciences for Health - University of Milan, Milan, Italy, ⁴Department of Infectious Diseases - ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ⁵Infectious diseases unit - ASST Santi Paolo e Carlo, Milan, Italy, ⁶ASST Fatebenefratelli Sacco - University Hospital, Milan, Italy, ⁷Infectious diseases unit - ASST Ovest Milanese, Legnano, Italy, ⁸Infectious diseases unit - ASST Lecco, Lecco, Italy, ⁹Infectious diseases unit - ASST Papa Giovanni XXIII, Bergamo, Italy, ¹⁰Infectious diseases unit - ASST Spedali Civili di Brescia, Brescia, Italy, ¹¹Brescia University, Brescia, Italy, ¹²Infectious diseases unit - ASST Cremona, Cremona, Italy, ¹³Infectious diseases unit - ASST della Valle Olona, Busto Arsizio, Italy, ¹⁴Division of Infectious Diseases, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy, ¹⁵Infectious diseases unit - Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico - University of Milan, Milan, Italy, ¹⁶Infectious Diseases Unit- Fondazione IRCCS, San Gerardo dei Tintori - University of Milano-Bicocca, Monza, Italy, ¹⁷Vita-Salute San Raffaele University, Milan, Italy, ¹⁸IRCCS San Raffaele Scientific Institute, Milan, Italy, ¹⁹University of Milan, Milan, Italy

Background: This study aims to assess changes in vaccination coverage (VC) among people living with HIV (PLWH) in the Lombardy Region in 2025, following the implementation of a vaccination coverage monitoring system in 2024.

Materials and Methods: Administrative data were used to identify PLWH as individuals with ≥ 1 antiretroviral (ARV) prescription (excluding TDF/FTC) or ≥ 1 HIV viral load record. Each person was assigned to an infectious diseases clinic (IDC) based on their latest prescription in the calendar year. Two cohorts (2024, 2025) were defined: PLWH identified between 1 January and 31 December of each year, with VC assessed on 31 December; thus, VC variation reflects changes occurred due to vaccination performed in 2025. VC was stratified by IDC, sex and age group (0–49, 50–64, ≥ 65). The analysis included vaccines recommended for PLWH by regional guidelines. Vaccination data were obtained from the regional registry and included all doses recorded in the Lombardy system, irrespective of the place of administration and setting.

Results: Table 1 summarizes age groups and sex distribution for the 2024 (n = 28,364) and 2025 (n = 29,322) cohorts. Figure 1 presents vaccination coverage (VC) for 2024 and 2025, while Figure 2 shows the changes in VC observed in 2025.

The changes in 2025 for selected vaccines are reported below, together with the minimum and maximum variations in first-dose coverage across IDCs.

Herpes zoster (HZ): +6.8% (3.3% - 15.7%)

Pneumococcus (PC): +3.8% (1.3% - 10.0%)

HPV: +4.5% (2.1% - 11.5%)

Haemophilus influenzae b: +2.7% (0.2% - 13.3%)

Hepatitis A (HAV): +1.4% (0% - 4.6%)

VC varied across IDCs in the overall population.

For PC, coverage in 2025 ranged from 24.7% to 71.5% overall across IDCs. In the ≥ 65 age group, variability remained wide, ranging from 33.3% to 83.2% in men and from 37.5% to 80.6% in women.

For HZ, overall coverage ranged from 11.5% to 60.6% across IDCs. Among individuals aged ≥ 65 years, coverage ranged from 15.9% to 71.4% in men and from 6.9% to 46.2% in women.

For HAV, overall coverage ranged from 8.3% to 28.9% across IDCs. In the 0–49 age group, coverage ranged from 13.7% to 42.7% in men and from 7.2% to 23.9% in women.

Conclusions: Overall VC improved in 2025 but substantial heterogeneity was observed across IDCs likely due to implementation of targeted strategies to enhance vaccination uptake, such as on-site vaccination during visits, altogether showing that IDCs play a pivotal role in promoting vaccination. VC varied by sex and age group. Higher HAV coverage among younger men likely reflects targeted recommendations (e.g., men who have sex with man), whereas other differences—such as pneumococcal VC in ≥ 65 —showed heterogeneity across IDCs despite age-based vaccination opportunities independent of HIV status. Establishing a monitoring system for VC among PLWH was important to assess immunization levels, increase awareness among IDCs and evaluate the impact of interventions.

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Vaccine response and public health impact in PWH

OC 76 KINETICS OF HUMORAL AND CELLULAR IMMUNE RESPONSES UP TO 3 YEARS AFTER MVA-BN VACCINATION

V. Mazzotta¹, E. Cimini², L. Bordi³, V. Barchi¹, S. Notari², A. Bettini³, G. Micheli¹, E. Tartaglia², C. Mija Casiana³, R. Schiavone¹, D. Farinacci¹, E. Girardi⁴, A. Marani⁵, F. Maggi³, A. Antinori^{1,5}

¹Clinical Infectious Diseases Department, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ²Laboratory of immunology, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ³Laboratory of virology, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ⁴Scientific Direction, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ⁵Health Direction, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Background: The ongoing mpox epidemic and the limited vaccine supply have raised concerns about the long-term effectiveness of the primary MVA-BN vaccination schedule. We evaluated humoral and T-cell immune responses up to three years after MVA-BN vaccination, according to prior smallpox immunisation.

Methods: Blood samples from individuals receiving a primary MVA-BN cycle (two doses for smallpox-naïve, one dose for previously vaccinated) were prospectively collected at each administration (T1 and/or T2) and at 1 (T2/T3), 6 (T4), 12 (T5), 24 (T6), and 36 (T7) months thereafter. Mpox virus-specific neutralising antibodies (nAbs) were measured by a 50% plaque reduction neutralisation test, and interferon- γ -producing MVA-BN-specific T cells by ELISpot. Statistical analyses included Kruskal-Wallis, Wilcoxon, and Mann-Whitney tests.

Results: We enrolled 102 men who have sex with men (MSM), median age 56.6 years (IQR 53.6–61.1) (Table 1); 6.7% had a history of childhood smallpox vaccination. Fifty-three (52%) were people living with HIV, mostly (83%) with CD4 > 500/mm³. IgG and nAb titres peaked one month after primary MVA-BN vaccination in both vaccine-naïve and previously smallpox-vaccinated participants. Thereafter, titers declined markedly in naïve individuals, with geometric mean titres falling below the detection threshold in most cases. In contrast, previously vaccinated participants maintained a robust humoral response (Figure 1A-B).

MVA-BN-specific T-cell responses followed a similar pattern in both groups: after the early rise, responses decreased substantially over time, starting to wane one year after the primary cycle up to the last timepoint, both in naïve and experienced groups (Fig. 1C). At three years, most participants were below the limit of detection (the median value detected in healthy donors).

Conclusions: Three years after primary MVA-BN vaccination, both humoral and cellular immunity waned substantially in smallpox-naïve individuals. In contrast, people with prior smallpox immunisation showed sustained antibody levels. T-cell response wanes in both groups. These findings suggest that smallpox-naïve populations may benefit from booster dosing to maintain long-term protection, whereas previously vaccinated individuals appear to preserve durable immunity.

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Vaccine response and public health impact in PWH

OC 77 PREVENTION OF RSV IN ADULTS AS A STRATEGY TO REDUCE ANTIBIOTIC CONSUMPTION AND ANTIMICROBIAL RESISTANCE IN ITALY

S. Occhineri¹, V. Baldo², P. Castiglia³, G. Gabutti⁴, A. Lombardi⁵, G. Marchetti⁶, M. Falcone¹

¹Infectious Diseases Unit, Azienda Ospedaliero Universitaria Pisana AOUP Cisanello, University of Pisa, Pisa, Italy, ²Department of Molecular Medicine, Public Health Section, University of Padova, Padova, Italy, ³Department of Medicine, Surgery and Pharmacy, University of Sassari, Italian Scientific Society of Hygiene, Preventive Medicine and Public Health (SItI), Sassari, Italy, ⁴Italian Scientific Society of Society of Hygiene, Preventive Medicine and Public Health (SItI), Cogorno (Ge), Adult Immunization Board (AIB), Cogorno, Italy, ⁵Infectious Diseases Unit, Fondazione IRCSS Ca' Granda Ospedale Maggiore Policlinico, Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy, ⁶Clinic of Infectious and Tropical Diseases, Department of Health Sciences, University of Milan, ASST Santi Paolo e Carlo, Milan, Italy

Background: Respiratory Syncytial Virus (RSV) is a major cause of seasonal morbidity and mortality among adults in Italy with an estimated 291,000 cases and more than 26,000 annual hospitalizations in adults. Although the viral cause of infection, evidence showed a consistent antibiotic (ATB) prescription rate. This is largely due to diagnostic uncertainty, the high risk of bacterial coinfection, and the severity of RSV presentations. Recent Italian cohort data show that over 60% of RSV-hospitalized older adults are prescribed ATBs during their hospitalization, even though confirmed bacterial coinfection rates are much lower. Vaccination reduces RSV-associated hospitalizations and severe respiratory illness, WHO framed RSV vaccination as a very promising tool also to reduce ATB prescription and to contain antimicrobial resistance (AMR). Objectives of this work were to collect evidence on the prescription of ATB for RSV adult patients in Italy and their reduction after vaccination.

Materials and Methods: We conduct a literature review about RSV clinical management in Italy including antibiotic exposure and RSV vaccination impact on ATB consumption. Where ATB event counts were available, study-level proportions were calculated. A DerSimonian–Laird random-effects meta-analysis of proportions was performed for independent primary care outpatient cohorts. An administrative database study on 12-month antibiotic exposure (ATC J01) was analyzed separately.

Results: Four peer-reviewed studies were selected plus a study analyzing the ATB prescriptions in a one year follow up of RSV-confirmed patients (Table 1). Among primary care outpatients the pooled rate of ATB prescription was 55.7% (95% CI 46.2–65.1%), $\tau^2 = 0$, compared with 77.0–78.7% in hospitalized RSV patients. In the administrative database study, during a 1 year follow-up 181/289 (62.6%) RSV-patients received systemic ATB. More prescribed were fluoroquinolones (33.2%), amoxicillin/beta-lactamase inhibitor (24.6%), macrolides (24.6%). The use of a static multi-cohort Markov model was the unique available report estimating the number of RSV cases and associated health outcomes projected in Italy in adults ≥ 75 y and high-risk adults ≥ 60 y with no RSV vaccination vs a single dose of adjuvanted RSVPreF3 OA vaccine in a three-year timeframe. Assuming vaccination rate of 75%, vaccine could decrease RSV related lower respiratory tract infections cases by 43%, among these patients.

Discussion: The use of ATB in the clinical management of RSV disease in adults in Italy turned out to be consistent, most prescriptions are in the WHO Watch or Reserve classes. Real-world effectiveness studies and physician surveys in Italy indicate that improved RSV prevention through vaccination will impactful reduce unnecessary ATB use, by decreasing RSV-related hospitalizations and clarifying the etiology of respiratory illness. This strategy will also improve general health, lower direct healthcare costs and tackling AMR.

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Vaccine response and public health impact in PWH

OC 78 T-CELL MEDIATED IMMUNE RESPONSES FOLLOWING RECOMBINANT HZ/SU VACCINE IN PEOPLE WITH HIV WITH DIFFERENT CD4+ T-CELL COUNT

V. Sala¹, R. Rovito¹, E. Zaninetta¹, C. Acampora¹, L. Benedetti², M. Augello¹, M. Iannetta^{2,3}, C. Tincati¹, G. Marchetti¹

¹San Paolo Hospital, ASST Santi Paolo e Carlo, University of Milan, Milan, Italy, ²Tor Vergata University of Rome, Rome, Italy, ³Policlinico Tor Vergata, Rome, Italy

Background: Varicella-zoster virus (VZV) reactivation is associated with herpes zoster (HZ). While the live attenuated vaccine showed limited efficacy, the recombinant subunit vaccine (HZ/su) has shown strong immunogenicity in immunocompromised individuals. As data in people with HIV (PWH) are limited to those with high CD4+ T-cell counts, we investigated HZ/su immunogenicity in PWH according to CD4+ T-cell counts, with a focus on cell-mediated response.

Materials and Methods: We consecutively enrolled virally suppressed PWH (≥ 18 years, on ART, HIV RNA < 50 copies/mL) receiving two HZ/su vaccine doses 2–6 months apart. Peripheral blood samples were collected before the first dose (T0) and one month post-second dose (T1), and peripheral blood mononuclear cells (PBMCs) were isolated. PBMCs were stimulated with a pool of gE peptides for 20h, and gE-specific CD4+ - CD8+ T-cell responses were assessed by intracellular cytokine staining (ICS) and T-cell activation-induced marker (AIM) assays integrated in one multiparametric flow cytometry panel (IL-2, IL-4, IL-10, IL-17, IFN- γ , TNF- α , CD3, CD4, CD8, CD69, CD137, CXCR5, CD45RA, CCR7).

Results: A total of 76 PWH were included in the study, 64 with CD4+ T-cell counts ≥ 350 cells/mm³ (high) and 12 with CD4+ T-cell counts < 350 cells/mm³ (low). The demographic features were comparable between groups, though subjects in the low group were older (Table 1). The distribution of CD4+ T-cell subsets did not significantly differ over time within each group or between groups at either time point (Fig. 1A). An increase over time in total gE-specific CD4+ T cells was observed in both groups, reaching significance only in the high group, particularly in the TEM subset (Fig. 1B). At T1, both study groups showed a higher frequency of polyfunctional Th1 gE-specific CD4+ T-cells compared with T0 across all analyzed CD4+ T-cell subsets; however, this increase was more pronounced in the high group, especially within the TEM compartment (Fig. 1C).

Conclusion: One month after the second dose, HZ/su induced gE-specific CD4+ T-cell responses in virally suppressed PWH across CD4+ strata, with stronger responses at higher CD4+ T-cell counts. These results confirm robust immunogenicity even in moderately immunosuppressed individuals and underscore the importance of CD4+ T-cell recovery in optimizing vaccine-induced cellular immunity, with potential implications for booster strategies in PWH.

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Expanding HIV prevention: PrEP, community services and real-world evidence

SC 1 INCIDENCE AND PREDICTORS OF RENAL TOXICITY AMONG PRE-EXPOSURE PROPHYLAXIS USERS IN THE ITALIAN PRIDE COHORT

M. Menozzi¹, S. Leone², G. Frate³, V. Barchi⁴, E. Caruso⁵, C. Tincati⁶, A.M. Lucchini⁷, A.M. Cattelan⁸, S. Lazzarin⁹, V.L. Del Negro¹⁰, M. Ridolfi¹¹, M. Augello¹², M. Cernuschi⁵, S. Nozza¹³, C. Mussini¹⁴, A. Antinori¹⁵, D. Moschese⁹, V. Mazzotta⁴

¹Infectious Disease Clinia, AOU Policlinico di Modena, Modena, Italy, ²Clinical Epidemiology and Biostatistics, National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy, ³Fondazione ICONA, Milano, Italy, ⁴Counseling, Test and HIV Prophylaxis and STI Unit, Regional AIDS Reference Center, National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy, ⁵Milano Checkpoint, Milano, Italy, ⁶Clinic of Infectious Diseases and Tropical Medicine, Department of Health Sciences, ASST Santi Paolo e Carlo, University of Milan, Milan, Italy, ⁷Multidisciplinary Center for Sexual Health (Ce.Mu.S.S.), Ospedale Oftalmico "Casimiro Sperino", ASL "Città di Torino", Turin, Italy, ⁸Padua University Hospital, Infectious and Tropical Diseases Unit, Padua, Italy, ⁹Department of Infectious Diseases, Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ¹⁰Checkpoint Plus Roma, Italy, ¹¹Department of Internal Medicine, Endocrine-Metabolic Sciences and Infectious Diseases, AOU Policlinico Umberto I, Rome, Italy, ¹²Clinic of Infectious Diseases and Tropical Medicine, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ¹³Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy, ¹⁴Infectious Diseases Unit, Azienda Ospedaliero-Universitaria Policlinico di Modena; University of Modena and Reggio Emilia, School of Medicine, Modena, Italy, ¹⁵Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases Lazzaro Spallanzani, IRCCS, Rome, Italy

Background: Oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) is highly effective for HIV prevention, although concerns about potential nephrotoxicity may influence long-term use. We evaluated the incidence, timing and determinants of renal toxicity within the Italian national PrIDE cohort.

Methods: We conducted a retrospective observational study among TDF/FTC-based oral PrEP users enrolled in the PrIDE national cohort with at least one estimated glomerular filtration rate (eGFR) measurement. Follow-up started at PrEP initiation and ended at renal event occurrence or at switching, discontinuation, or December 31, 2025 (cut date), whichever came first. Renal toxicity was defined as eGFR<60 ml/min/1.73m². Cox proportional hazards models were used to identify factors associated with renal toxicity; in stratified analysis by age-group, to address potential small-sample bias and sparse event limitations, Firth -penalized likelihood Cox models were applied. Non-renal adverse events, PrEP discontinuation, co-medication and substance use were also assessed.

Results: Among 1,583 PrEP users included, 15 participants (0.9%) developed renal toxicity (Table 1). Incidence rate per 100 person-years was 1.22 (95%CI 0.68–2.01), 0.70 (0.28–1.43) in <50 years and 3.54 (1.53–6.89) in ≥50 years. The Kaplan Meier curve (Figure 1) shows the cumulative probability of renal toxicity during follow-up. Median time from PrEP initiation to event was 127 days (IQR 106.5–136). No definitive PrEP discontinuations occurred among individuals experiencing renal events, and only one temporary interruption was reported.

Non-renal adverse events were uncommon (diarrhoea 5.9%, fatigue 1.5%, headache 1.3%, insomnia/nightmares 0.3% and skin rash 0.2%), with no age-group differences.

In multivariable Cox analysis, age ≥50 years (aHR 4.44, 95%CI 1.59–12.35; p=0.004) and use of physical performance-enhancing substances (aHR 8.41, 95%CI 2.31–30.60; p=0.001) were independently associated with renal toxicity (Table 2), in particular in the older group after stratification with Firth penalized likelihood Cox models.

Conclusions: In this large national real-world PrEP cohort, renal toxicity during TDF/FTC use was rare and occasionally led to interruption. Older age and physical performance-enhancing substances use identify individuals who may benefit from targeted renal monitoring supporting the overall favourable safety profile of oral PrEP.

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Expanding HIV prevention: PrEP, community services and real-world evidence

SC 2 PRISONS & COMMUNITY-LED ORGANIZATIONS: A FRUITFUL COLLABORATION TO IMPROVE PREVENTION INTERVENTIONS IN DETENTION FACILITIES

S. Penon¹, L. Cosmaro¹, S. Curridori¹, F. Falzetta¹, V. Walsh¹, A. Grisolia², T. Sebastiani², C. Cairone², R. Bartolotti², R. Ranieri²

¹Fondazione LILA Milano ETS, Milan, Italy, ²SC Direzione Coordinamento Carceri, ASST Santi Paolo e Carlo, Milan, Italy

Background: People living in prison (PLP) are at increased risk of blood-borne viruses (BBVs) and sexually transmitted infections (STIs), while often experiencing limited access to prevention information and services; nevertheless, prisons represent a key setting for reaching vulnerable and underserved populations.

For several years, the penitentiary health service at San Vittore Prison has established a structured collaboration with dedicated staff of LILA Milano, a community-based HIV/STI organization. LILA staff access the facility weekly to provide information about prevention, individual counseling, anonymous rapid testing for HIV, HCV, HBV and syphilis, vaccination counseling and promotion of vaccine uptake. This study describes this collaborative model as a best practice to address prevention and care gaps among PLP.

Material and Methods: At entry into San Vittore, all newly incarcerated individuals are offered voluntary screening for HIV, HCV, HBV, and syphilis by the penitentiary health service. LILA Milano subsequently contacts individuals who declined testing at intake, offering community-led, anonymous rapid testing and counseling. The organization also conducts group educational sessions in different prison wings, provides individual counseling to PLP living with HIV and/or viral hepatitis, and supports linkage to care when needed. In 2025, LILA Milano actively contributed to promoting a prison-wide vaccination campaign (HBV, HPV, DTaP-IPV).

Results: In 2025, 3,028 individuals entered the San Vittore Prison. Of these, 1,147 (37.9%) accepted voluntary screening at intake (Table 1). Among those not tested at entry, LILA Milano performed 120 rapid HIV tests (6.4%), 107 HCV tests (5.7%), 108 HBV tests (4.6%), and 86 syphilis tests (4.6%). Overall, 123 PLP underwent community-based testing in 2025; 96 (78%) were male and 44 (35.8%) were foreign nationals (Table 2). Unlike previous years, no reactive results were detected. Regarding vaccination, active promotion by LILA Milano significantly supported uptake during the 2025 campaign: the number of vaccine doses administered increased from 92 in the first semester to 2,702 in the second semester (Table 3).

Conclusions: A long-standing collaboration between prison health services and a community-based organization can effectively reach PLP who are otherwise harder to engage. Through diversified strategies—group education, individual counseling, anonymous rapid testing, and vaccination promotion—this integrated model increased screening coverage and markedly improved vaccine uptake, contributing to better health outcomes and wellbeing among PLP.

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Expanding HIV prevention: PrEP, community services and real-world evidence

SC 3 SERVICES AND CLINICAL PATHWAYS FOR HIV DIAGNOSIS FOR VULNERABLE POPULATIONS: INSIGHTS FROM A LARGE HIV CLINICAL CENTER WITH HUB-AND-SPOKE NETWORK

L. Cordier^{1,2}, M. Morosi^{1,2}, V. Iannone², L. Oreni², M.V. Cossu², A. Giacomelli^{2,3}, R. Giorgi², V. Micheli⁴, A. Dolci^{4,3}, A. Gori^{2,3}, A. Capetti^{1,2}

¹SSD Fragilità e Prevenzione, STI Jenner44 Clinic, Milan, Italy, ²Department of Infectious Diseases, Luigi Sacco Hospital, Milan, Italy, ³Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milan, Italy, ⁴Laboratory of Clinical Microbiology, Virology and Bioemergency Diagnostics, Luigi Sacco Hospital, Milan, Italy

Background: In recent years, HIV diagnoses in Italy have increased, particularly in Lombardy and the metropolitan area of Milan. In this context, counselling and testing services at local sexually transmitted infection (STI) centres play a pivotal role in prevention and early diagnosis, especially among vulnerable populations. We aimed to describe the hub-and-spoke service network of the Infectious Diseases Department at Luigi Sacco Hospital, which integrates the low-threshold, free-access territorial STI clinic "Jenner44" with specialized hospital-based facilities, and to analyze clinical and demographic characteristics of individuals diagnosed with HIV.

Methods: We conducted a retrospective observational study including adults ≥ 18 years who attended the Jenner44 STI Clinic between 1 January 2024 and 31 August 2025 and had a confirmed positive HIV test during the study period (either newly diagnosed or previously diagnosed and re-engaged in care). Demographic, clinical, and laboratory data, as well as linkage-to-care pathways, were extracted from the center's electronic database.

Results: A total of 63 individuals who tested positive for HIV were included. Among them, 35 (55.6%) were newly diagnosed with HIV, while 28 (44.4%) had a previously known diagnosis and attended for re-engagement in care. People with HIV were predominantly males (90.5%), with a median age of 33 years [IQR 28–39]. Majority were MSM (30, 47.6%), and 17.5% were transgender women (Table 1). The most represented ethnicity was Latin American (37/63, 58.7%), followed by Caucasian (19, 30.2%), African (5, 7.9%), and Asian (2, 3.2%). Only 42 individuals (66.7%) possessed a valid Italian healthcare card at the time of access. Most patients (53, 84.1%) accessed the STI clinic directly without referral. The most common reasons for testing were routine STI screening (10, 16%) and presence of clinical symptoms suggestive of HIV infection (13, 20.6%). Concomitant STI diagnoses were recorded in 42 subjects (66.7%): syphilis (33, 52.4%), Chlamydia trachomatis (3, 4.8%) and gonorrhoea (8, 12.7%). Only one individual (1.6%) reported previous post-exposure prophylaxis (PEP), and none reported pre-exposure prophylaxis (PrEP) use prior to diagnosis. Among newly diagnosed individuals, the median HIV RNA viral load was 30,300 copies/mL (IQR 3,300–115,000), and the median CD4+ T-cell count was 457 cells/mm³ (IQR 270–692). Regarding retention in care 48 individuals, 76.2% were actively followed either at the territorial clinic or at the hospital Infectious Diseases Department, while 9 patients were lost to follow-up.

Conclusions: Our findings highlight the critical role of low-threshold STI services integrated within a hub-and-spoke model in identifying HIV infections and facilitating early linkage to care, particularly among vulnerable foreign-born populations. This integrated organizational strategy appears effective in reducing barriers to diagnosis although retention in care remains a challenge.

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Expanding HIV prevention: PrEP, community services and real-world evidence

SC 4 PREVALENCE AND INCIDENCE OF HCV INFECTION IN A COHORT OF ITALIAN PREP USERS: TOO LOW TO BE RELEVANT?

A Forni^{1,2}, F. Peracchi^{1,2}, V. Brogna^{1,2}, A. Repishti^{1,2}, L. Luzi^{1,2}, E. Di Gennaro^{1,2}, G. Cavazza^{1,2}, M. Merli¹, N. Bana¹, C. Baiguera¹, M. Puoti^{1,2}, R. Rossotti^{1,3}

¹ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ²University of Milano-Bicocca, Milan, Italy, ³University of Verona, Verona, Italy

Background: HCV transmission among MSM is associated with high-risk behaviours such as, group sex, sharing syringes, fisting, and chemsex practices (including slamming). Despite this, the Italian Medicines Agency (AIFA) requires semestral HCV testing for all PrEP users, without diversification according to risk factors. Our analysis aims to evaluate prevalence and incidence of HCV infection in a cohort of PrEP users in Milan.

Material and Methods: This retrospective analysis included all individuals who initiated PrEP at our outpatient clinic from 2018 to 2024. Demographic and behavioural variables were collected and analysed with descriptive and nonparametric statistics. Prevalence and incidence per 100 patient-years (100PYFU) were calculated. Standard survival analyses were used to estimate the risk of and factors associated with HCV acquisition.

Results: A total of 767 PrEP users were enrolled, predominantly cisgender men, whereas a small proportion were transgender (0.9%) or non-binary (0.4%). The median age was 35 (IQR 30-41) years. A low rate of chemsex use (17%) and sex work (1.8%) emerged. Visits occurred at 3-month intervals. The median number of sexual intercours in the previous 3 months was 14 (IQR 7-24), including a median of 9 condomless sexual intercours (IQR 3-20). Table 1 summarizes full demographic and behavioural data. Median follow-up was 1.27 years (IQR 0.06-5.89).

Testing for HCV infection was positive in 7 cases, with a prevalence of 0.9% (95% CI 0.4-1.9). Over 992.6 person-years of follow-up, overall HCV incidence was 0.20 (95% CI 0.10-0.81) per 100PYFU. Kaplan-Meier analysis (Figure 1) showed a consistently low cumulative probability of HCV acquisition.

In multivariable Cox regression analysis, condomless sex was independently associated with HCV acquisition (aHR per 10 episodes 1.48; 95% CI 1.01-2.19), as was receptive anal sex (aHR 5.12; 95% CI 3.07-8.54), after adjustment for chemsex use, age, sex at birth, and number of follow-up visits. Of note, chemsex did not result associated with HCV acquisition.

Conclusion: This study described a very low prevalence and incidence of HCV infection among PrEP users in Milan. Although HCV has been associated with chemsex use, this association was not significant in our cohort, likely due to the small number of reported chemsex. This finding reflects also the low rate of slam sex in Southern European populations.

These data suggest the need of revising testing policies to optimize economic and healthcare staff resources.

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Expanding HIV prevention: PrEP, community services and real-world evidence

SC 5 FIRST DELIVERY OF LONG-ACTING INJECTABLE (CAB-LA) PRE-EXPOSURE PROPHYLAXIS (PREP) IN A COMMUNITY-BASED SETTING

V. Barchi¹, V.L. Del Negro², G. Del Duca¹, M. Maresca¹, G. Terracini¹, G. Frate¹, F. Cannone¹, R. Esvan¹, G. Micheli¹, C. Di Vilio¹, A. Giacinta¹, R. J. Steiner¹, S. Passacantilli¹, D. Farinacci¹, P. Faccendini¹, A. Antinori³, V. Mazzotta¹

¹National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy, Regional AIDS Reference Center, Rome, Italy, ²CheckPoint PLUS Roma, Italy, ³Health Direction, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Background: PrEP is a cornerstone of HIV-prevention, yet barriers are still present. Offering different PrEP options and alternative delivery settings may improve access and persistence. Long-acting injectable cabotegravir (CAB-LA) has recently been introduced in some Italian clinical centres, and community-based services (CBS) are already active in providing oral PrEP. Here we describe the first implementation of CAB-LA PrEP in a CBS in Rome.

Material and Methods: We conducted a pilot prospective study from July 2025 to February 2026. CBS volunteers assessed eligibility for CAB-LA and provided PrEP counselling. At the first injection, a 4th-generation Ag/Ab HIV and syphilis rapid test and pooled sampling for Chlamydia and Gonorrhoea were performed at CBS; blood for HIV-RNA was collected at CBS and processed in the hospital lab. Only HIV and STI rapid tests were performed before subsequent injections. No oral lead-in was given. Questionnaires exploring side effects, injectable experiences (Figure1), satisfaction, mental health, and stigma were collected (Figure2). All procedures were led by a specialized team (nurse, ID-specialist, peer) and provided with medical equipment to ensure safety standards comparable to a hospital setting (HS).

Results: Eight participants were enrolled. Self-reported socio-demographic, behavioural characteristics, along with reasons for CAB-LA access are shown in Table1. All participants were PrEP-experienced and reported a history of STIs. Only one delayed injection (<3months) was administered in the HS. Four users reached the eighth injection at the time of analysis: one was lost to follow-up (FU) after the first injection. At the fourth injection, 85,7% reported satisfaction with CAB-LA and adherence was generally rated as "very easy." Consistent condom use decreased from 50% at baseline to 14%, while the proportion reporting no condom use increased from 12% to 42,8%. Occasional drug use declined (25%to14%), with no overall increase in substance use. Baseline reports of depression and anxiety (12% each) were not reported at FU. Perceived high risk of HIV acquisition increased (37% to 57%), whereas perceived low risk decreased (67% to 28,5%) (Figure 2). Six mild-to-moderate injection-site reactions (ISR) were observed, five associated with transient sleep disturbance or temporary activity limitation. Three participants reported slight anticipatory anxiety related to injections. No HIV nor STI infections occurred during FU. Findings are limited by the small sample size and short FU.

Conclusions: In this small cohort, CAB-LA PrEP delivery in a community-based service was feasible, safe, and highly acceptable, with on-time dosing and good tolerability in this pilot. A decrease in consistent condom use suggests possible risk compensation, highlighting the need for ongoing counselling. Community-led, non-hospital pathways can pragmatically expand access to long-acting PrEP and should be scaled and evaluated in larger, longer FU cohorts.

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Expanding HIV prevention: PrEP, community services and real-world evidence

SC 6 DETERMINANTS OF ASYMPTOMATIC AND SYMPTOMATIC INCIDENT CHLAMYDIA AND GONORRHOEA INFECTIONS AMONG PREP USERS

S. Venturelli¹, G. Ghilardi², E. Nespoli², L. Comi¹, F. Borghi¹, A. Francavilla³, D. Ripamonti¹, F. Crippa¹

¹Infectious Diseases Unit, ASST Papa Giovanni XXIII, Bergamo, Italy, ²School of Medicine and Surgery, University of Milano-Bicocca, Monza, Italy, ³FROM Research Foundation: Fondazione per la Ricerca Ospedale di Bergamo – ETS, Italy

Background: Sexually transmitted infections (STIs) incidence is high among PrEP cohorts, driven by high-risk sexual behaviours and systematic asymptomatic screening. Emerging evidence questioning the benefit of quarterly Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) screening in asymptomatic men who have sex with men (MSM) on PrEP is currently challenging international guidelines. This study assessed overall STI occurrence in our cohort and, focusing on 2025 data, evaluated CT/NG incidence, risk factors, and determinants of symptomatic presentation.

Methods: Retrospective study including all individuals initiating PrEP between June 2018 and December 2025 at the Bergamo PrEP clinic (Italy). Incident STIs included gonorrhoea, chlamydia, syphilis, Mycoplasma genitalium, warts, Mpox, genital herpes and viral hepatitis. Follow-up (FU) visits were scheduled every three and four months for daily and on-demand users, respectively. Multiple logistic regression models examined predictors of CT/NG incidence and symptomatic presentation in 2025, including age, PrEP regimen, prior CT/NG infection and median number of quarterly sexual partners. Symptoms were defined as urethritis, pharyngodynia or proctitis.

Results: Of 611 individuals commencing PrEP, 150 were enrolled in 2025; 98% were cisgender males (96% GBMSM), median age was 36 years (IQR 30–44). On-demand PrEP was chosen by 383 (63%) at baseline. Median FU was 17 months (IQR 6–28); 150 users withdrew from FU. Among 481 users with at least one FU visit, 277 (58%) had at least one STI (total STIs: 827); 80 users (17%) had ≥4 incident STIs, accounting for 505 (61%) of all diagnoses (high-rate reinfection group). In 2025, 394 users attended at least one FU visit (1,078 total FU visits; median 3, IQR 2–4). NG was diagnosed in 109 users (153 infections) and CT in 63 users (74 infections). 43 (39%) NG-positive and 30 (48%) CT-positive users belonged to the high-rate reinfection group. Most infections were asymptomatic; symptoms were reported in only 27 (25%) and 9 (14%) users with NG and CT, respectively. Among 22 culture-positive NG infections, 68% were in symptomatic patients. On multiple logistic regression model, having >5 quarterly sexual partners and prior CT/NG infection were associated with higher risk of incident CT/NG (table 1). A separate model for symptomatic gonorrhoea (chlamydia was excluded due to the low number of symptomatic cases) showed that absence of prior CT/NG infection was associated with higher risk of symptomatic presentation (p value=0.054).

Conclusions: CT/NG risk was higher in users with prior CT/NG infections and higher number of sexual partners. Over 50% of 2025 CT/NG infections occurred outside the high-reinfection group, suggesting a remodelling of risk distribution. Prior CT/NG infections appeared protective against symptomatic gonorrhoea. Further studies are needed to characterise determinants of symptomatic infection and support tailored screening strategies.

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Monitoring the viral landscape

SC 7 WEST NILE VIRUS INFECTIONS IN PEOPLE LIVING WITH HIV IN NORTHERN ITALY: A SERO-REPOSITORY STUDY

C. Castilletti¹, G. Tiecco², S. Accordini¹, A. Pavesi², N. Ganesini¹, J. Logiudice², R. Passarelli Mantovani¹, B. Rossi², F. Gobbi^{1,2}, L.R. Tomasoni³, F. Castelli², SPARROW Group^{1,2}, E. Quiros-Roldan²

¹Department of Infectious-Tropical Diseases and Microbiology, IRCCS Ospedale Sacro Cuore Don Calabria, Negrar di Valpolicella, Verona, Italy, ²Department of Clinical and Experimental Sciences, Unit of Infectious and Tropical Diseases, University of Brescia and ASST Spedali Civili di Brescia, Brescia, Italy, ³Unit of Infectious and Tropical Diseases, ASST Spedali Civili di Brescia, Brescia, Italy

Background: West Nile virus (WNV) is increasingly reported in Italy, but its true prevalence remains uncertain. People living with HIV (PLWH) may be especially vulnerable given their potential risk of developing neuroinvasive disease. This study aimed to assess the seroprevalence and risk factors of WNV and Usutu virus (USUV) among PLWH in our cohort.

Methods: This retrospective single-center study included all PLWH routinely followed at the Brescia HIV Outpatient Clinic with at least one serum sample collected in 2022 and stored in the Brescia sero-repository. Serum samples were screened for WNV antibodies using first an ELISA test, all positive or borderline samples for IgG and IgM were then confirmed by immunofluorescence assay. In a second time, all positive samples were further characterized by microneutralization test against both WNV and USUV for differential diagnosis. Demographic, clinical, and HIV-related variables were extracted from medical records and systematically recorded. Associations between variables and seropositivity were evaluated by univariate logistic regression.

Results: Among 2,843 PLWH, the median age was 55 years; 76.2% were male and 87.2% were of Italian origin. Most participants had undetectable HIV-RNA and no history of ART interruption (94.2%). The mean CD4/CD8 ratio was 1.01 (SD±0.59). WNV infection was identified in 3.0% of participants, USUV infection in 0.6%, and co-infection in 0.2%. Fever was reported in 3.1% of confirmed cases, and no neuroinvasive disease was observed. Compared with WNV-seronegative PLWH (Table 1), individuals with positive neutralization assays for WNV or USUV were less frequently male ($p=0.001$) and differed significantly by geographic origin ($p<0.001$). WNV-Seropositivity was more common among participants born out of Europe, whereas Italian origin predominated among seronegative individuals. In logistic regression analyses, geographic origin was strongly associated with seropositivity. Compared with Italian-origin participants, those from Africa (OR 18.94, 95% CI 11.53–31.09), Asia (OR 20.41, 95% CI 9.18–45.36), and the Americas (OR 16.90, 95% CI 8.60–33.21) had significantly higher odds of WNV or USUV seropositivity (all $p<0.001$). Male sex was associated with lower odds of seropositivity (OR 0.51, 95% CI 0.34–0.77; $p=0.001$).

Conclusions: To the best of our knowledge, this is first study assessing WNV and USUV seroprevalence in PLWH. Our findings indicate a comparatively higher seroprevalence in this population than that reported in analogous Western blood donor cohorts. Most confirmed cases were asymptomatic and occurred predominantly in individuals born in endemic regions. These data suggest that migration from endemic areas represents the principal determinant of WNV exposure among PLWH in our cohort. Furthermore, HIV infection does not appear to significantly influence the clinical course of West Nile virus infection.

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Monitoring the viral landscape

SC 8 THE DISAPPEARANCE OF INFLUENZA B: EPIDEMIOLOGICAL SHIFT AND VIRAL COMPETITION DURING THE 2025-2026 SEASON IN GENOA, ITALY

M. Lucente¹, C. Fracalvieri¹, G. Garzillo¹, B. Galano¹, N. Nigro¹, G. Guarona², S. Ferrari¹, B. Giusto¹, R. Qosja¹, A. Orsi²

¹U.O. Igiene, IRCCS AOM- Azienda Ospedaliera Metropolitana, Genova, Italy, ²Dipartimento di Scienze della Salute (DiSSal), Università di Genova, Italy

Background: Surveillance of influenza virus circulation is crucial for monitoring the seasonal epidemiological dynamics of the disease. At the Regional Reference Laboratory of the Hygiene Unit of San Martino Hospital in Genoa, Italy, molecular diagnostics and influenza virus characterization are routinely performed.

During the 2024–2025 influenza season, co-circulation of all three viral strains was observed in comparable proportions, whereas in the current season only influenza A viruses have been detected showing a significant epidemiological shift. An in-depth molecular investigation was implemented to more accurately characterize and evaluate the detected cases.

Materials and Methods: During the 2025 - 2026 influenza season, a total of 4068 nasopharyngeal swab specimens were collected from patients presented to the hospital with influenza-like illness (ILI) and analyzed using a routine diagnostic multiplex real-time RT-PCR assay (Allplex Respiratory Panel 1-2-3, Seegene, South Korea), which enables influenza virus detection and subtyping.

Twenty-six samples with suitable cycle threshold (Ct) values for next-generation sequencing (NGS) analysis were randomly selected. Library preparation was performed using the Illumina Microbial Amplicon Prep-Influenza A/B kit (Illumina), and sequencing was carried out on the iSeq 100 platform (Illumina). Raw sequencing data (FASTQ files) were processed using the DRAGEN Microbial Amplicon pipeline (Illumina). Consensus sequences were subsequently evaluated using Nextclade.

Results: Of 4068 specimens analyzed, 1354 (33,3%) were positive for respiratory viruses multiplex real-time PCR and among these 443 (32,7%) were positive for influenza virus infection. Specifically, 214/443 (47,98%) samples tested positive for Influenza A/H3N2 and 229/443 (52,02%) for Influenza A/H1N1. No Influenza B viruses were detected (Figure 1).

The remaining 902 samples that tested positive for other respiratory viruses exhibited a heterogeneous infection pattern, as illustrated in Figure 2.

Nextclade analysis revealed that H3N2 viruses belonged almost exclusively to clade K (with one J.2.4 variant), while all H1N1 viruses were assigned to clade D.3.1.1.

Conclusions: The 2025-2026 season marks a major shift in viral influenza virus circulation, dominated by Influenza A and the exclusion of Type B. The dominance of clades K and D.3.1.1 suggests an ongoing antigenic drift that may impact vaccine effectiveness and clinical severity. These findings underscore the importance of genomic surveillance in predicting seasonal trends and optimizing antiviral strategies.

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Monitoring the viral landscape

SC 9 COMPARATIVE DIAGNOSTIC PERFORMANCE AND REFERRAL BURDEN OF SEVERAL ANAL CANCER SCREENING STRATEGIES AMONG MSM UNDERGOING FIRST HIGH-RESOLUTION ANOSCOPY

A. Lazzaro¹, E.N. Cavallari¹, M. Ridolfi¹, F. Alessi¹, L. Santinelli¹, C. Falvino¹, L. Maddaloni^{1,2}, O. Turriziani², A. Pernazza³, A. Crescenzi³, C.M. Mastroianni¹, G. d'Ettore¹

¹Dipartimento di Sanità Pubblica e Malattie Infettive, Sapienza Università di Roma, Roma, Italy, ²Dipartimento di Medicina Molecolare, Laboratorio di Microbiologia e Virologia, Sapienza Università di Roma, Roma, Italy, ³Dipartimento di Scienze Radiologiche, Oncologiche e Anatomo-Patologiche, Sapienza Università di Roma, Roma, Italy

Background: Optimal screening strategies for anal cancer in men who have sex with men (MSM) remain debated, particularly regarding the integration of anal cytology and human papillomavirus (HPV) testing and their impact on referral burden to anal resolution anoscopy (HRA). Real-world comparative data on diagnostic performance of different screening algorithms are limited.

Methods: We retrospectively analyzed data from MSM undergoing first HRA. For each participant, the most recent anal cytology and HPV test performed within 12 months before (or on) HRA were collected. Histological high-grade squamous intraepithelial lesion (HSIL), defined as anal intraepithelial neoplasia grade 2 or higher (AIN2+), was the primary endpoint.

Seven screening strategies were evaluated, grouped according to their biological and clinical rationale: human papillomavirus genotype 16 (HPV16); high-risk human papillomavirus (HR-HPV); low-grade squamous intraepithelial lesion or worse (LSIL+); atypical squamous cells of undetermined significance or worse (ASCUS+); ASCUS+ with HPV16; LSIL+ with HR-HPV; and ASCUS+ with HR-HPV. Diagnostic performance was assessed using complete-case analysis. Referral burden was estimated as the proportion of patients who would have been referred to HRA under each strategy and was additionally expressed as the number of HRA procedures required per HSIL detected. Differences in sensitivity between human immunodeficiency virus (HIV) strata were assessed using Fisher's exact test.

Results: A total of 317 MSM were included, whose 70.3% were living with HIV; median age was 44 years (IQR:36-53). HR-HPV demonstrated the highest sensitivity for HSIL detection (0.87), with moderate specificity (0.52) and high negative predictive value. Cytology-only strategies were associated with higher referral proportions and lower specificity. Combined strategies (ASCUS+ and HR-HPV; LSIL+ and HR-HPV) reduced referral burden compared with HR-HPV alone while maintaining acceptable sensitivity. HPV16-based strategies were highly specific (approximately 0.85-0.90) but markedly less sensitive (approximately 0.30-0.35), missing a substantial proportion of HSIL cases. Referral rates varied considerably across algorithms, translating into significant differences in HRA workload and HRA-per-HSIL ratios.

When stratified by HIV status, sensitivity estimates were comparable between MSM living with or without HIV across all strategies, and no statistically significant differences were observed.

Conclusions: In MSM undergoing first HRA, HR-HPV-based strategies maximized HSIL detection at the cost of increased referral burden, whereas HPV16-based approaches minimized HRA workload but compromised sensitivity. Combined cytology and HR-HPV algorithms provided a more balanced trade-off between detection and resource utilization. These findings support risk-adapted anal cancer screening strategies in MSM irrespective of HIV status.

Table 1

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Monitoring the viral landscape

SC 10 PERSISTENT HPV16 INFECTION DESPITE IMMUNE RECOVERY IN PEOPLE LIVING WITH HIV: ANALYSIS OF E6 AND E7 GENETIC VARIABILITY

S. Pauciullo¹, V. Zulian¹, R. Sciamanna¹, A. Coppola¹, M. De Sanctis¹, A. Borsellino², P. Del Porto², F. Del Nonno³, D. Colombo³, A. Scarabello⁴, A. R. Garbuglia¹

¹Laboratory of Virology, National Institute for Infectious Diseases "Lazzaro Spallanzani" (IRCCS), Rome, Italy, ²Department of Biology and Biotechnology "Charles Darwin", Sapienza University of Rome, Rome, Italy, ³Pathology Unit, National Institute for Infectious Diseases "Lazzaro Spallanzani" (IRCCS), Rome, Italy, ⁴Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases "Lazzaro Spallanzani" (IRCCS), Rome, Italy

Background: People living with HIV experience a markedly increased risk of HPV-related malignancies despite effective antiretroviral therapy. Persistent HPV16 infection represents the main driver of anal and oropharyngeal cancers in this population; however, the contribution of viral genetic variability to infection persistence and lesion development remains poorly understood. The HPV16 E6 and E7 oncoproteins play a central role in carcinogenesis by disrupting p53- and retinoblastoma-mediated cell cycle control, promoting cellular immortalization and malignant transformation. Variability within these oncogenes may influence viral persistence and oncogenic potential, particularly in immunologically vulnerable populations. We investigated HPV16 E6 and E7 variability in anal and oral infections among people living with HIV to explore potential associations with lesion grade, anatomical site, and immune status.

Material and Methods: Anal swabs and oral rinse samples were collected from 53 men who have sex with men living with HIV and receiving antiretroviral therapy. HPV genotyping was performed using real-time PCR, and HPV16-positive samples underwent targeted sequencing of E6 and E7 regions followed by phylogenetic analysis. Cytological findings included high-grade (HSIL), low-grade (LSIL), and negative for intraepithelial lesion or malignancy (NILM). Associations between viral variants, CD4+ T-cell counts, HIV RNA levels, and lesion grade were evaluated.

Results: A total of 51 E6 and 52 E7 sequences were obtained from persistent HPV16 infections. Most participants showed controlled HIV infection with median CD4+ counts of 681 cells/ μ L. HPV16 lineage A predominated (96.1%), mainly sublineages A1 (84.3%) and A2 (9.8%). The E6 region showed greater variability than E7, with the L83V substitution detected in 62.7% of cases across all cytological categories and anatomical sites. E7 sequences were highly conserved, with only one non-synonymous mutation identified. No site-specific variants were observed between anal and oral infections. Importantly, viral genetic variability was not associated with lesion severity, CD4+ T-cell count, or HIV viral suppression.

Conclusions: In people living with HIV receiving effective antiretroviral therapy, persistent HPV16 infection occurs independently of immune recovery and is characterized by highly conserved oncogenic regions across anatomical sites. These findings support the hypothesis that HPV persistence and cancer risk in this population may not depend on specific viral variants but rather on host-virus interactions, reinforcing the need for integrated HPV surveillance and cancer prevention strategies in HIV care.

Monitoring the viral landscape

SC 11 LOW INTEGRASE RESISTANCE DETECTED IN PEOPLE FAILING SECOND GENERATION INSTIS: FINDINGS FROM THE ARCA COHORT

A. Russo^{1,2}, A. Giacomelli^{4,5}, A. De Vito³, M. Mazzitelli^{6,7,8}, A. Shallvari⁹, W. Gennari¹⁰, V. Micheli¹¹, F. Lombardi^{7,8}, E. Pontali¹², S. Menzo¹³, A. Carbone⁷, M.C. Polisenio¹⁴, B. Bruzzone¹⁵, M.M. Santoro¹⁶, A. Borghetti¹⁷

¹Link Campus University, Rome, Italy, ²Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy, ³Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ⁴Department of Infectious Diseases, ASST FBF Sacco, Luigi Sacco University Hospital, Milan, Italy, ⁵Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy, ⁶Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ⁷Università Cattolica del Sacro Cuore, Roma, Italia - Dipartimento di Sicurezza e Bioetica, sezione Malattie Infettive, Rome, Italy, ⁸Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma, Italia - Dipartimento di Scienze Mediche e Chirurgiche - UOC Malattie infettive, Rome, Italy, ⁹EuResist Network GEIE, InformaPRO S.r.l., Rome, Italy, ¹⁰SSD Virologia-Microbiologia Molecolare, Azienda Ospedaliero-Universitaria di Modena, Modena, Italy, ¹¹Laboratory of Clinical Microbiology, Virology and Bioemergency Diagnostics, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ¹²Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ¹³Section of Legal Medicine, Department of Bioscience and Public Health, Marche Polytechnic University, Ancona, Italy, ¹⁴Clinic of Infectious Diseases, Department of Clinical and Surgical Sciences, University of Foggia, Foggia, Italy, ¹⁵Hygiene Unit, IRCCS - Policlinico San Martino Hospital, Genoa, Italy, ¹⁶Department of Experimental Medicine, University of Rome, Tor Vergata, Rome, Italy, ¹⁷Infectious Diseases Unit, Department of Clinical and Experimental Medicine, Azienda Ospedaliera Universitaria Pisana, Pisa, Italy

Background: Integrase strand transfer inhibitors (INSTIs) are now the standard backbone of first-line antiretroviral therapy (ART), but virological failure with development of resistance to second-generation INSTIs has been increasingly reported worldwide. Using real-world data from the Italian Antiviral Response Cohort Analysis (ARCA) database, we described virologic failure (VF) and resistance patterns among treatment-naïve people with HIV (PWH) starting an INSTI-containing regimen.

Methods: We included treatment-naïve PWH in ARCA who started first-line INSTI-based ART (BIC/TAF/FTC, DTG/TAF/FTC, DTG/TDF/FTC, DTG/3TC and DTG/ABC/3TC), with a zenith HIV-1 RNA ≥ 200 copies/mL. Participants contributed follow-up time while they remained on an INSTI-containing regimen; observation ended when VF, defined as HIV-RNA >1000 cp/mL or two consecutive HIV- RNA > 50 cp/mL, occurred on INSTI. We described baseline characteristics and compared individuals who maintained virologic suppression with those who experienced VF. In those with a genotype available at VF, we assessed INSTI resistance.

Results: We analysed 1296 PWH (21.0% female; median age 44 years [IQR 34–53]; median zenith HIV-1 RNA 90,500 copies/mL [21,038–316,396]; median CD4 nadir 272 cells/ μ L [91–459]; 10.3% AIDS presenters) (Table 1). First regimens were BIC/FTC/TAF (31.5%), DTG/FTC/TDF (23.3%), DTG/ABC/3TC (27.5%), DTG/FTC/TAF (10.6%), and DTG/3TC (7.1%). VF occurred in 120/1296 (9.3%) after a median of 67 weeks (39–124), with a median HIV-1 RNA at VF of 4163 copies/mL (399–60,687). Compared with those who did not developed VF during the time of observation, those with VF were more frequently of Black ethnicity, more often reported injecting drug use, had higher zenith HIV-1 RNA, lower CD4 nadir (Table 2). Genotypes at failure were available for 53/120 participants; among them, INSTI resistance mutations were detected in 3 (5.7%): one participant had G163R only, one had T66I only, and one had E97A plus E153F (Table 3). Interestingly, these integrase mutations detected were consistent with Stanford HIVdb-like susceptible or low-level resistance categories to second-generation INSTIs.

Discussion: In this real-world ARCA cohort of ART-naïve PWH starting contemporary INSTI-based ART, VF was seen in about 10% of cases and INSTI resistance at failure was rare, in line with the high genetic barrier of second-generation INSTIs. As genotyping was not available for all VFs, we may have missed very uncommon resistance events; however, the few resistant cases suggest that most episodes were driven by other factors, mainly treatment interruptions or poor adherence. This is supported by the higher VF frequency in people who inject drugs and in Black participants, and by the longer time to suppression in those with more advanced disease and higher baseline viral load.

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Monitoring the viral landscape

SC 12 CHARACTERISTICS AND PHYLOGENETIC ANALYSIS OF HIV-1 SUB-SUBTYPE A6 CIRCULATING/EPIDEMIC IN ITALY

C. della Ventura¹, F. Saladini², S. Tagliazucchi³, M. Zazzi², A. Gidari⁴, C. Mussini⁵, B. Rossetti⁶, R. Gulminetti⁷, P. Corsi⁸, C. Lazzaretti⁹, D. Segala¹⁰, M. Fabbiani^{2,11}, A. Shallvari¹², S. Rusconi¹, G. Zehender¹, A. Lai¹

¹Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy, ²Department of Medical Biotechnology, University of Siena, Siena, Italy, ³Molecular Microbiology and Virology Unit, Department of Laboratory Medicine and Pathological Anatomy, Azienda Ospedaliero Universitaria di Modena, Modena, Italy, ⁴Infectious Diseases Laboratory, Santa Maria della Misericordia Hospital, Perugia, Italy, ⁵Clinic of Infectious Diseases, University of Modena and Reggio Emilia, Italy, ⁶Infectious Diseases Unit, USL Toscana sud-est, Ospedale Misericordia, Grosseto, Italy, ⁷Infectious Diseases, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy, ⁸Infectious Diseases Unit, Azienda Ospedaliero-Universitaria Careggi, Florence, Italy, ⁹Infectious Diseases Unit, Arcispedale S. Maria Nuova, AULS Reggio Emilia, Reggio Emilia, Italy, ¹⁰Department of Translational Medicine and for Romagna, Azienda Ospedaliero Universitaria di Ferrara, University of Ferrara, Ferrara, Italy, ¹¹Infectious and Tropical Diseases Unit, Azienda Ospedaliero-Universitaria Senese, Siena, Italy, ¹²I-PRO, Rome, Italy

Background: A6, originally identified as a sister clade of A1 circulating in former Soviet Union, was recently reclassified as a new HIV-1 sub-subtype and many European countries had experienced an increase in the frequency of A6. Sub-subtype A6 is a risk factor for virological failure of long-acting injectables cabotegravir-rilpivirine. This study aimed to assess the prevalence of the A6 sub-subtype in Italy over the years and to characterise these strains in term of HIV diversity, drug resistance patterns, and clustering.

Material and Methods: All sequences from ARCA database previously attributed to subtype A sub-subtypes and those classified as CRF01_AE (n=597) were collected for re-subtyping through phylogenetic analysis. The first available PR-RT (n=157) and integrase (n=105) sequences collected from 2002 to 2025 were analysed. MEGA12 with Neighbour Joining approach was used for subtyping analysis. Transmission clusters were identified by using maximum likelihood approach and IqTree (TVM+F+R5 model) and Cluster Picker software. HIV Stanford database was used to define resistance mutations.

Results: A total of 157 (26.3%) subjects carrying A6 subtype were retrieved. Most individuals were male (87/157, 55.4%), with a median age of 37 years (IQR: 32-49 years). Based on partially available data, caucasian ethnicity was the most represented (77/83, 92.8%), with most individuals originating from Italy (n=49) and Ukraine (n=23). Sexual transmission was the most reported route of infection (42/59, 71.2%), followed by intravenous drug use (12/59, 20.3%).

The prevalence of subjects carrying A6 significantly increased over time ($p < 0.0001$), both when stratified into four-year intervals (0.1% to 1%) and when comparing the period before (2002–2021) and after (2022–2025) the start of the Russian/Ukrainian war (0.3% to 1%). Transmitted drug resistance (TDR) was detected in 15.1% (n=8), 3.8% (n=2) and 5.6% (n=2) for NRTI, NNRTI and INI, respectively. A62V, which is polymorphic in sub-subtype A6, was the most represented NRTI-associated mutation (n=8), K103N was the most frequent NNRTI-associated (n=2). No differences were observed in the distribution of resistance between Italians and foreign-born. Thirteen significant transmission clusters were identified (bootstrap ≥ 70), the largest encompassing 33 sequences collected between 2014 and 2025. A significantly higher proportion of Italians were included in transmission clusters compared to foreign-born (89% vs. 60%, $p < 0.001$) and individuals with sexual transmission compared to intravenous drug users (73.8% vs. 41.7%, $p = 0.037$). No differences were observed in cluster distribution considering sampling period.

Conclusions: This study provides valuable insight on HIV-1 A6 molecular epidemiology in Italy, demonstrating significantly increasing prevalence in recent years. Despite incomplete epidemiological data, the higher proportion of Italians in transmission cluster suggests ongoing local transmission in our country.

Shaping immune protection: vaccines, strategies across HIV and emerging infections

SC 13 HIV-CORE 007: A PHASE 1/2 RANDOMIZED, PLACEBO-CONTROLLED T-CELL VACCINE TRIAL IN ADULTS LIVING WITH HIV-1 WITH ANALYTICAL TREATMENT INTERRUPTION

S. Dispinseri¹, E. Bruzzesi¹, A. Baglivi¹, S. Bagaglio¹, M. Tolazzi¹, F. Sironi¹, P. Gallina¹, D. Cesana¹, S. Chiappetta², F. Ciceri¹, C. Corti¹, A. Crook³, C. Bonini¹, M. Novello¹, E. Tassi¹, E. Tomasi¹, N. Borthwick³, E.G.-T. Wee³, T. Hanke³, A. Soria⁴, A. Castagna¹, R. Dell'Acqua¹, G. Scarlatti¹

¹IRCCS Ospedale San Raffaele, Milan, Italy, ²Carlo Poma Hospital, ASST Mantova, Italy, ³The Jenner Institute, University of Oxford, Oxford, United Kingdom, ⁴Clinic of Infectious Diseases, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy

Background: The persistence of the HIV-1 reservoir demands lifelong combination antiretroviral therapy (cART), which remains the only effective strategy to contain viral replication. A therapeutic vaccine effectively controlling the virus could reduce disease progression and transmission. The HIV-CORE 007 trial evaluated the safety and immunogenicity of ChAdOx1- and MVA-vectored vaccines encoding conserved mosaic regions of HIV-1 (HIVconsvX) and, for the first time, assessed their capacity to achieve post-treatment virological control in early-treated adults living with HIV.

Methods: HIV-CORE 007 is a phase I/II, randomized, placebo-controlled, single-blind clinical trial (EudraCT 2019-003102-26) funded by Ministero della Salute (GR-2018-12367076). Main entry criteria were cART initiated during primary HIV infection and the plasma HIV-1 RNA levels maintained below 20 copies/mL for at least two years prior to enrolment. Thirty-three participants were planned, but 11 were enrolled, and randomized 2:1 to receive either prime-boost vaccination ChAdOx1.tHIVconsv1 (C1) at week 0, followed by MVA.tHIVconsv3 (M3) and MVA.tHIVconsv4 (M4) at week 4 (regimen C1-M3M4) or placebo (saline), via intramuscular injection. At week 12, participants were unblinded and offered an analytical treatment interruption (ATI). Safety monitoring included local and systemic recording of adverse events (AE), as well as laboratory evaluations. Secondary and exploratory objectives included IFN- γ ELISPOT, HIV-DNA quantification, and HLA typing.

Results: Vaccination was well tolerated: all recipients experienced expected mild-to-moderate local or systemic reactions (pain, fever, myalgia, malaise). Two grade 3 AEs occurred but were unrelated to the vaccines; no serious AEs were reported. Viral suppression was maintained throughout the vaccination phase, with stable CD4 and CD8 T-cell counts. All 7 vaccinees developed HIV-1-specific T-cell responses directed to HIVconsvX, the vaccine regions, whereas responses to non-vaccine related regions were heterogeneous, reflecting individual immune competence. No new or enhanced HIV-specific responses were observed in placebo recipients. All vaccinated participants accepted ATI whereas all placebo recipients declined. Following cART discontinuation, viral rebound occurred in all participants at different periods, with stable CD4 T-cell counts and no acute retroviral syndrome. cARTs was subsequently reinitiated according to protocol without complications.

Conclusions: We showed that C1-M3M4 vaccination is safe and immunogenic in people living with HIV-1. Despite limited recruitment, the data support further development of T cell-based therapeutic vaccines and help define correlates of post-treatment viral control.

Shaping immune protection: vaccines, strategies across HIV and emerging infections

SC 14 AN EXTRACELLULAR VESICLE-BASED T CELL VACCINE PLATFORM AGAINST HIV-1 CONSERVED ANTIGENS

M. Donnini, F. Manfredi, P. Leone, K. Pugliese, A. Giovannelli, M. Federico, F. Ferrantelli, C. Chiozzini

Istituto Superiore di Sanità, Rome, Italy

Human Immunodeficiency Virus type 1 (HIV-1) remains a major global health burden, with approximately 38 million people living with HIV worldwide. Although antiretroviral therapy (ART) effectively suppresses viral replication, lifelong treatment is required and viral rebound typically occurs upon interruption.

Despite decades of dedicated work, HIV-1 vaccine development has been hindered by genetic hypervariability and immune escape mechanisms, particularly against highly variable proteins such as Env. Targeting more conserved antigens by inducing robust T cell immunity represents a promising strategy for preventive and therapeutic vaccination. In a therapeutic context, T cell-based vaccines may offer an advantage over antibody-driven approaches by targeting infected cells, including those within the replication-competent reservoir. Notably, HIV-1 Gag-specific CD8⁺ T cell responses have been associated with improved viral control and lower set-point viremia in infected individuals.

We developed an innovative T cell vaccine platform based on endogenously engineered extracellular vesicles (EVs). This approach relies on intramuscular injection of DNA vectors expressing a biologically inactive mutant of HIV-1 Nef (Nefmut), which incorporates efficiently into EVs even when fused at its C-terminus with heterologous antigens. EV-associated antigens are taken up by antigen-presenting cells and presented via both MHC class I and II pathways, inducing coordinated antigen-specific CD8⁺ and CD4⁺ T cell responses. In preclinical models, this strategy has been already applied successfully against SARS-CoV-2 and tumors (HPV-associated and breast cancer), supporting the robustness and versatility of this platform.

To extend this platform to HIV-1, DNA vectors expressing HIV-1 p17, p24, and Tat antigens fused to Nefmut were generated. In vitro assays confirmed expression and efficient EV incorporation of all fusion proteins. In vivo, C57BL/6 mice were then immunized intramuscularly with DNA vectors encoding single or combined Nefmut/antigen constructs, followed by electroporation. Robust antigen-specific T cell responses were detected in splenocytes of immunized mice by IFN- γ ELISpot and intracellular cytokine staining (ICS) upon peptide stimulation. The combined p17/p24/Tat formulation induced stronger cellular responses compared to single-antigen constructs, demonstrating the absence of antigenic interference and supporting the rationale for multi-target T cell strategies that may provide an advantage in limiting viral escape. Overall, this EV-based vaccine platform elicits potent multi-epitope T cell responses against conserved HIV-1 antigens in vivo, highlighting its potential as a versatile strategy for T cell-based HIV-1 vaccination.

Ongoing studies in a mouse model of HIV-1 infection based on EcoHIV, a murine-adapted virus mimicking key aspects of HIV-1 infection, will assess functional protective efficacy against infection and correlates of protection.

Shaping immune protection: vaccines, strategies across HIV and emerging infections

SC 15 BASELINE CD4 COUNT INFLUENCES HPV VACCINE RESPONSE IN PEOPLE LIVING WITH HIV: TWO-YEAR FOLLOW-UP

L. Ansaldo^{1,2}, E. Tortellini³, M.S. Guardiani^{3,4}, S. Corazza¹, A. Carraro³, G. Mancarella¹, M. De Masi¹, D. Di Trento¹, A. Gasperin¹, M.A. Zingaropoli^{3,5}, F. Dominelli³, M. Proietti³, C. Giambi⁶, M. Tagliaferro⁷, U. Basile⁷, R. Marocco¹, C. Del Borgo¹, M. Lichtner⁴

¹Infectious Diseases Unit, S.M. Goretti Hospital, Latina, Italy, ²PhD course in Microbiology, Immunology, Infectious Diseases, and Transplants (MIMIT), University of Rome "Tor Vergata", Roma, Italy, ³Department of Public Health and Infectious Diseases, Sapienza University of Rome, Roma, Italy, ⁴Department of NESMOS, Sapienza University of Rome, Roma, Italy, ⁵Microbiology and Virology Unit, Policlinico Umberto I, Sapienza University of Rome, Roma, Italy, ⁶UOS Profilassi e sorveglianza malattie infettive, S.M. Goretti Hospital, Latina, Italy, ⁷Department of Clinical Pathology, S. M. Goretti Hospital, Latina, Italy

Background: HPV anorectal infection is the main cause of anal cancer in people living with HIV (PLWH). Data on HPV-specific T-cell responses to the nonavalent vaccine in PWH are limited. Given the critical role of cell-mediated immunity (CMI) in vaccine efficacy, we evaluated post-vaccination T-cell responses in PWH on Anti-retroviral Therapy (ART), from first vaccine dose until up to two years after vaccination.

Materials and Methods: we prospectively enrolled PWH on ART. Inclusion criteria were age ≥ 18 years, undergoing ART for at least 6 months, and naïve to HPV vaccination. Gardasil9 was administered at baseline(T0), after 2 and 6 months(T1); follow-up continued to 6 months(T2) up to 2 years(T3). We performed anal swabs for HPV DNA, and blood samples were collected for viro-immunological follow-up and to evaluate CMI by flow cytometry of CD4 and CD8 T cells producing IFN- γ , IL-2, or TNF α (responding cells) or all three cytokines (polyfunctional cells) after stimulation with a pool of HPV16 and 18 L1 peptides. Adjusted linear mixed models with random intercepts and slopes for individuals and robust standard errors were used to estimate mean levels of CD4 and CD8 responding and polyfunctional cells comparing groups stratified by baseline CD4(>500 vs ≤ 500 cells/ μ L) and prior HPV infection, documented by consulting all available clinical records collected prior to study. Models were adjusted for age, sex, CD4 nadir, HIV viral load suppression and CD4 at baseline.

Results: A total of 38 patients were enrolled; clinical characteristics are shown in Table1. Current T3 data were available for 31 patients out of 38 (82%). HIV viro-immunological control was maintained through T3, as shown in Table2. At T3, anorectal infection with at least one high-risk (HR) HPV genotype was detected in 22 out of 31 patients (71%), with a median number of HR genotypes of 2 (IQR 1–4), and a median of low risk (LR) genotypes of 1 (IQR 0–2). HPV16 infection had the highest prevalence among HR genotypes isolated (7/31 patients, 22,6%) as shown in Graph1. Concerning T-cell responses, at T1 participants with >500 CD4 cells/ μ L showed significantly greater increases in CD4-responding, CD4-polyfunctional, and CD8-responding cells compared to those with ≤ 500 CD4 cells/ μ L. At T2, a significant difference persisted for CD8-responding cells. By T3, most differences were no longer significant, except for CD8-polyfunctional cells, which showed a significant decrease in the >500 CD4 group compared to the ≤ 500 group (Table3). When stratifying the population by previous HPV infection, no significant differences emerged between the two subgroups.

Conclusions: In PLWH, baseline CD4 counts ≥ 500 /mmc are associated with stronger early immune responses to HPV vaccination with a significant increase of CD4+ and CD8+ polyfunctional T cells in comparison with PWH with <500 CD4+. Tailored vaccination schedules and follow-up may be warranted to ensure optimal and sustained protection.

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Shaping immune protection: vaccines, strategies across HIV and emerging infections

SC 16 COMPARISON OF SUBCUTANEOUS VERSUS INTRADERMAL ADMINISTRATION OF MVA VACCINE BOOSTER DOSE

V. Mazzotta¹, L. Bordini², E. Cimini³, D. Farinacci¹, S. Gili³, A. Bettini², J. Paulicelli¹, R. Esvan¹, C. Mija², F. Cristofanelli³, P. Faccendini⁴, P. Galli⁵, E. Girardi⁶, F. Maggi², A. Antinori^{1,5}

¹Clinical department, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ²Laboratory of Virology, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ³Laboratory of Immunology, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ⁴Pharmacy, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ⁵Health Direction, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ⁶Scientific Direction, INMI Lazzaro Spallanzani IRCCS, Rome, Italy

Background: The third-generation smallpox vaccine, MVA-BN, is now considered the primary preventive measure against mpox infection. A booster dose administered at least two years after the primary vaccination significantly enhances both humoral and cellular responses. Assessing whether the subcutaneous (SC) or intradermal (ID) administration route influences the magnitude of the response may inform public health strategies for maximising dose savings.

Methods: A prospective observational study was conducted in individuals who had completed a two-dose primary MVA-BN vaccination cycle and received a booster dose either subcutaneously (SC, 0.5 mL) or intradermally (ID, 0.1 mL), at least 2 years after. Blood samples were collected at the time of booster administration (T1), after 4 weeks (T2), and 8 weeks (T3). Anti-MPXV IgG titers were measured by immunofluorescence assay (IFA, clade IIb), neutralizing antibodies (nAb) by PRNT50 (clade IIb), and MVA-BN-responsive T-cells by ELISpot. Clinical and immunological features were compared between SC and ID groups using the Mann-Whitney tests.

Results: Among the 60 participants included, 34 (56.7%) received SC and 26 (43.3%) ID. Fifty-nine (98.3%) were males, with a median age of 43.3 years [IQR 36.7–50.0]; 6 of them (10.0%) were people with HIV (PWH) (Table 1). From T1 to T3, IgG titers increased significantly in both SC and ID groups ($p < 0.001$). Reactive sera increased from 47% to 100% in SC and 60% to 100% in ID. No difference in IgG titer increase was found between groups (Figure 1A). Additionally, nAb titers significantly increased from T1 to T3 ($p < 0.0001$), with reactivity ranging from 6% to 89% for SC; as far as ID is concerned, the percentage of reactivity ranged from 23% at T1, to 91% at T2 and to 82% at T3. Comparison between groups showed a significant advantage for ID over SC in the increase of nAb titers both at T1 ($p=0.634$) and T2 ($p = 0.0017$), while at T3 the differences between groups were not significant ($p=0.386$) (Figure 1B). MVA-specific T-cell response also improved from baseline to one month after administration in both the SC ($p<0.0001$) and ID ($p<0.002$) groups. No evidence of a difference in response variation between the two groups was found (data not shown).

Conclusions: Both subcutaneous and intradermal routes of administration of the MVA-BN booster dose elicit strong humoral and cellular responses, with a transient advantage for the intradermal route in improving the neutralizing response within the first 4 weeks following administration. These results support the use of the intradermal route for booster administration to conserve vaccine resources and optimise the possibilities for intervention in high-risk populations.

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Shaping immune protection: vaccines, strategies across HIV and emerging infections

SC 17 VACCINATION COVERAGE AND ADHERENCE TO VACCINES IN A TERRITORIAL SEXUALLY TRANSMITTED INFECTION (STI) CLINIC IN MILAN, ITALY: THE IMPACT OF AN INTEGRATED ON-SITE SERVICE

F. Gullone, L. Cordier, M. Morosi, E. Beyene Teklu, C. Archetti, A. Bramati, V. Ciarutti, A. Mantineo, C. Sturniolo, E. Villa, F. Pulejo, A. Capetti

SSD Fragilità e Prevenzione – STI Clinic Jenner 44 – Department of Infectious Diseases - ASST Fatebenefratelli Sacco, Milan, Italy

Background: STI clinics are facing a constant increase in new infections since the COVID-19 pandemic. Jenner 44 is a free, open-access STI clinic located in Northern Milan, serving the general population as well as hard-to-reach groups such as homeless individuals, migrants, and undocumented foreigners. Beyond disease detection, reporting, counselling, and treatment, since July 2024 we have implemented a proactive vaccination service for vaccine-preventable STIs - HBV, HAV, HPV and since September 2025, mpox.

Materials and Methods: We extracted clinical data from our local web-based eCRF, MTSWeb, and matched them with the regional vaccination programme database, ARVAX. Vaccination assessment and administration were primarily conducted by healthcare assistants in collaboration with nurses, with physician supervision and intervention reserved for complex cases. The analysis covered the period from the activation of the Jenner 44 Vaccination Center on the ARVAX platform (April 1, 2025) through December 31, 2025.

Results: All 2,540 individuals presenting for STI screening underwent systematic assessment of vaccination eligibility based on age, risk exposure, and prior immunization history. Of these, 926 (36.5%) initiated a vaccination course. The vaccinated population comprised 159 females (17.2%) and 767 males (82.8%), with a median age of 33.5 years. Foreign-born individuals represented 23.3% (n=216) of vaccinees, originating from 54 countries across South America (49%: Peru 37%, Brazil 26%), Asia (20%), Africa (11%), Europe (18%, including 58% from Eastern Europe), and Oceania (0.5%). Regarding documentation status within this foreign-born group, 182 (84.3%) had regular national health documentation, 22 (10.2%) held STP codes (Straniero Temporaneamente Presente - temporarily present foreigner), and 12 (5.5%) lacked any eligibility for the National Health System. HPV vaccine was most frequently administered (1,068 doses to 683 individuals), followed by HAV (409 doses to 291 individuals), HBV (262 doses to 163 individuals), and mpox (136 doses to 87 individuals). Regional guidelines initially limited mpox vaccination to contacts of confirmed cases until August 2025, with eligibility expanded thereafter. HBV vaccine was additionally used as a booster to elicit anamnestic responses in 18 individuals applying for HIV post-exposure prophylaxis. The service successfully completed 18 previously incomplete vaccination cycles initiated at other facilities.

Conclusion: Our experience demonstrates that on-site vaccination services with proactive promotion strategies substantially improve immunization uptake across the general population while proving particularly effective in reaching vulnerable groups—including undocumented migrants and homeless individuals—who face significant barriers to accessing mainstream vaccination services. This model offers a replicable strategy for enhancing vaccine-preventable STI prevention in urban settings.

Shaping immune protection: vaccines, strategies across HIV and emerging infections

SC 18 TEMPORAL KINETICS OF HUMORAL AND CELLULAR IMMUNITY AFTER MONOCLONAL ANTIBODY TREATMENT FOR SARS-COV-2 AND IMPACT OF VACCINATION TIMING: RENOIR STUDY

M. Camici¹, S. Meschi², E. Cimini³, A. Caioli⁴, J. Paulicelli¹, A. Oliva¹, M. De Vito², S. Gili³, M.M. Plazzi¹, G. Micheli¹, D. Mariotti², G. Matusali², F. Cristofanelli³, M. Fusto¹, E. Girardi⁵, F. Maggi², A. Antinori^{1,6}, V. Mazzotta¹

¹Clinical department, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ²Laboratory of Virology, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ³Laboratory of Immunology, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ⁴Epidemiology Unit, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ⁵Scientific Direction, INMI Lazzaro Spallanzani IRCCS, Rome, Italy, ⁶Health Direction, INMI Lazzaro Spallanzani IRCCS, Rome, Italy

Background: The impact of anti-SARS-CoV-2 monoclonal antibodies (mAbs) on adaptive immunity remain unclear, particularly regarding optimal timing for post-infection revaccination. We evaluated the longitudinal humoral and cellular immune responses after mAb therapy and compared two revaccination strategies.

Methods: We enrolled patients treated early with mAbs (sotrovimab or tixagevimab/cilgavimab) for mild-to-moderate SARS-CoV-2 infection. Four months after mAb administration, participants were randomised (1:1, open-label) to receive immediate vaccination (arm 1) or not (arm 2). Anti-Spike protein (anti-S) IgG, anti-nucleocapsid (anti-N) IgG, neutralising antibodies (nAbs) against XBB.1.16 and JN.1, were measured at baseline (BL) and at 1, 4, 6, 9, and 12 months, while T-cell responses to Spike and nucleocapsid peptides at BL, 1, 4 and 12 months. The primary outcome was the magnitude and durability of immune responses between groups over time. Groups were compared using t-test or Mann-Whitney U test for continuous variables and Fisher's exact test for categorical variables. Immune responses over time are shown as boxplots.

Results: Sixty-four patients were included (mean age 67±12 years; 47% male). BL characteristics were comparable between groups, except for prior vaccine doses (p=0.018) (Table 1). At BL, anti-S IgG, anti-N IgG, nAbs, and Spike- and nucleocapsid-specific T-cell responses were similar between arms. At randomisation, only the median value of anti-N IgG showed differences between arm 1 vs arm 2 (2.48 vs 1.55 log2S/CO; p=0.04). At month 6 (2 months post-vaccination), anti-S and anti-N IgG were significantly higher in the vaccinated versus not (13.44 vs 12.03 log2BAU/mL; p<0.001 and 2.33 vs 1.20 log2S/CO; p=0.02). nAbs titers were statistically higher for JN.1 in arm 1 (5.32 vs 4.32 log2reciprocal serum dilution; p=0.023), while similar for XBB.1.16 (6.32 vs 5.32 log2reciprocal serum dilution; p=0.66). By month 9, differences attenuated: anti-S IgG remained statistically higher in the vaccinated (12.02 vs 11.48 log2BAU/mL; p=0.034), with a trend for anti-N IgG (1.23 vs -0.29 log2S/CO; p=0.08) and comparable nAb titers levels. By 12 months, anti-Spike IgG median levels were fully comparable between groups (11.60 vs 11.59 log2BAU/mL; p=0.4). nAbs titers were similarly distributed for JN.1 (3.32 vs 3.32 log2reciprocal serum dilution; p>0.9) and XBB.1.16 (4.32 vs 4.82 log2reciprocal serum dilution; p>0.9). Spike- and nucleocapsid-specific T-cell responses were comparable, revealing a measurable response in both arms over time (Figure 1).

Conclusions: In mAb-treated patients with mild-to-moderate SARS-CoV-2 infection, vaccination after 4 months elicited a transient rise in anti-S IgG and neutralising activity, but this advantage progressively waned, and by 12 months, immune response was comparable between vaccinated and unvaccinated participants. These findings suggest a limited benefit of early vaccination in this setting.

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Clinical insights of Long-Acting treatment

SC 19 WEIGHT AND LIPID CHANGES AFTER SWITCHING TO LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE

G. Cologgi¹, L. Taramasso², E. Ricci³, S. Ferrara⁴, G. Orofino⁵, N. Squillace⁶, E. Pontali⁷, B. Menzaghi⁸, E. Sarchi⁹, G. Cenderello¹⁰, G. Pellicanò¹¹, G. Madeddu¹², T. Bini¹³, F. Lagi¹⁴, O. Bargiacchi¹⁵, M. Carleo¹⁶, E. Salomoni¹⁷, L. Pusterla¹⁸, L. Calza¹⁹, S. Rusconi²⁰, K. Falasca²¹, S. Martin²², R. Bellagamba²³, S. Piconi²⁴, G. De Socio²⁵, G. Angioni²⁶, A. Cascio²⁷, A. Di Biagio^{1,2}, P. Bonfanti⁸ and for the CISA study group

¹Department of Health Sciences (DISSAL), University of Genoa, Genoa, Italy, ²Infectious Diseases Unit, IRCCS Azienda Ospedaliera Metropolitana, Genova, Italy, ³Fondazione ASIA, Milan, Italy, ⁴Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy, ⁵Unit of Infectious Diseases, "Divisione A", Amedeo di Savoia Hospital, Torino, Italy, ⁶Infectious Disease Unit, Fondazione IRCCS San Gerardo dei Tintori, Monza - University of Milano-Bicocca, Monza, Italy, ⁷Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ⁸Unit of Infectious Diseases, ASST della Valle Olona - Busto Arsizio (VA), Italy, ⁹Infectious Diseases Unit, S. Antonio e Biagio e Cesare Arrigo Hospital, Alessandria, Italy, ¹⁰Infectious Diseases Department, Sanremo Hospital, Sanremo, Italy, ¹¹Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Messina, Messina, Italy, ¹²Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Italy, ¹³Unit of Infectious Diseases, San Paolo Hospital, Milano, Italy, ¹⁴AOU Infectious and Tropical Diseases, Careggi Hospital, Florence, Italy, ¹⁵Unit of Infectious Diseases, Ospedale Maggiore della Carità, Novara, Italy, ¹⁶Infectious Diseases and Gender Medicine Unit, Cotugno Hospital, AO dei Colli, Naples, Italy, ¹⁷SOC 1 USL CENTRO FIRENZE, Unit of Infectious Diseases, Santa Maria Annunziata Hospital, Florence, Italy, ¹⁸Infectious Diseases Unit, Ospedale S. Anna, Como, Italy, ¹⁹Infectious Diseases Unit, IRCCS Policlinico Sant' Orsola, University of Bologna, Italy, ²⁰Infectious Diseases Unit, ASST Ovest Milanese, Legnano and DIBIC, University of Milan, Italy, ²¹Clinic of Infectious Diseases, Department of Medicine and Science of Aging, G. D'Annunzio University, Chieti-Pescara, Chieti, Italy, ²²Department of Infectious Diseases, University of Campania Luigi Vanvitelli, Naples, Italy, ²³Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ²⁴Unit of Infectious Diseases, A. Manzoni Hospital, Lecco, Italy, ²⁵Infectious Diseases Clinic, Department of Medicine and Surgery, University of Perugia, Italy, ²⁶Infectious Diseases Unit, SS Trinità Hospital, Cagliari, Italy, ²⁷Unit of Infectious Diseases, Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties, University of Palermo, Palermo, Italy

Background: The long-acting (LA) treatment with cabotegravir (CAB) and rilpivirine (RPV) has been reported to have a neutral effect on weight and blood lipids in people with HIV (PWH) during treatment. However, few real-world data are available from observational cohorts.

Materials and Methods: This was a multicentre prospective observational study conducted within the SCOLTA (Surveillance Cohort Long-Term Toxicity Antiretrovirals) project. PWH RNA<50 copies/mL switched to CAB+RPV LA from 2022 onwards with at least one year of follow-up were included. Variables were compared using the paired t-test (1- and 2-years vs baseline). To determine the association between change from baseline and PWH's characteristics, we run a multivariate model including age, sex, BMI, CD4-T cells and the baseline value of the variable.

Results: A total of 671 PWH were enrolled, with a median follow-up period of 22 months (interquartile range, IQR: 13–29 months). The median age of the participants was 49 years (IQR 40–58) and median duration of ART was 10.3 years (IQR 6.4–16.7). The median body mass index (BMI) at enrolment was 24.6 kg/m² (IQR 22.6–27.0).

During the follow-up, mean weight did not change significantly in the study population, with a change of -0.25 kg (95% CI: -0.59 to +0.08, p = 0.1403) after one year and -0.18 kg (95% CI: -0.70 to +0.33, p = 0.4864) after two years. The multivariable analysis revealed that the probability of weight change was significantly associated with baseline BMI, with obese people experiencing a reduction in weight, significantly greater compared to normal-weight (mean estimate -2.79 kg, SE 0.64, p<0.0001), and those who were overweight showed a tendency towards significant reduction (mean estimate -0.75 kg, SE 0.38, p=0.052; see Figure 1). Age, sex and CD4 count did not correlate with the probability of weight change.

Regarding blood lipids, LDL levels remained stable during the study, while total cholesterol increased significantly, driven by an increase in HDL levels (Table 1).

Multivariable analysis revealed that trends in total cholesterol, HDL and LDL cholesterol were inversely correlated with their baseline values (mean estimated change: -0.36 ± SE 0.04, p <.0001; -0.39 ± SE 0.05, p <0.0001; and -0.38 ± SE 0.04, p <0.0001, respectively). HDL changes also showed a direct linear correlation with female sex (estimate: +4.02 ± SE 1.60, p = 0.0123) and age (estimate: +0.12 ± SE 0.05, p = 0.0322).

Conclusions: Body weight remained stable in SCOLTA after switching to LA CAB+RPV during two-years of observation. People with higher BMI at baseline were more likely to lose weight during treatment, confirming the feasibility of this regimen also in obese people and reassuring towards the concern of further weight gain and the consequent difficulty of achieving the proper injection depth. The modest but significant increase in cholesterol levels was driven by an increase in HDL, confirming the metabolic safety of the LA regimen.

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Clinical insights of Long-Acting treatment

SC 20 USE OF NEXT-GENERATION SEQUENCING (NGS) AS AN ADDITIONAL TOOL TO EVALUATE SUITABILITY OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE TREATMENT AND TAILORING FOLLOW-UP

G. Cologgi¹, M. Giurco¹, E. Pratolongo¹, B. Bruzzone², F. Stefanelli², N. Randazzo², V. Ricucci², M. Bassetti^{1,3}, A. Di Biagio^{1,3}, L. Taramasso³

¹Department of Health Sciences, University of Genoa - Genoa, Italy, ²Hygiene Unit, IRCCS Azienda Ospedaliera Metropolitana - Genoa, Italy, ³Infectious Diseases Unit, IRCCS Azienda Ospedaliera Metropolitana - Genoa, Italy

Background: Long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV) is an effective and well-tolerated antiretroviral switch option for virologically suppressed people with HIV (PWH). However, incomplete treatment history or unavailable historical Genotype Resistance Testing (hGRT) may limit access to LA therapy. We implemented Next-Generation Sequencing (NGS) on proviral DNA as an additional tool to refine eligibility, stratify virological failure (VF) risk, and tailor HIV-RNA monitoring frequency beyond current guideline recommendations.

Materials and Methods: In this single-center study, performed between September 2022 - January 2026, eligible PWH were stratified into low, intermediate, or high VF risk as described in Table 1. LA CAB+RPV was given every 56 days with a ± 7 days. HIV-RNA was monitored at 1 month after the initiation of LA therapy, then every 2, 4, or 6 months for high-, intermediate-, or low-risk PWH, differently from what is currently advised by BHIVA (British HIV Association) guidelines, recommending HIV RNA monitoring every 2 months in the first year of LA and every 4-6 months thereafter. PWH with at least 6 months of follow-up (FU) were included. VF was defined as single HIV-RNA >1000 copies/mL or repeated HIV-RNA >200 copies/mL.

Results: One hundred PWH with HIV-RNA <50 copies/mL started LA CAB+RPV (median FU 22 months, interquartile range [IQR] 12.8–28; median virological suppression 11 years, IQR 7–12). Seventy-four were classified as low risk, 11 intermediate, and 15 high (Table 2). hGRT on plasma RNA was available in 78 PWH (59 Sanger, 19 NGS), and 31 underwent proviral DNA NGS before LA initiation to complete resistance assessment. Proviral DNA NGS was more frequent in intermediate/high-risk groups (63.6% and 53.3%, respectively), compared with low-risk PWH (21.6%). Fourteen discontinued LA CAB+RPV, six due to adverse events. Transient detectable viremia (>50 copies/mL) occurred in four PWH (two: <200 copies/mL; two: 236 and 238 copies/mL), all classified as low risk. Repeat testing within two weeks showed <50 copies/mL in all cases. Of these, three switched to oral INSTI-based therapy, one continued LA without emergent RAMs detected on plasma RNA NGS performed at the time of HIV-RNA >50 copies/mL, and remaining thereafter with HIV-RNA <50 copies/mL. No VF occurred in any risk groups. During 20 months of follow-up, 501 HIV-RNA tests were performed, corresponding to approximately 300 fewer PCR assays than recommended by BHIVA guidelines.

Conclusions: Proviral DNA NGS enabled resistance assessment in PWH lacking historical genotypic data, supporting structured, risk-stratified eligibility for LA CAB+RPV. No VF occurred during FU, confirming feasibility and safety of this approach. Risk-adapted HIV-RNA monitoring reduced the number of assays without compromising virological control, supporting safe NGS-guided selection and tailored FU, while minimizing unnecessary medicalization and ensuring equitable access to LA therapy.

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Clinical insights of Long-Acting treatment

SC 21 VIROLOGICAL EFFICACY AND TOLERABILITY OF THE LONG-ACTING REGIMEN WITH RILPIVIRINE AND CABOTEGRAVIR: A QUEST FOR THE IDEAL CANDIDATE

G. Baldin¹, A. Ciccullo², F. Bassani³, A. Giacomelli⁴, A. Cervo⁵, D. Moschese⁴, E. Delmonte⁵, F. Lagi⁶, M. Rigoni^{3,7}, P.F. Salvo⁸, M. Fabbiani⁹, C. Fusetti³, G. d'Ettore¹⁰, G. Madeddu¹¹, C. Mussini⁵, A. Borghetti¹², S. Rusconi^{3,7}

¹Fondazione Policlinico Universitario A. Gemelli, IRCCS, Roma, Italy, ²Infectious Diseases Unit, Ospedale San Salvatore, L'Aquila, Italy, ³SC Malattie Infettive, ASST Ovest Milanese, Ospedale di Legnano (MI), Italy, ⁴Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ⁵Department of Infectious Diseases, Azienda Ospedaliero-Universitaria di Modena, Modena, Italy, ⁶Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy, ⁷Dipartimento di Scienze Biomediche e Cliniche, Università degli Studi di Milano, Milano, Italy, ⁸Catholic University of the Sacred Heart, Rome, Italy, ⁹Department of Medical Sciences, Infectious and Tropical Diseases Unit, University Hospital of Siena, Siena, Italy, ¹⁰Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ¹¹Infectious Diseases Unit, University of Sassari, Sassari, Italy, ¹²Infectious Diseases Unit, Department of Clinical and Experimental Medicine, Azienda Ospedaliera Universitaria Pisana, Pisa, Italy

Background: Clinical trials and observational studies have demonstrated the efficacy of CAB/RPV long-acting (LA) regimen, and some risk factors have been proposed as predictors of virological failure (VF); however, additional data are required to better characterize this outcome.

Material and Methods: We enrolled a cohort of virologically suppressed (VS), HBsAg - PWH starting CAB/RPV LA. We excluded PWH with HIV subtypes A1/A6, BMI>30 kg/m², presence of major RPV resistance mutations, or a history of prior VF on NNRTIs. We evaluated incidence of VF (defined as 2 consecutive HIV-RNA>50 cp/mL or a single HIV-RNA>1000 cp/mL), treatment discontinuations (TD), and time to VF and TD estimated by Kaplan-Meier curves. Predictors of VF and TD were evaluated using Cox regression. Genotypic resistance testing (GRT) results at VF were collected when available.

Results: Of 478 PWH who started CAB/RPV LA across 8 Clinical centers, 419 met inclusion criteria; exclusions were due to BMI>30 kg/m² (n=29), prior VF on NNRTIs (n=18), presence of major RPV mutation (n=6), and A1/A6 HIV subtype (n=7). Baseline characteristics are shown in Table 1.

During 692 PYFU (median FU 1.9 years), 5 VFs occurred (incidence 0.72 per 100PYFU). The probability of maintaining VS was 99.1% (±0.5%) at 48 wks and 98.1% (±0.9%) at 144 wks. Cox regression identified no significant predictors of VF. GRT at VF was available for 3 PWH and revealed resistance mutations: 1 participant experienced VF at 19 months after switching from RPV/DTG, developing E138A, M230L, and Q148R; a second, switching from TAF/FTC/RPV, had VF after 12 months with a newly detected Q148K (not present on prior GRT). A third experienced VF after 4 months with K103N, E138K, and Q148R; this latter case received the second injectable dose after 8 wks and had no prior GRT available. Two PWH with a determination of HIV-RNA>1000 cps/mL during FU continued CAB/RPV LA, with subsequent undetectability; one of them, had a HIV-RNA 1021 cps/mL after 24 months, 2 wks after HPV vaccination.

With respect to durability, 56 PWH discontinued CAB/RPV: the main causes of TD were injection-site reactions (ISR) (n=21, 4.9%), regimen intensification (n=10, 2.3%), neurological toxicity (n=7, 1.6%), and patient request (n=5, 1.2%). One participant occurred in HBV acute infection (previous HBsAg and HbcAb negative). 50% of TDs occurred within the first 6 months of FU.

In a sensitivity analysis, which included 138 PWH with known baseline BMI and HIV subtype, we found no VF.

Conclusions: These real-world data confirm the high efficacy and tolerability of CAB/RPV LA, supporting their role in individualized antiretroviral care. Although rarely, VF associated with emergence of resistance mutations did occur, including in patients switching from RPV-containing regimens. Larger studies with longer follow-up are needed to identify factors associated with VF and resistance emergence beyond the ones which are already known.

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Clinical insights of Long-Acting treatment

SC 22 LIFE AFTER LONG-ACTING THERAPY: WHAT HAPPENS WHEN CAB/RPV IS DISCONTINUED?

M. Giurco¹, L. Taramasso², E. Ricci³, N. Squillace⁴, S. Ferrara⁵, A. Parisini⁶, G. Orofino⁷, B. Menzaghi⁸, F. Lagi⁹, E. Sarchi¹⁰, L. Pusterla¹¹, G. Madeddu¹², L. Calza¹³, M.A. Carleo¹⁴, G. Cenderello¹⁵, G. Angioni¹⁶, K. Falasca¹⁷, E. Salomoni¹⁸, S. Rusconi¹⁹, G.F. Pellicano²⁰, T. Bini²¹, G. De Socio²², P. Bonfanti^{1,2}, A. Di Biagio^{1,2}, for the CISAI study Group

¹Department of Health Sciences (DISSAL), University of Genoa, Genoa, Italy, ²Infectious Disease Clinic, IRCCS Azienda Ospedaliera Metropolitana, Genova, Italy, ³Fondazione ASIA, Milan, Italy, ⁴Infectious Disease Unit, Fondazione IRCCS San Gerardo dei Tintori, Monza - University of Milano-Bicocca, Monza, Italy, ⁵Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy, ⁶Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ⁷Unit of Infectious Diseases, "Divisione A", Amedeo di Savoia Hospital, Torino, Italy, ⁸Unit of Infectious Diseases, ASST della Valle Olona - Busto Arsizio (VA), Italy, ⁹AOU Infectious and Tropical Diseases, Careggi Hospital, Florence, Italy, ¹⁰Infectious Diseases Unit, S. Antonio e Biagio e Cesare Arrigo Hospital, Alessandria, Italy, ¹¹Infectious Diseases Unit, Ospedale S. Anna, Como, Italy, ¹²Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Italy, ¹³Infectious disease Unit, IRCCS Policlinico Sant' Orsola, University of Bologna, Italy, ¹⁴Infectious Diseases and Gender Medicine Unit, Cotugno Hospital, AO dei Colli, Naples, Italy, ¹⁵Infectious Diseases Department, Sanremo Hospital, Sanremo, Italy, ¹⁶Infectious Diseases Unit, SS Trinità Hospital, Cagliari, Italy, ¹⁷Clinic of Infectious Diseases, Department of Medicine and Science of Aging, G. D'Annunzio University, Chieti-Pescara, Chieti, Italy, ¹⁸SOC 1 USLCENTRO FIRENZE, Unit of Infectious Diseases, Santa Maria Annunziata Hospital, Florence, Italy, ¹⁹Infectious Diseases Unit, ASST Ovest Milanese, Legnano and DIBIC, University of Milan, Italy, ²⁰Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Messina, Messina, Italy, ²¹Unit of Infectious Diseases, San Paolo Hospital, Milano, Italy, ²²Infectious Diseases Clinic, Department of Medicine and Surgery, University of Perugia, Italy

Background: The onset of adverse events (AEs) is the main cause of discontinuation of long-acting (LA) cabotegravir+rilpivirine (CAB+RPV) in observational and randomized studies. Nevertheless, data are scarce on the choice of the following oral regimen, on the potential additional AEs that develop during the pharmacokinetic tail of CAB and RPV, and on the virologic outcomes in people who discontinue LA treatment for reasons other than virologic failure (VF).

Materials and Methods: This is a multicenter, prospective, observational study conducted within the SCOLTA (Surveillance Cohort Long-Term Toxicity Antiretrovirals) project; it includes people with HIV (PWH) who discontinued LA CAB/RPV therapy after at least one follow-up visit. Descriptive statistics were used to summarize data.

Results: The study included 700 PWH on LA CAB+RPV, with an observed all-cause therapy interruption rate of 13.3% (93/700) and a median follow-up of 23 months (IQR 14-30). The main reasons for treatment discontinuation were AEs and the subject's decision, accounting for 47.3% (44/93) and 16.1% (11/93) of all interruptions, respectively (Table 1). Injection site reactions (ISRs) were the most frequent AE, accounting for 45.5% of cases, followed by arthromyalgias and infectious complications, each accounting for 11.4% of cases (Table 2). Excluding people who were lost to follow-up and the deceased, we evaluated the oral regimen selected after LA discontinuation in the remaining study participants. Among the subgroup that discontinued injectables for reasons other than VF, and excluding one subject who returned to the same PI-based therapy that was in place before initiating LA, 100% maintained a NNRTI- and/or INSTI-based regimen without the need to introduce new ARV classes or a PI-based therapy. Considering those who discontinued injectables due to VF, 4 out of 10 people switched to a PI-based regimen (Table 3).

The resumption of the same drug co-formulation utilized before the LA regimen occurred in 20.0% (2/10), 76.9% (15/65), and 84.1% (37/44) of PWH who interrupted LA due to VF, due to any cause other than VF, and due to AEs, respectively. Overall, 92.1% of regimens after LA interruption were NNRTI (16%), INSTI (57.3%), or NNRTI+INSTI (18.7%)-based. No new AEs were recorded after switching back to oral therapy throughout the whole cohort. Six months after resuming oral therapy, HIV-RNA loads <30 copies/mL and <200 copies/mL were recorded in 96.0% (72/75) and 98.7% (74/75) of individuals, respectively.

Conclusions: Among individuals who interrupted injectables for reasons other than VF, the majority returned to the same pre-LA oral co-formulation. The superimposition of CAB+RPV pharmacokinetic tail with an oral NNRTI and/or INSTI-based regimen did not lead to the development of AEs, even in people with a previous AE to CAB or RPV. Six months after the reintroduction of oral therapy, the virologic suppression rate was high throughout the cohort.

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Clinical insights of Long-Acting treatment

SC 23 SAFETY OF CABOTEGRAVIR + RILPIVIRINE LONG-ACTING REGIMEN AMONG PLWH WITH PREVIOUS HBV EXPOSURE: PRELIMINARY RESULTS OF THE SCRIBE STUDY

N. Bana¹, F. Artelli^{2,3}, G. Lapadula^{2,3}, P. Bonfanti^{2,3}, P. Vitiello⁴, C. Abeli⁴, M. Farinazzo⁴, L. Comi⁵, D. Rigamondi⁵, D. Valenti¹, M. Puoti^{1,2}, R. Rossotti¹

¹ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ²IRCCS San Gerardo dei Tintori, Monza, Italy, ³School of Medicine and Surgery, University of Milano Bicocca, Milan, Italy, ⁴ASST Valle Olona, Busto Arsizio (VA), Italy, ⁵ASST Papa Giovanni XXIII, Bergamo, Italy

Introduction: Cabotegravir + Rilpivirine long-acting regimen (CARLA) has no anti-HBV activity and is not recommended for PLWH with active HBV co-infection. No data exist on its hepatic safety among PLWH with resolved HepB (rHepB), especially among those with isolated HBcAb+ (IsHBcAb+).

Materials and Methods: Retrospective multicenter observational study including PLWH on CARLA. Primary aim was to demonstrate hepatic safety among PLWH with rHepB (HBsAg-, HBcAb+, HBsAb+/-), assessed by analysing FIB-4 and ALT trends. Temporal trends of FIB-4 and ALT were described using a mixed linear model with a random intercept and slope adjustment. The incidence rate of hepatitis flare (increase 3X the ALT normal values) was reported, and factors associated with hepatitis flare including Liver Steatosis assessed by HSI were described using standard survival analyses.

Results: 394 PLWH were included from 4 centres, with a median follow-up of 1.98 years (IQR: 0.99-2.53). Their main features are shown in Tab.1. The mixed model did not find any trend for worse evolution of ALT and FIB-4 values in rHepB compared with non-exposure to HBV (coef. -0.14, 95%CI -0.84-0.56, p=0.697 and coef. 0.01, 95%CI -0.02-0.03, p=0.669, respectively), as shown in Fig.1 and Fig.2. HSI score was significantly associated with ALT increase (coef. 0.88, 95%CI 0.61-1.15, p<0.001).

We observed 9/394 (2.3%) hepatitis flares: 4/283 (1.4%) among HBV-unexposed and 5/111 (4.5%) in PLWH with rHepB, 2/24 (8.3%) with IsHBcAb+: incidence was 0.8 and 2.7 per 100PYFU among PLWH HBV-unexposed and with rHepB, respectively (IRR 0.32, 95%CI 0.08-1.25, p=0.090). For people with IsHBcAb+, the incidence rate was slightly higher (6.0 per 100PYFU with IRR 0.18, 95%CI 0.04-1.30, p=0.080). Survival analyses did not find a role of rHepB in the risk of hepatitis flare, whereas a higher HSI score was slightly associated with hepatitis flare, even at the limit of statistical significance (aHR 1.11, 95%CI 1.00-1.23, p=0.061), as shown in Fig.3.

In IsHBcAb+ PLWH there was a significantly higher risk of flare (aHR 11.15, 95%CI 1.67-74.28, p=0.013), and for this population, a higher HSI had an impact (aHR 1.14, 95%CI 1.02-1.27, p=0.018).

No confirmed cases of HBV reactivation were observed. One person with IsHBcAb+ had a flare associated with HBsAb seroconversion and HBV DNA 17 IU/ml, followed by spontaneous resolution.

Conclusions: CARLA is safe, considering the FIB-4 and ALT trends among PLWH with rHepB. Hepatitis flares seemed to be related to Liver Steatosis. rHepB did not impact hepatitis flares risk, whereas IsHBcAb+ was associated with a higher risk of liver events, even though it was not related to HBV reactivation.

These results will be updated soon with data coming from other 4 Italian centres.

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Clinical insights of Long-Acting treatment

SC 24 IMPACT OF CABOTEGRAVIR/RILPIVIRINE ON PATIENT-REPORTED OUTCOMES: REAL-WORLD DATA FROM A MULTICENTER COHORT

A. Carraro¹, R. Marocco², G. Mancarella², A. Gasperin², L. Ansaldo², M. Guardiani³, V. Bertocchi⁴, V. Serena^{5,1}, L. Bresciani³, V. Speciale³, V. Kelmendi³, S. Iaquinandi³, V. Filippi¹, C. Pasquazzi¹, L. Germani¹, C. Del Borgo^{3,2}, M. Lichtner^{5,1}

¹Infectious Diseases Unit, Sant'Andrea University Hospital, Sapienza University of Rome, Rome, Italy, ²Infectious Diseases Unit, S. M. Goretti Hospital, Polo Pontino Sapienza University of Rome, Latina, Italy, ³Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ⁴Sapienza University of Rome, Rome, Italy, ⁵Department of Neuroscience, Mental Health and Sense Organs, Sapienza University of Rome, Rome, Italy

Background: The efficacy and safety of cabotegravir/rilpivirine (CAB/RPV) has been demonstrated and initial results suggest that it is preferred by people living with HIV (PWH). It is not yet known how much it actually affects quality of life and whether there are social factors that can predict its failure.

Methods: It is a prospective multicenter study (S.M. Goretti Hospital and Sant'Andrea University Hospital Infectious Diseases Clinics) where PROs (patient-reported outcomes) were collected before starting CAB/RPV and then every 6 months for up to two years (T0, T28 weeks, T52 w, T76 w, T100 w), via electronic forms.

Here we analyse some of them, until T52w: HIV Dependent Quality of Life(HIVDQoL), HIV Stigma Scale(HSS),HIV Treatment Satisfaction questionnaire status and change versions(HIVTSQs and HIVTSQc),PHQ-9(mental health assessment), GAD-7 (generalized anxiety disorder). The Spearman test was performed to assess correlations between continuous variables and longitudinal evaluations were conducted using the nonparametric Wilcoxon test and Friedman test.

Results: 44 people were involved, including 13 women at birth (29%) and 1black African person. Adherence was 74% at time T0, 46% at T28, 33% at T52 (higher among males). A total of 480 questionnaires were evaluated.

In HIVDQoL a slight increase in the total score was observed:T0: 244.5 [207–277.8]; T28: 256.5 [209.5–284.3]; T52: 257.0 [217.5–300.5];p=0.62. (Figure 1) Analyzing each items, there was a greater impact on the quality of vacations, the freedom to interact with new relationships(both p=0,07) (Figures 2 and 3). No linear correlation was observed between HIV-related parameters (as the duration of HIV infection) and the perceived quality of life. (Figure 8)

HSS does not change over time; the domains "disclosure concerns" and "concern with public attitudes" had the greatest impact on stigma (p<0.0001) (Figure 4). No correlation was observed between HSS and the duration of HIV infection. (Figure 9)

In GAD-7 a reduction in median scores was observed

(T0: 5 [2–8.25]; T28/T52: 3.5 [1.75–7.75], p=0,7); in PHQ-9 a reduction in scores was mainly observed among patients with initially moderate-to-high values, while those with high baseline scores remained elevated. (Figures 5 and 6)

The level of satisfaction at T0 was moderate to high, with a median cumulative score 70. At both time points T28 and T56, all participants expressed a favourable opinion of the long-acting therapy (plus 30 points), and satisfaction remained stable over time (p = 0.29) (Figure 7) without any concern for the pain at the site of inoculum. The preferred characteristics of CAB/RPV were flexibility and the minimal time required.

Conclusions: In general, PROs are important tools, moderately accepted by PWH, that can highlight serious issues. CAB/RPV continues to be a highly valued therapy even after 2 years of therapy, improving substantially certain aspects of daily life. However, it does not seem to have a clear and immediate impact on internalized stigma that should need a prolonged psychosocial intervention.

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Innovations in HIV care: services, networks and continuity

SC 25 PEOPLE DIAGNOSED WITH HIV AND IN CARE IN ITALY IN 2024: PRELIMINARY RESULTS FROM THE ONGOING THIRD NATIONAL SURVEY - CARPHA3 PROJECT

P. Piselli¹, L. Pugliese², V. Regine², E. Gennaro¹, C. Cimaglia¹, A. Caioli¹, A. Navarra¹, S. Leone¹, D. Cordella², C. Gubinelli¹, A. Caraglia³, E. Girardi¹, B. Suligo² and the CARPHA3 study group

¹Istituto nazionale per le malattie infettive "L. Spallanzani" – IRCCS, Rome, Italy, ²Istituto Superiore di Sanità, Rome, Italy, ³Ministero della Salute, Rome, Italy

Background: To achieve the Continuum of Care (CoC) targets proposed by Joint UN Programme on HIV/AIDS (95-95-95) in Italy, it is not possible to rely only on HIV/AIDS Italian surveillance systems which can only produce estimates, but are unable to provide complete information on people living with HIV/AIDS (PLWHA) currently in care and on their clinical characteristics. To fill this gap, the CARPHA3 study (Characteristics of Persons Living with HIV/AIDS in Italy), now in its 3rd edition, has been underway and will be able to produce update data on PLWHA currently living in Italy and their characteristics.

Material and Methods: The CARPHA3 study involves all active Public Infectious Diseases Clinical Units (PIDC) in Italy. During the initial phase of the study, we identified and verified all PIDCs providing care to PLWHA in 2024. A standardized data collection form was created to collect information on the aggregated number of PLWHA in care in 2024, those receiving antiretroviral therapy (ART) and those newly HIV diagnosed cases in 2024, as well as selected key demographic and clinical characteristics (i.e. sex, age, nationality, mode of transmission, CD4 cell count, viral load). A dedicated and secure web-based platform was specifically developed in Istituto Superiore di Sanità (ISS) to collect required data, and each center was granted access to the platform (through credentials sent via e-mail starting from Oct 2025) and complete data collection (planned to be completed within Apr 2026).

Results: Overall, 167 PIDCs active in 2024 were initially identified and invited to participate. Data collection is still ongoing and here we present the preliminary results of this investigation. Seventeen PIDCs (10.2%) declined to participate but contributed to the project providing the total number of PLWHA and the proportion of those in ART (10/17 already providing the data). The remaining 150 PIDCs (89.8%) have been granted access to the dedicated platform, and of these 103 (68.7%) accessed already the platform and started to complete data collection and completed by 71 (68.9%) (Figure 1). Overall considering PIDCs that already completed the data collection (n=71) adding data from ten PIDCs who declined, aggregated data from 58723 PLWHA were collected, which represent 41.2% of 142.5k individuals to be reached considering the last available estimation of the number of PLWHA with known infection in 2024 provided by ISS. Main characteristics of PLWHA from available data are shown in Figure 2.

Conclusions: Here we represent preliminary results from the ongoing CARPHA3 project, which will allow Italy to provide a real and comprehensive prevalence estimate for the country, rather than one based solely on estimates, useful for comparing national with other European and International countries participating in monitoring and prevention programs. Project supported and financed by Italian Ministry of Health: CCM (4393).

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Innovations in HIV care: services, networks and continuity

SC 26 SEARCHING FOR THE DENOMINATOR: PRELIMINARY FINDINGS FROM PRONTI PROJECT

G. Cruschelli¹, A. Caraglia², F. Centrone³, M. Chironna⁴, M. Farinella⁵, C. Galli⁶, S. Moriconi¹, V.A. Orlando⁴, C. Pasqualini⁷, M. Puglia⁸, L. Pugliese⁹, L. Rancilio¹⁰, V. Regine⁹, F. Voller⁸, L. Tavošchi¹, B. Suligo⁹

¹University of Pisa, Pisa, Italy, ²Ministry of Health, Rome, Italy, ³Policlinic of Bari, Bari, Italy, ⁴University of Bari, Bari, Italy, ⁵Mario Mieli, LGBTQIA+ Culture Center, Rome, Italy, ⁶Independent researcher, Rome, Italy, ⁷Piedmont Regional Service for the Epidemiology of Infectious Diseases (SeREMI), Alessandria, Italy, ⁸Tuscany Regional Health Agency, Florence, Italy, ⁹Italian National Institute of Health, Rome, Italy, ¹⁰Caritas Ambrosiana, Milano, Italy

Background: In Italy, the national HIV surveillance system reports newly diagnosed HIV cases but does not collect data on the total number of HIV tests performed. Therefore, trends in new diagnoses cannot be interpreted as related to testing activity. Information on the number of tests provides the denominator needed to contextualize incidence data and to better understand changes over time. Monitoring testing volumes can support public health planning by identifying differences in service provision and potential reductions or gaps in access to testing. The PRONTI project (Project on the Number of HIV Tests Performed in Italy), funded by the Italian Ministry of Health, aims to evaluate the availability and coverage of HIV testing by analyzing outpatient specialist administrative data. This study presents preliminary findings on the number of HIV tests performed in Italy between 2018 and 2023.

Materials and Methods: A retrospective analysis was conducted on HIV tests performed by the National Health Service between 2018 and 2023 among people aged ≥ 18 years living in Italy. Tests were identified using the national reimbursement code for first-level HIV testing, corresponding to the fourth-generation combined assay detecting anti-HIV-1/2 antibodies and HIV-1 p24 antigen. Data were extracted from national administrative healthcare databases that exclude screening for blood donations. The total number of screening tests was calculated for each year. Annual screening rates were computed as the number of tests performed divided by the resident adult population, both at the national level and by region.

Results: Between 2018 and 2023, the annual number of first-level HIV tests performed in Italy ranged from a minimum of 889,972 in 2020 to a maximum of 1,133,377 in 2018. Overall, roughly one million screening tests were performed annually. Testing volumes remained relatively stable over time, with a marked reduction in 2020, followed by a progressive increase. When standardized to the adult resident population, the average annual screening rate was 2.1%, ranging from 1.8% in 2020 to 2.3% in 2018. In 2023, the screening rate was 2.2%. Figure 1 reports the mean screening rates by region. Rates were generally higher in Northern and Central Italy than in Southern Italy and the Islands.

Conclusions: The reduction in the total number of tests observed in 2020 is likely attributable to the COVID-19 pandemic and the associated decrease in access to outpatient services. Preliminary findings indicate a North-South gradient in testing rates, suggesting potential disparities in access to HIV testing services across regions. Further analyses will include confirmatory and monitoring tests (immunoblot and HIV-RNA) and region-by-region comparisons between screening tests, confirmatory tests, and newly diagnosed cases. Establishing the denominator of testing activity is essential for better interpretation of national HIV surveillance data and to inform public health action.

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Innovations in HIV care: services, networks and continuity

SC 27 ENGAGEHIV: A MULTIDISCIPLINARY MODEL FOR PROACTIVE RE-ENGAGEMENT AND PREVENTION OF LOSS TO FOLLOW-UP IN PLWHA

M. Guastavigna¹, G. Orofino¹, A. Ianniello², A. Montalbano³, F. Onelia³, R. Ranotti⁴, S. Scignoli¹, G. Calleri¹

¹Tropical and Infectious Diseases Division A, Amedeo di Savoia Hospital, Turin, Italy, ²Laboratory of Microbiology and Virology, Amedeo di Savoia Hospital, ASL Città di Torino, Turin, Italy, ³Medical Science Department, University of Turin, Turin, Italy, ⁴Hospital Pharmacy, Amedeo di Savoia Hospital, Turin, Italy

Background: Loss to follow-up (LTFU) is the most extreme form of non-adherence in people living with HIV (PLWHA) and a critical barrier to achieving UNAIDS 95-95-95 targets. Engage HIV was developed at the Amedeo di Savoia Hospital in Turin, to systematically address retention in care through a proactive, multidisciplinary approach including active tracing and individualized re-engagement interventions.

Methods: 2161 medical records were reviewed and patients stratified into 3 categories: Optimal Retention ($\geq 90\%$ adherence to visits, labs and ART), Sub-optimal Retention ($< 90\%$), and LTFU (no clinical contact ≥ 18 months). Active tracing used regional and national health databases and registered clinical contacts. Individualized Engagement Plans were implemented for sub-optimal retention patients.

Results: Of 2161 PLWHA, 1338 (62%) showed optimal retention and 19 (0,8%) sub-optimal retention (Engagement Plan ongoing, with early adherence improvement observed).

804 (37,2%) were classified as LTFU

- 154 (19%) were untraceable: mean age 50.3y; 101M (66%), 53F (34%), ita 67 (43.5%), foreigners 87 (56.5%).
- Of 650 (81%) traceable patients:
 - 418 (64%) had died: cause was known in 258 cases (61.7%), of which 53 (20.5%) were HIV/AIDS-related and 205 (79.5%) non-HIV; cause was unknown in 160 cases (38.3%).
 - Of 232 (36%) living patients:
 - active tracing confirmed that 113 (49%) had been absorbed by other care centres over the years — a status that was previously uncertain or unknown for many of them: mean age 52.9y; 93M (82%), 20F (18%), ita 94 (83%), foreigners 19 (17%).
 - 21 (9%) patients actively returned to our centre as a direct result of proactive outreach: they were traced, contacted, and re-engaged through individualized care pathways: mean age 49.9y; 11M (52%), 10F (48%), ita 17 (81%), foreigners 4 (19%).
 - 22 (9.5%) patients are currently undergoing active re-engagement: mean age 56y; 17M (77%), 5F (23%), 17 ita (77%), 5 foreigners (23%)
 - 76 (33%) are under transfer verification: mean age 54y; 59M (77%), 17F (23%), 65 ita (85%), 11 foreigners (15%).

Conclusions: Engage HIV shows that applying systematic tracing yields real prevalence data rather than estimates, enabling accurate quantification of unmet need. Active outreach re-engaged 21 patients are the most impactful outcome in terms of individual health and prevention of onward transmission.

Conversely, the over-representation of younger, non-Italian patients among the untraceable group suggests that current database strategies are less effective for mobile populations with fewer stable administrative ties. The rigorous LTFU definition (≥ 18 months) combined with three-tier stratification enabled targeted intervention before full disengagement. The multidisciplinary framework proved essential to building sustainable re-engagement pathways. This model is replicable as a structured tool for improving retention in care in PLWHA.

Innovations in HIV care: services, networks and continuity

SC 28 THE ROLE OF AN INTEGRATED MULTIDISCIPLINARY CARE MODEL ON CONTINUITY OF CARE AND IMMUNO-VIROLOGICAL OUTCOMES IN A COMPLEX POPULATION LIVING WITH HIV INFECTION

D. Zaçe¹, S. Grammatico², V. Mazzearella², G. Trincia³, L. Sarmati^{1,4}

¹Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy, ²Polo Sanitario "Villa Glori", Cooperativa Roma Solidarietà, Caritas, Rome, Italy,

³Cooperativa Roma Solidarietà, Caritas, Rome, Italy, ⁴Infectious Diseases Unit, University Hospital Tor Vergata, Rome, Italy

Introduction: People living with HIV (PLWH) in vulnerable and marginalized conditions face substantial barriers to HIV care, resulting in reduced ART adherence, loss to follow-up, and higher risks of virological failure and mortality.

Methods: This retrospective study evaluates a residential care and/or home-based assistance model for highly vulnerable PLWH, led by Caritas Roma. The intervention includes multidimensional needs assessment, ART adherence monitoring, clinical follow-up, support to specialist visits, and health education. Clinical, behavioral, and social data were analyzed to assess effects on retention in care, ART adherence, and immuno-virological outcomes over 2015–2025.

Results: The study included 106 PLWH (Table 1), mostly male (60.4%) and Italian (77.4%). Most were unemployed (66.7%), and only 57.8% had stable housing. Alcohol use was reported by 37.9%, smoking by 85.7%, substance use history (PWID) by 54.6%, and psychiatric disorders by 69.4%, more frequently among patients in residential care. Compared with patients who received home-based assistance, those in residential care were younger, had longer HIV history, and were more often non-Italian, unemployed, and housing-unstable. They also reported higher lifetime exposure to violence and were less likely to have a caregiver (all $p < 0.01$).

The main risk factor for HIV infection was PWID (53.7%) (Table 2). Most patients were in CDC stage C3 (62.5%) with a CD4 nadir <200 cells/mm³ (80.2%). Factors associated with lack of adherence to ART in univariate analysis were younger age at diagnosis, being unemployed compared with being retired, housing instability, alcohol use, PWID, psychiatric disorders, and detectable viral load (>50 copies/mL) at entry into care.

Comparing the immuno-virological profile at entry and at the most recent available tests, CD4 lymphocyte count significantly increased at the last examination (431 vs 530 cells/mm³, $p < 0.001$), while the proportion of patients with CD4 count <200 cells/mm³ (29.8% vs 7.6%) decreased. The percentage of patients with detectable viral load (>50 copies/mL) significantly decreased from 23.6% at entry to 5.4% at the last available tests.

At the end of follow-up, 16 patients were discharged or no longer followed by the service due to lack of indication, 65 patients were still under care, 16 were transferred to other services, 6 had died, and 6 were lost to follow-up.

Discussion: This study provides concrete evidence of the effectiveness of an integrated residential intervention and home-based assistance in a complex population living with HIV. The findings may contribute to the development of sustainable, multidisciplinary, and person-centered strategies, particularly for the most vulnerable patients engaged in social inclusion programs, with potential benefits including improved public health outcomes, reduced inequalities, and optimized resource use.

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Innovations in HIV care: services, networks and continuity

SC 29 IMPLEMENTATION OF EMERGENCY DEPARTMENT BUNDLED TESTING FOR HIV, HBV AND HCV USING RESIDUAL SAMPLES: THE PROGRESSO-T PROJECT

M. Leone^{1,2}, F. Cecilia^{1,2}, S. Ciarpaglini^{1,2}, E. Perugini^{1,2}, D. Meloni¹, L. Benedetti¹, A. Giovannelli^{3,4}, M. Pelagalli^{3,4}, F. Tomassetti^{3,4}, D. Zacc¹, A. di Lorenzo^{1,2}, J.M. Legramante^{1,5}, C. Paganelli⁵, V. Malagnino^{1,2}, S. Bernardini^{3,4}, M. Pieri^{3,4}, L. Sarmati^{1,2}, A.M. Geretti^{1,2}, PROGRESSO-T (Promuoviamo maggiore accesso ai test) Study Team

¹Department of Medicine of Systems, University of Rome Tor Vergata, Rome, Italy, ²Department of Infectious Diseases, Tor Vergata University Hospital, Rome, Italy,

³Department of Experimental Medicine, University of Rome Tor Vergata, Rome, Italy, ⁴Department of Laboratory Medicine, Tor Vergata University Hospital, Rome, Italy,

⁵Emergency Department, Tor Vergata University Hospital, Rome, Italy

Background: Late diagnosis of HIV, HBV and HCV remains a major public health challenge. Emergency Departments (ED) provide a setting for opportunistic screening, although implementation is influenced by organisational constraints, staffing requirements and regulatory frameworks that continue to differentiate HIV from other infections. The Progresso-T project evaluated the feasibility, uptake and diagnostic yield of bundled testing for HIV, HBV and HCV in an ED in Rome.

Methods: Adult ED attendees were approached for HIV, HBV, HCV testing during predefined time slots across different days of the week. Testing was offered by dedicated personnel external to routine ED clinical staff. Written informed consent in multiple languages was required for HIV testing in accordance with national legislation. Rapid tests were performed on residual whole blood recovered from routine haematology testing, allowing screening to be completed without additional phlebotomy. Data collected included test uptake, availability of residual samples, test results (anti-HIV, HBsAg, anti-HCV), demographics and reasons for refusal.

Results: In this ongoing project, among 519 patients (53.6% men) offered bundled testing, 396 (76.3%) accepted (Fig 1). Individuals who accepted testing were younger than those who declined (mean age 53 vs 60 years; $p=0.006$), while acceptance did not differ by sex (men 78.1% vs women 78.5%; $p=0.99$). The highest acceptance rates (>90%) were in the periods 09:00-12:00 and 15:00-21:00. Among consenting individuals, residual samples were available for 353/396 (89.1%). For the remaining 43/396 (10.9%) without residual samples, 34/43 (79.1%) were successfully contacted by telephone to alert them to this; 9 (20.9%) could not be reached despite repeated attempts. Among 353 tested individuals, we identified 1 with HIV (0.3%), 2 with HBsAg (0.6%), and 6 with anti-HCV (1.7%) (Fig 1). Notably, 5/6 individuals with anti-HCV were born outside the national birth-cohort 1969-1989 screening target. Among the 123 patients who declined testing, 62.6% did not provide a specific reason, refusing to sign the HIV consent form; reported reasons included recent prior testing (17.1%), perceived absence of risk (12.2%), lack of interest in participation (6.5%) and fear of receiving a positive result (1.6%).

Conclusions: Bundled HIV, HBV and HCV testing in the ED using residual samples is feasible but is constrained by HIV-specific consenting processes and requires dedicated personnel. Uptake was high, and younger age and time of attendance were associated with higher acceptance. The identification of individuals with anti-HCV largely outside the national birth-cohort highlights the added value of ED-based opportunistic screening in reaching individuals not captured by existing strategies. Harmonisation and simplification of consent requirements across infections, together with integration into routine ED workflows, is critical to achieving scalable and equitable screening.

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Innovations in HIV care: services, networks and continuity

SC 30 TREND OF NUMBER OF TESTS FOR HIV IN COMMUNITY-BASED VOLUNTARY COUNSELLING AND TESTING (CBVCT) SETTINGS IN ITALY (2019–2025)

E. Gennaro¹, C. Cimaglia¹, G. Giupponi², M. Farinella³, I. Pennini⁴, S. Patrucco⁵, M. Cernuschi⁶, L. Rancilio⁷, P. Mell⁸, M. Stagnitta⁹, D. Masci¹⁰, N. Frattini¹¹, G. Moi¹², C. Nicoara¹³, S. Mattioli¹⁴, F. Leseri¹⁵, A. Caioli¹, S. Leone¹, A. Navarra¹, A. Caraglia¹⁶, E. Girardi¹, P. Piselli¹ for the Working Group of the project "Contribution of the Association to the continuum of care of persons living with HIV and AIDS"

¹INMI L. Spallanzani, Rome, Italy, ²LILA Milano, Milan, Italy, ³Circolo di Cultura Omosessuale "Mario Mieli", Rome, Italy, ⁴Arcigay, Padua, Italy, ⁵Arcobaleno AIDS, Turin, Italy, ⁶Associazione Solidarietà AIDS (ASA), Milan, Italy, ⁷CARITAS Ambrosiana, Milan, Italy, ⁸CICA, Bergamo, Italy, ⁹CNCA, Rome, Italy, ¹⁰Fondazione Villa Maraini, Rome, Italy, ¹¹Milano Checkpoint, Milan, Italy, ¹²Movimento Omosessuale Sardo (MOS), Sassari, Italy, ¹³Network Persone Sieropositive (NPS) Italia, Milan, Italy, ¹⁴PLUS, Bologna, Italy, ¹⁵Checkpoint PLUS Roma, Rome, Italy, ¹⁶Ministero della Salute, Rome, Italy

Background and Objectives: In recent years, Community-Based Voluntary Counselling and Testing (CBVCT) activities have undergone substantial reorganization in response to changes in healthcare services during the COVID-19 pandemic. This study aimed to evaluate Counselling and Testing (CT) activities delivered in non-healthcare settings between 2019 and 2025, focusing on the number of tests performed for HIV, as well as on the number of active centers and their geographical distribution.

Material and Methods: A survey was proposed to national non-governmental organizations (NGOs) and third-sector Associations involved in the fight against HIV/AIDS. Information relating to services offered for HIV testing was collected, in terms of number of accesses to CT, the number of HIV rapid tests performed and proportion of reactive results, as well as the percentage of subjects with a reactive result and those then linked to a clinical center. Data were presented at national level and separately according to geographical area (North-West, North-East, Center and South & Islands).

Results: Sixty-one organizations from all over Italy participated to the survey, offering testing for HIV and other STDs within the period of consideration. Considering that data on 2024 and 2025 are provisional since data collection is still ongoing, 90440 tests for HIV were performed during the investigated period, starting from 10k tests performed in 2019, to reach nearly 15.1 thousand in 2025, with a relevant reduction in 2020 (4.9k tests) and in 2021 (8.6k) due probably to COVID-19 restrictions (Figure 1). Overall, the percentage of reactivity for HIV was 0.53%, (all cases substantially linked to a clinical center for confirmation tests and therapy). The number of associations conducting testing activities has also increased considerably from 2019 to 2025, reaching a total of 59 centers in 2025 (see Table 1). Figure 1 shows the number of tests and organizations active in HIV testing, where is evident that during the study period the number of tests performed, and more importantly the number of active organizations, increased sensitively in all Italian areas considered (accounting for provisional data).

Conclusions: Although the COVID-19 pandemic initially had a negative impact on CBVCT activities, a gradual increase is confirmed in the number of associations performing HIV testing activities, alongside new associations that subsequently started such activities, with a consequent rise in the overall number of tests performed. This trend remains evident in 2024 and 2025, although the data are provisional.

* Project supported and financed by General Direction for Health prevention (ref 4023).

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Oral ART from different perspectives

SC 31 IMPLEMENTATION OF A SAME-DAY ART START MODEL IN A REAL-LIFE SETTING: EXPERIENCES FROM A CLINICAL CENTRE IN ITALY

G. Micheli, A. Caioli, R. Esvan, A. Giacinta, V. Barchi, D. Farinacci, R.J. Steiner, N. Braccialarghe, I. Abbate, C. Pinnetti, L. Fabeni, G. Frate, G. Rozera, E. Girardi, F. Maggi, A. Antinori, V. Mazzotta

National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy

Background: Many international guidelines, such as those by the World Health Organisation, endorse rapid ART initiation (RS) within 7 days of diagnosis, including same-day (SD) start, for all people with HIV (PWH) ready to initiate therapy.

While convincing evidence exists for this approach in low-resource settings, data are conflicting in high-resource settings, especially concerning long-term retention in care. Moreover, direct comparisons between SD and RS strategies remain limited.

Methods: Newly diagnosed PWH starting ART within 7 days from the first linkage to the HIV clinical centre (Baseline) were included (January 2024-June 2025). Baseline standard laboratory tests were performed, whose results not available before ART initiation. Primary outcomes were a) viral suppression (VS; HIV RNA <50 copies/mL) at 6 months; b) need for ART change once laboratory results were available; c) retention-in-care at 6 and 12 months. Categorical variables and continuous variables were assessed by Fisher's test and Wilcoxon rank sum as appropriate. Time to first documented VS was estimated by Kaplan-Meier curves, and Cox models adjusted for age, sex at birth, baseline HIV RNA, and CD4 cell count. A multivariable logistic regression was fitted to identify the major predictors of VS at 6 months.

Results: Characteristics of the cohort are reported in Table 1. Of the 120 included PWH, 45 (37.5%) were in RS group vs. 75 (62.5%) in SD group. 4/120 were previously exposed to PrEP (3 in SD vs. 1 in RS). At baseline, 3/119 had HCV antibodies (all RS), and 2/118 had detectable HBsAg (1 in each group).

No treatment modifications occurred once laboratory results were available. No IRIS episodes were documented.

At 6 months, 85.7% in RS groups vs. 88.7% in SD reached VS ($p=0.66$), and all PWH but 3 (all in SD group) reached VS at 12 months ($p=0.55$). Among participants with a 6-month VL available ($n=96$), baseline CD4 count <200/mm³ and higher HIV RNA (log) at baseline were significantly associated with lower VS at 6 months (Table 2).

After adjusting for potential confounders, no significant differences emerged in time to VS (aHR 1.006, 95% CI: 0.68 -1.49; $p=0.98$ for SD). The Kaplan Meier curve estimating the cumulative probability of achieving VS in the 2 groups is reported in Fig.1 (log-rank test 0.84). No major differences between the two strategies were found in 6-month retention-in-care ($p=1$), although short follow-up precluded long-term evaluation.

Conclusion: In this real-life high-resource setting, SD ART initiation was feasible and safe, with no IRIS and no need for ART modification after baseline assessment. 6-month virologic outcomes and time-to-viral suppression were comparable between SD and the rapid-start strategy, with retention rates also comparable at 6 months.

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Oral ART from different perspectives

SC 32 LONG-TERM TREATMENT DYNAMICS AND IMMUNO-VIROLOGICAL RECOVERY IN ADVANCED ART-NAÏVE PEOPLE WITH HIV

A. Vergori¹, P. Borrelli², A. Narducci¹, I.F. Bottalico¹, S.M. Ferrara¹, C. Grillo¹, F.R.P. Ieva¹, M. Polisenò³, A. Saracino³, A. Cianciaruso³, R. Schiavoni⁴, L. Mezzogori⁴, A. Di Biagio⁴, A. Santoro⁵, G.C. Marchetti⁵, C. Tincati⁵, S. Lo Caputo¹

¹Infectious Diseases Unit, A.O.U. Policlinico Foggia, University of Foggia, Foggia, Italy, ²Laboratory of Biostatistics, Department of Medical, Oral and Biotechnological Sciences, University "G. D'Annunzio" Chieti-Pescara, Chieti, Italy, ³Infectious Diseases Unit, A.O.U. Consorziale Policlinico Bari, University of Bari, Bari, Italy, ⁴Infectious Diseases Unit, IRCCS San Martino, University of Genova, Genova, Italy, ⁵Infectious Diseases Unit, ASST Santi Paolo e Carlo, University of Milano Milano, Italy

Background: Integrase strand transfer inhibitor (INSTI)-based antiretroviral therapy (ART) is recommended as first-line treatment for people with HIV (PWH). However, long-term real-world data on therapeutic stability, switching strategies, and immuno-virological outcomes in ART-naïve patients presenting with advanced HIV disease (AHD) remain limited. This study evaluated treatment dynamics and 5-year immuno-virological outcomes from HIV diagnosis in AHD PWH.

Methods: Multicentre observational study across five Italian centres including ART-naïve PWH with AHD diagnosed in 2019–2024. ART regimens and classes were recorded at treatment initiation (T0) and after 1, 2, 3, 4, and 5 years (T1–T5). CD4 count and HIV-RNA were assessed across visits. Treatment durability, switching patterns, and outcomes were analysed according to ART class.

Results: At T0, 224 PWH were enrolled, 54% AIDS presenters. Treatment initiation data were available for 220 participants; 4 did not start ART. INSTI-based regimens predominated at all timepoints (87-96%). Overall, 90.0% initiated INSTI; among them, three-drug regimens (3DR) were used in 97.6% (203/208) and two-drug regimen (2DR) in 2.4% (5/208). BIC/F/TAF was the most common initial regimen (64%, 140/219). The Sankey diagram showed high INSTI persistence over time, with most participants remaining on across timepoints. A substantial proportion of individuals were lost to follow-up (LTFU) at each interval, progressively reducing the number under observation. After 5 years, 30.3% were 2DR and 68.2% on 3DR.

CD4 counts increased progressively over follow-up in all cART initiation groups. In the INSTI group, median CD4 rose from 50.0 cells/mm³ at baseline to 465.5 at T5 and 347.0 at last follow-up; in the PI/b group, values increased from 36.5 to 413.0 and 324.0 cells/mm³, respectively. CD4 trajectories were broadly comparable across regimens, with no significant differences at any timepoint (figure 2 A). Baseline viral load was comparable across cART initiation groups (median 302,449.5 INSTI vs 86,313.5 NNRTI vs 169,195.0 PI/b copies/mL; p=0.142). Virological suppression rates were high throughout follow-up. At T1, suppression was achieved in 85.0% of INSTI, 50.0% of NNRTI, and 80.0% of PI/b recipients (p=0.308). A significant difference emerged at T2, favoring INSTI (94.3% vs 100.0% vs 73.3%; p=0.033), but this was not maintained at later timepoints (figure 2B).

Conclusions: In this real-world multicentre cohort of ART-naïve PWH with AHD, INSTI-based regimens were the predominant first-line strategy and demonstrated high durability over 5 years. Despite advanced immunosuppression at diagnosis, patients achieved robust immune recovery and high rates of virological suppression, broadly comparable across ART classes. However, a substantial proportion of participants were lost to follow-up, highlighting the need for strengthened linkage-to-care and retention strategies in this high-risk population.

Table 1, figure 1, figure 2A, figure 2B

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Oral ART from different perspectives

SC 33 LONG-TERM DURABILITY OF BIC/FTC/TAF IN VIROLOGICALLY SUPPRESSED PWH IN A REAL-WORLD SETTING

F. Lombardi^{1,2}, P.F. Salvo^{1,2}, G. Balzin¹, A. Carbone¹, G. Lenzi², C. De Vivo², E. Visconti¹, E. Tamburrini^{1,2}, S. Di Giambenedetto^{1,2}, C. Torti^{1,2}

¹Dipartimento di Scienze Mediche e Chirurgiche, UOC Malattie Infettive, Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma Italia, ²Dipartimento di Sicurezza e Bioetica sezione Malattie Infettive, Università Cattolica del Sacro Cuore, Roma Italia

Background: Single-tablet regimens (STRs) can increase treatment success and improve adherence by simplifying antiretroviral therapy in people living with HIV (PWH). Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) showed efficacy and tolerability in randomized trials as a switch strategy in virologically-suppressed PWH. The aim of this study was to assess, in a real-life setting of suppressed PWH who switched to BIC/FTC/TAF, the long-term durability of this regimen in terms of both virological suppression maintenance and treatment persistence.

Methods: This was a retrospective, observational, monocentric study including virologically suppressed (HIV-RNA <50 copies/mL) PWH who switched to BIC/FTC/TAF between 2019 and 2025. The primary endpoints were the rate of virological failure (VF, i.e. two consecutive HIV-RNA $\geq$ 50 copies/mL or a single HIV-RNA $\geq$ 1000 copies/mL) and treatment discontinuation (TD) for any reason. Survival analysis with Kaplan-Meier estimator was used to assess the cumulative probability of both VF and TD. Predictors of both outcomes were identified through multivariable Cox regressions.

Results: We included 615 PWH (Table 1). Overall, 39 VF occurred during a median follow-up of 2.6 years (3.6 per 100 person-years follow-up). The estimated probability of VF at 3 and 4 years was 5.3% and 7.8%, respectively. Higher viral zenith (aHR 1.64, 95%CI 1.08-2.48, $p=0.020$), was related to a higher probability of experiencing VF, while cumulative time (years) under suppression (aHR 0.991, 95%CI 0.98-0.99, $p=0.033$) was associated with a lower likelihood of VF. TD occurred in 101 cases (3.2 per 100 patients-year of follow-up), predominantly for simplification to dual regimen (55.5%) (59% 3TC/DTG and 31% cabotegravir/rilpivirine long acting, CAB/RPV LA). Seven discontinuations due to VF were reported (6.9%). Estimated probability of TD at 3 and 4 years was 15.5% and 19.4 %, respectively. Male sex (aHR 0.45, 95%CI 0.29-0.69, $p<0.001$) and Caucasian ethnicity (aHR 0.56, 95%CI 0.33-0.94, $p=0.03$) were associated with lower probability of TD. Among participants who did not discontinue BIC/FTC/TAF ($n=514$), 342 reached 3 years of follow-up, showing a marked increase in both CD4 cell count compared with BL (median change +6 cell/ μ L at 3 years, $p<0.001$), and CD/CD8 ratio (median change +0.09 at 3 years, $p<0.001$). Regarding to the lipid parameters, after 3 years we observed a significant decrease in both total cholesterol (-7.4 mg/dL, $p<0.001$), and triglycerides (-8.5 mg/dL, $p<0.001$). Similar results were confirmed among the 197 participants who reached 4 years of follow-up.

Conclusions: In this real-world setting of suppressed PWH, BIC/FTC/TAF demonstrated high long-term durability along with immunological recovery and improvements in lipid parameters. VF correlated with higher viral zenith and shorter cumulative time under suppression. TD was mainly driven by regimen simplification, with only seven cases attributable to VF.

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Oral ART from different perspectives

SC 34 12 MONTHS EFFECTIVENESS AND SAFETY OF SWITCHING TO BIC/FTC/TAF IN VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV ON ANY ARV-REGIMENS INCLUDING NNRTIS: A RETROSPECTIVE ANALYSIS (ESSENTIAL STUDY)

M.V. Cossu¹, D. Moschese¹, M. Matone¹, G. Carrozzo¹, G. Pozza¹, A. Poloni¹, L. Albini³, G. Forcina³, A. Riva^{1,2}, A. Giacomelli^{1,2}, A. Gori^{1,2,4}

¹Department of Infectious Diseases - ASST FBF SACCO, Milan, Italy, ²DIBIC Luigi Sacco, University of Milan, Italy ³Gilead Sciences S.r.l. - Italy, ⁴Centre for Multidisciplinary Research in Health Science (MACH), University of Milan, Milan, Italy

Background: Switching antiretroviral therapy (ART) in virologically suppressed (VS) people with HIV (PWH) may optimize genetic barrier, reduce pill-burden and drug-drug interactions, and improve safety. The ESSENTIAL Study assessed the real-world effectiveness and safety of switching to bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF), including switches from rilpivirine-based regimens.

Material and Methods: ESSENTIAL Study (GS-IT-380-7059) is a single-site retrospective study including VS (HIV-RNA <50 copies/mL for ≥3 months) PWH aged ≥ 18 years who switched to BIC/FTC/TAF at ASST Fatebenefratelli Sacco from July 2019 to April 2024. Demographic, clinical and immuno-virological data were collected at baseline (time of the switch), 6 and 12 months thereafter. The primary objective was the effectiveness of BIC/FTC/TAF at 6 and 12 months after the switch (observational analysis). A 95% Confidence Interval (CI) was calculated around the observed response rates with Wald asymptotic method. A subgroup analysis evaluated individuals switching from RPV/FTC/TAF.

Results: A total of 799 PWH were included; median age 53 years, 83% had ≥1 comorbidity, and 34% taking at least 3 concomitant medications (Table 1). The main reason for switching to BIC/FTC/TAF was to increase genetic barrier (Figure 1). Virological suppression at 6 and 12 months was 97.4% (95% CI 96.3 %-98.5 %) (observed 746/766) and 98% (95% CI 97%-99%) (observed 728/743), respectively. Treatment discontinuation occurred in 4.1% (95% CI 2.8%-5.5%) (observed 33/799) at 6 months and in 3% (95% CI 1.8-4.2%) (observed 23/766) between 6-12 months. Reasons for discontinuation are reported in Figure 2, with adverse events- or toxicity-related discontinuations accounting for a minority of all treatment interruptions. Among 103 PWH switching from RPV/FTC/TAF (baseline characteristics summarized in Table 2), virological suppression rates at 6 and 12 months were 93.9% (95% CI 89.2%- 98.6%) (observed 93/99) and 98% (95% CI 95.2%- 100%) (observed 96/98), respectively.

Conclusions: In a large real-world cohort with substantial comorbidity and polypharmacy, switching to BIC/FTC/TAF showed high virological effectiveness at 6 and 12 months, with few treatment-related discontinuations. High effectiveness was also showed in individuals switching from RPV/FTC/TAF, indicating BIC/FTC/TAF is an appropriate option for optimizing regimens in treatment experienced PWH.

This study is sponsored by Gilead Sciences.

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Oral ART from different perspectives

SC 35 DRIVERS OF B/F/TAF DISCONTINUATION: REFLECTING STRATEGY RATHER THAN FAILURE OR TOXICITY

V. Cogliandro¹, N. Squillace¹, E. Ricci², P. Maggi³, L. Taramasso⁴, B. Menzaghi⁵, E. Sarchi⁶, G.V. De Socio⁷, S. Piconi⁸, G.F. Pellicano⁹, T. Bini¹⁰, G. Madeddu¹¹, S. Martini¹², E. Pontali¹³, G. Cenderello¹⁴, A. Bandera¹⁵, B.M. Celesia¹⁶, G. Orofino¹⁷, S. Ferrara¹⁸, M.A. Carleo¹⁹, A. Cascio²⁰, A. Di Biagio⁴, P. Bonfanti¹, for the CISA Study Group

¹Infectious Diseases Unit, IRCCS San Gerardo Hospital-University of Milano-Bicocca, Monza, Italy, ²Fondazione ASIA Onlus, Buccinasco (MI), Italy, ³Infectious Diseases Unit, Università degli Studi di Enna "Kore", Italy, ⁴Infectious Diseases Unit, Ospedale Policlinico San Martino – IRCCS per l'Oncologia; Department of Health's Sciences, University of Genoa, Genoa, Italy, ⁵Unit of Infectious Diseases, ASST della Valle Olona – Busto Arsizio (VA), Italy, ⁶Infectious Diseases Unit, S. Antonio e Biagio e Cesare Arrigo Hospital, Alessandria, Italy, ⁷Unit of Infectious Diseases, Santa Maria Hospital, Perugia, Italy, ⁸Unit of Infectious Diseases, A. Manzoni Hospital, Lecco, Italy, ⁹Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, AOU Policlinico G. Martino, Messina, Italy, ¹⁰Clinic of Infectious Diseases, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ¹¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Italy, ¹²Infectious Disease Unit, University Hospital Luigi Vanvitelli, Naples, Italy, ¹³Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ¹⁴Infectious Diseases Department, Sanremo Hospital, Sanremo, Italy, ¹⁵Infectious Disease Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ¹⁶Unit of Infectious Diseases, Garibaldi Hospital, Catania, Italy, ¹⁷Division I of Infectious and Tropical Diseases, ASL Città di Torino, Italy, ¹⁸Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy, ¹⁹Infectious Diseases and Gender Medicine Unit, Cotugno Hospital, AO dei Colli, Naples, Italy, ²⁰Unit of Infectious Diseases, Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties, University of Palermo, Palermo, Italy

Background: Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is one of the most used and well-tolerated regimens. Nevertheless, a minority of people with HIV (PWH) discontinued treatment. We aimed to investigate the reasons for B/F/TAF discontinuation and the regimens to which PWH were subsequently switched.

Methods: Consecutive PWH enrolled in the SCOLTA project switching to or initiating their first antiretroviral treatment (ART) with B/F/TAF were included. PWH were followed up until treatment discontinuation and information about the following regimen was collected if possible.

Results: Of 1180 enrolled PWH, 1004 had at least one follow-up visit and entered the analysis. Mean age was 48.0 years (standard deviation 12.6), 75.9% were male, and 27.9% were naïve (N) to antiretrovirals at T0 (Table 1). The median observation time was 28 months (interquartile range 14-42). During the follow-up, 211 PWH (21%) discontinued the treatment.

The most frequent causes of B/F/TAF discontinuation were: simplification to dual therapy in 47 (22.3%) PWH, switch to long-acting treatment in 29 (13.7%), adverse events in 28 (13.2%), switch to other regimes due to drug-drug interactions in 17 (8.8%), death in 9 (4.3%), treatment failure in 6 (2.8%), patient's preference in 2 (0.9%) and pregnancy in 2 (0.9%). Other reasons were listed in 14 PWH (6.6%, 9 changes of referring center and 5 enrollments to a trial) and 57 (27.0%) PWH were lost to follow-up (Table 2).

Eighty (37.0%) had no known subsequent regimen (9 PWH died, 14 changed center or started a trial, 57 were lost to follow-up). Of the 131 remaining, we had information on the following treatment in 102 (76.7%), of which 1 was suspended for 9 months. Fifty-six (55%) PWH switched to another INSTI-based regimen, while 29 (28%) to a long-acting treatment.

Conclusions: In our cohort, B/F/TAF confirmed its durability and safety with very few adverse events or treatment failures. In real-world practice, discontinuation of B/F/TAF was unrelated to toxicity or failure. Instead, it reflected proactive strategies, including switches to long-acting therapy or simplification to dual regimens driven by clinical decision-making.

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Oral ART from different perspectives

SC 36 PERSISTING ADHERENCE CHALLENGES IN HIV TREATMENT: INSIGHTS FROM A TERTIARY HIV CLINIC

E. Vania¹, F.V. Segala¹, D. Mengato², D. Leoni¹, S. Gardin¹, A. Ferrari¹, G. Berti², L. Sasset¹, A. Cattelan^{1,3}

¹Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ²Hospital Pharmacy Unit, Azienda Ospedale-Università Padova, Padua, Italy,

³Department of Molecular Medicine, University of Padua, Padua, Italy

Background: Suboptimal adherence to antiretroviral therapy (ART) remains a key challenge in HIV care. We aimed to determine the prevalence of poor ART adherence and its independent predictors among people living with HIV (PLWH) attending a tertiary HIV clinic.

Methods: This observational, retrospective cohort study included PLWH followed at our outpatient HIV clinic between January 2024 and June 2025, who had been on ART for at least six months and had a follow-up of ≥ 60 days. Adherence was measured by the Proportion of Days Covered (PDC) from pharmacy refill records and poor adherence was defined as PDC $<90\%$. Prevalence was estimated with exact Clopper-Pearson 95% CIs. Univariate comparisons used Mann-Whitney U or chi-square/Fisher's exact tests, after assessing normality by Shapiro-Wilk test. Independent predictors were identified by multivariable logistic regression with multiple imputation by chained equations (MICE; $m=20$; Rubin's rules), reported as adjusted odds ratios (aOR) with 95% CI.

Results: Among 1,485 PLWH included (median age 54.0 years [IQR 44.0–61.0]; 72.8% male) (Table 1), the prevalence of poor adherence was 46.9% (95% CI: 44.4%–49.5%) (Figure 1). Median PDC was 82.0% (IQR 71.7–87.0%) in poorly adherent vs. 94.9% (92.1–97.5%) in adherent patients. On multivariable logistic regression with multiple imputation (Table 2), independent predictors of poor adherence were: younger age (aOR 0.98 per year, 95% CI 0.97–0.99; $p=0.001$), African region of origin (aOR 1.91, 95% CI 1.08–3.40; $p=0.027$), lower educational attainment ($p=0.002$), NNRTI-based regimen (aOR 1.40, 95% CI 1.08–1.83; $p=0.012$) and PI-based regimen (aOR 2.06, 95% CI 1.27–3.36; $p=0.004$) vs. INSTI-based, and ART regimen switch during follow-up (aOR 1.76, 95% CI 1.34–2.30; $p<0.001$). Long-acting therapy was found to be protective (aOR 0.54, 95% CI 0.31–0.94; $p=0.030$). Sex, alcohol use, depression, anxiety disorder, comorbidities, and HIV transmission risk factors were not independently associated with poor adherence after adjustment.

Conclusions: Nearly half of PLWH followed at our large Italian center show suboptimal adherence. Younger age, female sex, African origin, lower education, PI-based regimens, treatment switching, and alcohol use are independent determinants of poor adherence. Our results call for renewed clinical prioritization of adherence monitoring and intervention. This focus remains essential despite the availability of simplified, better-tolerated modern regimens, as treatment advances alone cannot overcome adherence barriers without comprehensive patient support.

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Grand Round Clinical Cases

CC 1 NOT ALWAYS AIDS-RELATED: A CASE REPORT OF MANGANESE TOXICITY MIMICKING NEUROLOGICAL OPPORTUNISM IN A PWH LOST TO FOLLOW-UP

A. Repishti^{1,2}, N.B. Bana², V. Brogna^{1,2}, A. Forni^{1,2}, L. Luzi^{1,2}, F. Peracchi^{1,2}, L. Rezzonico², G. Burastero², A. Pazzi², M. Vecchi², F. Crippa³, M. Puoti², R. Rossotti²

¹University of Milano-Bicocca, Milan, Italy, ²ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ³ASST Papa Giovanni XXIII, Bergamo, Italy

Background: The management of people living with HIV (PLWH) lost to follow-up can be challenging especially due to the possible onset of opportunistic infections. However, sometimes even in these individuals clinical scenarios can be not related to HIV infection but explained by the patient's medical history or habits.

Case presentation: We present the case of a 53-year-old man living with HIV since 2013 who was lost to follow-up in 2022 (at his last evaluation, HIV RNA was undetectable and CD4+ count was 586 cells/mm³). In May 2025 the individual presented to the Emergency Department due to weight loss (approximately 24 kg over three months), impaired hand-eye coordination, ideomotor slowing and lower limb weakness. During hospitalization viroimmunological restaging was performed: HIV RNA was 648,000 copies/mL and CD4+ count was 1 cell/mm³ (ratio CD4+/CD8+ 0).

All microbiological and radiological investigations ruled out AIDS-related conditions and other common causes of neurological symptoms. Brain MRI, chest and abdominal CT scan, quantiferonTB, cryptococcal antigen, CMV-DNA and CSF studies were negative, except for CSF HIV-RNA (46 copies/mL). After exclusion of opportunistic diseases, cART with BIC/TAF/FTC was reintroduced.

Neuropsychological assessment was performed to investigate ideomotor slowing: tests confirmed impaired cognitive and executive function with marked ideational and ideomotor retardation.

During the hospital stay a package containing undefined seeds, imported from Nepal, was found at the individual's bedside. The person, as part of his customary practices, had been taking this supplement daily for an indeterminate period of time. One tablet was sent to the Toxicologic reference centre to identify its components and a high concentration of manganese was detected (36 µg/g). This supplement was therefore discontinued with progressive significant improvement of neurological symptoms. At discharge HIV-RNA was 1,000 copies/mL and CD4+ count was 23 cells/mm³.

At a follow-up visit three months after discontinuation of his daily supplement no new neurological symptoms were reported and slight improvement in the neurocognitive profile was confirmed by neuropsychological testing. The patient had gained 5 kg and VL was undetectable.

Discussion and Conclusions: Manganese excess is known to cause neurotoxic effects due to its accumulation in the basal ganglia of the brain, a deposition that is not always radiologically detectable. This accumulation may lead to neurological manifestations ranging from slowed reactions and impaired hand-eye coordination to a Parkinsonism-like syndrome. However, similar symptoms may also be caused by opportunistic conditions typically observed in people living with HIV who discontinue antiretroviral therapy. Therefore, a correct evaluation of patient's habits and medical history, together with tests for opportunistic infections, may be needed to investigate every possible cause of neurologic deterioration.

Grand Round Clinical Cases

CC 2 PREGNANCY IN WOMEN WITH MULTIDRUG-RESISTANT HIV: DREAM OR REALITY?

T. Clemente¹, G. Festa², D. Canetti¹, N. Frattini³, G. Torkjazi², D. Diana^{2,4}, F. Passini², V. Spagnuolo^{1,2}, A. Castagna^{1,2}

¹Infectious Diseases, IRCCS San Raffaele Scientific Institute, Milan, Italy, ²Vita-Salute San Raffaele University, Milan, Italy, ³Milano Checkpoint ETS, Milan, Italy,

⁴University of Naples Federico II, Naples, Italy

Background: Pregnancy poses multiple challenges in HIV management, including drug safety, pharmacokinetic changes and maintaining viral suppression to prevent mother-to-child transmission (MTCT). This is particularly relevant in women with multidrug-resistant (MDR) HIV, in whom suppression can be difficult to achieve and maintain. We report 4 pregnancies in this population.

Methods: Case series of women with ≥ 3 -class-resistant HIV, followed at IRCCS San Raffaele, who experienced pregnancy.

Results: In August 2009, a 38-year-old woman with MDR HIV [HIV diagnosis in 1996; antiretroviral therapy (ART) since 1996; CDC stage C3; Figure1] conceived while suppressed on FTC+DRV+RTV+RAL, maintaining HIVRNA <50cp/mL during pregnancy. Delivery by cesarean section was uneventful, and the infant tested HIV negative. In November 2022, the woman was still suppressed on B/F/TAF, and her daughter was in good clinical condition. She was subsequently lost to follow-up.

Similarly, in February 2011, a 45-year-old woman with MDR HIV (HIV diagnosis in 1990; ART since 1998; CDC stage C3; followed since 1999; Figure2) achieved pregnancy through medically assisted reproduction (MAR). HIVRNA was <50cp/mL on ETR+DRV+RTV+RAL at conception and throughout pregnancy. Delivery by cesarean section was regular, and the infant had negative HIV serology, RNA, and DNA. At last follow-up (September 2025), the woman remained suppressed on DRV/c/F/TAF+DTG, and her daughter was healthy.

In June 2017, a 25-year-old woman with perinatally acquired HIV and subsequent MDR (HIV diagnosis in 1992; ART since 1994; no opportunistic infections; followed since 2012; Figure3) conceived while virologically suppressed on DTG/ABC/3TC+DRV/c. ART was unchanged in agreement with her to preserve adherence; close monitoring confirmed sustained suppression and adequate DRV levels. Delivery by cesarean section was uneventful, and the infant tested HIV negative. At last follow-up (June 2025), she had low-level viremia (56cp/mL) on DTG/3TC+DOR, and her daughter was well.

Finally, in February 2025, a 40-year-old woman with perinatally acquired HIV and near-pandrug resistance (HIV diagnosis in 1991; ART since 1991; CDC stage C3; followed since 2016; enrolled in the PRESTIGIO Registry; Figure4) started MAR while suppressed on DRV/c/F/TAF+DOR+subcutaneous LEN every 6 months. In anticipation of pregnancy, cobicistat was replaced with RTV for pharmacokinetic concerns. HIVRNA remained <50cp/mL, and pregnancy (started in November 2025) was ongoing without complications at last follow-up (February 2026).

Conclusions: Pregnancy in women with MDR HIV is a complex clinical scenario requiring individualized management in experienced centers. With suppressed viremia, shared decision-making, treatment optimization and close monitoring can support favorable outcomes and prevent MTCT. These cases reinforce sexual and reproductive health rights in women with MDR HIV and help dismantle persistent stigma through evidence-based care.

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Grand Round Clinical Cases

CC 3 INTRA-HOUSEHOLD TRANSMISSION OF MPOX: A FIVE-CASE FAMILIAL CLUSTER INCLUDING PERINATAL AND PEDIATRIC INVOLVEMENT

F. Pratavera¹, M. Cotrufo¹, S. Flammini¹, S. Ferin^{1,4}, F. Colavita², F. Carletti², M. Rueca², C.E.M. Gruber², C. Pittini³, L. Driuf⁴, V. Mazzotta², A. Antinori², C. Tascini^{1,4}, F. Maggi², S. Lanini^{1,4}

¹Infectious Disease Clinic, ASUFC, Udine, Italy, ²National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy, ³Division of Neonatology, University Hospital of Udine, Udine, Italy, ⁴Department of Medicine (DMED), University of Udine, Udine, Italy

Background: Mpox virus is a double-stranded DNA virus of the Orthopoxvirus genus of the Poxviridae family. Two genetic Mpox clades have been characterised: Central African (clade I) and West African (clade II).

After the first cases described in DRC in the 1970s, in 2022 the WHO reported that Mpox was endemic in several African countries; that same year, a global multi-country outbreak was described. Most patients reported high-risk sexual behaviour as a potential risk factor, but subsequent household transmission has also been described, even to children; perinatal transmission was observed, too.

Case Series: We describe a familial cluster of Mpox clade IIb (lineage A.2.2), involving five people (Figure 1).

The index case, a 38-year-old man infected after condomless sexual intercourse in Nigeria, presented with extensive genital and cutaneous lesions. Orthopoxvirus DNA was detected in a pharyngeal swab, a penile lesion swab, swabs of the cutaneous vesicles, and blood samples. He received 20 days of tecovirimat and required penile degloving surgery with subcutaneous curettage and removal of necrotic tissue, and subsequent penile reconstruction.

His 42-year-old pregnant wife developed mild mucocutaneous lesions around ten days after giving birth, and tested positive in a pharyngeal swab, blood sample, genital vesicle swab, urine sample, and vaginal swab; she was treated with 14 days of tecovirimat with full recovery.

Their 18-year-old daughter only tested positive for Orthopoxvirus on a pharyngeal swab. She started tecovirimat, which was stopped after 3 days due to lack of clinical signs of infection.

The 2-year-old daughter developed limited skin lesions but severe ocular involvement with conjunctivitis, orbital pseudopapillitis and preseptal pseudocellulitis of the right eye, successfully treated with systemic tecovirimat and topical cidofovir. Orthopoxvirus DNA was found on a pharyngeal swab, ocular swab and swab of the cutaneous vesicles.

The 10-day-old newborn, infected at birth, presented with cutaneous disease and mild conjunctivitis and recovered after oral tecovirimat. Qualitative testing for Orthopoxvirus DNA was positive on a pharyngeal swab, blood sample, ocular swab and swab of the cutaneous vesicles.

All patients achieved complete clinical resolution.

Conclusions: Even though incidence in non-endemic countries is now decreasing, Mpox diagnosis must be taken into account in patients with risk factors that present with suggestive signs and symptoms; their household contacts should be closely monitored for the development of clinical manifestations, especially children, who are more likely to experiment severe disease.

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Grand Round Clinical Cases

CC 4 CAR-T THERAPY IN A PERSON LIVING WITH HIV AND REFRACTORY DLBCL: SAFETY, VIROLOGICAL CONTROL AND MULTIDISCIPLINARY MANAGEMENT

G. Formica¹, M.C. Gagliano^{1,2}, V. Li Vecchi¹, R. La Sala¹, G. Sapienza³, G.M.E. Colomba⁴, O. Diquattro⁴, A. Santoro⁵, L. Castagna³, R. Bono³, G. Mazzola¹

¹Infectious and Tropical Diseases Unit, Villa Sofia - V. Cervello Hospital, Palermo, Italy, ²Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G D'Alessandro," University of Palermo, Palermo, Italy, ³Bone Marrow Transplant Unit, Villa Sofia - V. Cervello Hospital, Palermo, Italy, ⁴Microbiology and Virology Unit, Villa Sofia - V. Cervello Hospital, Palermo, Italy, ⁵Cytogenetic and Oncohematological Laboratory Unit, Villa Sofia - V. Cervello Hospital, Palermo, Italy

Background: Chimeric Antigen Receptor T cells (CAR-T) are genetically engineered T lymphocytes expressing a chimeric receptor that targets tumor cells. They represent an effective immunotherapy for onco-hematological malignancies. Data on CAR-T use in people living with HIV (PLWH) and non-Hodgkin lymphoma (NHL) remain limited, as these patients were historically excluded from clinical trials. However, emerging evidence is redefining this scenario.

Case Description: A 49-year-old man was diagnosed with stage IIIA diffuse large B-cell lymphoma (DLBCL), ABC subtype, with submandibular involvement and PET hypermetabolism with colliquative features. During staging, he was newly diagnosed with HIV-1 infection - AIDS. Baseline HIV RNA was 270,000 copies/mL, CD4+ T cells 154/mm³ (22%), CD4/CD8 ratio 0.3. Antiretroviral therapy (ART) with darunavir/cobicistat/tenofovir alafenamide/emtricitabine (DRV/c/TAF/FTC) was started concomitantly with six cycles of R-CHOP and standard prophylaxis, achieving metabolic partial response. Virological suppression was obtained after approximately six weeks. Three months later, disease progression occurred. The patient was referred for CAR-T therapy with axicabtagene ciloleucel (axi-cel). Bridging therapy with polatuzumab plus rituximab, followed by Axi-cel infusion after a standard lymphodepletion with fludarabine / cyclophosphamide (FLUCY). Treatment was well tolerated. No cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), or infectious complications occurred. ART was continued without any occurrence of drug-drug interactions. Post-infusion monitoring showed maintained viroimmunological control: HIV RNA, EBV DNA, and CMV DNA remained undetectable. Absolute lymphocyte count varied from 1700/mm³ (CD4 272/mm³, 16%) day 0, to 2400/mm³ (CD4 240/mm³, 16%) at day +60 and 2700/mm³ (CD4 243/mm³, 9%, CD4/CD8 ratio 0.1) at day +90. To date, PET imaging documented disease progression with increased SUV and lesion volume. Management of relapse is ongoing.

Discussion: In this case, CAR-T therapy showed an excellent safety profile, without typical toxicities or opportunistic infections. Available literature, although limited to case reports and small series, suggests a safety profile comparable to HIV-negative individuals. Reported complete remission rates are approximately 50%, though evidence remains scarce. Sustained virological suppression and strict ART adherence appear crucial.

Future Perspectives: Further evaluation of CAR-T cell expansion kinetics and investigation of HIV genetic material within the CAR-T genome are planned. Collection of additional cases will be essential to better define the safety and efficacy of CAR-T therapy in PLWH in the field of onco-hematological malignancies.

Grand Round Clinical Cases

CC 5 INTEGRATED MULTIDISCIPLINARY MANAGEMENT OF CHEMSEX AND HIV: A CASE REPORT

A. Bianchi¹, P.L. Vinti¹, S. Nozza², M.E. Traina³, M.M. Beltrami³, G. Fracca¹, M. Cernuschi^{1,2}

¹ASA ODV, Milano, Italy, ²San Raffaele Hospital, Milano, Italy, ³SerD Canzio, Fatebenefratelli Sacco, Milano, Italy

Background: Chemsex is increasingly reported among gay, bisexual and other men who have sex with men and is associated with higher exposure to sexually transmitted infections (STIs), mental health conditions and risk of disengagement from care. In Italy, collaboration between HIV clinics, addiction services and community-based organizations is not yet standardized. We present a case from a community-based chemsex support programme, highlighting the impact of a structured multidisciplinary intervention.

Case presentation: A 44-year-old European gay man was diagnosed with acute HIV infection in 2014 (CD4 580 cells/mm³; HIV-RNA 1,772,994 copies/mL). He promptly started antiretroviral therapy (ART) with EVG/COBI/FTC/TDF, later switched to BIC/FTC/TAF, and has maintained virological suppression since January 2015.

He reported an 8-year history of chemsex, mainly involving smoked cocaine (freebase), multiple admissions for addiction treatment and several STI diagnoses (syphilis, gonorrhoea, chlamydia). After moving to Italy, he was referred in January 2025 to our community-based chemsex support programme by his HIV doctor. During our initial assessment, use of methylenedioxypyrovalerone (MDPV) emerged. At first contact, he described himself as “a lost cause”.

A structured multidisciplinary intervention was activated, involving: (1) individual and group psychotherapy within our programme; (2) referral to a specialized addiction service with expertise on chemsex support, including psychiatric evaluation and follow-up; (3) coordination with the HIV clinic to monitor adherence, viro-immunological parameters and sexual health.

In February 2026, with sustained undetectable viral load (<50 copies/mL) and CD4 1070 cells/mm³, ART was switched to long-acting CAB/RPV. At that time, he had discontinued MDPV use for three months.

Discussion: Despite long-term virological suppression, chemsex represented a significant risk for poor ART adherence. The structured multidisciplinary network ensured retention in care, supported outpatient addiction treatment and allowed therapeutic optimization, including transition to long-acting CAB/RPV. In this context, long acting ART can support adherence and prevent treatment failure. In addiction settings, joint care within a coordinated network also provides psychological containment, reduces isolation and reinforces the experience of being seen and supported.

Conclusions: This case underscores the pivotal role of community-based chemsex services within integrated care pathways for people living with HIV. Close collaboration between community organizations, addiction services and HIV clinics may support adherence and create an appropriate context for addiction care.

Grand Round Clinical Cases

CC 6 BREAKTHROUGH HIV INFECTION AFTER 6 YEARS OF DAILY TDF/FTC ORAL PREP WITH CONFIRMED OPTIMAL ADHERENCE: A CASE REPORT

N. Bana¹, D. Moschese^{2,3}, L. Rezzonico¹, E. Caruso², C. Muccini^{2,4}, G. Burastero¹, A. De Bona^{2,5}, N. Frattini², F. D'Amico¹, M. Cernuschi², E. Simoncini¹, R. Rossotti¹, M. Puoti¹

¹ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ²Milano Checkpoint ETS, Milan, Italy, ³ASST Fatebenefratelli-Sacco, Milan, Italy, ⁴San Raffaele Scientific Institute, Milan, Italy, ⁵ASST Santi Paolo e Carlo, Milan, Italy

Background: Oral PrEP is highly effective for HIV prevention when adherence is optimal. True PrEP failures—HIV acquisition despite documented adequate drug exposure—are rare, and reported cases have typically occurred within the first 1–2 years of PrEP use. We report a late-breaking case of breakthrough HIV infection occurring after prolonged daily PrEP use, representing the longest duration before failure reported to date.

Methods: Clinical, behavioural, virologic, and pharmacologic data were collected from a 46-year-old MSM receiving daily TDF/FTC since 2019 through a community-based PrEP program in Milan, Italy. Adherence was assessed by self-report, pharmacy dispensing records, plasma and hair tenofovir therapeutic drug monitoring (TDM). HIV diagnosis, resistance testing, and treatment outcomes were reviewed.

Results: After approximately six years of daily PrEP, routine quarterly HIV testing identified seroconversion in October 2025. The patient reported high adherence (29/30 doses in the prior month), confirmed by pharmacy refill history and plasma tenofovir concentration (75 ng/mL within 24 hours of last dose), consistent with optimal recent adherence. Fourth-generation HIV Ag/Ab testing and Western blot were fully positive, with HIV-1 RNA 29,500 copies/mL and CD4 count 1,165 cells/mm³, making acute infection unlikely. GRT identified a recombinant HIV-1 strain (CRF24_BG) with M184V and K70E reverse transcriptase mutations, conferring high-level resistance to emtricitabine and low-level resistance to tenofovir. It was not possible to determine whether these resistance-associated mutations were transmitted at acquisition or selected during infection under drug pressure. Immediate antiretroviral therapy with FTC/TAF/DRV/c+DTG was initiated, achieving viral suppression (36 copies/mL) within one month. After that, the patient requested switching to long-acting regimen and he was started on CAB/RPV LA, with very good tolerability and maintaining viral suppression.

An hair sample was sent to the University of California in San Francisco (US) for TDM monitoring before cART start. Results came back in February 2026 and were consistent with correct daily TDF/FTC before the acquisition of HIV infection during PrEP (Fig.1 and Fig.2): in particular, tenofovir concentration remained >0.038 ng/mg in every hair segment, which is the median tenofovir hair concentration after 7 doses/week for 6 weeks.

Conclusions: This case represents a rare, well-documented true PrEP failure after the longest reported duration of daily TDF/FTC PrEP with confirmed optimal adherence. It highlights that breakthrough HIV infection can occur even after many years of successful PrEP use. Ongoing HIV surveillance and access to alternative strategies remain critical for long-term sustainability.

Figure 1, Figure 2

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Advanced Diagnostics

P 1 A NEW POINT OF CARE TESTING (POCT) FOR RESPIRATORY PATHOGEN DETECTION: COMPARISON OF THE HYSEN POCT ANALYZER WITH CONVENTIONAL RT-PCR

G. Garzillo¹, C. Fracalvieri¹, M. Lucente¹, B. Galano¹, M. Ferraris¹, G. Guarona², S. Ferrari¹, V. Chessa¹, R. Qosja¹, A. Orsi²

¹U.O. Igiene, IRCCS AOM- Azienda Ospedaliera Metropolitana, Genova, Italy, ²Dipartimento di Scienze della Salute (DiSSal), Università di Genova, Italy

Background: The diagnostic management of respiratory tract infections (RTIs) remains a challenge due to the overlapping clinical presentations of viral and bacterial pathogens. Especially in emergency departments, reducing the turn-around time (TAT) is crucial for patient triaging, initial clinical management and antimicrobial stewardship. Point of Care Testing (POCT) platforms offer decentralized molecular results in less than an hour. However, their integration into clinical workflows requires validation against high-throughput gold-standard methods. This study evaluates the diagnostic accuracy of the Hysen Biotech All-in-One Analyzer (POCT) in a real-world hospital setting.

Materials and Methods: A total of 358 nasopharyngeal swabs from symptomatic patients to Regional Reference Laboratory of Hygiene at the IRCCS AOM were analyzed. Each sample was processed using two methods:

1. Gold Standard: nucleic acids were extracted using the STARlet workstation (Seegene) and analyzed via multiplex RT-PCR using SARS-CoV-2/Flu/RSV and the Allplex™ Respiratory Panels 1-4 assays.

2. POCT: utilizing microfluidic-based PCR technology (MUR-24E chip), integrated automated extraction and detection to provide results in 59 minutes.

As the 2 platforms detect different sets of analytes (e.g., Allplex includes additional bacteria while POCT includes Coronavirus HKU1), the diagnostic performance was assessed by comparing only the results for the shared targets between the 2 panels. Statistical parameters were calculated based on these overlapping analytes.

Results: Out of 358 samples, 266 (74.3%) were positive by the gold-standard method. POCT demonstrated an overall sensitivity of 86.1% (229/266) and a specificity of 78.2%. The PPV was high at 92%, while the NPV was significantly lower at 66%, with an overall accuracy of 84%. A total of 127 (35%) showed some degree of discordance. Specifically, the POCT yielded 37 false-negative results. The most frequent "missed" pathogens were Influenza A (n=10), Human Rhinovirus (n=9), RSV (n=6), and Coronavirus 229E (n=4). Additionally, 20 false-positive results were recorded (including SARS-CoV-2 and various Coronaviruses). The lower sensitivity was particularly evident in samples with high Cycle Threshold values in RT-PCR, suggesting a higher limit of detection for the POCT platform compared to conventional RT-PCR. The concordant and discrepant results are shown in Figure 1 and Figure 2, respectively.

Conclusions: The POCT platform provides a user-friendly and rapid solution for respiratory screening, showing excellent PPV for major pathogens. However, the observed 14% gap in sensitivity and the low NPV (66%) represent a clinical concern. In high-risk patients, negative results obtained via POCT should be interpreted with caution and confirmed by standard RT-PCR. This study highlights that while POCT accelerates initial diagnosis, it should complement rather than replace centralized laboratory testing in complex hospital settings.

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Advanced Diagnostics

P 2 ANAL HPV SCREENING IN PLWH: SELF-SAMPLING CONCORDANCE AND OPTIMIZATION OF INVALID RESULTS

G.B. Tassone¹, M.A. Zingaropoli², Xh. Xhuli¹, E.N. Cavallari¹, E. Coratti¹, M. Bernassola², D.M. Rodio², L. Santinelli¹, S. Fontana¹, G. d'Ettore¹, G. Antonelli², O. Turriziani²

¹Sapienza University of Rome, Rome, Italy, ²Policlinico Umberto I, Sapienza University of Rome, Rome, Italy

Background: Anal cancer incidence is significantly higher in high-risk groups, particularly PLWH, yet international guidelines lack consensus on screening. Stigma and psychological discomfort hinder uptake. While HPV-DNA testing is cervical gold standard, anal application faces technical challenges and regulatory gaps. This study aimed to optimize anal HPV screening by evaluating a sequential dilution protocol to reduce the invalid results and assessing the diagnostic performance and concordance of self-collected (SCA) versus clinician-collected (CCA) anal swabs to overcome screening barriers.

Materials and Methods: Both SCA and CCA were analyzed using the Alinity m HR HPV assay (Abbott Molecular), detecting 14 high-risk genotypes. SCA were collected immediately prior to CCA. Samples failing the beta-globin internal control (invalid) underwent sequential 1:2 dilutions in a transport buffer to mitigate PCR interference. Diagnostic performance and agreement between SCA and CCA were evaluated.

Results: Between September 2023 and February 2026, 1,499 diagnostic specimens were analyzed. Samples were primarily cervical (888, 59.2%) and anal (577, 38.5%) (see Table). Anal samples showed significantly higher HPV positivity (57.1% vs 30.8%; $p < 0.0001$), multiple genotype detections (28.4% vs 11.7%; $p < 0.0001$), and invalidity rates (18.7% vs 0.2%; $p < 0.0001$) compared to cervical samples (see Table). Among PLWH undergoing anal HPV screening, a higher positivity rate was observed compared with non-PLWH (66.8% vs 49.4%, $p = 0.0002$), while the invalidity rates were comparable. Due to high invalidity in anal samples, a sequential dilution protocol was implemented: of 577 anal specimens, 187 (32.4%) were initially invalid. First and second dilution steps recovered 58 (31.0%) and 21 samples (16.3%), rescuing 79/187 (42.2%) and reducing final invalidity rate from 32.4% to 18.7%.

In a subgroup of 48 paired SCA and CCA, invalid rates were 10.4% (5/48) for SCA and 12.5% (6/48) for CCA. Using CCA as reference, SCA demonstrated 90.9% sensitivity (95% CI: 72.2–97.5) and 69.2% specificity (95% CI: 50.0–83.5) for HR-HPV detection, with moderate agreement ($\kappa = 0.48$, 95% CI: 0.22–0.74). Negative predictive value was 90.0%, supporting self-sampling as a rule-out strategy.

Conclusions: Anal samples present higher diagnostic complexity than cervical ones. A sequential dilution protocol effectively reduces PCR inhibition, minimizing re-sampling needs and accelerating diagnosis. The high sensitivity and negative predictive value of SCA, despite moderate specificity, support their feasibility as a patient-friendly screening tool to overcome stigma-related barriers and increase uptake in vulnerable populations. The high anal prevalence observed underlies the need to strengthen HPV vaccination in men and implement targeted screening strategies for PLWH.

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Advanced Diagnostics

P 3 EVALUATION OF WHOLE GENOME SEQUENCING OF HIV-1 PROVIRAL DNA (WGS-DNA) FOR DRUG RESISTANCE TESTING

F. Stefanelli¹, N. Randazzo¹, N. Nigro¹, M. Lucente¹, G. Garzillo¹, M. Ferraris¹, V. Chessa¹, R. Qosja¹, L. Taramasso¹, V. Ricucci¹, B. Bruzzone¹

¹IRCCS Azienda Ospedaliera Metropolitana San Martino Hospital, Genoa, Italy, ²University of Genoa, Genoa, Italy

Background: In the era of fully suppressive antiretroviral therapy, HIV-1 RNA is frequently undetectable and viral persistence resides in integrated proviral DNA. When historical resistance data are unavailable, sequencing of proviral HIV-1 DNA may recover archived resistance-associated mutations (RAMs) and support clinical decision-making. Whole-genome sequencing (WGS) extends this approach beyond pol, enabling broader RAMs assessment and genome integrity. We evaluated the feasibility and analytical performance of proviral WGS (WGS-DNA) and its association with quantitative HIV-DNA levels and markers of proviral defectiveness.

Materials and Methods: Proviral HIV-1 DNA was extracted from 200uL of frozen whole blood and quantified using the HIV-1 DNA assay (Diatheva) on automated platform (Elitech Ingenious). DNAs were amplified using the AD4Seq HIV Whole Genome (Arrow Diagnostics) and sequenced on the Illumina iSeq100 platform. FASTQs were processed through an in-house pipeline for coverage analysis. Resistance-associated mutations (RAMs) in the pol region were interpreted using the Stanford HIV Drug Resistance Database, as well as proviral defectiveness, assessed by evaluating APOBEC-associated hypermutation patterns, premature stop codons and unusual mutations.

Results: HIV-DNA levels ranged from 34 to 830 copies/10⁶ cells, reflecting substantial inter-individual variability. All samples were subtype B. WGS-DNA amplification was successful in 91.3% of samples (21/23). Among these, median genome coverage at 100× was 69.5% (IQR 51.4–78.9). High genome recovery (>80%) was achieved in 17.4% of samples at 100× and 48% at 30× depth. Coverage was heterogeneous across genomic regions (Figure 1), while amplicon-level analysis revealed dropout patterns (Figure 2). No correlation was observed between HIV-DNA levels and genome coverage (Spearman $\rho=0.09$, $p=0.71$). Markers of proviral defectiveness were also detected: APOBEC-related mutations in 28.6% of samples, stop codons in 23.8%, and unusual mutations in 19.0%. At least one pol RAM was identified in 61.9% of samples (detailed in Table 1). Stratification by HIV-DNA level suggested a higher relative abundance of defectiveness markers and pol RAMs in samples with <100 cp/10⁶ cells compared with the other groups.

Conclusions: HIV-1 WGS-DNA is technically feasible and demonstrates reliable analytical performance in the pol region, supporting resistance interpretation in suppressed individuals. Genome recovery across the full provirus is heterogeneous and not predicted by quantitative HIV-DNA levels alone, indicating that template integrity likely plays a major role. These findings support the use of proviral WGS for resistance assessment, while emphasizing the need to account for genome completeness and defectiveness when interpreting results. Ongoing analyses integrating additional clinical and virological parameters aim to refine predictors of sequencing success and define the clinical role of proviral WGS.

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Advanced Diagnostics

P 4 INTERPRETATIVE CHALLENGES OF RESPIRATORY SYNDROMIC PANELS: AGE-RELATED PREVALENCE, CO-DETECTION, AND CYCLE THRESHOLDS

M.A. Zingaropoli¹, G.B. Tassone², E. Coratti², D.M. Rodio¹, M. Bernassola¹, R. Campagna², L. Caivano², F. Pulcinelli³, F. Midulla³, G. Galardo⁴, A. Pierangeli², G. Antonelli², O. Turriziani²

¹Microbiology and Virology Unit, Policlinico Umberto I, Sapienza University of Rome, Italy, ²Department of Molecular Medicine, Sapienza University of Rome, Italy, ³Department of Pediatrics and Infantile Neuropsychiatry, Sapienza University of Rome, Italy, ⁴Department of Medical and Cardiovascular Sciences, Sapienza University of Rome, Italy

Introduction: Multiplex syndromic panels have revolutionized respiratory diagnostics, yet interpreting multiple positive targets remains challenging. This study evaluates age-related pathogen prevalence, seasonal dynamics, and Cycle threshold (Ct) values to establish a pathogen-specific hierarchy of clinical relevance.

Materials and Methods: In this retrospective, single-center study, nasopharyngeal specimens from hospitalized patients with suspected acute respiratory infections (ARIs) were analyzed using the QIAstat-Dx® Respiratory SARS-CoV-2 Panel. Patients were stratified into pediatric (<18years) and adult (≥18years) cohorts. Pathogen prevalence, co-detection patterns, and Ct values were compared. A median-based Delta Ct ($\Delta Ct = Ct_{\text{target}} - Ct_{\text{co-pathogen}}$) was calculated to determine pathogen dominance in co-detections.

Results: During the post-pandemic period (2023–2025), 2,479 nasopharyngeal swabs were analyzed; 54.4% tested positive for ≥1 pathogen. Positivity was significantly higher in pediatric vs adult patients (69.8% vs 28.4%; $p < 0.0001$). Predominant pathogens included Rhinovirus/Enterovirus (RV/EV, 42.2%), Respiratory syncytial virus (RSV, 15.1%), and Influenza (13.2%). Co-detections occurred in 24.7% of positive samples, primarily in pediatric group (28.6% vs. 8.8%; $p < 0.0001$); common combinations included RV/EV+Adenovirus (Adv) (15.9%) and RV/EV+RSV (12.0%). Statistically significant differences in Ct values between single and multiple detections were observed for two pathogens. For Adv and SARS-CoV-2, Ct values were significantly higher in samples positive for multiple targets compared to those observed for Adv and SARS-CoV-2 alone ($p = 0.0392$ and $p = 0.0071$, respectively) (Table). Semi-quantitative analysis revealed a replicative hierarchy: RSV and Influenza maintained low Ct values regardless of co-infection (“apex pathogens”), whereas RV/EV, Adv, and Bocavirus showed significantly higher Ct values when co-detected (“bystander”). Specifically, RV/EV Ct values were higher vs HMPV ($p = 0.0014$), HPIV ($p = 0.0007$), Influenza ($p = 0.0084$), and RSV ($p < 0.0001$). Similarly, Adv Ct values exceeded those of RSV ($p = 0.0046$) (Figure). Seasonal analysis confirmed perennial RV/EV circulation contrasting with sharp winter peaks for RSV and Influenza. A significantly higher percentages of B. pertussis-positive samples was detected in 2023/24 compared to 2024/25 (9.0 % versus 0.1%, $p < 0.0001$). Influenza positivity surged from 9.5% (winter 2023/24) to 24.5% (2024/25; $p < 0.0001$), driven by Influenza A/H3.

Discussion: Qualitative detection alone is insufficient for interpreting respiratory co-detections. Our ΔCt -based framework proposes a clinically actionable hierarchy: seasonal drivers (RSV/Influenza) typically dominate over persistent agents (RV/EV, Adv/Bocavirus). Integrating semi-quantitative data into syndromic panel reporting could enhance diagnostic stewardship, optimize antimicrobial use, and improve resource allocation in high-pressure clinical settings.

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Advanced Diagnostics

P 5 PERFORMANCE OF HIV-1 WHOLE-GENOME SEQUENCING IN HIV-RNA POSITIVE PLASMA SAMPLES

A. Callegaro¹, M. Mazzoni¹, S. Uceda Renteria¹, G. Bozzi², A. Parisi¹, V. Castelli², B. Mariani², A. Muscatello², A. Bandera^{2,3}, C. Alteri^{1,4}

¹Microbiology and Virology Unit, IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ²Infectious Diseases Unit, IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ³Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy, ⁴Department of Oncology and Hemato-oncology, University of Milan, Milan, Italy

Background: Whole-genome sequencing (WGS) of HIV-1 permits the comprehensive characterization of viral diversity, drug-resistance mutations, and transmission dynamics beyond the limits of pol sequencing. However, its implementation in clinical practice remains challenging.

Material and Methods: HIV-1 positive plasma samples were processed for WGS using the QIAseq xHYB HIV-1 kit (Qiagen) and sequenced on the MiSeq platform (Illumina). A fully reproducible analysis pipeline was implemented in Snakemake. Preliminary consensus genomes were generated using the HIV-1 reference K03455 and queried by BLAST against a custom database of complete HIV-1 genomes to select the best sample-specific reference. Consensus sequences and SNP tables were rebuilt using this reference. Variant calling was performed with LoFreq using a 1% allele frequency cut-off. Consensus sequences were aligned with 555 HIV-1 reference genomes, and subtype assignment was performed by maximum-likelihood phylogenetic inference in IQ-TREE2 under the GTR+G4 model. Drug resistance was also assessed.

Results: Nineteen HIV-1 RNA samples from drug-naïve individuals living with HIV with a median viral load of 3.05×10^5 copies/mL (interquartile range [IQR]: 5.51×10^4 – 9.98×10^5 copies/mL) were processed and analyzed by WGS. Sequencing performance demonstrated high overall genome recovery across samples, but for two (a B and a CRF02 subtype). The median genome coverage was 5,926x (IQR: 920x–45,961x). Median genome coverage at >100x depth was 95.15% (IQR: 88.13%–97.20%). A median of 3.87% of bases was at zero coverage (IQR: 1.06%–7.33%). Low-coverage regions were consistently observed at nucleotide positions 7110–7468 (K03455 coordinates), indicating systematic limitations in the env V3–V5 region. Phylogenetic analysis showed subtype B in 5 samples (29.4%), followed by CRF02_AG (4, 23.5%), CRF01_AE (2, 11.8%), and single representatives of A1, A6, CRF66_BF1, CRF46_BF1, 19_CPX, and 121_0107CN. Phylogeny confirmed pol-based subtype assignment for all samples except for an F1 pol sequence becoming a CRF66_BF1. Eight (47.1%) samples carried at least one resistance-associated mutation. While no major PI or INSTI resistance mutations were found, NRTI- and NNRTI-associated mutations were observed in 2 (11.8%) and 4 (23.5%) samples each. Outside pol, WGS identified two Dolutegravir-associated mutations in one 66_BF1 and one B sample (env A539V and Y61H). Fostemsavir-associated gp120 substitutions were detected in 5 samples (env M426L in one CRF66_BF1, M434I in one A1 and one CRF02_AG, M475I in one CRF01_AE, and M426R in one B), while only the accessory mutation to Lenacapavir T107A in gag was found in two CRF02_AG samples.

Conclusions: WGS enables comprehensive HIV-1 characterization beyond pol. Low coverage in env regions indicates the need for improved enrichment and analytical strategies to ensure complete genome reconstruction for clinical and surveillance applications.

Advanced Diagnostics

P 6 **PERSISTENT ATYPICAL HIV-1 VIREMIA DETECTED EXCLUSIVELY VIA THE POL TARGET USING A DUAL-TARGET (POL AND LTR) ASSAY: A CASE REPORT HIGHLIGHTING A NOVEL DIAGNOSTIC CHALLENGE**

A. Amendola, S. Belladonna, F. Smoquina, G. Capecci, V. Mazzotta, M.G. Bocci, F. Maggi, F. Forbici, L. Fabeni

National Institute for Infectious Diseases (INMI) "Lazzaro Spallanzani" IRCCS, Rome, Italy

Background: Monitoring HIV-1 viral load (plasma HIV-RNA, VL) in persons living with HIV-1 (PWH) is a cornerstone of clinical management to assess the efficacy of antiretroviral therapy (ART) and to track disease progression. Among currently available commercial assays for VL assessment, the Aptima HIV-1 Quant Dx assay (Hologic, Inc., San Diego, CA, USA) employs dual-target amplification of the pol region and the LTR combined with dual-probe detection using two distinct fluorescent probes, one specific for each amplified region. This design generates two VL measurements from the same plasma sample: one corresponding to pol and the other to LTR. In routine reporting, the final result of VL is typically based on the pol target, as it represents one of the most conserved regions of the viral genome and as the viremia derived from the LTR target generally does not significantly differ from the pol-based measurement.

We report the case of a 48-year-old PWH with plasma HIV-RNA consistently detectable only through amplification of the pol region, whereas the LTR target remained persistently undetectable with the Aptima assay.

Material and Methods: The patient was admitted to the Intensive Care Unit of the INMI due to severely compromised clinical conditions marked by interstitial pneumonia with positive SARS-CoV-2 antigen test, multiple concurrent infections (*Klebsiella pneumoniae*, *Aspergillus* spp., *Pneumocystis jirovecii*, and *Candida albicans*) and severe immunosuppression (CD4+ T-cell count: 59 cells/mm³; CD4/CD8 ratio: 0.050). During hospitalization, his clinical course was further complicated by reactivation of CMV, EBV, HHV-8, and TTV.

Results: At hospital admission, the patient presented with an unusual HIV-1 VL (534,708 copies/mL) measurable exclusively via amplification of the pol target using the Aptima assay, whereas the LTR target was not-detected. Antiretroviral therapy (ART) with Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide; BIC/FTC/TAF) was initiated, leading to a progressive decline in HIV-1 viremia to <30 copies/mL. During follow-up, VL remained detectable solely through the pol target, with persistent absence of signal from the LTR target.

Near full-length next-generation sequencing (NFL-NGS) of viral RNA in baseline plasma sample revealed an intact subtype B virus, including the LTR region. No resistance-associated mutations or deletions were identified.

Conclusions: Further investigations are ongoing. However, it should be noted that selective detection of VL through a single target is technically plausible with the Aptima platform, as it relies on two distinct fluorescent probes, each specific for one viral target. In prior studies, we described individuals on fully suppressive ART who exhibited high-level VL quantification exclusively via the LTR target. More recently, we have observed rare cases of PWH on ART showing viremia detectable only through the pol target, as illustrated in the present case.

Advanced Diagnostics

P 7 SOMETIMES LESS IS MORE: IMPACT OF INPUT VOLUME ON HIV-1 PROVIRAL DNA WHOLE-GENOME SEQUENCING

F. Stefanelli¹, N. Randazzo¹, N. Nigro¹, G. Garzillo¹, G. Guarona², S. Ferrari¹, S. Varesano¹, M. Giurco², A. Di Biagio^{1,2}, L. Taramasso¹, B. Bruzzone¹

¹IRCCS Azienda Ospedaliera Metropolitana San Martino Hospital, Genoa, Italy, ²University of Genoa, Genoa, Italy

Background: Proviral HIV-1 DNA genotypic resistance testing is increasingly used to compensate GRT-RNA unfeasibility in virologically suppressed individuals. However, the high proportion of defective proviruses within the latent reservoir may complicate the interpretation of resistance-associated mutations, particularly when occurring at APOBEC-driven hypermutation hotspots. We evaluated whether increasing blood input volume during extraction improves genomic coverage and overall sequence reliability in proviral HIV-1 whole-genome sequencing.

Methods: Frozen whole blood samples from HIV-1 infected individuals were processed in parallel using two extraction approaches: 400 μ L of blood eluted in 50 μ L and 200 μ L of blood eluted in 100 μ L (Elitech Ingenious automated platform). Proviral DNA, after HIV-DNA quantification, underwent whole genome amplification followed by sequencing on iSeq100 (Illumina). FASTQ data were compared for coverage and resistance associated mutations detection (RAMs). APOBEC-associated hypermutation patterns, as well as stop codons and unusual mutations were assessed using Stanford HIV drug resistance database.

Results: Eight subtype B samples were processed in parallel. HIV-DNA cp/10⁶ cells ranged from 15 to 830 (median 139; IQR 49–404.5). One low-copy sample (15 cp/10⁶ cells) failed amplification under both conditions and was excluded, leaving seven evaluable pairs. Median genome coverage $\geq 100\times$ was 69% with 200–100 compared to 49% with 400–50. Pol coverage $\geq 100\times$ was consistently higher with the 200 μ L protocol (median 100% vs 31%), showing that increasing input volume (400–50) did not improve genome coverage (Figure 1). Median sequencing depth was comparable between conditions, indicating that reduced coverage with higher input was not attributable to insufficient reads but likely to reduced amplification efficiency. Qualitative differences were substantial: APOBEC-associated mutations were detected in 85.7% of sequences generated with 400–50 compared to 28.6% with 200–100; Stop codons were observed in 71.4% vs 14.3%, respectively, and unusual mutations in 42.9% vs 14.3%, as showed in Figure 2. In two samples, the higher-input protocol was associated with marked increases in APOBEC-related substitutions accompanied by multiple premature stop codons.

Conclusion: Increasing blood input volume did not improve genome completeness in proviral HIV-1 WGS. Instead, higher input was associated with a marked increase in APOBEC-mediated hypermutation and premature stop codons, indicating preferential amplification of defective proviral templates rather than enhanced recovery of intact genomes. These findings demonstrate that, in proviral WGS, increasing template quantity does not inherently improve analytical performance and may compromise the biological reliability and interpretability of resistance profiles.

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Advanced Diagnostics

P 8 THE FUTURE IS NOW: HIV-1 WHOLE GENOME SEQUENCING FOR COMPREHENSIVE DRUG RESISTANCE TESTING

F. Stefanelli¹, N. Randazzo¹, N. Nigro¹, M. Lucente¹, C. Fracalvieri¹, B. Giusto¹, G. Cologgi², L. Taramasso¹, A. Di Biagio^{1,2}, B. Bruzzone¹

¹IRCCS Azienda Ospedaliera Metropolitana San Martino Hospital, Genoa, Italy, ²University of Genoa, Genoa, Italy

Background: Genotypic resistance testing (GRT) in HIV-1 is routinely restricted to the pol region, as it encodes the viral enzymes targeted by the main antiretroviral drug classes currently used in clinical practice. However, the introduction of novel drug classes targeting other viral proteins, such as capsid and entry inhibitors, requires us to go beyond pol. This is now possible thanks to Whole Genome Sequencing (WGS), which enables simultaneous assessment of resistance, subtype characterization and epidemiological information with a single sequence. This study evaluated the diagnostic performance of HIV-1 WGS compared with routine targeted pol-based GRT in a diagnostic setting.

Material and Methods: HIV-1 RNA-positive samples, having a different viral loads and subtypes, previously characterized by routine pol sequencing, were re-analyzed using a WGS assay on the Illumina iSeq100. FASTQ files were processed using a commercial software and an in-house bioinformatic pipeline. Sequencing performance was evaluated by median read depth (MRD) and coverage. Resistance-associated mutations (RAMs) within pol were compared with the reference method using the Stanford HIV Drug Resistance Database. WGS data were additionally leveraged for gag mutation profiling and phylogenetic subtype assignment.

Results: Forty-seven samples were analyzed. WGS achieved a MRD of 3494 reads and a median genome coverage of 94%, with gag and pol consistently covered at more than 95% across all viral loads, whereas some accessory genes and env showed reduced coverage uniformity at lower RNA levels. Viral load significantly affected genome coverage at 100x (Fig.1). RAMs analysis of the pol region showed 87.5% concordance between WGS and routine pol-based GRT; with 100% for major resistance mutations, 38% for accessory mutations, and 87% for other mutations. Discordances mainly involved variants close to the detection threshold. Genome-wide exploration revealed 57 natural gag polymorphisms, most frequent showed in Figure 2. No established lenacapavir RAMs were detected. Subtype assignment was evaluable in 41 samples due to incomplete genome coverage. Phylogenetic analysis showed 88% overall concordance with pol subtype assignment (36/41 samples). Concordance was higher for pure subtypes (93%), whereas discordances primarily involved Circulating Recombinant Forms (CRF), including reassignment from pure subtype to recombinant lineages based on WGS phylogenetic analysis (Fig. 3).

Conclusions: WGS demonstrated full concordance for clinically relevant major resistance mutations compared with routine pol sequencing, supporting its reliability for diagnostic resistance testing. Beyond pol, WGS enables genome-wide resistance surveillance and improved characterization of recombinant forms without additional laboratory workflow. These findings support the integration of WGS as a comprehensive and future-oriented tool for next-generation HIV drug resistance diagnostics.

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Ageing and HIV

P 9 AGING AND MORTALITY AMONG PEOPLE WITH DIAGNOSED HIV IN ITALY: RECENT TRENDS AND PROJECTIONS

A. Viguerie¹, V. Regine², L. Pugliese², B. Suligo²

¹University of Urbino, Urbino, Italy, ²Italian National Institute of Health, Rome Italy

Background: Antiretroviral therapy (ART) has substantially increased life expectancy among persons with diagnosed HIV (PWDH) in Italy, leading to an increasingly older population. This presents challenges, as older PWDH are more susceptible to age-related health morbidities compared to the general population. This study aims to quantify present and future demographic trends among Italian PWDH.

Methods: We use ensemble Kalman filtering to assimilate HIV surveillance data into a continuously age-structured demographic model to reconstruct PWDH mortality dynamics and demographic structure through 2024. These reconstructions are then used to generate data-driven projections of future age-structured mortality and incidence trends. Together with the reconstructed demographic profile, the projections are used to produce forecasts for HIV prevalence, incidence, and mortality in Italy through 2035.

Results: The PWDH population increased from approximately 112,000 persons in 2012 to 140,000 in 2024, and is forecast to reach 155,000 by 2035 (Figure 1). This growth is primarily driven by declining mortality, with further decreases projected. Persons over 60, estimated as 8.6% of the PWDH population in 2012, had increased to over 20% by 2020, and are projected to reach 47.2% by 2035. By 2030, over 10% of PWDH in Italy are projected to be over 75, compared to less than 1% in 2012 (Figure 2).

Conclusions: Our results demonstrate that the Italian HIV care infrastructure must prepare for a dramatic shift from managing a predominantly young-adult disease to caring for a majority-elderly population within the next decade, representing an unprecedented transformation in the nature and scope of required services.

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Ageing and HIV

P 10 BIC/FTC/TAF IN PEOPLE WITH HIV AGED ≥ 50 YEARS: A 24-MONTH REAL-WORLD ANALYSIS

G. Moi¹, A. De Vito¹, S. Spampinato², D. Bivona², S. Daquduqi³, S. Sofia⁴, G. Pantò⁴, C. Iacobello⁴, M. Averna², B. Celesia², A. Marino², G. Nunnari², G. Madeddu¹

¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ²Infectious Diseases Unit, ARNAS Garibaldi Hospital, Department of Clinical and Experimental Medicine, University of Catania, Catania, Italy, ³School of Medicine, University of Sassari, Sassari, Italy, ⁴Unit of Infectious Diseases, AOE "Cannizzaro", Catania, Italy

Background: The aging population of people with HIV (PWH) requires antiretroviral regimens that ensure long-term efficacy, tolerability, and durability. Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a recommended integrase inhibitor-based regimen with a favorable safety profile, but real-world long-term data in older individuals are limited.

Methods: We conducted a retrospective observational study including all experienced PWH aged ≥ 50 years who switched to B/F/TAF. Demographic, clinical, immunovirological, and metabolic data were collected at baseline and at 12 and 24 months. The primary outcomes were virological efficacy (HIV-RNA suppression), treatment discontinuation, and reasons for discontinuation. Secondary outcomes included changes in CD4 count and metabolic parameters. Kaplan–Meier analysis was used to estimate the probability of treatment discontinuation.

Results: A total of 182 PWH were included, with a median age of 58 years (IQR 54–62.2); 73.1% were male and 25.8% female. The population was predominantly Caucasian (97.8%), with a long history of HIV infection and significant comorbidity burden, including hypertension (28.0%), dyslipidemia (28.6%), and psychiatric disorders (14.3%). At baseline, 15.9% had HIV-RNA >50 copies/mL.

Virological suppression improved over time, with the proportion of individuals with target not detected (TND) increasing from 52.7% at baseline to 56.1% and 55.2% at 12 and 24 months, respectively, while the proportion with HIV-RNA >200 copies/mL markedly decreased during follow-up. CD4 cell count remained stable at 12 months and significantly increased at 24 months ($p=0.006$). The CD4/CD8 ratio showed a non-significant upward trend.

Metabolic parameters were largely stable over time. Total cholesterol showed a modest reduction at 12 and 24 months ($p=0.0005$ and $p=0.0097$, respectively). Triglycerides decreased at 24 months ($p=0.0049$). Liver and renal function parameters remained stable throughout follow-up.

Overall treatment durability was high. The cumulative probability of discontinuation was 3.37% (95% CI 1.53–7.34) at 12 months and 5.07% (95% CI 2.67–9.52) at 24 months. Discontinuations were uncommon and mainly due to adverse events, treatment simplification, patient decision, and virological failure. Discontinuation due to virological failure and adverse events remained rare.

Conclusion: In this real-world cohort of PWH aged ≥ 50 years, BIC/FTC/TAF demonstrated high virological efficacy, good immunological recovery, and a favorable metabolic profile up to 24 months. The regimen showed excellent durability, with low rates of discontinuation and very rare virological failure. These findings support the use of BIC/FTC/TAF as a safe and effective treatment option in older PWH, including those with multiple comorbidities.

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Ageing and HIV

P 11 **BOOSTED ANTIRETROVIRAL REGIMENS ARE STRONGLY ASSOCIATED WITH CLINICALLY SIGNIFICANT DRUG-DRUG INTERACTIONS IN PEOPLE LIVING WITH HIV AGED ≥ 65 YEARS**

R. Ferri, T. Ascione, S.G. Rizzello, M. Pontolillo, K. Falasca, J. Vecchiet

Clinic of Infectious Diseases, SS. Annunziata Hospital - G. D'Annunzio University, Chieti- Pescara, Italy

Background: As people living with HIV (PLWH) grow older, the clinical focus is progressively to the management of comorbidities and polypharmacy. In this context, drug-drug interactions (DDIs) represent an increasingly relevant safety issue, particularly in patients receiving pharmacokinetic boosting.

Methods: We performed a retrospective observational study including PLWH aged ≥ 65 years followed at a tertiary care centre. For each patient, we collected demographic data, number of chronic non-ART medications, antiretroviral regimen, CD4 count at diagnosis and CDC stage. All potential DDIs between ART and concomitant drugs were systematically assessed using the Liverpool HIV Drug Interactions Checker and classified as red (contraindicated), orange (potentially clinically significant), or yellow (weak interaction). Red and orange interactions were considered clinically significant. Polypharmacy was defined as ≥ 5 chronic non-ART drugs. Boosted regimens were defined as including ritonavir or cobicistat.

Results: Thirty patients were included (mean age 69.9 years). The mean number of chronic non-ART medications was 7.2; 80% of patients were exposed to polypharmacy and 23% were taking ≥ 10 drugs. Overall, 40% of patients experienced at least one clinically significant DDI. Weak (yellow) interactions were even more frequent (50%), highlighting a substantial background pharmacological burden even when interactions were not immediately contraindicated. Eight patients (26.6%) were receiving a boosted regimen. Clinically significant DDIs occurred in 87.5% of boosted patients compared with 22.7% of those on non-boosted regimens (OR ≈ 24). Polypharmacy (≥ 5 drugs) was associated with a four-fold increase in the odds of clinically significant DDIs (OR ≈ 4.2).

The drug classes most frequently involved reflected the comorbidity profile of ageing patients and included lipid-lowering agents, psychotropic drugs, and anticoagulant or antiplatelet agents, followed by cardiovascular drugs. Most clinically significant interactions were mechanistically related to CYP3A4 inhibition driven by boosted PIs, whereas CYP induction and absorption-related interactions were less prominent.

No consistent association was observed between immunological status at diagnosis and DDI risk. Notably, among patients with clinically significant DDIs, approximately half reported not routinely disclosing their HIV status to other specialists, potentially increasing the risk of unrecognized interactions outside dedicated HIV care.

Conclusions: In PLWH aged ≥ 65 years, DDIs are common and largely shaped by the intersection between ageing-related comorbidity and pharmacokinetic mechanisms. While polypharmacy contributes substantially to interaction risk, boosted regimens appear to be the strongest driver of clinically significant DDIs. Structured medication review using validated tools, together with improved interdisciplinary communication and HIV status disclosure, is essential to reduce preventable pharmacological harm in older PLWH.

Ageing and HIV

P 12 **CARDIOVASCULAR PREVENTION IN PEOPLE AGEING WITH HIV: STATIN UPTAKE IN LOMBARDY, 2019-2025**

S. Villa^{1,2}, M. Maffeo^{1,2}, C. Tincati³, V. Iannone^{4,2}, L. Rezzonico⁵, L. Pezzati⁶, F. Conti⁷, E. Quiros-Roldan⁸, C. Fornabaio⁹, P. Vitiello¹⁰, L. Pagnucco^{11,2}, A. Bandera¹², V. Spagnuolo¹³, P. Bonfanti^{14,15}, M. Melazzini¹, G. del Castillo^{1,2}, D. Cereda^{1,2}

¹Directorate General for Health, Lombardy Region, Milan, Italy, ²Regional Center for Infectious Diseases – CEREMI - Lombardy Region, Milan, Italy, ³Infectious Disease Unit, ASST Santi Paolo e Carlo, Milan, Italy, ⁴Infectious Disease Unit, ASST Fatebenefratelli Sacco, Milan, Italy, ⁵Infectious Disease Unit, ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ⁶Infectious Disease Unit, ASST Ovest Milanese, Legnano, Italy, ⁷Infectious Disease Unit, ASST Lecco, Lecco, Italy, ⁸Infectious Disease Unit, ASST Spedali Civili, Brescia, Italy, ⁹Infectious Disease Unit, ASST Cremona, Cremona, Italy, ¹⁰Infectious Disease Unit, ASST Valle Olona, Busto Arsizio, Italy, ¹¹Infectious Disease Unit, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy, ¹²Infectious Disease Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ¹³Infectious Disease Unit, Fondazione IRCCS San Raffaele, Milan, Italy, ¹⁴Infectious Disease Unit, IRCCS San Gerardo dei Tintori, Monza, Italy, ¹⁵University of Milano-Bicocca, Milan, Italy

Background: People ageing with HIV (PWH) have a higher risk of developing atherosclerotic cardiovascular disease (ASCVD) than the general population because of the direct effects of HIV, antiretroviral drugs, immune activation, and immunodeficiency. In Italy, about 50% of PWH is aged ≥ 50 years and 20% will be over 65 years by 2030.

A phase 3 trial published in 2023 – the REPRIEVE trial – reported strong evidence in ASCVD prevention, especially of major cardiovascular events, using statins in PWH. Following this, the European AIDS Clinical Society provided the first key recommendations on the use of moderate-intensity statins in PWH.

In the Lombardy Region, the increased ASCVD risk in PWH has led to the development of dedicated care pathways in 2025. However, little is known about the implementation at local level of the guidelines.

Material and Methods: We conducted a retrospective observational study analysing regional electronic health records from direct drug distribution and drug prescription from 2019 to 2025.

Direct distribution data were used to define the study population under antiretroviral therapy based on a combination of ATC codes recorded each year, using the first available date as the index one. Because one hospital has historically sent anonymized data, it was excluded from the analysis.

Using a pseudo-anonymized identifier, we ascertained whether the subject received any statin prescription, either alone or in combination with other lipid-lowering agents. Once a subject was classified as receiving statins, they were considered exposed for all subsequent years of observation.

Descriptive analyses were conducted to compute the share of PWH exposed to statins over the years, stratified by sex, age group, and country of origin.

Results: Across the study period, PWH ranged between 25,550, in 2019, to 26,651, in 2023. The proportion of subjects under statins increased from 17.8% in 2020 to 39.1% among all PWH in the region.

The proportion of PWH on statins increased over the study period, especially between years before (2019-22, 19.8%) and after the REPRIEVE trial (2023-25, 33.1%). Statin uptake in subjects aged 18-49 increased from 6.7% to 14.1%, from 24.1% to 37% among those 50-64 years, and from 43.6% to 54.8% among those 65+. The upward trend was consistent over time and did not differ by sex (Fig.1) or country of origin (Fig.2).

Comparing predictions from historic trends with observed post-2023 data (Fig.3), observed statin uptake exceeded projected values, especially among those aged 50-64 years, indicating an acceleration beyond prior trends.

Conclusions: This is the first analysis to explore the implementation of ASCVD prevention among the ageing population of PWH in Lombardy, with a comparison between the years before and after the REPRIEVE trial. Future analyses will further explore the ASCVD burden in this population to better guide future public health interventions in the region.

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Ageing and HIV

P 13 DYNAMIC OF BLOOD TELOMERE LENGTH IN ART-NAIVE PWH OVER TWO YEARS AFTER STARTING ART

F. Lombardi^{1,2}, M. Fabbiani³, P.F. Salvo^{1,2}, G. Balzin¹, A. Carbone¹, S. Colaiuda², E. Visconti¹, E. Tamburrini^{1,2}, C. Torti^{1,2}, S. Di Giambenedetto^{1,2}

¹Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma, Italia, Dipartimento di Scienze Mediche e Chirurgiche, UOC Malattie Infettive, ²Università Cattolica del Sacro Cuore, Roma, Italia, Dipartimento di Sicurezza e Bioetica sezione Malattie Infettive, ³UOC Malattie Infettive e Tropicali, Azienda Ospedaliero-Universitaria Senese, Siena, Italy

Background: People with HIV (PWH) show a marked shortening of blood telomere length (BTL) early after seroconversion. This is caused by uncontrolled viral replication with sustained immune activation, immunosenescence and inhibition of telomerase by HIV proteins. Antiretroviral therapy (ART) causes an increase in naive and central memory cells that have longer telomeres, leading to an overall BTL increase. However, it has been shown that several antiretroviral drugs negatively affect the BTL gain. We investigate the potential influence of starting INSTI-based ART and other factors on BTL variation over 96 weeks.

Methods: In this prospective longitudinal study, we enrolled ART-naive PWH who started ART from December 2018 to September 2025, with no AIDS events. We assessed BTL by monochrome multiplex qPCR (expressed as telomere to single-copy gene ratio, T/S) at the time of ART initiation (baseline, BL), virological success (VS) (achievement of HIV-RNA<50cps/mL), and at week 48 (W48) and 96 (W96). We used a repeated-measures mixed model to evaluate the dynamic of BTL over time and to identify other variables potentially affecting the BTL changes over time.

Results: We enrolled 94 participants who met the inclusion criteria (Table 1). The median age was 39 years, 81% were male, 83% were Caucasian and 96% had acquired HIV infection via sexual transmission. The median HIV-1 RNA load was 4.9 log₁₀ HIV-1 RNA cps/mL, the median CD4 cell count was 291 cells/ μ L, and the median CD4/CD8 ratio was 0.4. All PWH reached VS with a median time of 55 (IQR 27-115) days from ART initiation. The majority of participants (88%) started ART within one month from diagnosis, specifically most of them, 65% initiated a triple therapy (TT) and the remaining 35% started a dual therapy (DT). Overall, the mean BTL increased over the 2 years without reaching statistical significance ($p=0.152$). However, we observed no variation up to both VS ($+0.08$, $p=0.821$) and W48 ($+0.022$, $p=0.503$) and a significant gain at W96 when compared to BL ($+0.087$, $p=0.024$). BTL gain was associated with younger age (per 1 year increase mean change -0.05 95%CI -0.07 to -0.03 ; $p<0.001$). A stronger positive correlation was observed between the recovery of CD4 cell counts and BTL gain ($+0.167$, $p=0.002$). A sub-analysis restricted to the TT group did not identify any association with BTL change and use of TDF ($n=20$) or TAF ($n=41$) ($p=0.183$). In an additional sub-analysis including 60 PWH, 30 in the TT group and 30 in the DT group, matched for age, sex, zenith HIV-RNA and nadir CD4, the BTL gain was not correlated with a reduction of treatment burden ($p=0.125$).

Conclusions: In this setting, ART-naive PWH showed a smooth increase in the BTL over time soon after starting ART. However, they did not show any significant change in BTL after 1-year follow-up, while a marked gain was observed after two years. These data suggest a beneficial long-term effect of ART on telomere length recovery, regardless of regimen.

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Ageing and HIV

P 14 ESTIMATES OF HIV-DIAGNOSED AND HIV-UNDIAGNOSED USING ECDC HIV-MODELLING TOOL, ITALY 2010-2024

M. Dorrucchi, V. Regine, L. Pugliese, B. Suligoi

Department of Infectious Diseases, National Institute of Health, Rome, Italy

Introduction: Although the rate of new diagnoses in Italy has decreased over the past 10 years, late diagnoses increased since 2015. This could affect the extent and trend of undiagnosed infections and for this reason, our objective was to obtain an estimate of the number of individuals who ignore their HIV status, as well as monitor their trend.

Material and Methods: We applied the ECDC modelling tool (vers. 3.1.2) considering all HIV diagnoses registered in the Italian HIV Surveillance System from 2010 to 2024. In brief, the tool uses surveillance data categorized by CD4 count at diagnosis into four strata (≥ 500 , 350–499, 200–349, < 200) and apply a multi-state back-calculation assuming 1980 as the start of the epidemic, with user-defined intervals to specify the probability of diagnosis over calendar period. In particular, we made two alternative hypotheses on the probability of diagnosis: in the first (Model A) we assumed a constant diagnosis probability during 2010–2024 with a change in 2012 when all Italian regions were included in Surveillance System (100% coverage). In the second hypothesis (Model B), we added a change in 2017 approximately halfway through the period, when we observed a significant decrease in the diagnoses. Of note, in the models we did not consider possible deaths for the HIV diagnoses.

Results: Estimates of HIV-diagnosed and undiagnosed are shown in the figure by the model A and the model B. In both models, we estimated a similar increasing trend of total diagnosed, whilst a nearly constant decline in HIV-undiagnosed cases, with a slight increase starting in 2017 in model B (Figure). These estimates were for model A and B in 2024, respectively: 136.058 diagnosed (95% CI: 115.060 - 157.496) and 127.552 diagnosed (95% CI: 110.890 - 146.885), whilst those undiagnosed were 8.812 (7.424 - 10.332) and 9.800 (95% CI: 7.438 - 11.790).

Conclusions: We estimated a number of undiagnosed of about 8.800 to 9.800 according to different probability of diagnosis assumptions in the tool, with slightly higher model B-estimate, most likely due to the increase in late diagnoses in recent years. We estimated a decline in undiagnosed, independently of the assumptions made in diagnosis probability. The estimates of both total diagnosed and undiagnosed cases obtained using the tool were similar to those estimated at the beginning of the study period using other methods and sources, especially in the case of Model B (1). The most recent estimates of those diagnosed in 2024 should be confirmed by an ongoing CARPHA 3 study on all PLHIV in Italy.

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Ageing and HIV

P 15 FROM SURVIVAL TO MEANING: STIGMA, MULTIMORBIDITY AND INTIMACY AS CORE DIMENSIONS OF AGING WITH HIV IN ITALY

G. Giupponi¹, A. Castro², S. Penon³, M. Giannelli⁴, A. Bianchi⁵, S. Cecere⁶, N. Policek⁷, E. Marra⁸, C. Buellis⁹, G. Guaraldi¹⁰

¹LILA Nazionale Como Italy, ²University of Milan Bicocca Milan Italy, ³LILA Milano Italy, ⁴LILA Bari Italy, ⁵ASA Milan Italy, ⁶PLUS-rete Persone LGBT+ Bologna Italia, ⁷NPS Italia Milano Italia, ⁸Plus Roma Roma Italy, ⁹CICA Milano Italy, ¹⁰University of Modena e Reggio Emilia, Modena, Italy

Background: As the population of people living with HIV aged ≥ 50 years increases, understanding aging in this context requires moving beyond epidemiological indicators to actively listening to lived experience. Focus groups represent a key qualitative methodology to explore collective meaning-making, shared narratives, and socially embedded experiences that may remain invisible in quantitative surveys. Within the Italian Ministerial Project “Healthy Aging in People with HIV”, conducted in collaboration between the Azienda Ospedaliero-Universitaria Policlinico di Modena and 12 national HIV community-based associations and stakeholder organizations, focus groups were implemented as an initial exploratory phase. The objective was to capture the voices of older PWH, identify emerging psychosocial and structural needs, and generate an empirically grounded framework to inform subsequent national survey development and policy-oriented interventions.

Materials and Methods: Eleven focus groups were conducted nationwide with over 80 participants aged ≥ 50 years. Seven groups included participants aged 50–64 years and four involved participants aged ≥ 65 years. The FG protocol, co-constructed community stakeholders, explored topics about aging perceptions, HIV treatment and adherence, comorbidity management, cognitive concerns, quality of life, housing, relationships and intimacy, interactions with healthcare professionals, and experiences with the welfare system. Recorded sessions were transcribed verbatim, and analyzed using reflexive thematic analysis via Atlas.ti software. A collaboratively developed codebook guided iterative coding, theme refinement, and interpretative synthesis. Findings were triangulated with existing literature.

Results: Seven themes were Aging with HIV intertwines clinical management of the virus and comorbidities with psychological well-being, as persistent internalized and structural stigma hinders healthcare engagement and self-perception. People shift from early survival focus to seeking stability, relationships, and meaning; while HIV feels manageable, multimorbidity, frailty, and cognitive decline dominate aging concerns. Antiretrovirals are life-saving yet burdensome, needing better communication; intimacy suffers from shrinking networks, disclosure fears, and scarce services, fostering isolation. Peer communities provide belonging amid fragmented medical-social support, while views on death evolve with age, health, and relationships.

Conclusions: These national qualitative findings demonstrate that aging with HIV in Italy is shaped by the interaction of biomedical, psychosocial, relational, and structural dimensions. Healthy aging cannot be reduced to viral suppression or comorbidity control, but requires integrated, person-centered models addressing stigma, intimacy, community belonging, and end-of-life dialogue. These findings informed a national ministerial survey and provide evidence for restructuring care pathways.

Ageing and HIV

P 16 **NEGATIVE IMPACT OF ANTICHOLINERGIC BURDEN ON DEPRESSION, ANXIETY AND QUALITY OF LIFE IN OLDER PEOPLE LIVING WITH COMPARED TO HIV-NEGATIVE CONTROLS: DATA FROM ITALIAN MULTICENTRE GEPPPO COHORT**

B. Fioretti¹, S. Calza², S. Arsuffi¹, E. Goffi³, A. Coin⁴, C. Mussi⁵, A. Riva⁶, S. Piconi⁷, S. Nozza⁸, J. Milic⁹, N. Squillace¹⁰, G. Bellelli¹¹, G. Guaraldi⁹, A. Calcagno¹², A. Marengoni³, E. Focà¹

¹Division of Infectious and Tropical Diseases, Department of Clinical and Experimental Sciences, University of Brescia and ASST Spedali Civili of Brescia, Brescia, Italy, ²Unit of Biostatistics and Bioinformatics, Department of Molecular and Translational Medicine, University of Brescia, Brescia, Italy, ³Division of Geriatrics, Department of Clinical and Experimental Sciences, University of Brescia and ASST Spedali Civili of Brescia, Brescia, Italy, ⁴Division of Geriatrics, Department of Medicine (DIMED), University of Padova, Padova, Italy, ⁵Division of Geriatrics Medicine Dept of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Modena and Reggio Emilia, Italy, ⁶3rd Division of Infectious Diseases, University of Milano, Ospedale L. Sacco, Milano, Italy, ⁷Infectious Diseases Unit, Alessandro Manzoni Hospital, Lecco, Italy, ⁸Clinic of Infectious Diseases, San Raffaele Scientific Institute, Milano, Italy, ⁹Department of Surgical, Medical, Dental and Morphological Sciences, University of Modena and Reggio Emilia, Modena e Reggio Emilia, Italy, ¹⁰Infectious Diseases Unit, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy, ¹¹Acute Geriatric Unit, Fondazione IRCCS San Gerardo dei Tintori, Monza and School of Medicine and Surgery, University of Milano-Bicocca, Milan, Italy, ¹²Division of Infectious Diseases, Department of Translational medicine, UPO - Università del Piemonte Orientale, Novara, Italy

Background: Older people living with HIV (OPLWH) experience persistent immune activation, chronic neuroinflammation, and features of accelerated brain aging despite effective antiretroviral therapy. These mechanisms may reduce central cholinergic reserve and increase vulnerability to centrally acting medications. Anticholinergic burden (ACB) has been consistently associated with cognitive impairment in the general geriatric population, whereas its relationship with neuropsychiatric symptoms and quality of life has been less extensively investigated. Whether HIV status modifies these neuropsychiatric effects remains unclear.

Methods: We performed a cross-sectional analysis within the Italian multicenter GEPPPO cohort including 1,668 OPLWH and 121 HIV-negative controls aged ≥ 65 years. ACB exposure was defined as ACB ≥ 1 using the Anticholinergic Cognitive Burden scale. Outcomes included depressive symptoms (CES-D), anxiety (HAM-A), sleep quality (PSQI), and quality of life (EQ-5D-3L). Generalized linear models (Tweedie or Beta regression as appropriate) assessed associations between ACB, HIV status, and their interaction, adjusting for age, sex, BMI, multimorbidity, and polypharmacy. Complete-case analyses were performed for each outcome.

Results: OPLWH were younger than controls (69.8 ± 4.7 vs 79.5 ± 6.3 years; $p < 0.001$), predominantly male (82% vs 36%; $p < 0.001$), and had lower BMI (25.7 ± 4.3 vs 26.5 ± 4.0 ; $p = 0.037$). Polypharmacy was less frequent among OPLWH (14% vs 34%; $p < 0.001$), and ACB > 1 was also lower (9.4% vs 45%; $p < 0.001$).

Among OPLWH, ACB was independently associated with higher depressive symptoms (CES-D ratio=0.732; $p = 0.019$), higher anxiety (HAM-A ratio=0.489; $p < 0.001$), and lower quality of life (EQ-5D-3L estimate=0.676; $p = 0.013$), with a trend toward poorer sleep quality (PSQI ratio=0.643; $p = 0.093$) (Figure 1). No significant associations were observed among HIV-negative controls (all $p > 0.3$). Interaction analyses supported a differential effect of ACB according to HIV status across affective domains.

Conclusions: Anticholinergic burden was associated with worse affective and quality-of-life outcomes exclusively among OPLWH. These findings suggest that HIV-related neurobiological vulnerability may amplify the central effects of anticholinergic exposure. Structured medication review and deprescribing strategies may represent modifiable interventions to mitigate neuropsychiatric burden in OPLWH.

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Ageing and HIV

P 17 PATIENTS' AND PHYSICIANS' MOTIVATIONS FOR CONSIDERING LONG ACTING CABOTEGRAVIR AND RILPIVIRINE IN OLDER PEOPLE WITH HIV

A. Riva¹, J. Milic², B. Fioretti³, C. Candela⁴, F. Barrera⁵, N. Gemignani⁶, L. Curci⁷, S. Gardini⁸, N. Squillace⁹, A. Franzò¹⁰, A. De Vito¹¹, M.V. Cossu¹, S. Nozza⁴, S. Piconi⁶, G.V. De Socio⁷, L. Sasset⁸, P. Bonfanti⁹, B.M. Celesia¹⁰, G. Madeddu¹¹, S. Calza¹², E. Foca³, G. Guaraldi², A. Calcagno¹³

¹Department of Infectious Diseases, University of Milan, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ²Department of Surgical, Medical, Dental and Morphological Sciences, University of Modena and Reggio Emilia, Modena, Italy, ³Department of Infectious and Tropical Diseases, University of Brescia and ASST Spedali Civili Hospital, Brescia, Italy, ⁴Infectious Disease Unit, Università Vita Salute San Raffaele, Milano, Italy, ⁵Unit of Infectious Diseases, Department of Medical Sciences, University of Turin, Turin, Italy, ⁶Infectious Diseases Unit, Alessandro Manzoni Hospital, Lecco, Italy, ⁷Infectious Diseases Clinic, Santa Maria Della Misericordia Hospital, Department of Medicine, University of Perugia, Perugia, Italy, ⁸Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ⁹Infectious Diseases Unit, IRCCS Fondazione San Gerardo dei Tintori, Monza (MB), Italy, ¹⁰Unit of Infectious Diseases, Department of Experimental and Clinical Medicine, ARNAS Garibaldi Hospital, University of Catania, Catania, Italy, ¹¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ¹²Unit of Biostatistics and Bioinformatics, Department of Molecular and Translational Medicine, University of Brescia, Brescia, Italy, ¹³Department of Translational Medicine, University of Eastern Piedmont, Novara, Italy

Background: Long-acting injectable cabotegravir/rilpivirine (LA-CAB/RPV) represents an alternative to daily oral ART that may mitigate treatment fatigue and polypharmacy in older people with HIV (OPWH). Whether patient-physician motivational discordance observed in the general population persists in geriatric patients remains unclear.

Methods: We conducted a cross-sectional study including 928 OPWH aged ≥ 65 years from the GEPO cohort. Participants and physicians independently completed structured questionnaires on motivations for LA-CAB/RPV. Data are presented as number (%) or median (IQR).

Results: Median age was 69.9 years; 81% were male at birth. Median CD4 count was 649 cells/mm³, and 82% had HIV-RNA < 50 copies/mL. Multimorbidity and polypharmacy were present in 26% and 52%, respectively.

Overall, 351 participants (41%) were interested in LA-CAB/RPV. They had slightly lower CD4 counts and a different comorbidity profile (less osteoporosis and diabetes, more neoplastic disease). Main motivations were convenience (20%), forgetfulness (12%), and refusal of oral pills (5.5%). Among those not interested, reasons included bi-monthly hospital visits (36%, with preference for ≥ 6 -month intervals), satisfaction with current therapy (33%), and concomitant oral medications (12%). Psychosocial concerns persisted: 9.6% feared disclosing HIV status, 6.1% worried about forgetting pills, and 17.8% perceived pills as reminders of HIV (Figure 1).

Physicians considered LA-CAB/RPV in 387 cases (44%), mainly for treatment simplification (32%), combined clinical considerations (3.9%), and suspected suboptimal adherence (3.9%). Among those not considering it, reasons included perceived lack of need (19%), concomitant oral drugs (11%), hospital visit burden (14%), and implementation issues (10%). Resistance mutations to NNRTIs and INSTIs were reported in 8.6% and 1.9%, respectively; HBV infection in 1.3% (Figure 1).

Agreement between participants and physicians was moderate (70.6%, Cohen's kappa 0.34), with significant asymmetry ($p=0.035$): 37% of participants disagreed with physicians' interest, versus 30.8% of physicians disagreeing with participants' interest.

Conclusions: In OPWH aged ≥ 65 years, approximately 40% of both patients and physicians consider LA-CAB/RPV appropriate. Despite advanced age, multimorbidity and polypharmacy, the divergence in motivations closely parallels that described in younger populations. Patients prioritize convenience and psychosocial relief, whereas physicians focus on clinical simplification and long-term safety. These findings reinforce that chronological age per se should not be viewed as a barrier to offering long-acting therapy. Rather, within a healthy ageing framework, long-acting ART may represent an opportunity to support autonomy, reduce treatment burden, and address persistent stigma in later life.

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Ageing and HIV

P 18 THE HIDDEN WORKFORCE OF HIV AGING: CAREGIVING, STIGMA AND SYSTEM FRAGMENTATION IN THE ITALIAN MINISTERIAL HEALTHY AGING PROJECT

A. Castro², C. Buellis³, M. Belli¹, G. Giupponi⁴, G. Guaraldi¹

¹University of Modena and Reggio Emilia, Modena, Italy, ²University of Milan Bicocca, Milan, Italy, ³CICA, Milan, Italy, ⁴LILA Nazionale Como, Italy

Background: The rise of people living with HIV aged ≥ 60 years increases, caregiving dynamics are becoming a central yet underexplored dimension of aging with HIV. Compared to other chronic conditions, limited evidence addresses the experiences and needs of those caring for HIV elders particularly in relation to HIV-related stigma, multimorbidity, and fragmentation between health and social services. Within the Italian Ministerial Project "Healthy Aging in People with HIV".

Materials and Methods: We conducted 2 focus groups with professional and family caregivers, recruited via collaborations with the Polyclinic of Modena and 12 national HIV community-based associations and stakeholders. Their aim was to explore caregiving roles, unmet needs, and structural gaps shaping care trajectories for this social group. FG were recorded, transcribed verbatim, and analyzed using reflexive thematic analysis via Atlas.ti. An iterative, collaboratively developed codebook guided theme generation.

Results: Six interrelated themes were constructed regarding caregiving identity, stigma experiences, comorbidity management, system navigation, relational dynamics, and end-of-life perspectives. Specifically: Managing ageing and stigma, Surviving or living everyday, Lucky to be here, The burden of care, Housing and community, Death, dying, and meaning-making.

Caregivers of older people with HIV face intersecting challenges: HIV stigma amplified by ageism leads to concealment and isolation; multimorbidity and frailty overshadow viral control as key burdens; family members view care as relational reciprocity rather than a formal role, often coordinating fragmented services themselves (finding policies like Italy's Law 104/1992 inadequate). Professionals endure heavy emotional labor without support, while death is normalized in the community but poorly addressed institutionally through dialogue or palliative care.

Conclusions: Caregivers of older people with HIV represent a critical yet largely invisible workforce within the HIV aging ecosystem. Their narratives reveal relational resilience alongside significant systemic gaps in integration, psychosocial support, and anti-stigma interventions. Embedding caregivers within person-centered care planning, strengthening health-social integration, and expanding psychological and respite services are essential to promote healthy aging trajectories. These findings inform policy development and integrated care design within the broader Ministerial Healthy Aging framework.

Ageing and HIV

P 19 THE PICTORIAL FIT-FRAILTY SCALE AND PATIENT-REPORTED OUTCOMES IN OPTIMALLY-TREATED PERSONS WITH HIV

A. Barco¹, M. Sacchetti², O. Bargiacchi¹, F. Rinaldi¹, A.D. Frere², M. Colafigli³, F. Del Puente⁴, A. Lanzardo⁵, S. Tunesi⁵, D. Val⁶, F. Barrera⁶, L. Binaschi², A. Calcagno^{1,7}

¹SCDO Malattie Infettive, AOU Maggiore della Carità, Novara, Italy, ²S.S.D Psicologia Clinica, AOU Maggiore della Carità, Novara, Italy, ³Infectious Diseases Unit, U. Parini Hospital, Aosta, Italy, ⁴Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ⁵Infectious Diseases Unit, AOU SS Antonio e Biagio e C. Arrigo, Alessandria, Italy, ⁶Unit of Neurology, Maria Vittoria Hospital, Turin, Italy, ⁷Department of Translational Medicine, Università del Piemonte Orientale, Novara, Italy

Background: Frailty is increasingly recognized among persons with HIV (PWH) despite effective antiretroviral therapy (ART). The Pictorial Fit-Frailty Scale (PFFS) is a rapid visual tool potentially useful for identifying individuals at risk. We evaluated the association between PFFS-defined vulnerability and patient-reported outcome (PRO) impairments in optimally treated PWH.

Methods: In this cross-sectional study, 108 randomly selected antiretroviral-treated PWH attending outpatient care were enrolled. Clinical, therapeutic and demographic variables were recorded. Participants underwent mini-Addenbrooke Cognitive Examination Test (MACE), Beck Depression Inventory II (BDI-II), Hamilton Anxiety Rating Scale (HAM-A), Pittsburgh Sleep Quality Index (PSQI), EQ-5D-5L (QOL), Grooved Pegboard Test (GPT) and Pictorial Fit-Frailty Scale (PFFS). Data are shown as numbers (percentage) or median (IQR).

Results: All participants [median age 58 (51-64) years] were on antiretroviral treatment with HIV RNA<50 copies/mL. We recorded a long HIV duration [14.3 (4.2-19.5) years] and high CD4 count [537 (400-774) cells/mm³]. Comorbidities were common, including, dyslipidemia (40.0%), hypertension (37.8%), anxiety/depression disorders (24.4%), and diabetes (17.8%). Moderate/severe depressive symptoms were reported by 7 (BDI-II≥20, 6.5%) participants while moderate/severe anxiety by 30 (HAMA ≥18, 27.7%). We observed poor sleep quality (PSQI≥5) and low quality of life (EQ-5D-5L<90%) in 52 (54.2%) and 83 (84.7%) individuals. Low cognitive performance (MACE≤23) and impaired fine motor function (non dominant hand GPT≥2SD) were recorded in 23 (21.3%) and 29 (29.6%) study participants. PFFS frailty index was 0.16 (0.09-0.20) and identified 19 (17.6%) and 10 (9.3%) as moderately or severely frail: the domains mostly reported as abnormal were polypharmacy (36, 37.9%), social connections (26, 26.8%), and fatigue (13, 13.4%). Frailty index was associated with sleep quality ($\rho=0.413$, $p<0.001$), depressive symptoms ($\rho=0.596$, $p<0.001$), anxiety ($\rho=0.577$, $p<0.001$), and quality of life ($\rho=-0.505$, $p<0.001$).

Conclusions: In optimally treated PWH with durable virological control, the PFFS identifies individuals at increased risk of multidimensional impairment and worse patient-reported outcomes, including depression, anxiety, sleep disturbance, reduced quality of life. The PFFS may represent a practical first-line screening tool to flag patients warranting comprehensive geriatric or multidisciplinary assessment.

Antiretroviral Therapy

P 20 B/F/TAF VS DTG: SIMILAR DURABILITY, DIFFERENT REASONS FOR DISCONTINUATION. RESULTS OF A REAL-LIFE STUDY

V. Cogliandro¹, N. Squillace¹, E. Ricci², G. Orofino³, L. Taramasso⁴, B. Menzaghi⁵, P. Maggi⁶, S. Piconi⁷, G.F. Pellicano⁸, E. Sarchi⁹, G.V. De Socio¹⁰, G. Madeddu¹¹, R. Gulminetti¹², E. Pontali¹³, B.M. Celesia¹⁴, T. Bini¹⁵, E. Salomoni¹⁶, G. Cenderello¹⁷, S. Martini¹⁸, A. Bandera¹⁹, M.A. Carleo²⁰, S. Ferrara²¹, A. Di Biagio⁴, P. Bonfanti¹, for the CISAI Study Group

¹Infectious Diseases Unit, Fondazione IRCCS San Gerardo Hospital-University of Milano-Bicocca, Monza, Italy ²Fondazione ASIA Onlus, Buccinasco (MI), Italy, ³Division I of Infectious and Tropical Diseases, ASL Città di Torino, Italy, ⁴Infectious Diseases Unit, Ospedale Policlinico San Martino – IRCCS per l'Oncologia; Department of Health's Sciences, University of Genoa, Genoa, Italy, ⁵Unit of Infectious Diseases, ASST della Valle Olona – Busto Arsizio (VA), Italy, ⁶Università degli Studi di Enna "Kore", Enna, Italy, ⁷Unit of Infectious Diseases, A. Manzoni Hospital, Lecco, Italy, ⁸Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, AOU Policlinico G. Martino, Messina, Italy, ⁹Infectious Diseases Unit, S. Antonio e Biagio e Cesare Arrigo Hospital, Alessandria, Italy, ¹⁰Unit of Infectious Diseases, Santa Maria Hospital, Perugia, Italy, ¹¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Italy, ¹²Fondazione IRCCS Policlinico S. Matteo, Infectious Diseases, University of Pavia, Pavia, Italy, ¹³Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ¹⁴Unit of Infectious Diseases, Garibaldi Hospital, Catania, Italy, ¹⁵Clinic of Infectious Diseases, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ¹⁶Unit of Infectious Diseases, Santa Maria Annunziata Hospital, Bagno a Ripoli, Florence, Italy, ¹⁷Infectious Diseases Department, Sanremo Hospital, Sanremo, Italy, ¹⁸Infectious Disease Unit, University Hospital Luigi Vanvitelli, Naples, Italy, ¹⁹Infectious Disease Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ²⁰Infectious Diseases and Gender Medicine Unit, Cotugno Hospital, AO dei Colli, Naples, Italy, ²¹Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy

Background: Nowadays, the INSTI-based regimens with bictegravir (BIC) and dolutegravir (DTG) represent the cornerstone of antiretroviral treatment (ART). Our study aimed to investigate the durability of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) and DTG-based regimens and their safety in a real-life setting.

Methods: Consecutive people with HIV (PWH) enrolled in the SCOLTA project who either initiated their first ART with, or switched to a regimen containing BIC or DTG combination were included. DTG-based regimens comprised 2-drug regimens (2DR) with atazanavir, darunavir, rilpivirine or lamivudine (3TC) and 3-drug regimens (3DR) with 3TC/abacavir, F/TAF or F/TDF. PWH were followed up until treatment discontinuation and grade 3-4 adverse events (AE) were recorded. The observation was truncated to 48 months. Hazard ratios (HRs) and 95% confidence intervals (CIs) for discontinuation were estimated using the Cox proportional hazards model. A multivariate model including all variables that differed significantly between treatment groups or were associated with treatment interruptions was run, with a retention criterion set at $p=0.20$. A competitive model was also performed for each cause of discontinuation.

Results: Of 2668 enrolled PWH, 2359 were treated with one of the included regimens and had at least one follow-up visit: 1002 in B/F/TAF (42.3%), 595 (25.2%) in DTG-2DR and 762 (32.3%) in DTG-3DR regimens. In the DTG-2DR group, the most represented regimens were DTG/3TC (382, 64.2%) and DTG/RPV (134, 22.6%); in the DTG-3DR group, it was DTG/3TC/ABC (445, 58.4%). The baseline characteristics are reported in Table 1.

Forty-eight months after the study started, 199 (19.8%), 113 (19.0%) and 256 (33.6%) respectively discontinued the cohort treatment (reference B/F/TAF: HR 0.86, 95% CI 0.68-1.10 for DTG-2DR, HR 1.18, 95% CI 0.98-1.43 for DTG-3DR). In the multivariate model for any cause discontinuation (including sex, CD4, risk factor for HIV acquisition, CDC stage, naïve status, HIVRNA at T0, dyslipidemia and current ART regimen), higher CD4 at T0 were associated with lower risk. In contrast, female sex, past intravenous drug use, naïve status and entering the study with previous ART treatment but detectable HIVRNA were associated with higher risk of discontinuation.

In the competitive model, no difference emerged between treatment in the risk of discontinuation due to switch to LA, treatment failure, loss to follow-up or death. On the contrary, risk was higher in the DTG-3DR group (aHR 3.17, 95% CI 2.13-4.70) when discontinuation was due to AEs and lower in the DTG-2DR group when due to simplification (aHR 0.26, 95% CI 0.13-0.54) (Table 2).

Conclusions: In our cohort, a similar durability and safety profile was observed for BIC and DTG. Discontinuations due to adverse events were more frequent in the DTG-3DR group. These findings highlight that regimen composition may influence treatment interruptions beyond the choice of INSTI.

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Antiretroviral Therapy

P 21 **BREASTFEEDING IN AN ITALIAN WOMAN LIVING WITH HIV WITH SUSTAINED VIRAL SUPPRESSION: A CASE REPORT**

M. Mazzoccoli, N. Alfieri, S. Dalzero, M. Ierardi, C. Paramithiotti, M. Terragnoli, L. Terracciano, E. Zaninetta, S. El Oksha, M.C. Lavorato, C. Tincati, G.C. Marchetti, T. Bini

ASST Santi Paolo e Carlo, Milan, Italy

Background: Combination antiretroviral therapy (cART) in pregnant women living with HIV who maintain a persistently undetectable viral load reduces the risk of vertical transmission to less than 1% and permits vaginal delivery. Even among women with sustained virologic suppression, breastfeeding has traditionally been discouraged in high-income countries because of the residual risk of postnatal HIV transmission, which is estimated to be less than 1%, but not zero. However, recent international guidelines now recognize breastfeeding as a possible option for women with sustained viral suppression, if they receive appropriate counseling, are supported by a multidisciplinary team, and undergo close clinical monitoring.

Case Presentation: We report the case of a pregnant woman on cART with BIC/TAF/FTC (bictegravir/tenofovir alafenamide/emtricitabine) who elected to breastfeed. Throughout pregnancy, plasma HIV RNA levels remained consistently undetectable (<50 copies/mL), with documented excellent adherence and monthly clinical follow-up. A multidisciplinary team—including an infectious diseases specialist, an obstetrician-gynecologist, and a pediatrician—provided detailed counseling regarding the potential risks and benefits of breastfeeding. A dedicated informed consent form was developed in collaboration with the hospital's Department of Legal Medicine. Both the patient and her partner received comprehensive counseling and signed the informed consent following a structured shared decision-making process. The infant, born in February 2026, tested negative for HIV RNA at birth and is currently receiving oral zidovudine prophylaxis for 4 weeks. Both mother and infant are undergoing monthly monitoring with HIV RNA testing until cessation of breastfeeding. Breastfeeding will be discontinued if maternal HIV RNA exceeds 50 copies/mL or in the presence of bleeding nipple fissures. Both parents have been informed that, in accordance with current guidelines, the maximum planned duration of breastfeeding is 6 months.

Conclusions: This case highlights the ongoing paradigm shift in the management of breastfeeding among women living with HIV in high-resource settings. When managed within a structured multidisciplinary framework and under conditions of sustained maternal viral suppression, breastfeeding may be considered as part of an individualized, informed care plan. Careful monitoring, infant prophylaxis, and shared decision-making are essential to minimize residual risk while respecting maternal autonomy. Notably, a second pregnant woman at 25 weeks of gestation, also living with HIV with sustained viral suppression, has expressed her intention to breastfeed and will undergo the same structured counseling process. This suggests a growing acceptance of breastfeeding among women living with HIV in Italy and underscores the importance of establishing standardized protocols to support informed decision-making in this population.

Antiretroviral Therapy

P 22 CAUSES OF DISCONTINUATION OF CO-FORMULATED DOR/TDF/3TC IN ART-EXPERIENCED ADULTS WITH HIV-: REAL-WORLD DATA FROM A MULTICENTRIC STUDY IN FLORENCE, ITALY

G. Formica¹, C. Costa², G. Somma¹, C. Malcontenti³, M. Pozzi³, B. Borch³, C. Fiorelli³, L. Attala², M. Pittorru⁴, P. Corsi³, G. Sterrantino³, A. Bartoloni^{1,3}, F. Bartalesi², F. Lagi³

¹Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy, ²Infectious Diseases Unit, Santa Maria Annunziata Hospital, Bagno a Ripoli, Italy, ³Infectious and Tropical Diseases Unit, Careggi University Hospital, Florence, Italy, ⁴Hospital Pharmacy, Careggi University Hospital, Florence, Italy

Introduction: Doravirine (DOR), co-formulated with tenofovir disoproxil fumarate and lamivudine (DOR/TDF/3TC), is an NNRTI-based single-tablet regimen. Real-life data on DOR/TDF/3TC remain limited. We assessed durability, discontinuation rate and causes, with a focus on virological failure (VF) among individuals switching with suppressed viraemia.

Materials and Methods: We performed a retrospective multicentric cohort study including PLWH aged ≥ 18 years, ART-experienced, who switched to DOR/TDF/3TC and had ≥ 1 follow-up visit at two HIV centres in Florence, Italy. Follow-up started at DOR/TDF/3TC initiation and ended at discontinuation, loss to follow-up (LTFU), or October 2025. Among those switching with suppressed HIV-RNA, VF was defined as two consecutive HIV-RNA >50 copies/mL or a single HIV-RNA >1000 copies/mL. Among those switching with detectable HIV-RNA, incomplete virological response was defined as two consecutive HIV-RNA >50 copies/mL after 24 weeks. LTFU were censored and excluded from cause-specific discontinuation analyses.

Results: Overall, 169 participants were included with median follow-up 3.0 years (IQR 1.5–4.2); 67.5% had >2 years of follow-up. At switch, 146 (86.4%) had undetectable HIV-RNA and 23 (13.6%) had detectable HIV-RNA (Table 1). Most participants switched from a three-drug regimen (154/169; 91.2%), with TAF included in 50.9% of pre-switch backbones. Moreover, 8.9% came from a simplified dual therapy (Table 2).

Overall, 38 discontinuations occurred (22.5%), corresponding to 7.73 per 100 person-years (95% CI 5.63–10.63). Discontinuations were mainly due to physician's choice ($n=17$; 10.1%) or grade 1 toxicity ($n=12$; 7.1%), while VF was uncommon ($n=4$; 2.7%; 0.94 per 100 person-years, 95% CI 0.35–2.51) (Table 2; Image 1). Among those with detectable viraemia at switch, 18/23 (78.3%) achieved undetectable HIV-RNA after switching. In 3 out of 4 VF cases, failure occurred in the presence of pre-existing resistance to TDF/3TC and/or NNRTIs (including 179E); new NRTI and/or NNRTI mutations emerged in two cases, including 138K in one case (Table 2).

Conclusions: In this real-world multicentric cohort, switching to DOR/TDF/3TC showed good durability, with discontinuations mostly driven by tolerability and clinical/patient preference rather than virological failure. VF among those switching with suppressed HIV-RNA was rare and frequently associated with baseline resistance, supporting DOR/TDF/3TC as a viable switch option in ART-experienced individuals.

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Antiretroviral Therapy

P 23 CHANGING TAF/FTC/RPV TO TAF/FTC/BIC: EFFICACY, TOLERABILITY, TREATMENT SATISFACTION AND CONVENIENCE. RESULTS FROM THE SWITCH STUDY

G. Orofino¹, O. Bargiacchi², M. Guastavigna¹, A. Ianniello³, G. Bo⁴, F. Onelia⁴, A. Montalbano⁴, A. Barco², F. Rinaldi², G. Calleri¹

¹Tropical and Infectious Diseases Division A, Amedeo di Savoia Hospital, Turin, Italy, ²Infectious Diseases, A. O. Universitaria "Maggiore della Carità" di Novara, Novara, Italy, ³Laboratory of Microbiology and Virology, Amedeo Di Savoia Hospital, ASL Città Di Torino, Turin, Italy, ⁴Medical Science Department, University of Turin, Turin, Italy

Background: The Switch study is a retrospective observational study conducted at two centres in Northern Italy, evaluating efficacy, tolerability, treatment satisfaction and convenience in patients switched from the single-tablet regimen (STR) TAF/FTC/RPV to TAF/FTC/BIC between 2022 and 2024. The rationale was based on the potential advantages of the new STR in terms of higher genetic barrier and forgiveness, removal of food-related administration restrictions, and a more favourable drug-drug interaction (DDI) profile. The study received Ethics Committee approval.

Methods: Eligibility criteria included: current treatment with TAF/FTC/RPV, virological suppression (<50 copies/mL) for at least 12 months, naive status to TAF/FTC/BIC, and no documented resistance to bictegravir. Viroimmunological and clinical data were collected at 24 and 48 weeks for all patients who received TAF/FTC/BIC for at least 48 weeks. Treatment satisfaction was assessed at the same timepoints using the HIV Treatment Satisfaction Questionnaire (HIV-TSQ), administered as part of standard clinical practice at our centre.

Results: The switch was proposed to 81 PLWH; 75 (92.6%) accepted: 60 male (74%), 15 female (26%), mean age 51 years (21-81y), mean CD4 count at switch 643 cells/ μ L, mean ratio CD4/CD8 1,01. There were 7 discontinuations (9.3%): 4 simplifications to dual therapy (including 1 long-acting), 1 for weight gain, 1 lost to follow-up, and 1 for renal insufficiency. Of the 68 patients (91%) who reached 48 weeks, no virological failure was observed; mean CD4 count increased to 734 cells/ μ L, mean ratio CD4/CD8 1,03. Treatment satisfaction scores improved from 48 to 66 on the HIV-TSQ.

Conclusions: Switching from TAF/FTC/RPV to TAF/FTC/BIC, both modern and widely used STRs, appears safe and effective. The improvement in HIV-TSQ scores suggests that this switch addresses key factors underlying long-term adherence and persistence, including convenience of administration and reduced interaction burden.

Antiretroviral Therapy

P 24 CLINICAL SUCCESS AND SIMPLIFIED MANAGEMENT IN PEDIATRIC HIV: TRANSITIONING FROM MULTI-DRUG LIQUID FORMULATIONS TO SINGLE-TABLET REGIMENS (STR)

M. Stracuzzi¹, F. Marinacci¹, C. Coppola¹, V. Giacomè^{1,2}

¹Pediatric Infectious Diseases, Luigi Sacco Hospital, ASST FBF SACCO, Milan, Italy, ²Dipartimento di Scienze Biomediche e Cliniche "Luigi Sacco", Università degli Studi di Milano, Italy

Background: Pediatric HIV management has historically been clinically challenging due to complex regimens involving multiple liquid antiretroviral formulations. These regimens often present barriers to adherence due to demanding dosing schedules and suboptimal palatability. The introduction of pediatric Single-Tablet Regimens (STR) represents a significant advancement. This study evaluates the clinical outcomes of pediatric patients transitioning from multi-drug liquid therapies to simplified STR options.

Material and Methods: A retrospective analysis was conducted on a cohort of 9 pediatric patients (ages 1 to 11 years) followed at the Pediatric Infectious Disease Unit of the Luigi Sacco Hospital. The study included patients previously treated with multi-drug regimens consisting of various liquid formulations who subsequently switched to a once-daily STR. Clinical stability, virological suppression, and therapeutic adherence were monitored.

Results: The majority of patients (8 out of 9) demonstrated excellent clinical outcomes and high therapeutic adherence following the switch to STR. Specifically, 4 patients transitioned to the combination of Abacavir/Dolutegravir/Lamivudine (ABC/DTG/3TC) and 5 patients transitioned to the combination of Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF). Throughout the follow-up period, patients remained immuno-virologically stable, maintaining undetectable HIV-RNA viral loads and CD4+ T-cell counts within the normal range for their age. Notably, one patient (a 2-year-old female) in the ABC/DTG/3TC group discontinued the therapy due to documented intolerance specifically related to the drug's palatability. Excluding this single case, the simplification of the therapeutic protocol led to consistent clinical success and optimized management across the cohort regardless of the specific pharmacological combination prescribed.

Conclusions: Switching from complex multi-drug liquid protocols to Single-Tablet Regimens (ABC/DTG/3TC or BIC/FTC/TAF) is highly effective and generally well-tolerated in the pediatric population. Therapeutic simplification significantly improves management for both patients and caregivers by reducing the treatment burden. While palatability remains a critical factor for adherence in very young children, STR currently represents the gold standard for ensuring long-term virological success and improving the quality of life in pediatric HIV management.

Antiretroviral Therapy

P 25 COMMUNITY-BASED PEER-LED HIV TESTING AND LINKAGE TO CARE AMONG ADOLESCENTS IN SOUTHWEST CAMEROON: IMPLICATIONS FOR REDUCING HIV-RELATED MORBIDITY

T.E.A. Adeola¹, A. Fontu², L. Kana³, N. Julienne⁴, E.N. Cyril⁵

^{1,2}Cameroon, Alliance for Community Initiative, Kumba, Cameroon, ^{3,4}Presse Jeune Development, Yaounde, ⁵Cameroon, Community Center for Integrated Development, Muyuka, Cameroon

Background: Adolescents and young women in sub-Saharan Africa remain disproportionately affected by HIV. In Muyuka Subdivision (Southwest Cameroon), HIV prevalence among adolescent girls is estimated at 2%, approximately twice that of their male counterparts. Nationally, only 32% of young women aged 15–24 demonstrate comprehensive HIV knowledge. Delayed diagnosis and suboptimal linkage to antiretroviral therapy (ART) contribute significantly to preventable HIV-related morbidity and mortality. Community-based strategies may accelerate early diagnosis and improve linkage to care.

Methods: We implemented a community-based, peer-led HIV prevention and testing intervention between January and December 2023. Twenty-one trained peer educators delivered structured HIV/STI education sessions and facilitated voluntary counseling and testing (VCT) across multiple communities in Muyuka. Services included HIV and STI testing with standardized pre/post-test counseling, male and female condom distribution, lubricant provision, partner notification counseling, and structured referral to ART clinics and psychosocial support services. Primary outcomes included number reached, testing uptake, HIV positivity rate, and successful linkage to care.

Results: A total of 1,520 adolescents and young people were reached (700 females [46%], 820 males [54%]); age distribution was 15–19 years (15%), 20–24 years (72%), and >24 years (13%). Two VCT campaigns engaged 680 adolescents (44.7% uptake). Nine individuals tested HIV-positive (overall positivity: 1.32%; males 0.18%, females 0.63%). All newly diagnosed participants (100%) were successfully linked to HIV care. Prevention commodities distributed included 2,822 male condoms (79%), 770 female condoms (21%), and 192 lubricants. Higher positivity among females reinforces gender disparities in HIV vulnerability.

Conclusions: This peer-led, community-based testing model achieved high uptake and 100% linkage to care among newly diagnosed adolescents, addressing critical gaps in the first and second UNAIDS 95-95-95 targets. Early identification and prompt referral are essential to reducing HIV-related morbidity among high-risk youth. Scaling adolescent-focused, peer-driven testing strategies may represent a cost-effective approach to accelerate epidemic control in resource-limited settings.

Antiretroviral Therapy

P 26 DOES TIMING OF ART INITIATION AFFECT IMMUNOVIROLOGICAL OUTCOMES IN ISTI ERA? PRELIMINARY DATA FROM A MULTICENTER STUDY IN APULIA

M. Polisenò¹, A. Cianciaruso¹, N. Colavito¹, A. Lugli¹, A. Narducci², A. Vergori², S. Lo Caputo², F. Di Gennaro¹, A. Saracino¹

¹Clinic of Infectious Diseases, Department of Regenerative and Precision Medicine and Jonian Area (DiMePre-J), University of Bari, Bari, Italy, ²Infectious Diseases Unit, A.O.U. Policlinico Foggia, University of Foggia, Foggia, Italy

Background: International guidelines recommend prompt initiation of antiretroviral therapy (ART) following HIV diagnosis. However, real world data evaluating the immunovirological impact of early versus delayed ART start, remain limited. We aimed to assess the probability of achieving virological suppression (VS) and immune recovery (IR) among people with HIV (PWH) starting their first ART within 14 days from HIV diagnosis (early start) versus after 14 days (delayed start) and to identify predictors of suboptimal virological response.

Methods: We enrolled all adult PWH initiating ART between 2021-2025 in the two major HIV Clinics of our region. PWH lacking information regarding date of ART start and/or without any follow-up record after this event were excluded. Baseline characteristics were summarized according to early versus delayed ART start. Kaplan-Meier curves were used to assess I) the time to VS (2 consecutive VL <50 cp/mL registered within the 12 (±3) months after ART start) and its probability according to early vs delayed ART start and II) among PWH with <500 baseline CD4, the time to IR (defined as the composite outcome of a CD4 count>500 cell/mm³ and/or CD4/CD8 ratio >1 and/or an increase of 200 CD4 from baseline within 24 months after ART start) and its cumulative probability according to ART timing. A Cox regression model was used to assess the Hazard Ratio (H.R.) with 95% Confidence Interval (C.I.) of failure to achieve 12-month VS based on baseline characteristics.

Results: Overall, 161 PWH were included, whose characteristics are displayed in Table 1. The median time from diagnosis to first clinical visit and to ART start was 7 (IQR 2-17) and 18 (8-31) days respectively; 82 PWH (51%) started ART within 14 days. Compared to the delayed ART start group, early starters were more frequently hospitalized (47% vs 35%, p=0.041), with advanced disease (38% vs 21%, p=0.02) and/or reported AIDS diagnosis (28% vs 13%, p=0.016).

First line ART of choice was mostly BIC/FTC/TAF (72%), followed by DTG/3TC (14%), TAF/FTC DOR + TXF/XTC (7%), TAF/FTC/DRV/c (6%), with similar distribution between the two groups.

After median 20 (19-24) weeks, 67% achieved VS. Among those eligible for IR analysis, 72% reached the composite endpoint after median 18 (9-32) weeks. Both the probability of VS and IR were comparable according to timing of ART start (Figure 1 A. and B.).

Being heterosexual (aHR 12.93, 95% CI 1.62–103.43), and starting with a protease inhibitor (aHR 20.62, 95% CI 2.03–209.91) were independently associated with failure to achieve 12-month VS.

Conclusions: In this realworld setting, over half of PWH initiated ART within 14 days. ART timing did not appear to impact VS, which was more influenced by clinical and sociodemographic factors. Larger studies are warranted to better clarify the impact of ART timing on achieving IR.

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Antiretroviral Therapy

P 27 DURABILITY AND REASONS FOR DISCONTINUATION OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN VIROLOGICALLY SUPPRESSED ADULTS WITH HIV: A MULTICENTER REAL-WORLD EXPERIENCE IN TUSCANY (LAHIV)

F. Lagi¹, S. Trevisan², M. Fabbiani³, B. Rossetti⁴, M. Piccica⁵, A. Pampaloni⁶, S. Modica¹¹, B. Menichini⁷, S. Costarelli⁸, C. Bianco⁹, G. Sarteschi¹⁰, M. De Gennaro¹¹, M. Turco¹², V. Donini², M. Maruotto², P. Corsi¹, M. Pozzi¹, M. Tumbarello³, D. Messeri⁷, C. Costa⁵, B. Adriani⁶, C. Nencioni⁴, D. Tacconi⁹, S. Sani⁸, A. Vincenti¹⁰, L. Pisano¹², F. Bartalesi⁵, A. Bartoloni^{1,2}

¹SOD Malattie Infettive, Azienda Ospedaliero-Universitaria Careggi, Università degli Studi di Firenze, Italy, ²Dipartimento di medicina sperimentale e clinica, Università degli studi di Firenze, Italy, ³Azienda Ospedaliero-Universitaria Siena, Università degli Studi di Siena, Italy, ⁴UO Malattie Infettive, Ospedale di Grosseto, Azienda USL Toscana Sud Est, Italy, ⁵SOC Malattie Infettive, Ospedale Santa Maria Annunziata, USL Toscana Centro, Italy, ⁶UO Malattie Infettive, Azienda Ospedaliera Prato, Azienda USL Toscana Centro, Italy, ⁷SOS Malattie Infettive, Azienda Ospedaliera Pistoia, USL Toscana Centro, Italy, ⁸UO Malattie Infettive, Azienda Ospedaliera Livorno, USL Toscana Nord-Ovest, Italy, ⁹UOC Malattie Infettive, Azienda Ospedaliera Arezzo, USL Toscana Sud-Est, Italy, ¹⁰UO Malattie Infettive, Nuovo Ospedale Apuane, USL Toscana Nord-Ovest, Italy, ¹¹UO Malattie Infettive, Azienda Ospedaliera Lucca, USL Toscana Nord-Ovest, Italy, ¹²S.C. Dermatologia, P.O. Piero Palagi, Usl Toscana Centro, Italy

Background: Long-acting cabotegravir plus rilpivirine (CAB+RPV) is the first intramuscular antiretroviral regimen approved for maintenance of HIV-1 virological suppression. Real-world data on durability and reasons for discontinuation are still limited.

Methods: This multicenter observational study included adults with HIV-RNA <50 copies/mL from 11 centres in Tuscany, Italy, including academic and non-academic institutions, reflecting a regional real-life setting. Participants were followed from the first CAB+RPV injection until treatment discontinuation, death, or last visit. Discontinuation (TD) was defined as regimen switch or two consecutive missed injections and was prospectively recorded, then classified a posteriori as virological failure (VF), toxicity/adverse reactions, patient-related reasons, or medical decisions. VF was defined as two consecutive HIV-RNA >50 copies/mL or a single HIV-RNA >1000 copies/mL. Kaplan–Meier analyses estimated treatment durability.

Results: We included 244 participants, contributing 330.3 person-years of follow-up (median 1.5 years, IQR 0.6–2.1). Median age was 51.3 years (IQR 44–57), 79.9% were male (Table 1). Twenty-seven participants (11.7%) discontinued CAB+RPV, corresponding to a TD rate of 8.1 per 100 py (95% CI 5.6–11.9). Median time to TD was 42 weeks (95% CI: 14–72). The probability of remaining on treatment was 91.5% (95% CI 86.6–94.6) at 1 year and 86.1% (95% CI 79.7–90.6) at 2 years (Figure 1). TD was mainly due to adverse events (n=9; 3.6%), VF (n=7; 2.8%), or patient preference (n=6; 2.4%) (Table 2). We observed, 7 VF (VF rate 2.1 per 100 person-years, 95% CI 1.0–4.4), including 2 HIV-RNA values between 50 and 200 copies/mL, 1 isolated cerebrospinal fluid viral escape, and 4 VF with HIV-RNA >1000 copies/mL. Among these 4 cases, NNRTI resistance mutations were present at baseline in one case and NNRTI and INSTI resistance emerged in another (1 out of 3), with viral resuppression after switching to TAF/FTC/DRV/c. All VFs occurred despite adherence to scheduled injections. Shorter duration of virological suppression prior to switch was associated with TD. Calendar year of LA ART initiation was significantly associated with TD. Compared with individuals initiating LA therapy in 2022, the risk was lower for those starting in 2023 (HR 0.30, 95% CI 0.12–0.78) and 2024 (HR 0.17, 95% CI 0.05–0.56). This temporal trend suggests a possible learning-curve or implementation effect during the early rollout of LA ART, with improved patient selection and management over time (Figure 2).

Conclusions: In this region-wide real-world cohort including academic and non-academic centres, CAB+RPV showed good durability in routine clinical practice. TD rates were slightly higher than those reported in clinical trials but broadly consistent with other observational studies and may partly reflect the complexities of real-life implementation during the early adoption phase.

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Antiretroviral Therapy

P 28 EARLY VIROLOGICAL RECOVERY IN PATIENTS WITH EXTREME HIV VIREMIA: IMPACT OF TREATMENT HISTORY AND CDC CLINICAL STAGE

G. D'Agati^{1,2}, C. Conti^{1,2}, D. Marrali^{1,2}, S. Urso^{1,2}, M. Trizzino^{1,2}, L. Pipitò^{1,2}, A. Cascio^{1,2}

¹Infectious and Tropical Diseases Unit, Sicilian Regional Reference Center for the Fight Against AIDS, AOU Policlinico "P. Giaccone", Palermo, Italy, ²Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G D'Alessandro", University of Palermo, Palermo, Italy

Background: Individuals presenting with extremely high HIV viremia (HIV-RNA $\geq 1,000,000$ copies/mL) frequently exhibit advanced disease and social vulnerability. The influence of treatment history and CDC (centers for disease control and prevention) clinical stage on early virological recovery in this setting remains insufficiently characterized.

Material and Methods: We conducted a retrospective observational study including adults with HIV-RNA $\geq 1,000,000$ copies/mL followed at the Policlinico "Paolo Giaccone" University Hospital of Palermo between 2020 and 2025. Demographic, clinical, immunological, virological, and treatment-related data were collected. Outcomes included virological suppression at 6 months and a $\geq 3 \log_{10}$ reduction in HIV-RNA. Analyses were performed, stratifying patients by treatment status (naïve vs non-naïve) and CDC classification.

Results: Twenty-seven patients were included; 22 were male (82%), with a male-to-female ratio of 4.4:1 and a median age of 44 years. Most patients were Caucasian (82%), while 18% were Black; 22% presented critical socio-assistential conditions. Antiretroviral therapy-naïve status was observed in 78%. HIV transmission risk factors included homosexual exposure (44%), intravenous drug use (4%), and other routes (11%). At diagnosis, acute retroviral syndrome (ARS) was present in 19%, CDC stage B conditions in 26%, and AIDS-defining conditions in 52%; 59% required hospitalization. Baseline median HIV-RNA was 2,250,000 copies/mL; 22% had ≥ 5 million copies/mL and 19% ≥ 10 million copies/mL. Median CD4 count was 104 cells/mm³, median CD4 percentage 16%, and median CD4/CD8 ratio 0.1. Genotypic resistance testing showed full susceptibility in 70%. Initial regimens were predominantly integrase strand transfer inhibitor-based (89%). Virological suppression at 6 months was achieved in 41% of evaluable patients. Suppression occurred more frequently in naïve than in non-naïve individuals. A $\geq 3 \log_{10}$ HIV-RNA reduction was observed in 56% overall and was markedly more common among naïve patients (44%) than non-naïve patients (11%), while failure to achieve this response was predominantly observed in non-naïve subjects (37%). Median HIV-RNA reduction at 1 month was $3.7 \log_{10}$ in naïve patients and $3.5 \log_{10}$ in non-naïve patients. Virological decline was greatest in patients diagnosed during ARS (median $-4.9 \log_{10}$ at 1 month) compared with those presenting with AIDS (median $-3.7 \log_{10}$).

Conclusions: In patients with extreme HIV viremia, both treatment history and CDC clinical stage strongly influence early virological recovery. Antiretroviral-naïve patients and those diagnosed during acute retroviral syndrome achieved the most pronounced virological decline, whereas non-naïve status and AIDS presentation were associated with delayed and less robust responses. These findings underscore the critical role of early diagnosis and prompt initiation of effective therapy to optimize virological outcomes in this high-risk population.

Antiretroviral Therapy

P 29 EXTREME POTENCY OF LENACAPAVIR PLUS LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN A HEAVILY IMMUNOCOMPROMISED HTE PATIENT: RAPID VIROLOGICAL SUPPRESSION AND THE RISK OF IRIS

A. Franzò¹, B. Bellocchi¹, A. Marino¹, V. Moscatt¹, M. Coco¹, V. Boscia¹, G. Vinci¹, M. Gussio¹, R. Caruso², G. Cannata³, B.S. Cacopardo¹, G. Nunnari¹, B.M. Celesia¹

¹Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, ARNAS Garibaldi Hospital, University of Catania, Catania, Italy, ²Unit of Anaesthesia and Intensive Care Unit, ARNAS Garibaldi Nesima Hospital, Catania, Italy, ³Unit of Anaesthesia and Critical Care Medicine III - CAST, Policlinico University Hospital, Catania, Italy

Background: Cabotegravir and Rilpivirine (CAB/RPV) is the most widely utilized Long-Acting (LA) injectable therapy in People living with HIV (PLWHIV); its use in Heavily Treatment-Experienced (HTE) patients is currently limited by guidelines, low genetic barrier and historical mutations. The all-injectable strategy pairing the capsid inhibitor Lenacapavir (LEN) with CAB/RPV is an emerging salvage approach. While some international reports and real-world data suggest a potential use, clinical experience in rescue patients remains limited.

Material and Methods: We report the case of a 37-year-old woman living with HIV since 2014 (CDC stage C3, CD4 + 102/mm³). Her therapeutic history was marked by multiple changes of treatment due to low tolerance and failures with regimens involving NRTI, NNRTI, PI and INSTI. Historical mutations included: Q148H and G140S for INSTI; V179E and Y181C for NNRTI. Her last oral regimen, BIC/FTC/TAF, failed due to poor adherence, confirmed by negative TDM. The opportunity of full LA strategies was proposed to make sure the full adherence. The rescue regimen LEN + CAB/RPV was initiated when CD4+ cell count was 27/mm³ (3%) and HIV-RNA 332,000 copies/mL. Oral LEN loading (under direct observation) was followed by CAB/RPV and subcutaneous LEN. Viral Load was monitored weekly and a baseline NGS on HIV-DNA and RNA was performed.

Results: The regimen demonstrated exceptional potency, with HIV-RNA dropping below the detection limit (<30 copies/mL) within 30 days (fig. 1). After a few days from the beginning of LA therapy the patient developed a Herpes Labialis reactivation, fever and increase of cough but unfortunately refused hospitalization. A therapeutic 5 days cycle of Amphotericin B liposomal was administered in Day Hospital to treat a visceral leishmaniasis reactivation. Oral Trimethoprim/Sulfamethoxazole prophylaxis, previously just occasionally taken due to referred intolerance, and steroids were resumed. Finally the patient was admitted to our department for a severe respiratory failure later diagnosed as PJP the day after the subcutaneous dose of LEN. VL was 90 copies/ml and CD4 63 cell/mm³ (8%). Due to a rapid deterioration of respiratory function until ARDS, the patient was transferred to the Intensive Care Unit for invasive ventilation and two days later a Veno-Venous ECMO treatment was applied. Despite the aggressive treatment, the patient died 3 weeks later. NGS DNA results revealed the presence of the known Y181C mutation and a new H221Y but, surprisingly, the absence of PI/INSTI mutations.

Conclusions: LEN+CAB+RPV LA combination can induce a rapid and vigorous virological response even in HTE patients with archived resistance. However, the potency of this regimen can trigger IRIS, especially when CD4 are below 50 cell/ μ l and compliance with opportunistic infection prophylaxis was inconsistent. Further studies and experience can clarify the role of this therapy in Heavily Treated Patients.

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Antiretroviral Therapy

P 30 IMMUNOLOGICAL OUTCOMES AFTER SWITCH TO LONG-ACTING CABOTEGRAVIR/RILPIVIRINE: A REAL-WORLD MONOCENTRIC EXPERIENCE

A. Gizzi, M. Abbott, F. Guida Marascia, S. Agrenzano, C. Imburgia, A. Sanfilippo, G. Pipitone, C. Iaria

Infectious Disease Unit - ARNAS Civico-Di Cristina-Benfratelli, Palermo, Italy

Background: Long-acting injectable cabotegravir/rilpivirine (CAB/RPV-LA) is an effective maintenance strategy for virologically suppressed people living with HIV, improving treatment convenience and potentially adherence. Real-world data on immunological trends after switching from oral regimens remain limited.

Methods: We conducted a monocentric observational study at an Infectious Diseases outpatient clinic managing approximately 500 patients annually. Over the last four years, 43 virologically suppressed patients were switched from oral antiretroviral therapy to CAB/RPV-LA. Three patients discontinued treatment (one transferred care, one stopped due to post-injection asthenia, malaise and arthralgia, and one by personal preference), leaving 40 patients currently receiving the long-acting regimen. Baseline characteristics were: 31 males and 9 females, mean age 50 years. Previous regimens included DOR/3TC/TDF (n=3), DTG/3TC (n=7), BIC/TAF/FTC (n=13), DTG/3TC/ABC (n=5), DTG/RPV (n=4), DRV/C/TAF/FTC (n=3), EVG/C/TAF/FTC (n=2), RAL+DRV/C (n=2), and RAL+TAF/FTC (n=1). For immunological analysis, only patients with at least 6 months of follow-up and available paired laboratory data were included (n=24). CD4+ T-cell count, CD4 percentage, and CD4/CD8 ratio were compared pre- and post-switch using paired statistical tests.

Results: After ≥6 months of CAB/RPV-LA, significant immunological improvements were observed. Mean CD4+ T-cell count increased from 577.7 to 659.1 cells/μL (mean difference +81.5 cells/μL; paired t-test, p=0.0048). CD4 percentage increased from 32.9% to 35.3% (median difference +2.89%; Wilcoxon signed-rank test, p=0.0115). The CD4/CD8 ratio improved from 1.01 to 1.08 (median difference +0.11; Wilcoxon signed-rank test, p=0.0186) (Table 1). Treatment was overall well tolerated, with a low discontinuation rate (3/43, 7%).

Conclusions: In our real-world monocentric experience, CAB/RPV-LA was well tolerated. Among patients with at least six months of follow-up, switching to long-acting therapy was associated with a significant improvement in CD4+ T-cell count, CD4 percentage, and CD4/CD8 ratio. Although limited by sample size and observational design, these findings suggest a favorable immunological trend after switching, supporting the effectiveness and safety of long-acting therapy in clinical practice.

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Antiretroviral Therapy

P 31 IMPACT OF NEUROPSYCHIATRIC ADVERSE EVENTS AFTER SWITCH FROM BICTEGRAVIR-INCLUDING TO DORAVIRINE-INCLUDING TRIPLE ANTIRETROVIRAL REGIMEN IN CLINICAL SETTING

L. Serroni, M. Ferrara, M. Tettoni, L. Trentini, S. Bonora

Unit of Infectious Diseases, Department of Medical Sciences, University of Torino, Torino, Italy

Background: Bictegravir (BIC) has a lower risk of neuropsychiatric adverse events (NPAEs) than other integrase strand transfer inhibitors (INSTIs), including dolutegravir and raltegravir. NPAE rates vary by drug and study design. In randomized trials, prevalence is $\leq 1\%$ for both dolutegravir and BIC, whereas real-world studies report wider ranges. Discontinuations are uncommon and mainly associated with pre-existing psychiatric disorders or prior intravenous drug use. Although BIC-based regimens are widely used, its specific NP impact remains unclear. Aim of our study was to explore the NPAEs outcome after switching from a BIC- to doravirine (DOR)-including triple regimen.

Material and Methods: People living with HIV (PLWH) followed at the Amedeo di Savoia Hospital in Turin who were receiving BIC/FTC/TAF and reported new onset or worsening of anxiety, mood disturbances, or impaired sleep quality were evaluated for switching to a doravirine-based triple regimen with TAF/FTC, according to clinical judgment.

Anxiety, depression, and sleep quality were assessed at baseline and at weeks 4, 24, and 48 using the HAM-A, BDI-II, and PSQI questionnaires, respectively.

Results: Thirteen participants were enrolled from March 2020 to August 2025 and switched TAF/FTC plus DOR. Demographic characteristics are reported in Table 1 and Table 2. All 13 participants completed the 24-week follow-up, whereas only four had available data at the one-year follow-up. Virological suppression (<20 cp/mL) was maintained at 24W and 48W after switch. Neuropsychiatric adverse event scores showed a statistically significant improvement at week 4 (HAM-A $p=0.054$; BDI-II $p=0.013$; PSQI $p=0.034$) (Image 1), with greater benefit observed in more severe cases (Image 2); this improvement was sustained at week 24, with no significant differences compared to week 4.

Conclusions: All NPAEs reported by participants significantly improved or resolved after BIC discontinuation, supporting a potential role of antiretroviral therapy. The observed improvement in anxiety, depression, and sleep quality suggests a positive impact on quality of life and indicates that a DOR-based regimen may represent a safe alternative for individuals who develop NPAEs during BIC/TAF/FTC treatment. Given the small sample size and the multifactorial nature of neuropsychiatric disorders, larger studies are needed to confirm these observations.

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Antiretroviral Therapy

P 32 LONG-TERM RENAL OUTCOMES AFTER SWITCH TO BICTEGRAVIR: DETERMINANTS OF CLINICALLY SIGNIFICANT DECLINE AT WEEK 144 IN THE BICTEL COHORT

L. Bortolani, R. Donà, A. Lazzaro, F. Alessi, M. Ridolfi, E. Altavilla, C. Carafa, S. Figliomeni, G. Ceccarelli, C.M. Mastroianni, G. d'Ettorre

Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy

Background: Long-term real-world data on bicitegravir/tenofovir alafenamide/emtricitabine (BIC/TAF/FTC) remain limited. Within the BICTEL cohort, this single-tablet regimen has demonstrated sustained virological effectiveness, favourable safety, and encouraging improvements in immune markers over extended follow-up. Although overall renal function remained largely stable after switching, without progressive deterioration beyond week 48, aggregate analyses identified a modest decline in estimated glomerular filtration rate (eGFR) over time. The clinical relevance and determinants of this decline remain unclear. We therefore aimed to identify predictors of clinically significant renal deterioration at week 144 (w144).

Methods: We conducted a retrospective interim analysis within the BICTEL cohort including people living with HIV (PLWH) who switched to BIC/FTC/TAF and had available eGFR measurements at baseline and w144. Clinically significant renal decline was defined a priori as a $\geq 10\%$ reduction in eGFR from baseline to w144. Independent predictors of renal decline were assessed using multivariable penalized logistic regression, using Firth method and adjusting for age, baseline eGFR, hypertension, diabetes, and pre-switch backbone (TDF-based vs non-TDF-based regimens). Odds ratios (OR) with 95% confidence intervals (CI) and corresponding p-values were reported.

Results: Among 125 patients with available renal follow-up at week 144, 31.2% experienced a $\geq 10\%$ decline in eGFR. Baseline characteristics are summarized in Table 1.A. In penalized multivariable logistic regression analysis, diabetes (OR 5.7; 95% CI 1.6–20.5; $p=0.007$) and prior TDF exposure (OR 5.2; 95% CI 1.0–26.3; $p=0.048$) were independently associated with clinically significant renal decline. Baseline eGFR, age, and hypertension were not significantly associated. Full results are reported in Table 1.B.

Conclusions: Within the BICTEL cohort, clinically significant renal decline at 144 weeks after switching to BIC/FTC/TAF was not uniformly distributed but concentrated in patients with underlying diabetes and prior TDF exposure. These associations persisted after penalized regression, suggesting that metabolic vulnerability and legacy TDF exposure may contribute to long-term renal trajectories. Although subgroup sizes were limited, these findings refine previous aggregate observations and underscore the importance of pre-switch history and comorbidity burden when interpreting long-term renal outcomes in real-world settings. Overall renal stability at the population level supports the favorable renal safety profile of BIC/FTC/TAF, while a risk-stratified approach to long-term monitoring may be warranted. Larger studies are needed to confirm these associations and further clarify the interaction between metabolic vulnerability and prior antiretroviral exposure.

The project has been partially supported by a Gilead Sciences Medical grant.

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Antiretroviral Therapy

P 33 LONGITUDINAL IMMUNOLOGICAL AND METABOLIC OUTCOMES IN TREATMENT-EXPERIENCED WOMEN SWITCHING TO B/F/TAF: A 24-MONTH DUAL-CENTER REAL-WORLD STUDY

V. Speciale¹, A. Gasperin², G. Mancarella², R. Marocco², D. Di Trento², L. Ansaldo², M. De Masi², A. Di Nardo¹, L. Mazzanti¹, L. Bresciani¹, S. Iaquinandi¹, S. Vita⁴, V. Filippi³, A. Carraro³, C. Pasquazzi³, C. Del Borgo², M. Lichtner⁴

¹Sapienza, University of Rome, Italy, ²Infectious Disease Department, Santa Maria Goretti Hospital, Latina, Italy, ³Infectious Disease Department, Sant'Andrea Hospital, Rome, Italy, ⁴Department of NESMOS, Sapienza, University of Rome, Italy

Background: Data on the longitudinal immunological and metabolic outcomes of treatment-experienced women with HIV switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) remain limited. We aimed to characterize women with prior antiretroviral treatment switching to B/F/TAF and to evaluate 24-month virological durability, immunological evolution, and metabolic changes in a real-world setting.

Methods: We conducted a longitudinal observational study including treatment-experienced women with HIV who switched to B/F/TAF at two Italian centers. Women with available data at baseline (time of switch) and at least one follow-up visit (12 and/or 24 months) were included, regardless of HIV-RNA levels at switch.

Immunological outcomes included CD4 count and CD4/CD8 ratio. Metabolic outcomes included body weight, body mass index (BMI), fasting glucose, total cholesterol, HDL, LDL, and triglycerides. Virological suppression (HIV-RNA <50 copies/mL) was assessed at 12 and 24 months.

Longitudinal changes across baseline, 12 and 24 months were assessed using Friedman test, followed by Wilcoxon signed-rank tests with Bonferroni correction when appropriate. Effect sizes were estimated using Kendall's W and rank-biserial correlation coefficients.

Results: Thirty-seven treatment-experienced women were included.

Median CD4 count increased from 684.5 cells/mm³ at baseline to 743 cells/mm³ at 24 months ($p_{\text{adj}} = 0.0095$ for baseline vs 24 months), with moderate effect size. The CD4/CD8 ratio improved significantly over time (Friedman $p = 0.0019$), with significant increases between 12 and 24 months and between baseline and 24 months.

Body weight increased from 64 kg at baseline to 66.5 kg at 24 months (Friedman $p = 0.0067$), with significant increase between 12 and 24 months. Similarly, BMI showed a significant longitudinal increase ($p = 0.0067$).

No significant longitudinal changes were observed in total cholesterol, HDL, LDL, or triglycerides. Fasting glucose showed a modest global variation that did not remain significant after correction for multiple comparisons.

Virological suppression rates remained high throughout follow-up (84.2% at baseline, 92.1% at 12 months, and 94.6% at 24 months).

Conclusions: In this dual-center cohort of treatment-experienced women switching to B/F/TAF, we observed significant immunological improvement and sustained virological control over 24 months, accompanied by a moderate increase in weight and BMI but without significant deterioration of lipid profile. These findings support the long-term effectiveness and metabolic stability of B/F/TAF in women in real-world settings.

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Antiretroviral Therapy

P 34 OUTCOMES OF DORAVIRINE-BASED REGIMENS IN VIROLOGICALLY SUPPRESSED ART-EXPERIENCED PERSONS WITH HIV: DATA FROM THE ICONA COHORT

A. d'Arminio Monforte¹, A. Tavelli^{1,2}, R. Gagliardini³, L. Taramasso⁴, N.B. Bana⁵, N. Squillace⁶, T. Bini⁷, D. Segala⁸, E. Quiros-Roldan⁹, S. Lo Caputo¹⁰, A. Saracino¹¹, A. Antinori³ on behalf of the ICONA Foundation Study Group - ICONA cohort

¹ICONA Foundation, Milan, Italy, ²National PhD Programme in One Health approaches to infectious diseases and life science research, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy, ³Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy, ⁴Infectious Disease Clinic, IRCCS Ospedale Policlinico San Martino, Genova, Italy, ⁵Department of Infectious Diseases, ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ⁶Department of Infectious Diseases, IRCCS San Gerardo dei Tintori, Monza, Italy, ⁷Clinic of Infectious Diseases, ASST Santi Paolo e Carlo, Milan, Italy, ⁸Infectious Diseases Unit, Department of Translational Medicine, University of Ferrara, Ferrara, Italy, ⁹Department of Clinical and Experimental Sciences, Unit of Infectious and Tropical Diseases, University of Brescia, ASST Spedali Civili di Brescia, Brescia, Italy, ¹⁰Clinic of Infectious Diseases, Department of Clinical and Surgical Sciences, University of Foggia, Foggia, Italy, ¹¹Clinic of Infectious Diseases, Department of Precision and Regenerative Medicine and Ionian Area, Polyclinic of Bari, University Hospital Polyclinic, University of Bari, Bari, Italy

Background: Randomized clinical trials demonstrated the efficacy of Doravirine (DOR) both in ART-naïve and pre-treated, virologically suppressed PWH. We aim to verify the outcome of ART-experienced virologically suppressed PWH on 3DR-DOR-including regimens in the real-world setting in Italy.

Methods: Observational study from the ICONA Cohort. Inclusion criteria: PWH ≥18 years-old, initiating DOR after July 2019 (availability of DOR in Italy) switched while virologically suppressed (HIV-RNA ≤50 cps/ml) from any other regimen to a 3DR-DOR-based regimen.

Primary endpoints: -time to treatment failure (TF): virological failure (VF: HIV-RNA>50 copies/mL in 2 consecutive determinations or single >1000 copies/ml followed by ART change) or DOR discontinuation for toxicity/failure; - changes in mean CD4, CD4/CD8, total cholesterol, LDL, HDL, Triglycerides after DOR switch. Reasons for DOR discontinuation were collected as reported by the treating physician.

The cumulative probability of TF was calculated by Kaplan-Meier curves.

Adjusted and unadjusted Cox regression models were used to estimate the risk of time to TF according to selected exposures of interest (sex, age ≥65 years, being born in Italy, previous NNRTI use and CD4 at first ART and at DOR switch).

Mixed linear models with random intercept and slope were used to estimate the mean CD4 and CD4/CD8 ratio and lipids changes from DOR initiation at different timepoints.

Results: A total of 640 PWH were included: 78% males, 7% age ≥65y, 82% born in Italy, 2.7% with CD4<200 cells/mm³ at DOR-switch, 29.4% with CD4<200 cells/mm³ at first ART start, 51% on previous NNRTI-based regimen, 88.3% with 3TC/TDF as backbone; 66% reached 96-weeks of follow-up and 42% the 144-weeks. Full description in Table1. In a median follow-up of 132 weeks (80-175), TF occurred in 40 cases (15 VF/discontinuation for failure and 25 discontinuations for toxicity: 7 gastrointestinal intolerance, 5 allergic reactions, 4 anxiety/insomnia, 3 osteopenia and 6 other): the probability of TF was 4.5% (95%CI 3.1-6.5) at 48w and 6.2% (4.5-8.6) at 96w. In the multivariable Cox analysis, sex, age, being born in Italy, CD4 at ART initiation, were not predictive of TF, while PWH with CD4<200/mm³ at DOR switch had higher risk of time to TF (aOR 3.56, 95%CI 1.03-12.29); previous NNRTI-including ART was marginally protective (aOR 0.47; 95%CI 0.21-1.05) (Table2). Mean CD4 counts as well as the lipid parameters (cholesterol, LDL and triglycerides) showed improvements overtime, with significant improvements during follow-up (Figure1).

Conclusion: In our single-arm study, switching to 3DR-DOR with undetectable HIV-RNA is a successful strategy that resulted only in 6.2% probability of treatment failure by 96 weeks. PWH with CD4<200/mm³ should be treated with caution. The safe profile of DOR on lipid assets was also confirmed in our study.

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Antiretroviral Therapy

P 35 PRESCRIBING APPROPRIATENESS AND ECONOMIC SUSTAINABILITY OF ANTIRETROVIRAL THERAPY: IMPACT OF A MULTIDISCIPLINARY PHARMACIST-INFECTIOUS DISEASE SPECIALIST COLLABORATION

M. Degli Antoni¹, S. Enisci², L. Zanichelli¹, C. Colarossi¹, A. Ruggieri¹, M.C. Granelli², F. Trapani¹

¹Infectious Diseases Unit, AUSL Piacenza, Piacenza, Italy, ²Hospital Pharmacy and Direct Drug Distribution Unit, AUSL Piacenza, Piacenza, Italy

Introduction: Antiretroviral therapy (ART) requires careful management due to the expanding range of available regimens, increasing comorbidities among people living with HIV (PLWH) and its economic impact on healthcare systems. In this context, collaboration between hospital pharmacists and infectious disease specialists may improve prescribing appropriateness, optimize treatment and support cost containment.

Materials and Methods: From March to December 2025, a collaborative program between the Hospital Pharmacy and the Infectious Diseases Unit was implemented to optimize antiretroviral regimens. Meetings were held every two months to review ongoing treatments, evaluate potential switches to less obsolete regimens with lower toxicity and jointly assess efficacy, tolerability and economic implications. Detailed reports were performed, documenting the clinical rationale for each modification and its associated pharmacoeconomic outcomes.

Results: A total of 630 PLWH are currently under care at our clinic. In 2024, ART-related expenditures amounted to €3,836,710.71, representing a 5% increase compared with 2023 (€3,632,691.16), alongside 25 new patient referrals. Based on this trend, the projected additional expenditure for 2025 was estimated at €200,543.

Between March and December 2025, five multidisciplinary meetings were conducted. Figure 1 shows the 2024 and 2025 expenditure curves, showing a significant downward trend in spending compared with expectations, with annual total savings of €72,912.73. During study period, 80 therapeutic switches were performed (13% of total regimens), of which 55 (69%) were to lower-cost options. Table 1 summarizes the main characteristics of the study population and the key features of the therapeutic changes. Protease inhibitor- and abacavir-based therapies markedly declined, whereas single-tablet formulations, doravirine- and tenofovir disoproxil fumarate-based treatments increased; integrase inhibitor-containing regimens remained stable.

The main reasons for cost-reducing switches (Figure 2) were treatment simplification (36%), proactive optimization (31%), and transition to long-acting injectable therapy (20%). Nearly one-third of high-cost switches were driven by virological failure. To date, no virological failures or treatment-related toxicities have been reported following the ART changes.

Conclusion: Therapeutic modifications implemented as part of the collaborative program led to a significant reduction in ART expenditure, representing a relevant pharmacoeconomic result. This was accompanied by a closer monitoring of ongoing regimens, associated with a marked decrease use of obsolete medications, reduction of pill burden, adoption of long-acting therapies and continuous optimization of patients' cardiometabolic profiles. These findings support the effectiveness of a multidisciplinary collaboration in achieving optimized and sustainable management of ART.

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Antiretroviral Therapy

P 36 REAL-WORLD DURABILITY, SAFETY AND CHANGES IN LIPID AND BODY WEIGHT PROFILES WITH B/F/TAF: A 24-MONTH OBSERVATIONAL STUDY

A. Gasperin¹, G. Mancarella¹, V. Speciale², R. Marocco¹, M. De Masi¹, D. Di Trento¹, L. Ansaldo¹, A. Di Nardo², L. Mazzanti², S. Vita³, A. Carraro³, M. D'Achille⁴, V. Rossi⁴, C. Del Borgo¹, M. Lichtner⁵

¹Infectious Disease Department, Santa Maria Goretti Hospital, Latina, Italy, ²Sapienza, University of Rome, Italy, ³Infectious Disease Department, Sant'Andrea Hospital, Rome, Italy, ⁴Nurse Unit, Infectious Disease Department, Santa Maria Goretti Hospital, Latina, Italy, ⁵Department of NESMOS, Sapienza, University of Rome, Italy

Introduction: B/F/TAF is one of the most commonly used and effective single-tablet antiretroviral therapies (ART) for people living with HIV (PLWH). Over time, we are increasingly concerned about the quality of life of PLWH, focusing not only on effectiveness and safety but also on weight gain and changes in lipid profiles.

In this study, we aim to evaluate not only virological and immunological effectiveness but also weight gain and changes in lipid profiles over 24 months in a real-life cohort of PLWH who either started B/F/TAF as a treatment switch or as naive patients.

Methods: We conducted an observational retrospective study in two peripheral hospitals (S.M. Goretti Hospital, Latina, and Sant'Andrea Hospital, Rome), including PLWH who started or switched to a B/F/TAF regimen during follow-up at our centres, for whom all required virological, immunological, metabolic and weight data were available at baseline and after 12 and 24 months. A descriptive analysis was then performed, using the Mann-Whitney test for continuous variables and the chi-square test for categorical variables.

Results: The total number of recruited patients was 44 naive patients and 129 who switched to B/F/TAF. In both groups, the majority were male (91% and 71%, respectively), with mean ages of 48 and 55 years. The most frequent comorbidities were hypertension and dyslipidaemia, with no significant differences between the two groups. 56.8% of naive patients and 55% of those who switched showed severe immunosuppression, with CD4+ cells <200 cells/mm³. Regarding the viro-immunological aspect, naive patients showed a marked improvement in CD4+ cells, while both groups showed good viro-suppression and a progressive increase in the CD4+/CD8+ ratio.

No significant differences were observed in terms of glycaemia, triglycerides and BMI, with the latter showing a slight increase in both groups, more pronounced in the naive group. A significant difference was evident in weight gain, with 7 kg vs 1 kg ($p < 0.00001$). Total cholesterol, HDL and LDL also increased, with increases of 39 vs -3, 12 vs 0 and 21 vs 1,2 mg/dl, respectively ($p < 0.00001$).

Within the switch group, we then compared patients switching from an INSTI-based therapy (85 patients) with those switching from a therapy with a PI or an NRTI (44 patients). Regarding immunological outcomes, the INSTI-derived group showed a smaller improvement in CD4 count and CD4/CD8 ratio ($p = 0.0003$) than the overall group, whereas the lipid profile and weight gain were comparable between the two groups, with no significant difference.

Conclusion: These findings support the durability, effectiveness and safety of B/F/TAF, but also highlight the need for further management of weight and lipid-related issues in this population.

Antiretroviral Therapy

P 37 RETENTION IN HIV CARE AND LOSS TO FOLLOW-UP IN A SINGLE-CENTRE COHORT: A 10-YEAR ANALYSIS

A. Bilotta¹, A. De Vito¹, E. Ghisu¹, A. Colpani², A. De Filippi³, G. Moi¹, G. Madeddu¹

¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ²Unit of Infectious Diseases, Department of Medicine, San Francesco Hospital ASL-3 Nuoro, Nuoro, Italy, ³School of Medicine, University of Sassari, Sassari, Italy

Background: Retention in HIV care is essential to achieve sustained viral suppression and to prevent morbidity, mortality, and onward transmission. However, a proportion of people with HIV (PWH) disengage from care and become lost to follow-up (LTFU). We aimed to quantify LTFU in our centre and to identify baseline factors associated with disengagement.

Methods: We conducted a retrospective cohort study including all PWH in care at our centre between January 1, 2015 and December 31, 2024. PWH were followed until LTFU or administrative censoring on December 31, 2025. LTFU was defined as no clinic visit, laboratory testing, or antiretroviral drug pick-up for ≥ 12 months. Retention over time was estimated using Kaplan–Meier methods. Cox proportional hazards models were used to identify factors associated with LTFU, including gender, country of birth, and HIV transmission risk category.

Results: A total of 818 PWH were included (Figure 1). The mean age was 45.5 ± 11.0 years; 69.9% were male, 27.3% female, 2.8% transgender women. Most were Italian-born (84.6%). During 7,224 person-years of follow-up, 115 LTFU events occurred (incidence rate 1.59 per 100 person-years). Estimated retention in care was 85.5% at 10 years (95% CI 82.8–87.8) (Figure 2). Among LTFU PWH, the mean age was 39.6 ± 10.9 years (Table 1). Transmission risk was heterosexual in 48.7%, MSM in 14.8%, PWID in 17.4%, and unknown in 14.8%. Two-thirds were Italian-born (66.1%). Median nadir CD4 count was 362 cells/mm³ (IQR 206–577), and 19.1% had a prior AIDS diagnosis. Co-infections included HCV in 20.7% and HBV in 3.5%. Comorbidities were relatively uncommon. During the follow-up, 38 deaths occurred (4.7%), with non-AIDS infections being the most frequent cause (23.7%), followed by AIDS-related conditions, malignancies, and cardiovascular diseases (each 13.2%); 18.4% of deaths had an unknown cause.

The main reasons for LTFU were inability to contact the individual (60.0%) and transfer to another centre (37.4%), while incarceration accounted for 1.7%. Among LTFU individuals, 11 deaths were identified, most with an unknown cause. In multivariable analysis, MSM (HR 0.36, 95% CI 0.21–0.62) and PWID (HR 0.39, 95% CI 0.23–0.65) had a lower risk of LTFU compared to heterosexual transmission, whereas unknown transmission risk was associated with a higher risk (HR 2.82, 95% CI 1.59–4.99). Italian-born individuals had a lower risk of LTFU (HR 0.28, 95% CI 0.19–0.42).

Conclusions: In this cohort, long-term retention in HIV care was high, yet LTFU remains a relevant issue, largely driven by people who become uncontactable. Strategies to improve people tracing and linkage to care across centres are needed, particularly for more vulnerable populations.

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Antiretroviral Therapy

P 38 SWITCH FROM DRV/C/FTC/TAF TO BIC/FTC/TAF IN VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV

G. Massobrio¹, M. Muccio², G. Cologgi¹, G. Sbraccia¹, M. Nofri², S. Cardaci², M. Bassetti^{1,2}, L. Taramasso², A. Di Biagio^{1,2}

¹Department of Health Sciences (DISSAL), University of Genoa, Genoa, Italy, ²Department of Specialist Medicine, Infectious Disease Clinic, IRCCS Azienda Ospedaliera Metropolitana, Genoa, Italy

Background: Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (DRV/c/FTC/TAF) is a protease inhibitor (PI)-based single-tablet regimen with high efficacy and genetic barrier. However, PIs are associated with metabolic complications, including dyslipidemia and insulin resistance. Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF), a second-generation INSTI-based regimen, provides comparable efficacy and resistance barrier and may offer improved metabolic tolerability. Clinical and virological data on this switch remain limited.

Materials and Methods: We conducted a retrospective, single-center study of people with HIV (PWH) who received DRV/c/FTC/TAF between September 2020 and October 2025. Participants were included if virologically suppressed (HIV-RNA <50 copies/mL) for ≥12 months and with at least two visits and laboratory evaluations during the study period. PWH were analyzed separately if they switched to BIC/FTC/TAF (Group A) or did not switch (Group B). Data were collected at -6 months, baseline, 6 and 12 months post-switch, including total cholesterol, LDL, HDL, triglycerides, glucose, CD4+ cell count and HIV-RNA. Index date corresponded to the switch date in Group A and to a randomly assigned reference date in Group B. Duration of PI exposure and concomitant drugs affecting lipid or glucose metabolism were recorded. Virological failure was defined as two consecutive HIV-RNA >50 copies/mL. Longitudinal changes were analyzed using linear mixed-effects models ($p \leq 0.05$).

Results: Of 92 PWH on DRV/c/FTC/TAF, 77 were included; 60 switched to BIC/FTC/TAF and 17 continued DRV/c/FTC/TAF. Injection drug use as HIV acquisition risk factor was reported in 42/60 (70.0%) PWH in Group A and 14/17 (82.4%) in Group B. Median PI exposure was 13.8 years (IQR 11.1–19.7) in Group A and 16.5 years (IQR 13.0–17.2) in Group B. All PWH maintained virological suppression. Statins were used by 11/60 (18.3%) PWH in Group A and 3/17 (17.6%) in Group B. After the index date, total cholesterol appeared stable in Group A while increasing in Group B, although differences were not significant. Similar patterns occurred for LDL, with a pre-index trend toward greater reduction in the switch group and numerical reversal post-index, without significant between-group differences. HDL, triglycerides and glycemia showed minimal changes. CD4+ count and HIV-RNA trajectories did not differ (Table 1).

Conclusions: Although participants on DRV/c/FTC/TAF often present adherence challenges, all maintained virological suppression after switching to BIC/FTC/TAF, supporting the use of INSTI-based therapy even in traditionally difficult-to-treat populations. In the current era of cardiovascular risk prevention, ART modification alone should not replace guideline-recommended statin therapy. Moreover, metabolic benefits may not be fully captured by routine laboratory parameters; therefore, a clinical advantage cannot be excluded while maintaining virological suppression.

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Antiretroviral Therapy

P 39 SWITCH TO A ONCE-DAILY SINGLE-TABLET REGIMEN IN CHILDREN LIVING WITH HIV WITH SUBOPTIMAL ADHERENCE: VIROLOGIC AND IMMUNOLOGIC OUTCOMES

V. Santoiemma, C. Cafagno, A. Orlandi, D. Tricarico, D. Caselli

Giovanni XXIII Pediatric Hospital, Bari, Italy

Background: Children living with HIV may experience difficulties maintaining viral suppression, particularly when adherence to multi-pill antiretroviral therapy (ART) is suboptimal. Single-tablet regimens (STRs) may improve adherence and virologic control. Bictegravir/emtricitabine/tenofovir alafenamide is a once-daily fixed-dose combination approved for pediatric use according to weight.

Materials and Methods: We conducted a retrospective case series of six children living with HIV with documented suboptimal adherence to prior three-drug ART and incomplete viral suppression. Therapy was simplified by switching to once-daily bictegravir/emtricitabine/tenofovir alafenamide using weight-appropriate formulations (standard in four children; low-dose pediatric formulation in two). Adherence was assessed by caregiver report and pharmacy refill data. HIV-1 RNA and CD4+ T-cell counts were evaluated at baseline and after 1–3 months. Safety was monitored during routine follow-up.

Results: After switching to the STR, five of six children showed improved adherence. HIV-1 RNA declined markedly within one month, and most achieved viral suppression by three months. CD4+ T-cell counts increased consistently, indicating immunologic improvement. The regimen was well tolerated, including the pediatric formulation. One child remained non-adherent and did not achieve viral suppression.

Conclusion: In this real-world series, treatment simplification to a once-daily STR was associated with improved adherence, rapid virologic response and immunologic recovery in most children living with HIV who previously experienced adherence challenges. Persistent non-adherence in one case underscores the need for comprehensive adherence support beyond regimen simplification.

Antiretroviral Therapy

P 40 THE INTERPLAY OF CONGENITAL HIV INFECTION AND RENAL FUNCTION: ASSESSING LONG-TERM OUTCOMES IN PEDIATRIC AND ADOLESCENT POPULATION

S.G. De Maria, G. Lorenzetti, A. Cascone, C. Tripiciano, M. De Luca, L. Romani, L. Cursi, L. Colagrossi, R. Scutari, C.F. Perno, S. Bernardi

Bambino Gesù Pediatric Hospital, Rome, Italy

Background: Despite improvements in preventing vertical transmission, pediatric HIV remains a global concern. Early ART has greatly improved survival, yet long-term challenges persist, including renal comorbidities. While ART reduces HIV-related kidney injury, some agents—such as TDF—may cause nephrotoxicity, whereas newer drugs like TAF and INSTI-based regimens offer improved renal safety. For perinatally infected patients, early ART and regular renal monitoring are essential to minimize long-term renal burden.

Materials and Methods: This retrospective descriptive study at Bambino Gesù Children's Hospital (Rome, Italy) included children and adolescents with perinatally acquired HIV born between 2000 and 2025. Demographic, clinical, and laboratory variables were collected from medical records, focusing on renal function (creatinine, eGFR, proteinuria) and ART exposure. Statistical analyses were performed using GraphPad Prism, with results expressed as mean $\pm$ SD or median $\pm$ IQR; significance was set at $p < 0.05$.

Results: A total of 53 patients were enrolled (Table 1), among whom 10 (4 males, 6 females; median ages 17 and 13.5 years, respectively) presented renal abnormalities. Of these, seven exhibited ultrasound-detected renal alterations and three had proteinuria above normal values. Sixty percent of the cohort had AIDS at diagnosis. The median duration of ART was 6.5 years, with treatment initiated at a median age of 20 months. Among patients with renal abnormalities, 50% had started ART late (>24 months), compared with 31% of early-treated controls (1–6 months) (Figure 1). The renal group showed a median of 5.5 years of active HIV replication, versus 7 years in controls. Adherence was similar between groups (30% vs 27.9%). Renal function was preserved in the renal group, with median serum creatinine of 0.66 mg/dL and eGFR of 132.3 mL/min/1.73 m², while albumin levels and BMI were within normal ranges. Regarding ART regimens, 70% of the renal cohort were receiving an INI-based regimen upon renal involvement, with one patient on PI-based therapy and one on an NRTI-based regimen (Figure 2).

Conclusions: HIV and ART exert interconnected yet opposing effects on renal function, making pediatric populations an informative model for studying these dynamics without adult confounders. Continuous renal monitoring and optimized ART are therefore essential to prevent chronic kidney injury and to support long-term health through strategies balancing therapeutic efficacy and renal safety.

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Antiretroviral Therapy

P 41 TREATMENT OF ADVANCED NAIVE HIV-INFECTED PATIENTS WITH BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE IN HIV ADVANCED NAIVE PATIENTS: DATA FROM A REAL-LIFE COHORT

S. Martini¹, A. Russo¹, G. Ricciardiello¹, C. Cacace¹, F. La Guardia¹, L. Salmoni¹, A. Masiello², V. Iodice², A. Del Villano², M. Pisaturo¹, C. Sagnelli^{1,2}, N. Coppola¹

¹UOC Malattie infettive Università degli studi della Campania Luigi Vanvitelli, Napoli, Italy, ²AORN Sant'Anna e San Sebastiano di Caserta, Italy

Background: Advances in HIV research have enabled antiretroviral therapy to achieve high efficacy associated with an optimal quality of life for the patient. This is largely due to the introduction of integrase inhibitors (INIs) that show not only great potency, but good tolerability and solidity, representing the best option to start treatment. These regimens represent a milestone also for the treatment of advanced naïve patients, although there are not clear indications in literature. Our aim is to evaluate retrospectively the outcome of HIV advanced naïve patients admitted to our Unit and treated with a regimen based on Bictegravir/Emtricitabine/Tenofovir alafenamide (BFTAF). The primary objectives of the analysis were the evaluation of rate of surviving, the decay of plasmatic viral replication after starting antiretroviral treatment, the improvement of CD4⁺ count. Secondary objectives were evaluation of the discontinuation rate of BIC/FTC/TAF for eventual adverse events, the rate of occurrence of IRIS, eventual metabolic disorders.

Materials and Methods: We have admitted 26 HIV advanced naïve patients at our Unit from 2020 to 2024, treated with BFTAF. We have evaluated the follow-up data at 1, 6 and 12 months after the start of therapy. Viral replication, CD4⁺ count, metabolic and clinical parameters were evaluated. The mean recovery of CD4⁺ during follow-up, the average time needed to viro-suppression and the eventual onset of IRIS were also considered.

Results: At baseline, enrolled population resulted 81% male, 65% Italian with a median age of 50 years and were all classified as C3. Average duration of hospitalization was 34 days. Average CD4⁺ count was 63 cells/μl, with a 58% of patients who have a value < 50 cells/μl. The average HIV-RNA was about 800.000 copies/ml with 81% of patients with HIV-RNA > 100.000 copies/ml. BFTAF has been introduced in therapy on average after 7 days to reduce risk of IRIS. No case of IRIS was in fact observed and no one discontinued therapy. After 1 month of treatment, average CD4⁺ count was 120 cells/μl, while the rate of viro-suppression resulted 23%. After 6 months of follow-up, average CD4⁺ count increased to 222 cells/μl and viral undetectability was obtained in 88% of patients. No metabolic alterations were observed considering also the short follow-up. After 12 months, average CD4⁺ count increased to 345 cells/μl, viral undetectability remained stable in 88% of patients and a trend of progressive increasing cholesterol was noted.

Conclusions: Our data confirmed efficacy of BFTAF in the treatment of HIV advanced naïve patients. We observed no death, no IRIS and good control of viremia already in the first 6 months with CD4⁺ count higher than 200 cells/μl in 62% of patients. There are not clear indications in international guidelines about the best regimen in this scenario. Our real-life data show that a triple therapy, INI based, may ensure viro-immunological efficacy, already in 6 months, in accordance with literature.

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Antiretroviral Therapy

P 42 TREATMENT OPTIMISATION IN ANTIRETROVIRAL-EXPERIENCED SUBJECTS TREATED WITH DARUNAVIR 600MG BID INCLUDING REGIMES

D. Ripamonti¹, D. Valenti², A. Francavilla², L. Comi¹, S. Venturelli¹, N. Galizzi¹, F. Borghi¹, F. Zoboli¹, F. Crippa¹, M. Zazzi³

¹ASST Papa Giovanni XXIII, Bergamo, Italy, ²FROM - Fondazione per la Ricerca Ospedale di Bergamo - ETS, Bergamo, Italy, ³Department of Medical Biotechnology, Virology Unit, University of Siena, Siena, Italy

Introduction: Boosted darunavir (DRV) dosed 600mg BID has been a key antiretroviral treatment (ART) regimen for circumventing extensive resistance to protease inhibitors (PIs) in heavily treated people with HIV (PWH). The advent of new agents, including INSTIs and doravirine, has favoured DRV dose reduction or replacement, improving metabolic profile, pill burden and cost. The aim of this study was to assess the virologic efficacy of switching from DRV 600mg BID-including regimens in ART experienced PWH.

Methods: Retrospective and single centre study on DRV BID discontinuation in virologically suppressed PWH. The primary end point was virological failure (VF) defined by confirmed plasma HIV RNA >200 copies/ml (or a single value followed by regimen modification) anytime during follow-up. Genotypic DRV susceptibility (S), low- (L), intermediate (I)- or high-resistance (H) was interpreted according to the current Stanford algorithm. Clinical and laboratory data were collected from electronic health records.

Results: A total of 44/52 (85%) subjects previously started on DRV BID were switched to other regimens. Thirty-seven (84%) were males, 20 were past IVDUs and 9 were MSM. At time of switch, median age (IQR) was 56 (51-60) years, median (IQR) ART duration was 24 (28-20) years, median (IQR) time on DRV BID was 105 (60-160) months, 18 subjects had AIDS, while 19 subjects (43%) were already on 2-drug regimens with DRV BID. A total of 33 (75%), 40 (91%), 38 (86%) and 9 (20%) had major resistance mutations to PIs, NRTIs, NNRTIs and INSTIs, respectively. Major resistance mutations to DRV were detected in 14 (32%) subjects, with low- and high-level resistance in 12 (27%) and 2 (0.04%), respectively. Median follow-up time after switching was 54 (21-87) months. During the follow-up, a total of 9 subjects died (causes known in 5 subjects and not AIDS-related). VF occurred in 3 subjects (1 died for liver decompensation, 1 died for meningitis and 1 switched back to DRV BID). At last control, 16 (36%) were receiving DRV 800mg, 6 (14%) a fostemsavir-based therapy, while 31 (70%) and 19 (43%) were on a once-a-day or 2-drug regimen, respectively. The last median (IQR) CD4 count available was 708 (450-989) cells/ml. Median (IQR) TG and LDL cholesterol changed from 153 (112-196) and 172 (162-226) to 121 (94-177) and 184 (168-218) mg/dl, respectively, soon after switching.

Conclusions: Treatment optimization guided by genotypes allowed to switch most subjects (70%) from DRV BID to a once-a-day regimen, and many (43%) on a 2-drug regimen, maintaining long term virological efficacy.

Antiretroviral Therapy

P 43 TRENDS IN REAL-WORLD ANTIRETROVIRAL THERAPY USE IN THE LOMBARDY REGION, 2023–2025

A. Pedot^{1,2}, M. Maffeo^{3,20}, G. Del Castillo^{1,20}, N. Bana⁴, T. Bini⁵, A. Giacomelli^{3,21,20}, M. Mena⁶, M. Cerri⁷, S. Pagano⁸, M. Bottanelli⁹, E. Quiros-Roldan^{10,11}, C. Fornabaio¹², A. Vavassori¹³, G. Mule¹⁴, L. Pagnucco^{15,20}, A. Bandera¹⁶, P. Bonfanti¹⁷, A. Castagna^{18,19}, M. Melazzini¹, D. Cereda^{1,20}

¹Directorate General for Health - Lombardy Region, Milan, Italy, ²Department Biomedical Sciences for Health - University of Milan, Milan, Italy, ³ASST Fatebenefratelli Sacco - University Hospital, Milan, Italy, ⁴Department of Infectious Diseases - ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ⁵Infectious diseases unit - ASST Santi Paolo e Carlo, Milan, Italy, ⁶Infectious diseases unit - ASST Ovest Milanese, Legnano, Italy, ⁷Infectious diseases unit - ASST Lodi, Lodi, Italy, ⁸Infectious diseases unit - ASST Sette Laghi, Varese, Italy, ⁹Infectious diseases unit - ASST Lecco, Lecco, Italy, ¹⁰Infectious diseases unit - ASST Spedali Civili di Brescia, Brescia, Italy, ¹¹Brescia University, Brescia, Italy, ¹²Infectious diseases unit - ASST Cremona, Cremona, Italy, ¹³Infectious diseases unit - ASST Mantova, Mantova, Italy, ¹⁴Infectious diseases unit - ASST della Valle Olona, Busto Arsizio, Italy, ¹⁵Infectious diseases unit - Fondazione IRCCS Policlinico San Matteo, Pavia, Italy, ¹⁶Infectious diseases unit - Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico - University of Milan, Milan, Italy, ¹⁷Infectious Diseases Unit - Fondazione IRCCS, San Gerardo dei Tintori - University of Milano-Bicocca, Monza, Italy, ¹⁸Vita-Salute San Raffaele University, Milan, Italy, ¹⁹IRCCS San Raffaele Scientific Institute, Milan, Italy, ²⁰Regional Center for Infectious Diseases - CEREMI - Lombardy Region, Milan, Italy, ²¹Department of Biomedical and Clinical Sciences - University of Milan, Milan, Italy

Background: The aim of this study is to describe antiretroviral (ARV) therapies prescribed to people with HIV(PWH) in the Lombardy Region, using real-world data to assess the alignment of clinical practice with current treatment recommendations and to identify potential areas for improvement.

Methods: Administrative data on ARV drugs prescribed through Italian National Health System were used to identify PWH, defined as individuals with at least two ARV prescriptions within 270 days, excluding ARV used for pre-exposure prophylaxis. Data from 1 January 2023 to 31 December 2025 were included for people aged ≥18 years. For each calendar year, individuals were classified by ARV regimen and infectious disease clinic (IDC) according to the last dispensing of the year; those not attributable to any IDC were categorized as “other”, and for one IDC data were available only for 2025.

The analysis assessed ARV use across the Lombardy Region and individual IDCs, highlighting variations in prescribing patterns and changes in the proportion of specific regimens between 2023 and 2025.

Results: In 2025, 30,327 PWH were identified based on ARV prescriptions. Of these, 74% were male; the median age was 57 years (IQR 48–62), and 19% were born abroad.

Figure 1 shows the proportion of patients receiving a single-tablet regimen (STR) and CAB/RPV. It increased from 83.6% to 88.1% in the Lombardy Region between 2023 and 2025 and, in 2025, varied across IDCs from 81% to 93%.

The five most commonly used ARV regimens in 2025 are listed below, with the percentage of PLWH receiving each regimen and the range across IDCs (highest to lowest) shown in brackets:

BIC/TAF/FTC (n=9753; 32%) [49.7%–16.4%]

DTG/3TC (n=8931; 29%) [39.9%–17.8%]

RPV/FTC/TAF (n=2041; 7%) [15.7%–1.5%]

CAB/RPV (n=1835; 6%) [11.6%–0.48%]

DTG/RPV (n=1683; 5%) [17%–2%]

Between 2023 and 2025, the largest increases in prescriptions were observed for BIC/TAF/FTC (+9.8%), DTG/3TC (+4.4%), and CAB/RPV (+1.2%), while the greatest decreases were seen for DTG/ABC/3TC (–3.9%), RPV/FTC/TAF (–3.7%), DRV/c/FTC/TAF (–2.0%).

Conclusions: Between 2023 and 2025, the uptake of dual regimens, INSTI-based combinations, and long-acting injectable therapies increased, consistent with the recommendations outlined in the regional care pathway document (P-PDTA), updated in 2025, which facilitates the local implementation of national and international guidelines. Despite this overall improvement, relevant heterogeneity in prescribing patterns across IDCs persisted, which is unlikely to be explained solely by differences in patient case-mix. A regional monitoring system has been established and is regularly shared with clinicians, providing benchmarking data on regimen use across IDCs and supporting quality improvement initiatives. This process has already promoted progressive revision and replacement of outdated regimens. These findings reinforce its role as a governance tool and highlight areas for targeted quality improvement interventions.

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Antiretroviral Therapy

P 44 UNDETECTABLE AT LAST: VIRAL SUPPRESSION AFTER OVER 30 YEARS IN A PERSON LIVING WITH PAN-RESISTANT HIV FOLLOWING LENACAPAVIR INTRODUCTION

D. Diana^{1,2}, T. Clemente³, D. Canetti³, C. Muccini³, G. Annicchiarico³, C. Ballabio¹, A. Castagna^{1,3}, V. Spagnuolo^{1,3}

¹Vita-Salute San Raffaele University, Milan, Italy, ²University of Naples Federico II, Naples, Italy, ³Infectious Diseases, IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: HIV is characterized by high genetic variability and the capacity to develop drug resistance. Pan-resistant HIV describes infection with a virus harboring resistance-associated mutations across at least five antiretroviral classes, resulting in the absence of fully active drugs and severely limited treatment options.

Case presentation: A 66-year-old man living with HIV since 1986 and chronic hepatitis B virus (HBV) coinfection has initiated Antiretroviral Therapy (ART) in 1990. The treatment was frequently taken irregularly due to reported adverse events and poor adherence, therefore the virus (X4 tropic) developed resistance to all drugs in the four major antiretroviral classes (NRTIs, NNRTIs, PIs, INSTIs) and temsavir. Virological failure was also documented during treatment with enfuvirtide, although no resistance mutations were identified [Fig. 1].

Multiple AIDS-defining events were experienced with a persistently inadequate CD4+ count (90 cells/mm³ in January 2026; median CD4 since 1997: 50 cells/mm³ [IQR 24–85] [Fig. 2]).

Background therapy was progressively optimized to atazanavir/cobicistat (300/150 mg once daily), emtricitabine/tenofovir alafenamide (200/10 mg once daily) and islatravir/doravirine (0.75/100 mg once daily); however, only partial plasma HIV-RNA stabilization was achieved from 2019 onward (median HIV-RNA since 2019: 1065 copies/mL [IQR 533–2630]) following initiation of intravenous ibalizumab (800 mg every 2 weeks after a loading dose) [Fig. 3]. Slight recovery of the CD4 count was observed (Median CD4 count since 2019: 60 cells/mm³ [IQR 31–93]).

Complete virological suppression was attained only after the introduction of lenacapavir in January 2026. Subcutaneous lenacapavir 927 mg every 6 months (with an oral loading dose) was initiated together with bictegravir (B)/F/TAF 50/200/25 mg qd, while continuing ibalizumab and DOR/ISL, to achieve an undetectable viral load, reducing pill burden, increase adherence and minimize adverse events. This change was made taking into account the HBV coinfection, the lack of previous exposure to lenacapavir, the lack of exposure to integrase inhibitors in the previous 6 years and the possible residual activity of ibalizumab. Virological suppression was achieved after only 14 days and for the first time in more than 35 years of ART. HIV-RNA remained <200 copies/mL in the next month and neither lenacapavir-related adverse events nor signs of immune-related inflammatory syndrome were reported.

Conclusions: Virological suppression may be achievable even in the setting of pan-drug resistance and significant adherence challenges through careful optimization of antiretroviral therapy, taking into account residual drug susceptibility and innovative routes of administration. Lenacapavir, with its novel mechanism of action and long-acting formulation, may represent a pivotal therapeutic option for these highly vulnerable individuals.

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Antiretroviral Therapy

P 45 VALIDATION OF THE 90% PROPORTION OF DAYS COVERED THRESHOLD AGAINST THE WHO 95% VIROLOGICAL SUCCESS TARGET IN PEOPLE LIVING WITH HIV

F.V. Segala¹, E. Vania¹, D. Mengato², D. Leoni¹, S. Gardin¹, A. Ferrari¹, G. Berti², L. Sasset¹, A. Cattelan^{1,3}

¹Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ²Hospital Pharmacy Unit, Azienda Ospedale-Università Padova, Padua, Italy,

³Department of Molecular Medicine, University of Padua, Padua, Italy

Background: The Proportion of Days Covered (PDC) is widely used to measure antiretroviral therapy (ART) adherence, with a threshold of $\geq 90\%$ conventionally defining adequate adherence. Empirical confirmation of this threshold in contemporary real-world cohorts, particularly in the context of the UNAIDS 95% virological success target, remains clinically relevant. In this study, we aimed to characterise the relationship between PDC and virological outcomes across the full adherence spectrum.

Methods: Observational retrospective cohort study including all people living with HIV (PLWH) attending our HIV Outpatient Clinic between January 2024 and June 2025, on stable ART for at least 6 months. Adherence was measured by the Proportion of Days Covered (PDC) from pharmacy refill records. The virological outcome was the worst HIV-RNA recorded during follow-up. The probability of achieving HIV-RNA < 200 cp/mL across the PDC spectrum was modelled using logistic regression with a natural spline ($df=4$), with 95% confidence intervals. Virological outcome distribution across PDC bins was summarised as proportions in three categories: suppressed (< 50 cp/mL), low-level viremia (50–200 cp/mL), and overt viremia (> 200 cp/mL). Independent predictors of virological success were identified by multivariable logistic regression.

Results: Among 1,086 patients with available viral load data, the forgiveness curve demonstrated a steep increase in virological success probability as PDC approached 90%, with the curve reaching and exceeding the 95% success threshold precisely at PDC = 90% (Figure 1A). In the PDC 90–94% bin, 95.2% of patients achieved HIV-RNA < 200 cp/mL, meeting the WHO target (Figure 1B). Virological suppression (< 50 cp/mL) exceeded 90% in patients with PDC $\geq 90\%$ and increased progressively with higher adherence. On multivariable logistic regression (Table 1), each 10% increment in PDC was independently associated with significantly higher odds of virological success (aOR 1.51, 95% CI 1.29–1.77; $p < 0.001$), after adjustment for age, sex, region of origin, years on ART, baseline CD4 count, and ART switch during follow-up. Origin from the WHO African region (aOR 0.34, 95% CI 0.18–0.64; $p < 0.001$) and higher baseline CD4 count (aOR 1.16 per 100 cells/ μ L, 95% CI 1.05–1.29; $p = 0.005$) were additional independent predictors.

Conclusions: In this real-world cohort, a PDC threshold of 90% corresponds to the UNAIDS 95% virological success target, providing empirical validation of the conventional 90% PDC cutoff. These findings support the use of PDC $\geq 90\%$ as a clinically meaningful and operationally actionable adherence benchmark in routine HIV care.

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Antiretroviral Therapy

P 46 VIRO-IMMUNOLOGICAL EFFECTIVENESS OF DOR/3TC/TDF AS A SWITCH REGIMEN AFTER 144 WEEKS OF OBSERVATION IN THE DOROTEA STUDY COHORT

A. Ciccullo¹, G. Balducci², A. Tommasi³, A. Cervo⁴, G. Formica⁵, M.V. Cossu⁶, M. Fabbiani⁷, E. Altavilla⁸, G. Madeddu⁹, S. Colaiuda¹⁰, F. Lagi⁵, C. Papalini³, A. Giacomelli⁶, C. Mussini⁴, S. Di Giambenedetto^{2,10}

¹Infectious Diseases Unit, Ospedale San Salvatore, L'Aquila, Italy, ²Infectious Diseases Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, ³Department of Medicine and Surgery, Section of Infectious Diseases, University of Perugia, Perugia, Italy, ⁴Department of Infectious Diseases, Azienda Ospedaliero-Universitaria di Modena, Modena, Italy, ⁵Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy, ⁶Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ⁷Department of Medical Sciences, Infectious and Tropical Diseases Unit, University Hospital of Siena, Siena, Italy, ⁸Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ⁹Infectious Diseases Unit, University of Sassari, Sassari, Italy, ¹⁰Catholic University of the Sacred Heart, Rome, Italy

Background: We aim to assess the virological and immunological effectiveness of DOR/3TC/TDF as a switch regimen after 144 weeks in clinical practice.

Material and Methods: This was an observational study enrolling virologically-suppressed people with HIV (PWH) switching to DOR/3TC/TDF in the multicenter cohort DOROTEA. Clinical history and virological parameters were collected. Kaplan-Meier survival analysis was performed to evaluate time to virological failure (VF), defined as one HIV-RNA >1000 copies/mL or two consecutive HIV-RNA >50 copies/mL, and Cox regression to explore predictors of VF.

Results: Overall, 439 PWH were included: 314 (71.5%) were males, with a median age of 51 years (IQR 43-58). Full population characteristics are shown in Table 1.

During 1098.3 PYFU, we observed 30 VF (2.73 per 100 PYFU). Of the 30 VF events, 11 (36.7%) maintained DOR/3TC/TDF and all regained virological suppression during follow-up, suggesting transient viremia rather than confirmed treatment failure.

Estimated probabilities of maintaining virological suppression at 48 and 144 weeks were 97.2% (SD±0.9) and 91.4% (SD±1.6), respectively.

At multivariate analysis, having experienced a prior VF (vs. not having a history of VF, aHR 6.04, 95%CI 2.13-17.18, p=0.001) was significantly associated with a higher risk of VF while a longer exposure to ARV (per 1-year increase, B -0.12, aHR 0.88, 95%CI 0.79-0.99, p=0.035) was inversely associated with VF, after adjusting for years of HIV infection, CDC stage, peak HIV-RNA, CD4+ cell count at baseline and CD4+ nadir count. VF occurred predominantly among individuals with a prior history of VF: at 144 weeks, the probability of maintaining virological suppression was 93.3% in those without prior VF compared to 72.5% in those with prior VF (log-rank p<0.001).

Regarding emergent resistance mutations, among individuals with available genotypic testing at failure (9/30), no emergent resistance mutations to doravirine, lamivudine or tenofovir disoproxil fumarate were detected.

Finally, CD4+ cell count and CD4/CD8 ratio progressively improved over time, with statistically significant increases at weeks 48, 96, and 144, indicating sustained immunological recovery. In particular, CD4+ cell increase was more pronounced in PWH with lower CD4+ count at baseline (per 10 cell/uL more, B -1.6, p=0.001) and less pronounced in those with a higher peak HIV-RNA (B 36.0, p=0.021) and a higher nadir CD4+ cell count (per 10 cell/uL more B 2.5, p=0.006) after adjusting for age, sex at birth, CDC stage, years since HIV diagnosis and years of ARV exposure.

Conclusions: In this real-world cohort, switching to DOR/3TC/TDF was associated with high rates of sustained virological suppression over 144 weeks, low incidence of virological failure, and no evidence of emergent resistance. Immunological parameters continued to improve over time. These findings support the long-term robustness of this regimen in virologically suppressed PWH.

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Antiretroviral Therapy

P 47 VIROLOGICAL, IMMUNOLOGICAL AND METABOLIC OUTCOMES AFTER SWITCH TO DUAL THERAPY WITH LAMIVUDINE + DORAVIRINE IN VIROLOGICALLY SUPPRESSED PEOPLE LIVING WITH HIV (PLWH): A 24-MONTH REAL-WORLD STUDY

F. Vignale, K. Luzi, L. Caiazza, G. Vandì, C. Biagetti

Clinic of Infectious Diseases, Infermi Hospital, Rimini, Italy

Background: Two-drug maintenance strategies represent a valuable option for PLWH with long-term viral suppression and multiple comorbidities. Dual regimens with lamivudine (3TC) are commonly combined with protease inhibitors (PI) or integrase inhibitors (INI); however, Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) have historically been limited by concerns regarding genetic barrier. Doravirine, a newer NNRTI with favorable resistance profile and tolerability, may represent a suitable option. Real-world long-term data remain limited.

Methods: We conducted a single-center retrospective observational study including virologically suppressed PLWH followed at the Infectious Diseases Clinic of Rimini Hospital between 2021 and 2025, who switched to dual therapy with lamivudine plus doravirine. Virological failure (VF) was defined as two consecutive HIV-RNA >50 copies/mL, one HIV-RNA >200 copies/mL followed by switch, or one HIV-RNA >1000 copies/mL. Paired changes in metabolic parameters from baseline to 6 and 12 months were assessed using Wilcoxon signed-rank tests. The observation period was 24 months for viro-immunological parameters and 12 months for metabolic outcomes.

Results: During the study period 96 PLWH received doravirine plus lamivudine, 40 were female (41, 7%), with a median age of 59 years (IQR 53–64). Characteristics of the study population are reported in Table 1. Median duration of viral suppression before switch was 180 (118–240) months. Comorbidity burden was substantial. No resistance mutations to 3TC/NNRTI were documented in available historical data. During follow-up, two patients (2.1%) discontinued DOR/3TC: one patient (1.0%) experienced virological failure, with two consecutive HIV-RNA measurements slightly above 50 copies/mL (51 and 72 respectively). RNA sequencing at failure was not feasible; however, proviral DNA testing did not reveal resistance mutations. The second patient (1.0%) discontinued treatment and returned to the previous antiretroviral regimen by personal preference. CD4 counts remained stable with a slight increase at 12 and 24 months; the CD4/CD8 ratio improved over time, including among CDC stage 3 patients. Metabolically, total cholesterol decreased at 6 months (203 to 187 mg/dL; $p=0.0097$) and 12 months (198 to 183 mg/dL; $p=0.0030$). LDL cholesterol showed a significant reduction at 12 months (114 to 105 mg/dL; $p=0.0256$), triglycerides decreased at 12 months (110 to 98 mg/dL; $p=0.0011$); HDL cholesterol remained unchanged. To date, no major clinical events have been documented among patients on dual doravirine/lamivudine therapy.

Conclusions: In our cohort, switch to lamivudine plus doravirine demonstrated a favourable safety and efficacy profile, maintaining viral suppression, stable/improving immunological markers and a favourable metabolic profile. DOR/3TC may represent a viable maintenance option in carefully selected patients with long-term suppression and multiple comorbidities.

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Cancer

P 48 EXTRACAVITARY PRIMARY EFFUSION LYMPHOMA AS AN HHV-8-DRIVEN LYMPHOPROLIFERATIVE DISORDER IN ADVANCED HIV: A CASE SERIES

E. Matteini¹, M. Bibas², I. Mastrorosa¹, A. Mondì¹, C. Pinnetti¹, S. Grisetti¹, F. Baldini¹, D. Colombo³, F. Del Nonno³, V. Mazzotta¹, A. Antinori¹

¹HIV/AIDS Unit, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Roma, Italy, ²Hematology Service, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Roma, Italy, ³Pathology Unit, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Roma, Italy

Background: Primary effusion lymphoma (PEL) is a rare and aggressive human herpesvirus 8 (HHV-8)-driven B-cell lymphoma occurring predominantly in immunocompromised individuals, particularly people living with HIV (PLWH). Rarely, it presents as solid tumors without effusions, known as the extracavitary variant (extracavitary PEL, EC-PEL).

Material and Methods: We retrospectively describe three cases of EC-PEL diagnosed in PLWH at a tertiary referral center during the years 2025-2026. Clinical presentation and viro-immunophenotypic features were reviewed. Diagnoses were established according to WHO Classification of Tumours of Haematolymphoid Tissues (5th edition).

Results: Demographic, HIV-related, and PEL-related data are shown in Table 1.

Case 1: A 29-year-old man with newly diagnosed advanced HIV infection presented with gastrointestinal (GI) mass lesions (Figure 1). Histology demonstrated an HHV-8-positive, CD30-expressing plasmablastic large-cell proliferation with an aberrant immunophenotype and high proliferative index. Findings supported aggressive EC-PEL involving the upper GI tract. The patient received four cycles of chemotherapy (R-CHOP regimen) in combination with antiretroviral therapy (dolutegravir plus emtricitabine/tenofovir disoproxil). Despite endoscopic evidence of favorable response, whole-body 18F-FDG PET/CT demonstrated persistence of a single intensely FDG-avid lymph node (SUVmax 19) in hypogastric region. Histology documented a CD20-negative lymphoproliferative disease. Considering the immunohistochemical profile, intensification of chemotherapy was planned.

Case 2: A 43-year-old man with newly diagnosed advanced HIV infection was admitted with severe pancytopenia, diffuse lymphadenopathy, and hepatosplenomegaly. Lymph node biopsy showed HHV-8-positive, high-grade plasmablastic/anaplastic lymphoma with aberrant immunophenotype, partial CD30 expression, EBV co-infection, and very high proliferation, leading to the diagnosis of EC-PEL. Despite supportive care and chemotherapy (one cycle), the course was rapidly progressive.

Case 3: A 58-year-old man with long-standing well-controlled HIV infection and a prolonged history of HHV-8-associated lymphoproliferative disorders (Kaposi's sarcoma, multicentric Castleman disease, and diffuse large B-cell lymphoma) demonstrated progression over the years to overt EC-PEL. Lymph node biopsy demonstrated HHV-8-positive high-grade plasmablastic/immunoblastic lymphoma with aberrant immunophenotype, CD30 expression, and high proliferative index. The patient rapidly progressed to death after diagnosis, before chemotherapy initiation.

Conclusion: Our data confirmed that EC-PEL is a highly aggressive AIDS-defining event associated with dysregulated HHV-8-driven lymphoproliferation, heterogeneous clinical presentation, and poor prognosis. Awareness of extracavitary presentations and routine HHV-8 testing in atypical lymphoid proliferations in PLWH is essential to prompt diagnosis and interventions.

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Cancer

P 49 FIVE-YEAR CANCER MORTALITY AMONG PEOPLE WITH HIV: A MONOCENTRIC RETROSPECTIVE STUDY

M. Matone¹, G. Pozza¹, D. Dalu², L. Oreni¹, C. Fasola², M.V. Cossu¹, G. Carrozzo¹, A. Poloni¹, C. Fusetti¹, D. Moschese¹, N. La Verde², A. Gori^{1,3,4}, A. Giacomelli^{1,3}

¹Department of Infectious Diseases, ASST Fatebenefratelli Sacco, Luigi Sacco University Hospital, Milan, Italy, ²Department of Oncology, ASST Fatebenefratelli Sacco, Luigi Sacco University Hospital, Milan, Italy, ³Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milan, Italy, ⁴Centre for Multidisciplinary Research in Health Science (MACH), Milan, Italy

Background: Malignancies have become a major cause of morbidity and death in people with HIV (PWH) with a progressive shift from AIDS-defining cancers (ADCs) to non-AIDS-defining cancers (NADCs). We aimed to evaluate five-year mortality among PWH with malignancies.

Materials and Methods: We conducted a retrospective monocentric cohort study including adult PWH followed at the Department of Luigi Sacco Hospital (Milan, Italy) and diagnosed with cancer between 2000 and 2019. Follow up ended on 31st December 2024. Cancers were classified as ADCs or NADCs, further stratified into virus-related and non-virus-related. Patients were grouped according to the period of cancer diagnosis: 2000–2007 and 2008–2019, based on the introduction of integrase inhibitors in clinical practice. Five-year all-cause and cancer-specific mortality were estimated by means of Kaplan Meier curves. Cox proportional hazards models were used to assess mortality risk across different periods, adjusting for sex assigned at birth, age, HIV transmission risk group, previous AIDS diagnosis, and HCV co-infection.

Results: Among 4,473 PWH, 472 patients (10.6%) developed at least one malignancy, accounting for 490 cancer diagnoses. At five years, 35.3% (95% CI 31.1–39.5) of PWH with a cancer diagnosis had died, with lower mortality observed in the more recent period (43.8% [95% CI 37.3–50.3] in 2000–2007 vs 28.2% [95% CI 22.8–33.6] in 2008–2019; $p < 0.001$). Among ADCs, five-year all-cause mortality decreased markedly from 38.8% (95% CI 30.8–48.8) to 12.5% (95% CI 6.8–23.1), with a parallel reduction in cancer-specific deaths (aHR 0.28 [95% CI 0.13–0.58]; $p < 0.001$). The greatest five-year all-cause mortality reduction was observed among PWH with non-Hodgkin lymphoma (aHR 0.33 [95% CI 0.14–0.77]). Virus-related NADCs also exhibited a significant all-cause mortality reduction, (56.1% [95% CI 42.8–73.5] to 31.2% [95% CI 21.5–45.4]; aHR 0.25 [95% CI 0.13–0.51]; $p < 0.001$), particularly for hepatocellular carcinoma (aHR 0.13 [95% CI 0.05–0.36]). PWH with non-virus-related NADCs experienced a less pronounced decline in all-cause mortality, from 50.0% (95% CI 38.8–64.4); to 37.3% (95% CI 29.7–46.8), (aHR 0.48, 95% [CI 0.29–0.80]; $p = 0.005$). Among PWH with lung cancer, five-year all-cause mortality decreased from 84.6% (95% CI 67.1–99.9) to 68.0% (95% CI 52.0–89.0), although this reduction was not statistically significant (aHR 0.41 [95% CI 0.14–1.20]; $p = 0.103$) (Table 1, Figure 1).

Conclusions: In our cohort, cancer-related mortality declined over time both for ADCs and virus related NADCs. Since the magnitude of the reduction was not the same for all NADCs, targeted prevention, early diagnosis, and optimized oncological care in aging PWH are warranted.

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Cancer

P 50 FROM GUIDELINES TO CLINICAL PRACTICE: LUNG CANCER SCREENING ADHERENCE, PRELIMINARY DATA FROM THE MODENA HIV COHORT

F. Calandra Buonauro¹, E. Delmonte¹, F. Prandini¹, U. Calvi¹, A. Cervo², G. Cuomo², M. Menozzi², C. Mussini¹

¹Infectious Diseases Clinic, University of Modena and Reggio Emilia, Modena, Italy, ²Infectious Diseases Clinic, Azienda Ospedaliero-Universitaria, Policlinico of Modena, Modena, Italy

Background: With increased life expectancy of people living with HIV (PLWH), non-AIDS-defining cancers (NADCs) represent a major cause of cancer-related morbidity and mortality. Among these, cancers with effective screening strategies are key targets for prevention, yet real-world data on screening uptake in PLWH remain limited. The aim of the study was to evaluate the gap between the 2023 European AIDS Clinical Society (EACS) Guidelines and clinical practice.

Methods: This single-centre retrospective study included PLWH aged ≥ 18 years actively followed at the Modena HIV Clinic (Modena, Italy) between January 1st, 2023, and December 31st, 2025. Electronic charts and radiology records were reviewed to identify lung CT scans among individuals eligible per EACS 2023 criteria: current or former smokers (quit < 15 years), age between 50–80 years, pack-years > 20 . Adherence was defined as CT execution during the study period: none (no CT performed ever), partial (one CT), or full (≥ 2 CTs). Socio-demographic, behavioural, HIV-related, and cancer-related variables (including biopsy and results) were collected. Descriptive analyses were performed by adherence category.

Results: Preliminary data include 405 former (N=174) or current smokers (N=231). Among former smokers, 29% were eligible (N=46), while 71% of current smokers met criteria (N=113). In the eligible group (N=159), male-to-female ratio was 4:1 (120 vs 39), mean age 61 years (IQR 58–65), mean HIV duration 32 years (IQR 22–39), and mean CD4+ nadir 221/ml (IQR 110–327). HIV-RNA was undetectable in 99% (N=156); mean pack-years was 37 (IQR 28–43). Socio-demographic characteristic and HIV-related variables were stratified for adherence, as shown in Table 1.

Of the 159 eligible individuals, 113 (71%) had no adherence, 39 (25%) partial adherence, and 7 (4%) full adherence. Adherence was higher in individuals with shorter HIV duration ($p=0.006$). CT results were negative in 26 (56%) cases. Nodules > 1 cm, < 1 cm, and multiple micronodules were detected in 9 (19%), 5 (11%), and 4 (8.7%) cases, respectively. Biopsy was performed in 4 cases, confirming 3 lung cancers. Screening uptake and results were described as a cascade of care model in Figure 1. Additionally, 18 (11%) individuals underwent lung CT scan for other reasons; 7 showed nodules/micronodules and 2 biopsies were positive for malignancy.

Conclusion: These preliminary findings confirm the importance of lung cancer screening in PLWH. A not negligible gap exists between guidelines recommendation and clinical practice in CT execution, that in our population was not guided by specific behavioural or socio-demographic determinants. A major effort should be done integrating risk algorithms and screening programs within routine clinical practice to allow earlier and proactive diagnosis of lung cancer.

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Cancer

P 51 UPTAKE OF ANAL CANCER SCREENING AMONG TRANSGENDER WOMEN WITH HIV

S. Lazzarin¹, C. Fusetti¹, F. Caruso¹, A. Giacomelli^{1,2}, L. Oreni¹, M.V. Cossu¹, F. Petri¹, V. Iannone¹, C. Gervasoni¹, A.L. Ridolfo¹, A. Riva^{1,2}, A. Gori^{1,2}, D. Moschese¹

¹Department of Infectious Diseases, ASST Fatebenefratelli-Sacco University Hospital, Milan, Italy, ²Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy

Background: Transgender women with HIV (TWWH) have the highest incidence of HPV-related anal cancer. Current guidelines recommend initiating anal cancer screening in this population at age 35, with repeat screening at 1–2-year intervals. Nevertheless, TWWH remain medically underserved, facing structural and healthcare-related barriers that limit access to preventive services. This study aimed to assess anal cancer screening uptake among TWWH receiving care at our centre.

Materials and Methods: TWWH receiving care at the Clinic of Infectious Diseases (ASST FBF-Sacco, Milan) at the time of publication of the 2024 International Anal Neoplasia Society guidelines were included. We assessed the proportion who underwent at least one anal cancer screening between February 1, 2024, and February 1, 2026. Screening-related variables included HPV-16 positivity, cytology results, and concomitant bacterial sexually transmitted infections (bSTIs). Baseline sociodemographic and behavioural characteristics, HIV-related parameters, and HPV vaccination status were collected. Associations between these variables and screening uptake were evaluated using logistic regression analysis.

Results: Seventy-eight TWWH were included, predominantly of South American origin, with a median age of 48 years (IQR 41–56). The median duration of HIV infection was 14 years (IQR 8–21). A previous AIDS-defining condition was reported in 29.5%, and median nadir CD4+ count was 257 cells/μL (IQR 113–393). At baseline, 93.6% of participants were virologically suppressed, with a median CD4+ count of 691 cells/μL (IQR 463–966). Engagement in sex work was reported by 73.1%, and only 12 (15.4%) had received a full course of HPV vaccination (Table 1). Overall, 32% of participants underwent at least one anal cancer screening during the study period. Among those screened, HPV-16 was detected in 33.3%, cytology was negative in 76%, and concomitant anal bSTIs were identified in 8.3% (Table 2). In multivariable logistic regression analysis, only previous HPV vaccination was independently associated with anal cancer screening uptake (aOR 6.33, 95% CI 1.62–24.74, p=0.008).

Conclusions: Anal cancer screening uptake among TWWH in our cohort was low, despite clear guidelines recommendations. This finding highlights gaps in the delivery of preventive services to a highly vulnerable population, likely reflecting stigma, systemic barriers and limited access to care. Although HPV vaccination was independently associated with screening uptake, this association may reflect greater healthcare engagement, prior screening history, or increased clinician and patient awareness rather than a direct effect of vaccination itself. The lack of a control group with comparable anal cancer risk, such as men who have sex with men, precludes direct comparisons in screening uptake. Nevertheless, these findings suggest that targeted strategies are needed to improve access to anal cancer screening in this high-risk population.

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Epidemiology, Social Sciences and PROs

P 52 2011-2025 HEALTH AND SOCIAL CARE FOR PLWH IN HIV/AIDS OUT-OF-HOSPITAL FACILITIES IN LOMBARDY

L. Rancilio, T. Bianchini, C. Castelli, M. Deghi, G. Gaiera, P. Meli

Coordinamento Case Alloggio per persone con HIV/AIDS della Lombardia (CRCA Lombardia) - CICA, Milano, Italy

Opened at the end of the 1980s, the Lombardy HIV/AIDS Family Homes seek to care to the significant health and social needs of PLWH who have been referred to them by the national health service.

Material and Methods: Since 2011, the "Coordinamento Case Alloggio per persone con HIV/AIDS della Lombardia (CRCA Lombardia)" has been collecting anonymized data about its guests by an extended C.E.R.C.A.Re. project form. The assessment form used annually by CRCA includes several items from the AIDASS (form for multidimensional assessment used in the Lombardy Region since 2001) and is enriched with additional aspects regarding substance addictions, support needs, criminal problems, and social situation (relational, economic, housing). This allows for the assessment of various aspects of the guests' health and social care needs and their evolution over time. The sum of the total scores ranges from 0 to 1500, with a maximum of 1100 points assigned to health needs and 400 to social needs.

Results: Between 2011 and 2025, 1076 people, hosted in CRCA HIV/AIDS facilities in Lombardy, had a complete evaluation. 170/1076 (15,8 %) came from abroad: 86/803 men, 66/252 women, 18/21 transgender; 102/170 (60 %) from Africa, 36 from Central-South America, 27 from Europe, 5 from Asia. At the time of first observation 47/170 were without a residence permit (RP).

2.6 % of Italians versus 23.5% of foreigners were aged 19-35, 60.6 % versus 51.2 % 36-50, 51.9 % versus 25.3 % 51-65, while those aged over 65 represented 4.9 % of Italians and 0% of foreigners.

Notably, the average overall score for Italian guests has remained relatively stable over the observation period. In contrast, the average score for foreign guests, especially those without a residence permit, has remained consistently higher, especially from 2019 onwards (Fig.1). No significant differences related to sex were observed.

By breaking down the total score into the various components, it can be observed that the scores for physical disability (Fig. 2) and social problems (Fig. 3) contribute to a greater extent for the non-Italian population, while the average values for psychiatric problems (Fig. 4) or assistance needs (Fig. 5) do not differ significantly in the three groups. Problems arising from addiction are still present to some extent in the Italian population (Fig.6).

During the observation period, many guests experienced one or more transfers to other care units, sometimes at a lower level of care in the event of clinical and/or social improvement. Some foreign nationals without a residence permit subsequently obtained one, while a smaller proportion lost their permit.

Considering the average total time spent in CRCA HIV services, it can be noted that Italian citizens remain on average much longer in each type of service (Table 1).

It is therefore necessary to work in order to provide guests with the opportunity not only to receive health care but also to have a chance of integration into society.

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Epidemiology, Social Sciences and PROs

P 53 A DECADE OF HEPATITIS C PREVENTION IN YOUNG PEOPLE: A PATIENT ASSOCIATION-LED EDUCATIONAL MODEL IN SCHOOL AND COMMUNITY SETTINGS IN SOUTHERN ITALY

A. Cavallaro, M.C. Muscio, M. Bartoli, M. Conforti

Associazione Epac-ETS, Monza, Italy

Background: Long-term educational initiatives are crucial for HCV elimination, yet their sustainability can be challenged by external factors. The Italian patient association Epac-ETS has run "Una vita un fegato. La prevenzione inizia a scuola," a school- and community-based prevention program in the province of Salerno, Southern Italy, since 2015. This study evaluates its long-term effectiveness and resilience, particularly in the context of the COVID-19 pandemic.

Material and Methods: A structured educational program was implemented annually. The intervention consisted of in-person seminars delivered in a diverse range of settings. Crucially, the outreach extended beyond high schools to include key community-based organizations such as a beauty school (to address iatrogenic risks), a women's health association, and social cooperatives serving vulnerable youth. The program ran continuously from 2015 to early 2020, faced a two-year interruption (2020-2022) due to the COVID-19 pandemic, and successfully resumed in late 2022. Program effectiveness was evaluated via an anonymous pre-test/post-test questionnaire.

Results: Over its entire course (2015-2026), the program is projected to reach a total of 6,765 participants (table 1). The project demonstrated remarkable resilience, achieving its highest participation levels in the two years immediately following the pandemic-related pause (n=1,016 in 2022/23 and n=995 in 2023/24). Analysis of the questionnaires revealed that baseline knowledge of HCV was often suboptimal, with specific gaps concerning transmission risks via tattoos and piercings. In contrast, post-intervention questionnaires consistently showed a high level of correct responses and a comprehensive understanding of HCV transmission routes and prevention strategies.

Conclusions: A patient association-led educational model, targeting both general and specific youth populations, is a highly effective and resilient strategy for significantly increasing HCV prevention knowledge. The program's ability to successfully restart and achieve sustained high participation after a forced two-year halt underscores its robustness and community acceptance. This model serves as a powerful example for public health initiatives facing external disruptions.

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Epidemiology, Social Sciences and PROs

P 54 A PHYSICIAN-SUPERVISED, NURSE-LED MODEL FOR LONG-ACTING ANTIRETROVIRAL THERAPY: PATIENT-REPORTED EXPERIENCE FROM A DEDICATED OUTPATIENT SERVICE

M.V. Cossu¹, M. Matone¹, D. Moschese¹, A. Bergna¹, A. Riva^{1,2}, A.L. Ridolfo¹, C. Gervasoni¹, A. Gori^{1,2,3}

¹Department of Infectious Diseases - ASST FBF Sacco, Milan, Italy, ²DIBIC Luigi Sacco, University of Milan, Italy, ³Centre for Multidisciplinary Research in Health Science (MACH), University of Milan, Milan, Italy

Background: Long-acting injectable antiretroviral therapy requires structured service models to ensure appropriate administration, adherence to scheduled injections, and effective patient tracking. Service organization may significantly influence accessibility, acceptability and retention in care. We describe the implementation of a physician-supervised, nurse-led outpatient clinic dedicated to long-acting cabotegravir/rilpivirine (LA-CAB/RPV) and assess patient experience and satisfaction.

Methods: A dedicated outpatient service for LA-CAB/RPV was implemented at our center in October 2022, coinciding with the introduction of the long-acting formulation into clinical practice. The service operates Monday through Thursday (8 hours/day), with additional Saturday morning availability (4 hours). Daily activities are managed by two dedicated nurses under continuous physician supervision. Key organizational features include: (1) a dedicated direct phone line, (2) WhatsApp-based appointment scheduling and rescheduling and (3) direct nurse-physician linkage enabling prompt clinical evaluation when required. Patient experience was assessed using an anonymous QR code-based satisfaction survey administered in January-February 2026 to all patients who had initiated LA-CAB/RPV at our center, regardless of ongoing treatment status, including those who had discontinued therapy prior to survey administration.

Results: Overall, 372 patients initiated LA-CAB/RPV at our center: at the time of survey administration, 342 (92%) were still receiving treatment. A total of 274 patients completed the survey (response rate 80%).

Access and Communication: Contact with the clinic was rated as "very easy" by 72% and "quite easy" by 24% of respondents. The dedicated phone line facilitated appointment management for 77% of patients, while WhatsApp-based rescheduling was considered "very useful" for 82%. Clinic opening hours were considered adequate for 85%. **Treatment Convenience:** LA-CAB/RPV was perceived as more convenient than daily oral ART by 95% of respondents (70% "much more convenient") and clinic visits were described as minimally burdensome by 84%. Notably, 89% of patients reported never having considered treatment discontinuation due to visit frequency or organizational burden.

Overall Satisfaction: Satisfaction score was 9.1/10.

Conclusions: A physician-supervised, nurse-led service model integrating flexible scheduling, digital communication tools, and close physician-nurse collaboration was associated with high patient satisfaction (mean score 9.1/10) and low perceived organizational burden among individuals treated with LA-CAB/RPV. The inclusion of patients who had discontinued therapy enhances the generalizability of these findings and supports the central role of optimized service delivery in promoting patient acceptance and sustained engagement in long-acting ART programs.

Table 1, Figure 1

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Epidemiology, Social Sciences and PROs

P 55 ANALYSIS OF THE CHARACTERISTICS OF PWH FOLLOWED AT THE INFECTIOUS DISEASES CLINIC OF UDINE: A HISTORICAL COHORT STUDY

T. Semenzin¹, C. Tascini^{1,2}, S. Lanini^{1,2}

¹University of Udine Department of Medicine (DMED), Udine, Italy, ²Infectious Diseases Clinic, Azienda Sanitaria Universitaria Friuli Centrale (ASU FC), Udine, Italy

Background: Combination antiretroviral therapy (cART) has transformed HIV infection into a chronic condition, substantially improving survival and quality of life, leading to a progressively ageing population of people with HIV (PWH) in Italy with an increasing burden of chronic comorbidities. Nevertheless, the distribution of clinical characteristics is not uniform across the country. Friuli-Venezia Giulia represents a distinctive demographic and healthcare setting for which systematic clinical and metabolic data are lacking. This study aims to provide an updated regional overview of the characteristics of PWH followed at the Infectious Diseases Clinic of Udine in northeastern Italy.

Methods: We conducted a retrospective observational historical cohort study including adult PWH followed at the Infectious Diseases Clinic of Udine (Friuli-Venezia Giulia, Italy). Demographic, clinical, viro-immunological, metabolic, and therapeutic data were collected for 437 patients. A cross-sectional analysis was performed to describe the most recent characteristics of the cohort, while a longitudinal descriptive analysis evaluated trends in key viro-immunological and metabolic parameters between January 2021 and August 2025. Statistical analyses included descriptive methods, logistic and linear regression models, and mixed-effects models for repeated measures.

Results: The median age of the cohort was 52.9 years (IQR 44–61), with a predominance of males (62.7%). Sexual transmission accounted for over 80% of infections, with MSM (men who have sex with men) representing the largest risk group in more recent years. Over time, patients were diagnosed at older ages, with a significant increase in age at diagnosis and a parallel reduction in AIDS diagnoses and CD4+ nadir severity. Most patients were virologically suppressed and receiving ART, predominantly integrase inhibitor-based regimens (67.7%), with widespread use of single-tablet regimens and TAF. Cardiometabolic risk factors were highly prevalent, including smoking (35.2%) and type 2 diabetes mellitus (9.6%). Longitudinal analyses demonstrated stable virological suppression, progressive immunological recovery and modest but relevant changes in lipid and metabolic profiles over the observation period.

Conclusions: This study provides the first regional description of PWH followed in Friuli-Venezia Giulia, showing excellent virological control with widespread use of modern, well-tolerated antiretroviral therapies. The progressive ageing of the cohort highlights the growing relevance of cardiovascular and metabolic comorbidities. Despite an overall favourable metabolic profile, continuous monitoring and personalised prevention strategies are warranted. These findings support integrated multidisciplinary care and provide a basis for future regional and prospective studies on long-term ART outcomes.

Epidemiology, Social Sciences and PROs

P 56 BETWEEN CONTROL AND SILENCE: CHEMSEX PRACTICES, DISCLOSURE, AND STIGMA IN AN ITALIAN REGIONAL SURVEY

S. Mattioli, S. Cecere, S. Maugeri, M. Degli Esposti, P. Morabito, G. Spreafico, E. Richero

Plus aps - PrEP Point Plus, Bologna, Italy

Background: Chemsex—the use of psychoactive substances during sexual intercourse—has been widely discussed, yet robust data remain limited due to the strongly contextual nature of the phenomenon, which is influenced by regional economic, social and cultural factors. This study provides a territorial snapshot of chemsex practices in the Emilia-Romagna region, Italy.

Methods: From November 1, 2025, to January 31, 2026, an anonymous online questionnaire was administered to LGBTQ+ adults living in Emilia-Romagna. The study was open to HIV-positive and HIV-negative persons who reported at least one chemsex experience in the previous 12 months.

Results: A total of 217 questionnaires were collected. Overall, 27.65% of respondents reported engaging in chemsex. Among them, 95% identified as male and 4.8% as female. Most participants were employed (80%) with a medium/medium-high income, were single (55%) or in an open relationship (28%). Most of the responses come from Bologna and from gay people (Tab. 1 and 2).

Among participants engaging in chemsex, 43.3% reported being HIV-positive (99% undetectable), while 6.7% were unaware of their HIV status. Nearly 40% of people living with HIV did not disclose their status. Besides, 54% had not discussed chemsex with their infectious disease specialist, mainly due to lack of opportunity, fear of judgment, or the perception that the topic was not relevant for the physician. Half of HIV-positive respondents reported feeling invisible or unsupported within the LGBTQ+ community.

Among HIV-neg respondents (48.3%), 24% were not using PrEP and 7% reported informal or non-prescribed (“sauvage”) PrEP use.

Chemsex engagement had lasted more than three years for 61.6% of participants, with 30% reporting monthly sessions and 18.3% almost every weekend.

The most commonly used substances were mephedrone (23.7%), sniffed cocaine (10%), GHB/GBL (8.9%), and MDPV (5.3%). A substantial part of participants also uses poppers (23%) and cannabis (13.6%).

Most respondents (80%) did not report an increase in STIs associated with chemsex, 88% reported no history of overdose and 70% reported not losing control during sessions. Nevertheless, 25% reported missing workdays due to substance use, 20% experienced sexual abuse during chemsex sessions. Among HIV-negative participants, only 10% had accessed PEP, 1 to 3 times in the previous year. Overall, 58% reported feeling judged for engaging in chemsex.

Conclusions: This study highlights several critical issues, including limited communication between HIV+ people and IDs on chemsex, persistent difficulties in HIV status disclosure despite the U=U paradigm, and feelings of invisibility within the LGBT community. In Emilia-Romagna, chemsex appears to be relatively contained; however, some apparently contradictory responses suggest possible underreporting or normalization of risk. Further research is needed to better understand these dynamics and to inform targeted, non-judgmental interventions.

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Epidemiology, Social Sciences and PROs

P 57 **BEYOND THE SCREEN: IDENTIFYING INFORMATIONAL GAPS AND COMMUNICATIVE PATTERNS IN STI PREVENTION FOR STUDENTS OF SOME SCHOOLS IN THE AREA OF ROME**

A. Colucci, C. Gallo, M. Schwarz, R. Dalla Torre, E. Fanales Belasio, P. Gallo, A. D'Agostini, R. Valli

Unità Operativa Ricerca psico-socio-comportamentale, Comunicazione, Formazione, Dipartimento Malattie Infettive, Istituto Superiore di Sanità, Rome, Italy

Background: Sexually transmitted infections (STIs), including HIV, may lead to severe short and long-term consequences for sexual and reproductive health. Young people often underestimate their risk, resulting in delayed diagnoses in the absence of symptoms, and frequently rely on unreliable online sources before accessing appropriate services.

This study examines an intervention conducted in the metropolitan area of Rome to assess students' knowledge needs regarding STI risk and prevention.

Material and Methods: This study, carried on through the collaboration between Istituto Superiore di Sanità and some schools in Rome, from January 2025 to April 2025, targeting 359 students from high schools. The study focused on the students' knowledge needs and in order to do this a short anonymous questionnaire was submitted to them.

The questionnaire is structured in closed and open questions in the following areas:

1. Knowledge of terms such as HIV, AIDS, STIs;
2. Information channels through which students get information;
3. Information channels through which students would like to be informed;
4. Specific questions about HIV, AIDS and STIs to which students would like timely answers.

The responses to the 359 questionnaires were analysed through a mix of qualitative and quantitative methodologies, including topic modelling, clustering and text mining techniques, the study analysed student responses and identified key informational gaps, concerns, and preferences.

Results: With regard to students' knowledge, the term HIV/AIDS had previously been heard by 63% of respondents, whereas STIs were recognized by only 37%. Although 65.1% of students reported a preference for receiving information through schools and teachers, this does not correspond to their actual behaviour: 68.8% indicated social media as their primary source of information.

The qualitative analysis of open-ended responses, conducted through word cloud visualization and thematic examination, identified "knowledge," "further understanding," and "prevention" as the most frequently recurring terms. These findings suggest a strong interest and willingness among young people to deepen their understanding of these topics, consistent with the quantitative results.

Conclusions: Such interventions represent a valuable opportunity to gather meaningful insights into the language and communication patterns of the school-age population involved. Identifying communication strategies tailored to the target group is crucial to ensure that interventions effectively fulfill their objectives of promoting young people's sexual and reproductive health, guiding them beyond mere online information gathering, and equipping them with the skills to critically assess the content they encounter on their phone screens.

Epidemiology, Social Sciences and PROs

P 58 BEYOND VIRAL SUPPRESSION: BIOMEDICAL REDUCTIONISM, CULTURAL COMPETENCE, AND PSYCHOSOCIAL NEEDS AMONG GBQ MEN LIVING WITH HIV IN ITALY

E. Mura^{1,2}, F. Cocco³, I. Massa⁴, G. Dessì¹, D. Lasio³

¹LILA Cagliari OdV, Cagliari, Italy, ²Dipartimento di Scienze Politiche e Sociali, Università degli Studi di Cagliari, Cagliari, Italy, ³Dipartimento di Pedagogia, Psicologia, Filosofia, Università degli Studi di Cagliari, Cagliari, Italy, ⁴Centre for Social Studies, University of Coimbra, Portugal

Background: In Italy, HIV remains embedded in moralising narratives that sustain stigma and shape both public discourse and healthcare encounters. Although antiretroviral therapy has transformed HIV into a manageable condition, the social and emotional consequences of living with the virus -including its impact on intimacy, disclosure, and identity- often persist and may be insufficiently addressed within routine care.

Methods: Within the QueerIS (Queer Intimacies and Services) project, we conducted 21 semi-structured interviews with gay, bisexual and queer (GBQ) men living with HIV in Italy. Interviews explored psychological well-being, sexual and relational life, disclosure practices, and experiences with healthcare and support services. Data were analysed through Critical Discourse Analysis to examine how participants narrated HIV, stigma, and care, and how broader cultural and political framings were reflected in everyday experiences.

Results: Participants frequently depicted HIV services as strongly biomedicalised, focused on testing, treatment adherence, and viral suppression, with limited space for discussing sexuality, relationships, mental health, and the relational dimensions of prevention. Disclosure emerged as a high-stakes, strategic process shaped by fear of rejection and social exclusion, intersecting with queerphobia and structural inequalities. While U=U was commonly reported as being mentioned by clinicians, several accounts suggested difficulties in fully internalising its implications in intimate contexts, with residual anxiety and concerns about being perceived as “dangerous.” These difficulties were linked to brief consultations, fragmented psychosocial referral pathways, and limited opportunities for supportive dialogue. At the same time, participants described markedly positive care experiences in settings characterised by culturally competent staff, affirming attitudes towards sexual and gender diversity, and the presence of peer workers or community organisations. These contexts were perceived as safer and more trust-building, facilitating communication, engagement, and meaning-making beyond biomedical outcomes. Overall, experiences suggested substantial heterogeneity in service practices and in the extent to which psychosocial dimensions were integrated into care.

Conclusions: Effective HIV care should move beyond viral suppression by integrating structured psychosocial support, stigma-informed communication, and training for providers on sexual health, minority stress, and disclosure counselling. Promising practices identified by participants -culturally competent and affirming environments, and peer/community involvement- should be considered as scalable good practices to reduce service heterogeneity and improve equity in quality of care. Public policies and community interventions should also promote accurate, inclusive narratives (including U=U) to reduce serophobia and enhance quality of life.

Epidemiology, Social Sciences and PROs

P 59 **BREAKING BARRIERS TO HIV TESTING: THE ROLE OF LILA IN REACHING THE UNTESTED PEOPLE IN ITALY**

G. Dessi, G. Giupponi, P. Perone

LILA Lega Italiana per la Lotta contro l'AIDS, Como, Italy

Background: LILA (Italian League for Fighting AIDS) has been operating in Italy since 1987, providing support for PLWHIV and focusing on prevention. LILA, since 2010, have started rapid HIV testing services; since 2012, has participated in the European Testing Week, since 2017 testing services are open across 7 locations. Each year LILA welcomes hundreds of people providing pre-test STI counseling, rapid testing for HIV, HCV, and Syphilis. In cases of reactivity, individuals are accompanied to local clinics for confirmatory laboratory testing at NHS facilities in partnership with LILA; in case of confirmed diagnosis, counseling is provided. These data refer to the period from October 2024 to September 2025 across the sites in Bari, Cagliari, Como, Florence, Milan, Turin, and Trento.

Material and Methods: During the counseling, exposure to STIs is assessed through sexual behavior, drug use and prevention habits (vaccinations, testing, condom use, and PrEP). Data are collected with Cobatest form, ensuring comparability within the network.

Results: LILA testing services recorded an increase of visits, tests performed and reactive results compared to the same period in the previous year. Specifically, 2,477 people were reached (1,453 men, 978 women, 46 non-binary); the mean age was 29.2 years, 85.6% Italians. The largest age group was 20–29 years (46.9%), then 30–39 (30.3%) and 40–49 (11.8%). Notably, 43.2% had never tested before and 16.3% had already been in LILA. About behaviors: 50.9% did not use a condom during their last sexual encounter, 3.6% practiced Chemsex and only 2.9% reported using PrEP. Overall, perceived exposure to HIV risk (84.1%) was the primary motivation for testing (had sex without condom: oral 64.5%, vaginal 54.4%, anal 27%). During the year, 5,389 tests were performed (HIV 2,419, Syphilis 1,666, HCV 1,304). Reactive results were obtained for 39 tests (HIV 14, Syphilis 10, HCV 15). For HIV: 9 cases were confirmed and linked to care. For Syphilis, 5 cases were confirmed; for HCV, 3 active infections were confirmed.

Conclusions: Testing services at LILA report growing numbers year after year, with visits doubling compared to the COVID-19 period. Since 2017, a total of 17,407 tests for HIV, 6,917 for Syphilis, and 5,922 for HCV have been offered. The data indicate that the CBVCT approach offered by LILA effectively overcomes barriers to HIV test: over 40% chose a LILA-site for their first-ever HIV test. Moreover, 16.3% of contacts used the service more than once and 22.8% reached LILA through word-of-mouth. The CBVCT also provides an opportunity to discuss prevention and harm reduction strategies, like PrEP: while 42.2% already knew it, 9.4% expressed interest in this prevention strategy and only 2.9% used it. Finally, vaccination data are concerning: users reported to be vaccinated: HBV 71.8%, HPV 31%, HAV 28.4%. Better coordination with the NHS could facilitate an increase in vaccination coverage, as it is a key tool for prevention.

Epidemiology, Social Sciences and PROs

P 60 CARE PATHWAYS AND TREATMENT EXPERIENCE IN OLDER PEOPLE WITH HIV: EVIDENCE FROM THE ITALIAN HEALTHY AGING SURVEY

G. Guaraldi¹, A. Castro², C. Buellis², M. Belli³, J. Milic¹, G. Giupponi⁴

¹University of Modena and Reggio Emilia, Modena, Italy, ²University of Milano Bicocca, Milan, Italy, ³CICA, Milan, Italy, ⁴LILA Milano, Milan, Italy

Background: The Italian Ministerial Project “Healthy Aging in People with HIV”, funded by the Ministry of Health and conducted in collaboration between the Azienda Ospedaliero-Universitaria Policlinico di Modena and 12 national HIV community-based associations, aims to generate national evidence on aging with HIV. Within this framework, the present analysis focuses specifically on how older people living with HIV perceive their care pathways, relationship with HIV treatment services, and their experience with antiretroviral therapy.

Objective: To characterize the perceived quality of care, service integration, and treatment-related concerns among PWH aged ≥ 50 years in Italy, with particular attention to infectious disease centers, general practitioners, HIV associations, and antiretroviral regimens.

Materials and Methods: In February 2026, participants across Italy aged ≥ 50 were recruited nationwide through clinical centers and community networks. For this analysis, variables related to care engagement and treatment experience were examined, including: satisfaction with infectious disease specialists, general practitioners, medication collection services, and HIV associations; perceived coordination between health and welfare services; adherence to ART; concerns about disclosure when taking medication; and perceived saliency of HIV linked to daily treatment.

Results: A total of 472 PWH (mean age 59.3 ± 8 years; mean duration of HIV 23.9 ± 12 years) participated. Geographically, 59.3% resided in Northern Italy, 30.7%

in Central regions, and 10% in Southern regions or Islands. Although a majority reported satisfaction with infectious disease specialists (63%), satisfaction levels were substantially lower for general practitioners (42.2%) and other health professionals (37.7%), suggesting suboptimal integration between specialist and primary care. Satisfaction with medication collection services was 51%, highlighting variability in access experiences. Most participants (83.4%) reported full adherence to ART, while only 1.1% reported frequently missing doses. However, concerns related to disclosure during medication intake were reported by 27.1% of individuals aged 50–64 and 22.4% of those aged ≥ 65 . HIV saliency triggered by daily ART was a frequent or daily experience in both age groups (59.6% and 57.6%, respectively), suggesting that

treatment remains a constant reminder of HIV status despite long-term clinical stability. Regarding caregiving and support, 35.4% reported having a caregiver, while 55% did not; among those without a caregiver, only 6.8% reported a current unmet need for one.

Conclusions: These findings urge rethinking Italy's organizational models for aging with HIV: prioritize integrating specialist HIV centers with primary care, improving health-welfare coordination, and adopting person-centered shared-care frameworks to address the long-term clinical and psychosocial needs of this population, moving beyond specialist-only paradigms.

Epidemiology, Social Sciences and PROs

P 61 CHEMSEX AND THE TRANSFORMATION OF EROTIC FANTASY: A SURVEY STUDY

G. Fracca, M. Manfredini, A. Antonino, A. Bianchi, M. Cernuschi

ASA ODV Milano, Italy

Background: Chemsex practice is known to alter sexual experience, but the specific impact of substances on users' erotic fantasy life remains poorly understood. Understanding whether and how chemsex transforms sexual imagination, and whether these transformations are perceived as belonging to one's identity or as externally imposed, has significant clinical implications for psychotherapeutic treatment.

In his Three Essays on the Theory of Sexuality (1905), Freud argued that sexual fantasies are not arbitrary products of the mind but reflect the emotional history of the subject: they crystallise around a nodal point of meaning constructed in childhood to make sense of the body and of adult sexuality, which then unconsciously shapes desire throughout life. This theoretical framework gains renewed relevance in the light of contemporary research: the 2024 study Fantasy Made Flesh (Andrian, Werburg, Klopp and Schwab, Journal of Sex Research), conducted on a network analysis of 1,338 participants, demonstrated that internet pornography interacts significantly with sexual fantasies, particularly non-conventional ones such as BDSM, effectively operating as a mainstream vehicle for specific erotic scripts. Chemsex substances may act through an analogous but pharmacologically amplified mechanism: just as repeated media exposure shapes and reinforces fantasy content, the psychoactive properties of drugs, particularly MDPV, may intensify and accelerate the crystallisation of new erotic material, potentially overwriting or destabilising pre-existing desire.

Material and Methods: A self-administered online survey was distributed through the channels of partner associations, collecting just over 100 responses from chemsex users. The questionnaire explored: the perceived difference between sober and chemsex-induced sexual fantasies; the role of substance type, frequency of use, and years of experience in shaping fantasy transformation; the subjective evaluation of that transformation (positive, negative, or integrated); and whether new erotic content was experienced as authentic or alien to sober identity.

Results: Both duration and frequency of use contribute to the transformation of sexual desire, but current high-frequency use is most strongly associated with the emergence of fantasies perceived as entirely new and unrelated to sober experience. High-frequency users are more likely to evaluate this transformation negatively, while occasional users, particularly long-term veterans, show greater integration or acceptance of the change. Regular and frequent chemsex practice increases the perception that desires explored in that context are externally imposed and non-authentic to sober identity. The large majority of users, regardless of frequency, express a desire to modify or discontinue the role of chemsex in their lives.

Conclusion: The transformation of erotic fantasy under chemsex is significantly shaped by frequency of use and substance type, with high-frequency use most strongly associated with a sense of estrangement from one's sober desire. Given the limited sample size, this survey should be replicated on a larger scale to broaden the content explored and achieve greater statistical significance.

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P 62 CLINICAL CASE: MDPV-RELATED CHEMSEX ADDICTION IN A 25-YEAR-OLD MSM — INTEGRATED MULTI-AGENCY INTERVENTION

G. Fracca

ASA ODV, Milano, Italy

Clinical case: MDPV-related Chemsex addiction in a 25-year-old MSM — integrated multi-agency intervention

Background: Chemsex-related MDPV abuse in young MSM users can rapidly escalate into severe psychiatric and occupational impairment, requiring coordinated multi-agency intervention. We present the case of a 25-year-old man referred to the ASA therapeutical group through parental initiative following a psychotic breakdown.

Material and Methods: The patient was enrolled in the weekly ASA Chemsex group after a first psychotic episode secondary to near-daily MDPV use, including during working hours. Following frequent relapses and sick leave from work, he was referred to the SerD. A subsequent HIV seroconversion triggered a second psychotic decompensation requiring inpatient admission. Upon discharge, a multi-disciplinary care network was established, including: the ASA group, individual psychotherapy at the SerD, psychoeducational SerD groups, psychiatric pharmacological support, and follow-up with the infectious disease specialist who had communicated the diagnosis. The patient's parents were concurrently supported by a psychologist, with a focus on fostering the patient's sense of autonomy and empowerment rather than reinforcing controlling dynamics.

Results: Gradual detoxification was achieved. The patient returned to work and began engaging in affective and sexual relationships no longer mediated by substances. A key factor in the outcome was the continuous dialogue between the ASA group psychologist and the individual therapist at the SerD: themes emerging in the group setting were systematically elaborated in individual sessions, ensuring clinical coherence across the network. This process was made possible by a specific dynamic inherent to the group setting: the sexual fantasies driving substance-fuelled sexuality are often so extreme and so distant from what can be spoken aloud in an individual session that they can surface only within the group, through the normalising effect of sharing with peers who recognise them as their own. This mediation allowed the patient to gradually bring his darkest and most self-destructive fantasies into individual therapy, where they could be elaborated and worked through.

Conclusion: This case illustrates how MDPV-related Chemsex addiction in young users may require integrated, multi-agency intervention combining group and individual psychotherapy, psychiatric support, infectious disease care, and family psychoeducation. The active collaboration between all clinicians involved — and in particular the ongoing exchange between group and individual therapists — was decisive in supporting recovery.

Epidemiology, Social Sciences and PROs

P 63 COMMUNITY-BASED PEER-SUPPORT PROGRAM INTEGRATED INTO A HOSPITAL-BASED TESTING SERVICE: A DESCRIPTIVE ANALYSIS OF A PILOT PROGRAM

G.V. Calvino¹, N. Braccialarghe², G. Scarfo¹, V. Barchi², A. Giacinta², R. Esvan², G. Micheli², A. Antinori², V.L. Del Negro¹, V. Mazzotta²

¹Checkpoint Plus Roma, Rome, Italy, ²Istituto nazionale per le malattie infettive "L. Spallanzani" IRCCS Rome, Italy

Background: International agencies, such as WHO and UNAIDS, agree that Communities play a pivotal role in the global HIV response by expanding access to prevention and treatment and by shaping resilient Health Systems. Peer Support (PS) is a collaborative relationship in which people with shared life experiences offer each other understanding, encouragement, and practical guidance. In clinical settings, both for people who are newly diagnosed and for those willing to test, PS enhances holistic HIV care by offering immediate, empathetic guidance and reducing fear, stigma, and isolation. We describe a pilot PS program integrated into an HIV outpatient service offering HIV/STI testing.

Method: From January to December 2025, trained volunteers from a community LGBTQA+ association provided PS to people attending the clinic for testing. We collected sociodemographic and behavioral characteristics, reasons for testing, and perceived HIV risk. A descriptive analysis was performed.

Results: Among 68 users, most were male (54, 79%) and Italian (60, 92.3%), with a median age of 34 (IQR: 34-44). Table 1 describes the main characteristics of the study population. The most common reason for testing was a routine check-up (75.4 %), and 50 users (79.4%) reported at least one prior HIV test. In the past 3 months, 52 individuals (86.7%) reported 0–5 sexual intercourses; homosexual intercourses accounted for the most frequent kind of sexual activity (28, 53.9%). Twenty clients (36.4%) reported a prior sexually transmitted infection (STI) diagnosis, three in the prior 3 months.

Overall, PS delivered 151 interventions: counselling accounted for 56.3% (85/151) and rapid testing for 43.7% (66/151). Rapid tests included HIV (41, 27.2%), syphilis (15, 9.9%), and HCV (10, 6.6%); tailored information was provided alongside each test (Table 2).

Single-theme counselling focused on Pre-Exposure Prophylaxis (PrEP) (20.5%), STIs (9.9%), vaccines (9.3%), and HIV-related topics (8.6%).

Regarding intensity, 18 users (26.9%) experienced single-themed counselling, 17 (25.6%) received a single rapid test only, and 33 (48.5%) received 2 -6 interventions; 27 users (38.8%) received at least one test plus single-theme counselling, and 6 users (9%) benefited from multiple-themed counselling.

Conclusions: Integrating community peer support into a hospital-based testing service is feasible, enriching the patient experience and complementing healthcare staff activities. It provides a reference model for both users and operators belonging to the same communities, playing a crucial role in promoting prevention tools (e.g. PrEP and vaccination) and raising sex-positive and safer-sex awareness.

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Epidemiology, Social Sciences and PROs

P 64 COMPARISON OF HIV INCIDENCE BETWEEN MSMS, HETEROSEXUAL MALES AND FEMALES IN ITALY FROM 2012 TO 2024

L. Pugliese, V. Regine, B. Suligoi

Department of Infectious Diseases, National Institute of Health, Rome, Italy

Background: Among new HIV diagnoses, the most represented mode of transmission has always been male-to-male sexual contact (MSM), followed by male heterosexual contact and subsequently female heterosexual contact (1). The aim of this study is to estimate the incidence of new HIV diagnoses and its trend over time among MSM, heterosexual males and females in Italy.

Material and Methods: Data on new HIV diagnoses notified in the Italian Surveillance System from 2012 to 2024 were analyzed. The incidence of new HIV diagnoses was calculated as ratio between the number of new HIV diagnoses in MSM, heterosexual males, and females and the estimated number of MSM, heterosexual males, and females per 100,000 adult inhabitants. The denominators were calculated using results of the 2023 IPSOS survey (2) that shows that MSM account for 8% of the male population, heterosexual males for 92% of the males, and heterosexual females for 99% of the female population (3).

Results: The incidence among MSM between 2012 and 2024 was higher than that observed among heterosexual males and females. HIV incidence among MSM was about 18 times higher than that among heterosexual males, and this ratio remained stable between 2012 and 2024. The incidence among heterosexual males was 1.6 times higher than that among heterosexual females, and the ratio remained stable throughout the study period. The incidences in these three populations showed similar temporal trends in the study period, with a decrease until 2020 and an increase in the following period. The decline in incidence among MSM started in 2012, whereas among heterosexual males in 2017 and among heterosexual females in 2018. In 2024 the HIV incidence was 42.9, 2.5 and 1.4 diagnoses per 100,000 respectively among MSM, heterosexual males and females.

During the study period, the median age was higher among heterosexual males, 41 years (IQR: 33-51), compared to MSM 36 years (IQR: 29-45) and heterosexual females 34 years (IQR: 28-44). The proportion of foreigners was 18.8% among MSM, 30.2% among heterosexual males, and 51.8% among heterosexual females. More than half (56.0%) of new HIV diagnoses had a CD4 count below 350 cells/ μ L (defined as late diagnosis), the highest proportion of late diagnoses was observed among heterosexual males (65.3%), followed by heterosexual females (58.1%), and MSM (47.1%).

Conclusions: The trend of the incidence of new HIV diagnoses appears to be similar across the three populations, showing an initial decrease until 2020 and an increase afterwards. MSM constitute the population group with the highest HIV incidence throughout the entire study period, which could be due to higher risk awareness and more frequent HIV testing (leading to a lower proportion of late diagnoses), or higher HIV spread in this group. It remains crucial to promote prevention through screening initiatives that facilitate access to testing and improve early HIV diagnosis, including opt-out testing strategies.

Epidemiology, Social Sciences and PROs

P 65 DEMOCRATIZING U=U: ADDRESSING EDUCATIONAL DISPARITIES IN HIV LITERACY IN BRESCIA

M. Stizioli, A. Bergomi, C. Davini, A. Sala, G. Varia

Brescia Checkpoint ETS, Brescia, Italy

Background: The "Undetectable = Untransmittable" (U=U) principle is a cornerstone of modern HIV prevention. In Brescia, there has been a significant lack of institutional public awareness campaigns on this topic. This study aims to investigate U=U awareness specifically among individuals accessing testing services in informal, non-clinical settings, in order to identify persisting knowledge gaps.

Material and Methods: Between October 2024 and February 2026, the Brescia Checkpoint provided HIV testing to 170 individuals within various informal and non-clinical settings. The study adopted a two-step approach: participants first completed an anonymous demographic questionnaire; subsequently, a one-on-one counseling interview was conducted. This interview served a dual purpose: to assess the participants' pre-existing awareness of U=U and to provide comprehensive scientific information.

Results: Overall awareness of the U=U principle was 64.7% (110). As illustrated in Table 1, data analysis shows that knowledge is predominantly concentrated among gay men, individuals under 30, and those with a university education. Notably, a significant gap exists at the opposite end of the educational spectrum: only 4 individuals with a middle school education (2.3% of the total sample) were aware of U=U. Prior to the interview, 35.3% of the total population remained either uncertain or completely unaware of the principle.

Conclusions: While the sample size is limited, these findings demonstrate that U=U awareness in Brescia remains a privilege of highly educated groups and specific communities. This underscores the transformative role of community-based organizations: through counseling interviews, they democratize scientific knowledge, translating clinical data into accessible information for the territory. To bridge this gap, it is essential to intensify outreach and testing events in informal settings, ensuring that U=U becomes a universal tool to de-stigmatize HIV across all social strata.

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Epidemiology, Social Sciences and PROs

P 66 DETERMINANTS OF HIV AND STI TESTING UPTAKE: FINDINGS FROM A STUDY CONDUCTED BY THE ISTITUTO SUPERIORE DI SANITÀ

E. Fanales Belasio, P. Gallo, A. Colucci, R. Valli, M. Schwarz, R. Dalla Torre, C. Gallo, A. D'Agostini

Unità Operativa Ricerca psico-socio-comportamentale, Comunicazione, Formazione, Dipartimento Malattie Infettive, Istituto Superiore di Sanità, Rome, Italy

Background: Testing for HIV and STIs is crucial for early diagnosis, timely treatment and prevention of onward transmission of these infections. Screening after potential risk exposure is strongly recommended by public health authorities and relies on adequate awareness and access to information. However, testing uptake may be influenced by social determinants, educational level, and stigma, potentially leading to missed or delayed diagnosis.

Material and Methods: A telephone survey was conducted through anonymous interview among users of Italy's AIDS and STIs Helpline of the Istituto Superiore di Sanità (ISS) with the aim of evaluating the propensity to testing and the potential impact of social determinants. A structured questionnaire was built to gather information on social-educational status, partnership, sexual behaviour, testing for HIV and STIs and potential stigma and prejudices related to these diseases. Data were collected and analysed by using IBM® SPSS® statistics v.28.0.1.1 software.

Results: A total of 332 AIDS and STIs Helpline of the ISS users participated in the study, predominantly male (88.6%) and aged 25–39 years (51.9%). Regarding sexual behaviour in the previous six months, 66.9% reported heterosexual intercourse, 16.2% reported homosexual intercourse, and 14.5% reported no risk exposure. Overall, 81.3% had undergone HIV testing and 62.3% testing for other STIs, either due to perceived risk or as routine screening. Among those not tested, the main reasons were trust in partners or low perceived risk.

Testing was mainly performed in public centers (43.1%), followed by private facilities (30.4%), and only 5.4% of participants reported significant barriers to access. However, one third expressed concerns about being seen or judged when accessing testing services, and over two thirds were reluctant to discuss HIV/STI testing with family or friends.

Conclusions: Most AIDS and STIs Helpline users reported undergoing HIV testing primarily due to perceived infection risk, whereas STIs testing was less frequently reported, highlighting the need for integrated testing strategies. Although access barriers to public or private facilities were indeed limited, stigma and social factors continue to influence individuals' predisposition to testing for HIV and STIs.

Epidemiology, Social Sciences and PROs

P 67 **FOUR YEARS OF ANCONA CHECKPOINT: CHARACTERISTICS OF TESTED POPULATION AND OUTCOMES OF NEWLY DISCOVERED HIV INFECTIONS**

S. Caucci^{1,2}, L. Saracin^{2,3}, P. Pauri², A. Costantini⁴, L. Butini^{4,5}

¹Microbiology Unit, Azienda Ospedaliero Universitaria delle Marche, Ancona, Italy, ²Ancona Checkpoint, Ancona, Italy, ³Ass. Opere Caritative Francescane, Ancona, Italy, ⁴Clinical Immunology Unit, Azienda Ospedaliero Universitaria delle Marche, Ancona, Italy, ⁵Anlaids Marche APS, Italy

Background: By offering free and anonymous rapid tests for HIV, HCV and syphilis, since 2022 Ancona Checkpoint (ACP) engages subjects with limited access to diagnostic facilities, providing an opportunity for early diagnosis, and assistance in connecting to healthcare centers. This analysis summarizes four years of activity, with particular focus on the clinical outcome of newly diagnosed HIV infections.

Methods: Data from March 2022 to December 2025 were analyzed using COBATEST database. Demographic and behavioral characteristics were considered. Subjects with a reactive HIV rapid test underwent confirmatory laboratory testing within 24 hours and initial immunologic evaluation within 48 hours.

Results: A total of 3462 subjects accessed ACP over the study period; the annual trend showed a progressive increase, with a 2.7 fold rise from 2022 to 2025. The population remained stable in terms of gender distribution, with prevalence of males, and sexual orientation, with prevalence of heterosexual subjects. Age patterns showed a progressive shift toward subjects over 50 yrs (9.8%, 6.8%, 4.5% and 15.3% in 2022, 2023, 2024 and 2025, respectively) (Fig1A). 26% of subjects resided outside the Ancona area, home of the only checkpoint operating in Marche region. A marked increase in foreign-born subjects (55.3%) was also observed in 2025 (Fig1B). Testing was requested mostly for screening rather than following risk behavior. Knowledge of PrEP remained low (31.7% in 2022 and 36.6% in 2025). Over the four-year period, the cumulative HIV prevalence was 0.32% (11/3462); all the 11 positive rapid HIV tests received laboratory confirmation. Subsequently, patients accessed healthcare system and started ART within 5 days on average. Among new cases, 54.5% were males aged 18-30 years; most were foreign-born (81.8%). MSM represented the 45.5%. CD4 T cell count at diagnosis ranged from 118 to 1270 cell/mm³ (median of 498 cell/mm³), whereas median CD8 count was 1053 cell/mm³ and CD4/CD8 ratio below 1 in all but two cases. Most subjects (80%) had HIV-RNA >104 copies/ml (median 125355). No drug resistance mutations were detected. All the patients started antiretroviral therapy (ART) with either 3TC/DTG (n=6) or FTC/TAF/BIC (n=5). During follow-up (median 31 weeks, range 13-153), nine subjects achieved complete viral suppression (HIV-RNA <20 copies/ml or undetectable), while the other two were lost shortly after the first evaluation.

Conclusions: Ancona Checkpoint shows significant potential in reaching large numbers of subjects, including those at high-risk of infection or socio-economically disadvantaged. Although HIV prevalence was relatively low, access to healthcare facilities was easy for newly diagnosed patients, ART uptake immediate, linkage to care efficient, suppression of HIV replication rapidly achieved in the large majority of cases. These results highlight the crucial role of checkpoints within the framework of prevention and early diagnosis of HIV disease.

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Epidemiology, Social Sciences and PROs

P 68 HETERONORMATIVE CLINICAL FRAMEWORKS AND STI RISK ASSESSMENT AMONG WOMEN WHO HAVE SEX WITH WOMEN IN ITALY

I. Massa¹, F. Cocco², E. Mura^{3,4}, D. Lasio²

¹Centre for Social Studies, University of Coimbra, Portugal, ²Dipartimento di Pedagogia, Psicologia, Filosofia, Università degli Studi di Cagliari, Cagliari, Italy, ³Dipartimento di Scienze Politiche e Sociali, Università degli Studi di Cagliari, Cagliari, Italy, ⁴LILA Cagliari OdV, Cagliari, Italy

Background: Women who have sex with women (WSW) are often perceived as a population at low or negligible risk for HIV and other sexually transmitted infections (STIs). This perception persists in both public health discourse and clinical practice, particularly in gynaecological settings where sexual health is often framed around penile–vaginal intercourse and reproduction. Evidence suggests these assumptions may lead to gaps in risk assessment, prevention counselling, and STI screening among WSW. This study examines how heteronormative clinical frameworks shape sexual health communication, risk perception, and preventive practices among WSW in Italy.

Materials and Methods: A qualitative study was conducted between 2025 and 2026 with 27 participants of diverse sexual orientations and gender identities. Most identified as cisgender women (n=25), and two as non-binary. Data were collected through semi-structured interviews lasting 60–90 minutes, conducted in person or online. The interview guide explored disclosure of sexual history, experiences with gynaecological care, STI risk perceptions, preventive behaviours (e.g., barrier methods, testing), and sources of sexual health information. Interviews were audio-recorded, transcribed, and analysed using thematic analysis.

Results: Participants frequently reported that healthcare providers assumed heterosexual activity, rarely inquired about same-sex practices, and primarily focused on contraception and reproductive health. Several respondents indicated that their sexual activity was classified as “not at risk” or “not complete,” leading to limited discussion of STI prevention. Many participants described low perceived susceptibility to certain STIs, often based on the absence of penile penetration. Preventive practices varied considerably: while some reported regular gynaecological check-ups, routine STI screening was uncommon and typically not recommended by clinicians. Barriers to disclosure included fear of misunderstanding, minimisation of their sexual practices, and previous experiences of heteronormative assumptions in healthcare settings. The findings suggest that underestimation of STI risk among WSW is shaped not only by individual knowledge gaps but also by structural features of clinical communication and biomedical definitions of sexual exposure.

Conclusions: Queer women in Italy may experience partial invisibility in sexual healthcare due to heteronormative and reproduction-centred clinical frameworks. This invisibility contributes to inconsistent risk assessment, limited preventive counselling, and possible under-screening for STIs. Public health strategies and clinical guidelines should adopt more inclusive definitions of sexual activity, improve provider training on women's health, and promote routine behaviour-based risk assessment rather than identity-based assumptions. Addressing these gaps is essential to ensure equitable access to STI prevention and comprehensive sexual healthcare.

Epidemiology, Social Sciences and PROs

P 69 HIV-RELATED STIGMA AMONG HEALTHCARE WORKERS IN ITALY: RESULTS FROM A KNOWLEDGE ATTITUDES AND PRACTICES HIV SURVEY

S. Vita¹, A. Carraro², R. Marocco³, L. Mazzanti², V. Speciale², L. Bresciani², V. Filippi⁴, C. Pasquazzi¹, L. Germani⁴, C. Del Borgo³, M. Lichtner¹

¹Department of Neurosciences, Mental Health, and Sense Organs, NESMOS, Sapienza University of Rome, Rome, Italy, ²Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ³Infectious Diseases Unit, SM Goretti Hospital, Sapienza University of Rome, Latina, Italy, ⁴Department of Molecular Medicine, Sapienza University of Rome, Rome, Italy, ⁴Infectious Diseases Unit Sant'Andrea, Rome, Italy

Background: Despite generally good HIV knowledge, gaps persist in practical knowledge, testing behaviours and attitudes. Stigmatising beliefs remain common and routine HIV testing is not consistently promoted. Targeted, profession-specific interventions integrating HIV education, stigma reduction and institutional policies are needed to normalise testing and ensure equitable care, supporting the goal of ending the AIDS epidemic by 2030.

Methods: We conducted a cross-sectional study between December 2025 and February 2026 using the KAP HIV questionnaire. An anonymous online survey was administered to healthcare workers operating in Rome and its metropolitan area. A convenience sample was recruited through direct personal contact, including telephone outreach. The questionnaire collected socio-demographic characteristics, HIV knowledge (maximum score 12), attitudes and self-reported practices towards people living with HIV. Descriptive analyses were performed, and comparisons between physicians and non-physicians were conducted using appropriate statistical tests.

Results: Overall HIV knowledge was good (mean score 9.6/12), with high recognition of U=U (78.4%), PrEP (80.3%) and sexual transmission (88.9%), although only 54.0% correctly identified appropriate HIV testing timing after exposure. When comparing professional groups, physicians (including trainees) demonstrated significantly higher knowledge scores than non-physicians (mean 9.99 vs 9.35 out of 12; $p = 0.005$), with differences mainly driven by more technical items such as HIV testing timing. Overall, explicit moralistic stigma was relatively infrequent, and strong support was observed for the sexual and reproductive rights of people living with HIV (>84% agreement). However, a proportion of respondents endorsed restrictive or blame-oriented beliefs, including attributing HIV to irresponsible behaviour (12.2%) and supporting sexual restrictions for individuals with detectable viral load (25.2%). Comparing groups, non-physicians were more likely than physicians to endorse stigmatising beliefs, particularly the perception that people living with HIV do not care about transmitting the infection (7.3% vs 0%; $p = 0.004$) and that HIV is acquired due to irresponsible behaviour (16.0% vs 7.4%; $p = 0.040$).

Conclusions: Despite good HIV knowledge and broad support for PLWH rights, gaps persist in testing practices and workplace behaviours. Subtle forms of stigma remain evident, particularly in precautionary practices and restrictive beliefs. Targeted, profession-specific interventions integrating updated HIV education, stigma-reduction training and institutional policies are needed to normalise HIV testing and ensure equitable, non-discriminatory care, supporting the goal of ending the AIDS epidemic by 2030.

Epidemiology, Social Sciences and PROs

P 70 IMPROVEMENT IN PATIENT-REPORTED OUTCOMES (PROs) AFTER ONE YEAR OF LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE

S. Rapino¹, S. Arsuffi¹, S. Calza², G. Tiecco¹, B. Fioretti¹, C. Anzoni¹, I. Polesini¹, F. Castelli¹, E. Quiros-Roldan¹, E. Focà¹

¹Clinica di Malattie Infettive e Tropicali, Università degli Studi di Brescia e ASST Spedali Civili di Brescia, Italy, ²Unità di Biostatistica e Biomatematica e Unità di Bioinformatica, Dipartimento di Medicina Molecolare e Traslazionale, Università degli Studi di Brescia, Italy

Background: Implementation of long-acting injectable antiretroviral therapy (LAI-ART) may significantly improve the quality of life of people living with HIV (PLWH). Patient-reported outcomes (PROs) are key tools to assess this impact. This study evaluated satisfaction with LAI-ART in a cohort of PLWH.

Methods: This prospective single-center study enrolled PLWH who switched to bimonthly LAI-ART with Cabotegravir (CAB) and Rilpivirine (RPV) between January 2023 and October 2024, with follow-up through November 2025. PROs were assessed using the EQ-5D (Quality of Life and Health Status Scale), the HIV-TSQs (HIV Treatment Satisfaction Questionnaire, status version), and the Resilience Scale (RS) before LAI-ART initiation (T0) and after 6±1 months (T1) and 12±1 months (T2).

Results: Overall, 60 individuals were included; 49 (81.6%) were male, with a mean age of 47.1 years (SD 11.0). All participants completed baseline PROs assessments; 56 completed T1 and 52 completed T2 (8 discontinued LAI-ART). At T0, mean EQ-5D scores were very high, ranging from 1 to 1.3 across all domains, with a mean self-rated health status of 84.8/100. The HIV-TSQs showed the lowest baseline scores in items related to compatibility of ART with lifestyle (mean 5.2/6) and willingness to continue current ART (5.05/6). Baseline RS scores were also high, exceeding 5.5 in all measured items (Figure 1).

Regarding HIV-TSQs, scores increased across all domains at both follow-up visits. The side effects item showed a mean score of 5.67/6 at T1 and 5.8/6 at T2. The most pronounced improvements over time were observed in domains related to treatment burden, convenience, flexibility, and fit with lifestyle. Most participants reported high satisfaction with continuing LAI-ART (5.94/6 at both T1 and T2) and would recommend it (6/6 at T1, 5.94/6 at T2).

EQ-5D quality-of-life scores remained high throughout follow-up. Self-perceived health status showed a modest improvement at T1 (86.49/100) and a slight decline at T2 (84.64/100), remaining comparable to baseline. RS scores remained substantially stable over time, with minimal variability. However, interest in the surrounding environment progressively increased, while energy for daily activities, after an initial improvement at T1, declined at T2.

Conclusions: Quality of life, resilience, and treatment satisfaction scores increased and remained high in the first year following LAI-ART initiation. These findings highlight the value of PROs in assessing patient satisfaction and the impact of LAI-ART, supporting improved clinical practice and the development of personalized care pathways.

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Epidemiology, Social Sciences and PROs

P 71 INTEGRATING MALE AND FEMALE CONDOM SOCIAL MARKETING TO STRENGTHEN COMMUNITY-BASED HIV PREVENTION IN KUMBA AND ITS ENVIRONS, SOUTHWEST CAMEROON: SEVEN-YEAR IMPLEMENTATION OUTCOMES (2009–2016)

A. Fontu¹, T.E. Adeola¹, E. Joseph¹, E.N. Cyril², L. Kana³

¹Alliance for Community Initiative, Kumba, Cameroon, ²Community Center for Integrated Development, Buea Cameroon, ³PRESSE JEUNE DEVELOPPEMENT, Douala Cameroon

Background: Condoms are a key biomedical intervention for HIV and STI prevention, yet consistent uptake remains suboptimal in sub-Saharan Africa, particularly for female condoms due to access and sociocultural barriers. Evidence on long-term, community-based integration of male and female condom social marketing is limited. This study summarizes seven years of implementing Universal Access to Female Condoms (UAFC) FC2 project alongside male condom social marketing community-based interventions in Kumba and surrounding peri-urban areas, focusing on uptake, empowerment, and community-reported outcomes (CROs, equivalent to patient-reported outcomes, PROs)

Methods: From 2009–2016, interventions were implemented in partnership with Association Camerounaise pour le Marketing Social (ACMS) under the Central Africa AIDS Prevention Project (PPSAC). Strategies included:

- Establishing 35 hairdressing salons and 4 community-based organizations as female condom distribution hubs
- Expanding retail networks through 120 wholesalers, retailers, and informal outlets
- Peer-led interpersonal communication and behavior change campaigns targeting women and youth (n≈5,200 reached annually)
- Routine monitoring of distribution, coverage, and community-reported outcomes, including self-reported condom use, confidence in negotiating condom use, and outlet functionality

Results:

- Condom distribution outlets increased fivefold (35 → 175), with 65 new outlets created and 40 revitalized, covering urban and peri-urban Kumba
- Annual distribution: male condoms increased 200% (150,000 → 450,000 units); female condoms increased 620% (2,500 → 18,000 units)
- Peer-led outreach improved self-reported condom negotiation confidence among women from 34% to 78% and consistent use among youth from 22% to 63%
- Monthly distribution targets consistently met (>95% adherence), with stockouts reduced to <2% annually
- Local partnerships enabled sustainability, with >80% of outlets remaining operational post-intervention

Conclusions: Integrating male and female condom social marketing with peer-led, community-based outreach significantly enhances access, uptake, and gender-responsive outcomes in HIV prevention. Coupling supply chain expansion, demand generation, and empowerment strategies creates a scalable, sustainable model, with implications for replication in other low-resource urban and peri-urban African settings. Importantly, the use of community-reported outcomes (CROs/PROs) highlights the value of capturing the perspectives of beneficiaries to evaluate behavioral and programmatic impact.

Keywords: HIV prevention, condom social marketing, female condoms, peer-led interventions, community-based distribution, community-reported outcomes (CROs/PROs), Kumba, Southwest Cameroon, sub-Saharan Africa.

Epidemiology, Social Sciences and PROs

P 72 LESSAIDS: BARRIERS TO HIV TESTING AND MISSED HEALTHCARE OPPORTUNITIES BEFORE DIAGNOSIS IN SOUTHERN ITALY

A. Russo^{1,2}, S. Martini², G. Ricciardiello², M. Carleo³, F.M. Fusco⁴, N. De Gennaro⁵, A. Gallicchio⁶, A. Masiello⁷, E. Zappulo⁸, A. Auricchio⁹, M. Trizzino¹⁰, P. Fusco¹¹, A. Giaccone¹², V. Esposito³, V. Sangiovanni⁴, A. Saracino⁵, E. Manzillo⁶, C. Sagnelli⁷, I. Gentile¹³, A. Prozzo⁹, A. Cascio¹⁰, A. Russo¹⁴, A. Franco¹², E.M. Trecarichi¹, N. Coppola²

¹Link Capus University, Rome, Italy, ²UOC Malattie Infettive, AOU Vanvitelli, Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy, ³UOC Malattie Infettive e Medicina di genere, PO Cotugno, AORN dei Colli, Naples, Italy, ⁴UOC Malattie Infettive dell'immunodepresso, PO Cotugno, AORN dei Colli, Naples, Italy, ⁵UOC Malattie Infettive, AOU Bari, Università degli Studi di Bari "Aldo Moro", Bari, Italy, ⁶UOC Malattie Infettive e dell'immigrazione, PO Cotugno, AORN dei Colli, Naples, Italy, ⁷UOC Malattie Infettive, AORN di Caserta, Caserta, Italy, ⁸UOC Malattie Infettive, AOU Federico II, Università degli Studi di Napoli "Federico II", Naples, Italy, ⁹UOC Malattie Infettive, AO Antonio Cardarelli di Campobasso, Campobasso, Italy, ¹⁰UOC Malattie Infettive, AOU Palermo, Università degli Studi di Palermo, Palermo, Italy, ¹¹UOC Malattie Infettive, AOU Renato Dulbecco, Catanzaro, Italy, ¹²UOC Malattie Infettive dell'età geriatrica, VII Divisione, PO Cotugno, AORN dei Colli, Naples, Italy, ¹³Università degli Studi di Napoli Federico II, Dipartimento di Medicina Clinica e Chirurgia, Naples, Italy, ¹⁴UOC Malattie Infettive, AOU Catanzaro, Università degli Studi "Magna Grecia", Catanzaro, Italy

Background: Late HIV diagnosis remains frequent in Italy. We investigated patient-reported barriers to HIV testing and patterns of healthcare access in the 12 months before HIV diagnosis, focusing on differences by clinical severity.

Methods: LESSAIDS is a multicenter prospective observational study enrolling 140 adults with new HIV diagnosis (March 2025–February 2026). Participants completed a predefined questionnaire on barriers to testing; healthcare contacts in the previous 12 months were described. Comparisons were performed between groups defined by CDC Classification (CDC C vs other than CDC C). Categorical variables are reported as n (%) and continuous variables as median (IQR). χ^2 /Fisher's exact and Kruskal–Wallis test were used as appropriate.

Results: Compared with non–CDC C (n=91), CDC C participants (n=49) were older (49 [40–52] vs 40 [31–48] years; p=0.003) and were all symptomatic at diagnosis (49/49, 100% vs 34/91, 37.4%; p=0.001). Sexual activity distribution differed (heterosexual: 34/47, 72.3% vs 26/88, 29.6%; MSM: 11/47, 23.4% vs 56/88, 63.6%; p=0.001). Sexually transmitted infections in the last year were less frequently reported in CDC C (8/47, 17.0% vs 29/88, 33.0%; p=0.048). Reasons for testing differed markedly: symptoms were the main driver in CDC C (44/49, 89.8% vs 27/91, 29.7%) whereas screening predominated in non–CDC C (64/91, 70.3% vs 5/49, 10.2%; p=0.001). In the year before diagnosis, CDC C participants more often attended the emergency department (≥ 1 visit: 21/36, 58.3% vs 13/59, 22.0%; >1 visit: 8/36, 22.2% vs 2/59, 3.4%; p=0.001) and tended to report >1 medical visit overall (27/45, 60.0% vs 31/80, 38.8%; p=0.058). After HIV diagnosis, time to infectious diseases visit was shorter in CDC C (2 [0–5] vs 5 [2–8] days; p=0.001), but time from infectious diseases consultation to ART initiation was longer (9 [4–15] vs 3 [0–8] days; p=0.001). Test refusal after a recommendation was more frequent in CDC C (any refusal: 15/46, 32.6% vs 10/87, 11.5%; p=0.005). "Did not know where to go" emerged as a more relevant barrier in CDC C (very important: 5/41, 12.2% vs 1/77, 1.3%; p=0.02).

Conclusion: Advanced HIV disease was associated with more acute-care use, more frequent prior test refusal, and actionable navigation barriers. Systematic HIV testing should be offered in emergency settings in order to improve access pathways and reduce late diagnosis.

Table 1

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Epidemiology, Social Sciences and PROs

P 73 LONGITUDINAL ART ADHERENCE AND CLINICAL RETENTION IN WOMEN LIVING WITH HIV: A 32-YEAR RETROSPECTIVE STUDY ON THE POSTPARTUM TRANSITION AND LONG-TERM MATERNAL OUTCOMES

D. Segala^{1,2}, G. Amaddeo¹, P. Mori², R. Cultrera^{1,3}

¹University of Ferrara, Ferrara, Italy, ²Azienda Ospedaliero Universitaria di Ferrara, Ferrara, Italy, ³Azienda Unità Sanitaria Locale di Ferrara, Ferrara, Italy

Background: HIV pregnancy care ensures viral suppression, yet maintaining retention in care and antiretroviral therapy (ART) adherence remains a major challenge in the postpartum period, threatening long-term maternal health.

Material and Methods: A 32-year retrospective study (1994–2025) was conducted at the Ferrara HIV Center, including all women living with HIV (WLWH) with at least one pregnancy. The research evaluated ART adherence and clinical follow-up during pregnancy and the three years post-delivery. By analyzing clinico-demographic variables, we aimed to identify barriers to care and implement targeted strategies. A specific focus was placed on postpartum to optimize clinical management and long-term retention in care beyond the immediate delivery period.

Results: We enrolled 49 WLWH (81 pregnancies), mostly aged >45 (53.06%), Italian (53.06%) or African (34.69%) origin. Infection duration before pregnancy was <10 years in 75.5%. Comorbidities (32.66%) included psychiatric (10.2%), treatment-related (10.2%), gastrointestinal (8.16%), and neurological (4.08%) disorders. Of 60 births, 54.3% were C-sections, 9.87% vaginal. Adherence during the first pregnancy was high (ART 81.63%; follow-up 89.8%) but declined postpartum to 63.26% and 79.59%, respectively, with a 10.2% loss-to-follow-up. No significant differences in non-adherence emerged by HIV diagnosis timing (38.8% during pregnancy vs. 41.9% otherwise). Significant disparities emerged by origin: foreign-born women, particularly of African descent, exhibited higher non-adherence. In this subgroup, rates were 30.7% for ART and 15.3% for follow-up during pregnancy, with follow-up non-adherence rising to 38.46% postpartum. Maternal age influenced engagement: non-adherence peaked in women under 25, while those over 45 showed the most consistency. Thus, origin and younger age are stronger predictors of care interruption than the timing of diagnosis (Tables 1, 2, 3).

Conclusions: This study identifies a dual-phase pattern: while pregnancy drives high ART adherence, levels drop postpartum. The three-year period following delivery is a critical window of vulnerability, as neonatal care often supersedes maternal self-care once the incentive of preventing vertical transmission diminishes. It appears necessary to implement structured, multidisciplinary support strategies extending beyond the obstetric period. Given the impact of psychiatric and neurological comorbidities, integrated care is essential for this aging population. Furthermore, findings demand tailored retention interventions for younger patients and foreign-born women, as psychosocial and cultural challenges, rather than diagnosis timing, are the primary drivers of treatment interruption. In conclusion, clinical management must shift toward long-term, patient-centered models prioritizing the postpartum transition. Targeted strategies are imperative to ensure sustained viral suppression and safeguard maternal health.

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Epidemiology, Social Sciences and PROs

P 74 “LOVE ME WHILE PLAYING SCHOOL”: A CURRICULUM FOR LEARNING ABOUT AFFECTIVITY AND SEXUALITY IN SCHOOLS

I. Ciciolla, A. Calluso, N. Catucci, M. Di Tullio, R. Giusto, M. Giannelli, G. Labianca, A. Degiosa, I.V. Lanera

C.A.M.A. – Centro Assistenza Malati Aids – OdV ETS, Bari, Italy

Background: The project was an educational program dedicated to affectivity and sexuality, designed for secondary school students, and was conducted with second- and third-year classes at the "De Viti De Marco" Technological Institute in Triggiano (BA) during 2025.

Materials and Methods: Fifteen classes were involved: eight second- and seven third-year classes, for a total of 361 students. We conducted three two-hour sessions for each class, for a total of 90 hours.

The overall objectives were to promote students' psychological and physical well-being and raise their awareness of emotional, sexual, and digital issues.

Educational tools were provided to understand and manage their emotional and sexual development; we raised students' awareness of the importance of gender diversity and identity development, educating them about online safety, and preventing risks related to sexting and sexually transmitted diseases; and we promoted an inclusive understanding of sexuality, with a particular focus on disabilities.

An educational comic book was distributed in print and online, providing information on the topics covered, and awareness brochures conveyed key messages of the training program, designed to strengthen learning and create a positive connection between students and the project.

We conducted interactive lessons with direct student involvement, with discussions led by experts (psychotherapists and sexologists). Practical and interactive activities were conducted, encouraging critical reflection and active peer discussion. A final questionnaire was distributed to assess students' knowledge.

Results: 361 students responded to the questionnaire. Participants were between 15 and 17 years old, 39.6% female and 60.4% male. The results, in summary, are: 10.25% believe that the timing of physical changes during adolescence is the same for everyone. 21.9% believe that penis size increases sexual pleasure. 34.9% believe that pain during first sexual intercourse is abnormal. 39.9% believe that a person's identity is not built by comparing themselves to others. 23.3% do not know whether a person's gender identity coincides with their biological sex. 35% are unaware or do not consider the stereotype to be a rigid opinion. 45.7% are unaware of the existence of medications that prevent people living with HIV from infecting others. Finally, 21.3% believe it is possible to share sexually explicit photos/videos online without consent.

Conclusions: These data confirm the need for education on affectivity and sexuality in high schools. Clear, scientifically sound information and a space for guided discussion can help students develop greater awareness, respect, and responsibility in relationships, both in real life and online.

Epidemiology, Social Sciences and PROs

P 75 MANAGEMENT OF A COMPLEX CHEMSEX CASE: AN OPPORTUNITY FOR LINKAGE TO CARE AND RETENTION IN CARE

A. Antonino¹, A. Bianchi¹, G. Fracca¹, D. Zagato¹, P. Testoni¹, P. Vinti¹, C. Soligo¹, M. Manfredini¹, S. Nozza², M. Cernuschi^{1,2}

¹ASA Onlus ODV, Milano, Italy, ²San Raffaele Hospital, Milano, Italy

Background: our organization provides a community-based chemsex support service, where peer workers first receive requests by phone, collect contact details and refer to a psychotherapist for follow-up. The psychotherapist schedules an assessment interview, to evaluate the individual's needs, and collaboratively identify the most appropriate interventions.

Case Presentation: G, is a 49 years old gay man living in Milano. He contacted our service in April 2025, reporting problematic chemsex and asking for support to stop using MDPV. He already tried to stop using MDPV multiple times without success, but was encouraged to retry by a peer who succeeded. He had used PrEP but stopped for more than one year. G started smoking freebase cocaine five years earlier, and after developing an addiction he switched MDPV. He reported daily drug use as a form of self-medication for an unrecognized depressive condition, marked by severe social withdrawal, self-neglect, isolation, low self-esteem, non-affective sexuality and increasing awareness of the toxic effects associated with frequent and high-dose drug use. September 2025 was his most critical period, soon after a job demotion, his main source of stability after the end of a significant relationship, he was admitted to the ER for severe distress, panic attack, and MDPV-induced paranoid ideation. After the anamnestic data, a multi-level intervention was planned together: temporary relocation away from Milan to facilitate substance abstinence and regain clarity, individual psychotherapy and psychiatric follow-up once moving back to Milan. Following a relapse, he started treatment with an antipsychotic and a mood stabilizer. In November G had a skin rash and significant health-related anxiety concerning sexual health. He went for an STI screening which led to an HIV diagnosis. We supported G in scheduling and attending his first consultation at the HIV clinic. Initial laboratory findings revealed advanced HIV infection, close to AIDS progression. ART with BIC/FTC/TAF was started immediately, and was well tolerated and effective. Since January 2026, G. is attending group psychotherapy sessions and was referred to addiction services (SerD).

Discussion: Having access to an integrated support and care network can enhance confidence in leaning on others to regain wellbeing and facilitate effective linkage to care. Such a network offered to G represents an opportunity to avoid isolation and to re-engage actively in his own recovery process, despite emotional vulnerability due to MDPV addiction and an HIV diagnosis. The moment of the HIV was pivotal for taking advantage of this network. Integration of chemsex support in the PrEP programme could have supported retention in care and effective use for HIV prevention. This case highlights the value of coordinated, multi-level care pathways, as essential conditions for successful retention in care, for HIV and chemsex. Our service was supported by ViiV healthcare.

Epidemiology, Social Sciences and PROs

P 76 MAPPING SCHOOL-BASED SEXUALITY EDUCATION INTERVENTIONS IN ITALIAN CONTEXT, 2021-2025

A. Cappagli, A. Chinelli, G. Papparatto, L. Tavoschi

Department of Translational Research and New Technologies in Medicine and Surgery, Pisa, Italy

Background: In Italy, sexuality education (SE) is not included in school curricula. According to WHO Europe and UNESCO guidelines, school-based SE (SBSE) represents a key public health strategy for HIV and other sexually transmitted infections (STIs) prevention. Young people aged 15–24 account for a significant proportion of new STI diagnoses, highlighting the importance of targeted prevention strategies within the school setting.

The first national survey of SBSE activities (2016–2020) pictured a highly heterogeneous scenario in terms of geographical coverage, providers, content and educational approaches. Such heterogeneity conditions equal access to accurate and evidence-based information, potentially limiting the effectiveness of sexual health promotion efforts among adolescents.

Systematically mapping SBSE is therefore crucial to understand whether Italian adolescents have equitable access to effective sexual health promotion initiatives, such as the globally recognised effective approach of Comprehensive Sexuality Education (CSE).

This study builds upon the 2016–2020 survey, with the aim of generating an updated, structured and comparable picture of the activities carried out between 2021 and 2025.

Methods: An online questionnaire will be used to gather information on the duration, providers, objectives, content, methodologies, and assessment methods of SBSE activities. The survey will be disseminated to all the entities and individuals involved in sexual health promotion within the school context, including: local health authorities, civil society organizations and professional federations. The providers will be recruited through targeted emails following a desk review on national databases (es. PROSA), using a network-based strategy and a snow-ball sampling.

Descriptive analyses of the data collected will be conducted, while an evaluation framework adapted from UNESCO will be used to qualitatively assess the different types of activities.

Expected results: We expect to (i) describe the national distribution and main characteristics of SBSE activities implemented in Italy in 2021–2025; (ii) classify activities by degree of alignment with UNESCO guidelines and to identify CSE interventions; (iii) identify gaps and inequities in coverage, inclusivity and evaluation practices, with implications for STI/HIV prevention.

Conclusion: This study will provide an updated and comprehensive picture of SBSE activities in Italian schools and enable comparison with previously collected data. Findings will contribute to inform sexual health promotion and STI/HIV prevention strategies in school settings, highlighting resisting gaps to high-quality educational activities for all Italian adolescents.

Epidemiology, Social Sciences and PROs

P 77 MONO-SYMPTOMATIC THERAPEUTICAL GROUP FOR CHEMSEX USERS: 7 YEARS OF CLINICAL EXPERIENCE IN MILAN

G. Fracca, M. Manfredini, M. Cernuschi, A. Bianchi, A. Antonino

ASA ODV, Milano, Italy

Background: ASA was the first association in Italy to recognise the potential harms of Chemsex abuse. In 2019 it established the first mono-symptomatic therapeutical group for Chemsex users in Italy, embedded within a historical and well-established organisation in the Milan MSM scene, offering a place of cure free from stigma and medicalization.

Material and Methods: Weekly semi-open psychoanalytic group, led by a professional psychotherapist and a community volunteer. Advertised through the association's website, gay venues, HIV clinics, and Grindr. The current model includes two weekly in-person groups and one weekly online group for participants outside Milan. The project collaborates with the public health network, in particular addiction treatment centres (SerD) and psychiatric specialists, ensuring integrated medical and psychological care when needed.

Results: The service reaches over 60 users per year. A clinical polarisation emerged between users of non-smokable substances (mephedrone, GHB) — who frequently do not self-identify as addicted despite years of use — and users of smokable substances (MDPV, methamphetamine). Addiction risks are comparable across both groups; no distinction by substance is made in the groups. MDPV abuse is associated with severe psychotic and paranoid episodes, more effectively managed through group confrontation than individual therapy, with psychiatric support provided through the SerD network in acute cases. Among the most assiduous participants, cessation was achieved; a proportion discontinued and were lost to follow-up.

Conclusion: The psychoanalytic mono-symptomatic group model — grounded in peer confrontation and the shared bond of "I am like you" — has proven effective in treating Chemsex-related addiction in the Milan MSM community. The integration with SerD and psychiatric services, combined with the synergy between therapist and community volunteer, has been key to bridging cultural gaps and ensuring continuity of care.

(ASA was supported by Viivhealthcare)

Epidemiology, Social Sciences and PROs

P 78 NEUROPSYCHOLOGICAL DISORDERS IN WOMEN LIVING WITH HIV: IMPACT ON QUALITY OF LIFE

E. Muresu¹, A. De Vito¹, G. Brugnani², M.E. Fajardo¹, G. Madeddu¹

¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ²School of Medicine, University of Sassari, Sassari, Italy

Background: People living with HIV (PWH) are at increased risk of neuropsychological symptoms and disorders compared with the general population. Women with HIV (WLWH) have a higher risk than men with HIV and women without due to biological and psychosocial factors, and dual gender and HIV-related stigma. However, these disorders are often underdiagnosed and undertreated, and few studies focus exclusively on the female population.

Methods: A monocentric, observational cross-sectional study was conducted between March and July 2025 at the Infectious Diseases Unit of Sassari. Sociodemographic, clinical, laboratory, and therapeutic data were collected from the Sardinian HIV database and clinical records.

Neuropsychological symptoms were assessed using six self-report questionnaires: EQ-5D-5L, PSQI, HAM-A, CES-D, and HIVTSQ-12, along with an adherence questionnaire. Associations between questionnaire scores and EQ-VAS were evaluated using linear regression. Statistical significance was set at $p < 0.05$.

Results: The study included 60 WLWH with a median age of 57.4 years (IQR 48.8–61.0), of whom 71.7% were postmenopausal. The median duration of HIV infection was 24.4 (IQR 10.6–34.3) years (Table 1).

Participants showed high levels of treatment adherence, with over 98% reporting adherence $\geq 80\%$ and 81.7% reporting full adherence. Laboratory data at the moment of questionnaire collection are shown in Table 2.

The results showed that the median HAM-A score was 9 (IQR 4.5–15): 84.5% of women reported mild anxiety, and 15% mild-moderate to severe anxiety symptoms. Depressive symptoms had a median score of 11.5 (IQR 7–16.5), with a prevalence of clinically relevant depressive symptoms in 28.3% of participants. The PSQI median score was 5 (IQR 4–7), and 46.7% of participants showed impaired sleep quality. The majority of women reported no significant limitations in mobility, self-care, or usual activities. However, 51.7% reported pain or physical discomfort, and 30% reported moderate to severe anxiety or depression. Median perceived health status was 80 (IQR 70–90) (Table 3).

Linear regression analysis demonstrated significant associations between neuropsychological factors and perceived health status (Table 4). Higher CES-D scores were associated with lower EQ-VAS scores, as were higher HAM-A, PSQI, and HIVTSQ-12 scores, which were positively associated with perceived health status.

Conclusion: The study findings highlight the frequency and clinical relevance of neuropsychological symptoms among WLWH. The significant association between neuropsychological symptoms and poorer quality of life underscores the need to integrate Patient-Reported Outcomes into clinical practice systematically. These results support the importance of early screening and ongoing monitoring programs based on a multidisciplinary, patient-centred, and gender-sensitive approach to reduce underdiagnosis, improve quality of life, and indirectly improve the clinical outcome of HIV infection.

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Epidemiology, Social Sciences and PROs

P 79 NOI, DONNE. FROM PERIMENOPAUSE TO MENOPAUSE. A PARTICIPATORY SUPPORT MODEL FOR WOMEN LIVING WITH HIV

D. Russo¹, A. Moznich¹, A. Palmitesta¹, D. Peruzzi¹, S. Dalzero², L. Taramasso³, N. Policek^{1,4}

¹NPS Italia Aps, Milan, Italy, ²Department of Obstetrics and Gynaecology, DMSD San Paolo Hospital Medical School, University of Milan, Milan, Italy, ³Infectious Diseases Unit, Policlinico San Martino Hospital - IRCCS, Genoa, Italy, ⁴Executive Director, European AIDS Treatment Group (EATG), Brussels, Belgium

Background: Menopause is a universal yet highly individualized life stage. In Women living with HIV, the perimenopausal and menopausal transition may involve complex physical and psychological symptoms that overlap with HIV-related conditions or antiretroviral therapy effects. Women living with HIV show a higher burden of mental health conditions compared with HIV-negative peers, and severe menopausal symptoms have been associated with reduced adherence to antiretroviral therapy. Targeted, community-informed interventions are therefore needed to address these unmet and often under-recognized needs.

Objectives: The project “Noi, Donne. From Perimenopause to Menopause” aims to explore the needs and priorities of Women living with HIV during midlife transition; promote empowerment and peer support; develop a sustainable peer mentoring model; and produce a holistic, accessible guide offering practical and comprehensive support throughout perimenopause and menopause.

Methods: By March 2025, two online focus groups were conducted with 14 Women living with HIV aged 44–65 years from Northern, Central, and Southern Italy. Sessions were moderated by peer mentors with the support of a multidisciplinary team (infectious disease specialist, psychologist). An inductive qualitative content analysis was performed to identify key themes and priorities related to the menopausal transition. Findings informed a structured participatory co-creation process that led to the development of a holistic, practice-oriented guide. To ensure scientific rigor, qualitative results were integrated with a focused literature review providing evidence-based support for the information and recommendations included. The guide was disseminated through the association’s communication channels. An annual programme of online peer meetings was also implemented to ensure continuity of support and to provide a safe, confidential space for experience sharing and mutual support.

Preliminary Results: Discussions highlighted unmet informational needs, uncertainty in symptom interpretation, concerns regarding sexual health and psychological wellbeing, and a strong demand for structured peer-sharing spaces. The guide and online community represent tools to improve awareness, reduce isolation, and enhance patient–provider dialogue.

Conclusions and Future Directions: Noi, Donne” represents a community-based participatory model addressing midlife health in Women living with HIV. In 2026, the programme will expand through monthly peer-mentoring sessions and specialist-led discussions to consolidate a scalable and replicable model of psychosocial and clinical support.

Epidemiology, Social Sciences and PROs

P 80 PADOVA CHECKPOINT: THE FIRST YEAR EXPERIENCE

M. Falaguasta^{1,2}, G. Borgato^{1,2}, F. Sguotti², G. Giardina^{1,2}, F. Barbaro^{1,3}, A. Ferrari^{1,3}, D. Leoni^{1,3}, S. Cavinato^{1,3}, E. Vania³, Calandrino³, L. Sasset^{1,3}, A. Cattelan^{1,3}

¹Anlaids sez. Padova APS, Padova, Italy, ²PadovaCheckpoint, Padova, Italy, ³UOC Malattie Infettive e Tropicali AOPD, Padova, Italy

Background: Aligned with the recommendations from international agencies such as ECDC, UNAIDS and WHO, the Italian PNAIDS recognizes the Third Sector as a strategic stakeholder in enhancing access to testing and ensuring earlier diagnosis of HIV and sexually transmitted infections (STIs). This is particularly important for key populations who are less likely to access conventional health and social care services.

Materials and Methods: To facilitate earlier HIV/STI diagnosis and, where possible, to reduce incidence through targeted awareness and educational interventions, Padova Checkpoint was established in January 2025. This community-based service aims to:

- increase awareness of combination prevention strategies (e.g. PrEP, PEP, vaccinations, etc.);
- provide linkage and navigation to local health services, facilitating access to care;
- promote empowerment of people living with HIV (PLWH) by addressing prejudice, stigma and discrimination;
- encourage a proactive approach to overall health, raising awareness of integrated healthcare interventions such as gender-affirming hormone therapy (GAHT).

Results: In 2025, Padova Checkpoint received a total of 117 requests for single or multiple services, leading to 106 individuals being taken into care (see Figure 1).

The overall service delivery indicates that several individuals benefited from ongoing care pathways (see Figure 2), with 34% of these services being provided via telemedicine.

Notably, reactivity was observed in the rapid HIV tests, prompting immediate referral to the Infectious Diseases Unit of the Padua University Hospital for confirmatory testing and initiation of antiretroviral therapy. The gender distribution of service users was as follows: 62 cisgender men (53%), 32 cisgender women (27.4%), 14 transgender women (12.0%), 1 non-binary individual (0.9%), and 8 individuals did not declare their gender (6.8%).

The predominant age group was 26–35 years (47%), followed by 36–45 years (28.2%), individuals >45 years (10.3%), and those aged 18–25 years (6%). Age data were unavailable for 10 individuals.

Conclusions: The first-year data demonstrate that Padova Checkpoint, particularly through its collaboration with the Infectious Diseases Unit of the Padua University Hospital, has significantly contributed to the protection of sexual health, especially among vulnerable key populations less likely to access traditional health and social care services.

It is essential for this project, initially launched as a pilot initiative in the Veneto Region, to evolve into a structured service. Furthermore, expanding collaborations with other stakeholders involved in health promotion and care will enhance benefits for all.

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Epidemiology, Social Sciences and PROs

P 81 PATHWAY FOR THE PSYCHOPHYSICAL WELL-BEING OF PEOPLE LIVING WITH HIV

S. Negri¹, R. Galipò², P. Ferri², D. Mainieri¹, M. Massa¹, L. Butini³

¹ANLAIDS Lombardia, Italy, ²ANLAIDS Lazio, Italy, ³ANLAIDS ETS

Advances in scientific research and the effectiveness of antiretroviral therapies have profoundly transformed the prognosis of HIV infection, which is now managed as a chronic condition. Despite these advances, psychological and social challenges associated with an HIV diagnosis persist. HIV continues to evoke stigma, fear, guilt, and social isolation, complicating emotional adjustment and interpersonal relationships. Living with a chronic condition entails a redefinition of personal and social identity, particularly in the case of HIV. This contribution is based on the experience of ANLAIDS Lazio and ANLAIDS Lombardia in promoting the psychological and social well-being of people living with HIV, with a particular focus on newly diagnosed individuals and long-term treatment retention.

The project aims to enhance the well-being of people living with HIV by strengthening autonomy, dignity, and social participation through psychological support that aims to facilitate acceptance of the diagnosis; reduce emotional distress and anxiety-depressive symptoms; enhance personal resources and coping strategies; support treatment adherence; and assist with relational challenges and disclosure processes. Social support interventions focus on reducing isolation and stigma by promoting social, occupational, and housing inclusion, empowerment and active citizenship through an integrated approach combining psychological well-being, lifestyle factors, and medical care.

ANLAIDS Lazio and ANLAIDS Lombardia provide free psychological and social counseling services through telephone counseling and individual in-person sessions. Interventions include psychological support, counseling for couples and families, and referral to social and health services. At the social level, ANLAIDS implements practical support interventions. In Lombardia, these include financial assistance, housing support, access to soup kitchens and shelters, home delivery of medications, and solidarity grocery initiatives developed in collaboration with local community networks.

Data collected between 2020 and 2025 indicate that approximately 2,150 psychological consultations—both online and in-person—were provided to people living with HIV, either directly or through referrals from clinical centers. Additionally, the Lombardia branch recorded 1,697 transportation services; 1,080 solidarity grocery shopping interventions; 85 home deliveries of medications; and payment of household utility bills for 67 users. These findings demonstrate the effectiveness of an integrated care model.

The project contributes to achieving the goals of the “second 95” (access to and retention in therapy) and the “fourth 95” (quality of life and equity in care), with particular attention to socially vulnerable populations. Comprehensive care for people living with HIV must extend beyond pharmacological treatment, encompassing relational, social, and emotional dimensions that support treatment adherence and quality of life.

Epidemiology, Social Sciences and PROs

P 82 PERSONALITY TRAITS AND HEALTH LOCUS OF CONTROL IN PEOPLE LIVING WITH HIV: ONE YEAR AFTER LONG-ACTING THERAPY

A. Romeo^{1,3}, M. Ferrara², V. Maccario², L. Trentini^{2,3}, M.C. Tettoni², S. Bonora²

¹Department of Psychology, University of Turin, Turin, Italy, ²Department of Medical Sciences, University of Turin, C/o Infectious diseases Unit, Amedeo di Savoia Hospital, Turin, Italy, ³Anlaids sezione Torino ODV, Italy

Background: People living with HIV (PLWH) face various health-related challenges. Even in similar situations, reactions to care processes can vary depending on individual factors, such as personality. Indeed, Smith's (2006) health behaviour model suggests that personality influences health behaviours. Health locus of control (HLC) refers to how much control an individual believes they have over their health: internal or external. Those with high internal HLC believe their behaviours impact their health status. Those with high external HLC believe their health is impacted by people or external forces (Wallston & Wallston, 1982). This longitudinal study aimed to investigate personality traits and HLC in PLWH after one year of long-acting antiretroviral therapy (LA-ART). Furthermore, it examined how personality affects HLC, medical adherence, and quality of life (QoL).

Material and Methods: A total of 45 PLWH were recruited from the Infectious Diseases Unit at Amedeo di Savoia Hospital in Turin. Participants were asked to complete a survey during the first (T0) and seventh (T1) administrations of LA-ART. Data collected included socio-demographic and clinical information (included QoL and medical adherence), personality traits through the Brief Form of the Personality Inventory for DSM-5 (PID-5 BF), and health locus of control through the Multidimensional Health Locus of Control-C (MHLC-C).

Results: Regarding HLC, measured with MHLC-C, paired t-tests showed significant differences between the T0 and T1 evaluations on the chance subscale ($t(44)=-3,387$, $p<0.001$) and on the doctors subscale ($t(44)=-3,010$, $p=.002$). The linear regression analyses showed that the antagonism subscale of PID-5 BF (indicated manipulation, grandiosity, hostility) was a positive predictor of the chance subscale of MHLC-C at T1 ($\beta= .377$; $p= 0.11$). Furthermore, psychoticism subscale of PID-5 BF (indicated unusual beliefs/experiences, eccentricity) appeared to be a negative predictor of the doctor subscale of MHLC-C at T1 ($\beta= -.343$; $p= 0.21$). Pearson correlations showed that: detachment subscale of PID-5 (indicated withdrawal, anhedonia) was negative associated with QoL both at T0 ($p=0.11$) and T1 ($p=0.17$); "negative affectivity" subscale of PID-5 (indicated anxiety, emotional lability) was negative associated with QoL level at T0 ($p=0.15$); "disinhibition" subscale of PID-5 (indicated irresponsibility, impulsiveness, risk-taking) was negative associated with medical adherence ($p<.001$).

Conclusions: LA-ART seems to alter perceptions of control over health. After one year, people seem to rely more on chance and doctors, experiencing a decrease in internal control. Reduced internal control over health also seems influenced by personality traits. These latter factors also appear to affect QoL and adherence, regardless of the new LA-ART. Understanding the role of personality and HLC in PLWH is important for the development of personalized health interventions.

Epidemiology, Social Sciences and PROs

P 83 REACHING BEYOND KEY POPULATIONS: FIVE YEARS OF EXPERIENCE IN COMMUNITY-BASED RAPID HIV/STI TESTING

N. Frattini¹, P. Vinti¹, E. Caruso¹, P. Russo^{1,2}, L. Nekrasova¹, R. Repossi¹, I. Gotti^{1,3}, D. Zagato^{1,4}, M. Cernuschi^{1,4}

¹Milano Check Point ETS, Milano, Italy, ²CIG Arcigay Milano ODV, Milano, Italy, ³ANLAIDS Sezione Lombarda ETS, Milano, Italy, ⁴ASA ODV, Milano, Italy

Background: Community-based testing plays a key role in facilitating early HIV diagnosis. This study was conducted in a high-volume community-based HIV testing service in Italy, also a member of the European COBATEST network. We aimed to describe the population of clients attending our service between 2019 and 2023 and explore differences between sub-populations.

Methods: We conducted a retrospective descriptive analysis of anonymous data routinely collected during pre-test counselling for rapid HIV/syphilis testing, between January 2019 and December 2023. Demographic and behavioural data was collected on the COBATEST online platform by community health workers. Data were stratified by gender identity, sexual orientation and key population status, using descriptive statistics. Key population categories were not mutually exclusive, as clients could report more than one.

Results: Between 2019 and 2023, we provided 8'387 rapid HIV tests. Gender identity, sexual orientation and key population status of clients are described in Table 1. 5080 tests were provided in our checkpoint (60.6%), 2750 in outreach settings outdoors (32.8%); 557 tests in other/not specified locations (6.6%). Figure 1 presents the number of tests performed in all locations (A), in the checkpoint (B) and in outreach settings (C), stratified by year and key and other population status. Figure 2 presents the percentage of tests performed among each key and other population by year, in all locations (A), in the checkpoint (B) and in outreach settings (C).

Testing volume declined markedly in 2020 and rebounded from 2021 onward, with a particularly strong recovery in outreach activities. Excluding 2020 data, the number of tests provided to GBMSM, migrants and trans and gender diverse (TGD) people constantly increased over time, with some differences across locations. Tests provided to men and women who are not part of a key population remained stable between 2021 and 2023. Tests were provided to GBMSM and migrants more likely at the checkpoint, while to TGD people and cisgender women in outreach settings.

Conclusions: Our service attracts a diverse population of clients, mostly members of key population, in line with its design and goals. Still, approximatively 25% of test are provided to heterosexual men and women not part of any key population, proving the effectiveness of our service delivery model also beyond its intended audience. As outdoor outreach testing was available to everyone but was delivered close to queer meeting places, observed differences between settings likely reflect a combination of convenience, opportunity, comfort, and social acceptability rather than targeted programming or testing preferences. Differences between outreach- and venue-based settings suggest that different locations play complementary roles in service delivery. To reduce new and late HIV diagnoses, public health authorities should prioritize strategies to reach beyond key populations.

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Epidemiology, Social Sciences and PROs

P 84 SUBOPTIMAL ADHERENCE AND HEALTH CONCERNS IN PEOPLE WITH HIV TAKING ANTIRETROVIRAL TREATMENT IN ITALY: RESULTS FROM THE POSITIVE PERSPECTIVES 3 STUDY

D. Moschese¹, M.V. Cossu¹, M. Cascio², D. Gotti³, E. Capoferro³, T. Bendall⁴, T.F. Hwang⁵, C. Okoli⁴, A. Appiah⁴, N. Nwokolo⁴, R. Patel⁴

¹Department of Infectious Diseases, Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ²European AIDS Treatment Group (EATG), Bruxelles, Belgium, ³ViiV Healthcare, Verona, Italy, ⁴ViiV Healthcare, London, UK, ⁵ViiV Healthcare, Singapore, Singapore

Background: Patient engagement and experience are essential for identifying treatment and research priorities in global HIV communities. The Positive Perspectives 3 (PP3) study is a global, cross-sectional survey capturing experiences, needs, and challenges of people with HIV in 29 countries. This analysis explored specific needs of people with HIV living in Italy.

Methods: This analysis utilised interim data, including treatment adherence, treatment satisfaction, and self-reported health status, from adults with HIV in Italy taking antiretroviral therapy (ART). Suboptimal treatment adherence was defined as self-reporting any non-adherence behaviour (a mistaken or intentional missed dose, not following prescription instructions, or taking extra medication) as occurring often, sometimes, or always. Descriptive data were summarised with percentages, and Firth's bias-reduced logistic regression analysis was used to estimate odds ratios (ORs).

Results: Among 140 participants, 62% (82/140) identified as male, 43% (60/140) each identified as gay and heterosexual, and median (range) age was 56 (36-75) years. Eight participants were taking long-acting (LA) ART, and 132 were taking non-LA ART; 81% (107/132) were on daily oral single-pill regimens, while 15% (20/132) were on 2-pill regimens. Almost all (93%; 111/139) participants in the full population reported that their healthcare provider described them as virologically suppressed; however, about half (49%; 68/132 [7 respondents on LA ART and 125 on non-LA ART]) had suboptimal treatment adherence in the last 12 months. The most common types of suboptimal adherence were intentionally missing doses (39%; 52/132), not following prescription instructions (34%; 45/132), and mistakenly missing doses (33%; 44/132). Participants were more likely to report suboptimal adherence if they were assigned female at birth (male vs female, OR=0.35; P=0.043) or had a period of >5 years between HIV diagnosis and treatment initiation (≤6 months vs >5 years, OR=5.63; P=0.011). Participants also reported needs and challenges regarding their current ART regimen; 57% (70/122) agreed their current medication could be improved and 75% (92/122) were worried about forgetting or missing medication. Among participants that self-reported health, many had only fair, poor, or very poor self-perceptions of their mental health (54%; 60/112), sexual health (63%; 70/112), physical health (46%; 52/112), and overall health (48%; 52/112), indicating a need to improve care in this group.

Conclusion: Though participants in Italy reported that ART was effective, a large proportion reported suboptimal adherence in the last 12 months, indicating the potential for poorer personal and public health outcomes. This analysis also identified poor self-reported health and the need for improved treatment regimens as issues that should be addressed during care. Further analysis of the full data set, including people with HIV taking LA ART, is in progress.

Epidemiology, Social Sciences and PROs

P 85 TEMPORARY NON-RESIDENT FOREIGNER LEGAL STATUS IS ASSOCIATED TO LATE PRESENTATION AMONG NEW HIV DIAGNOSES IN MILAN, 2025

G. Bozzi¹, M. Pernich^{1,2}, V. Castelli¹, A. Pastena¹, B. Mariani¹, A. Muscatello¹, A. Bandera^{1,2}

¹Infectious Diseases Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano, Italy, ²UNIMI - Università degli studi di Milano, Milano, Italy

Background: According to the latest national epidemiology data, almost 40% of individuals who received a HIV diagnosis in Italy in 2024 was a late presenter with a total CD4 T cell count lower than 200/mcL, the immunologic threshold for AIDS defining events.

We analyzed all new HIV diagnoses made in 2025 at our tertiary hospital in Milan, Italy, aiming at characterizing factors associated to advanced naïve status, to investigate the possible impact of socioeconomic barriers on late diagnosis.

Methods: Retrospective observational monocentric study. Demographic and clinical data from all individuals receiving a HIV diagnosis in 2025 at IRCCS Policlinico, Milan, were included in the analysis. Chi-square and Fisher's exact tests were used for comparisons.

Results: A total of 50 new diagnoses were made in 2025. Median age was 34 years. Overall, 8/50 (16%) were cis female, 6/50 (12%) were MtoF transgenders, 36/50 (72%) were male; 23/50 (46%) were Italian, 27/50 (54%) were foreigners, of whom 8 (16%) had a "non-resident" temporary legal status (STP).

Route of transmission was sexual in 37/50 cases (20 MSM, 17 HE), the others were IDU or other/unknown route.

Overall, 7/50 (14%) had clinical and/or serologic criteria for acute infection.

Half cohort (25/50) harbored a non-B HIV subtype.

Upon diagnosis, median HIV RNA was 168000 cp/mL and CD4 count was 275/mcL; 32/50 (64%) had T CD4 counts < 350/mcL, 20 (40%) had counts < 200/mcL, and 9 (18%) were AIDS presenters.

Presenting with T CD4 counts lower than 200 showed an association to STP (p 0.03).

No other demographic or clinical item showed a significant association to poor immunologic status at diagnosis.

Conclusions: Characterizing new HIV diagnoses made in 2025 in our tertiary center in Milan we obtained a cohort widely comparable to epidemiology data from Italy, with particular regard to migration (from both a population and HIV genetic standpoint), and late diagnoses, accounting for over 60 and 40% with T CD4 counts <350 and <200, respectively.

Being a non-resident with temporary legal status, allowing only for urgent medical care, showed a significant association to presenting with less than 200 T CD4 cells, the immunologic thresholds for AIDS. This, even in the context of universal national healthcare system, highlights a socio-economic barrier to access to care, calling for targeted public health interventions.

Epidemiology, Social Sciences and PROs

P 86 THE CENTRAL ROLE OF THE PROFESSIONAL EDUCATOR IN HIV THERAPEUTIC ADHERENCE

G. Notore^{1,2}, I. Schenone^{1,4}, L. Ferrari^{1,5}, G. Manzi^{1,2}, A. Amoretti^{1,2}, F. Cucchetti^{1,2}, F. Tatta^{1,4}, F. Fadda^{1,4}, E. Pontali^{1,5}

¹ANLAIDS Sezione Liguria, Genoa, Italy, ²University of Genoa, Genoa, Italy, ³IRCCS AOM Ospedale Policlinico San Martino, Genoa, Italy, ⁴Ente Ospedaliero Ospedali Galliera, Genoa, Italy

Background: Therapeutic adherence among people living with HIV (PLWH) is shaped by a complex interplay of clinical, psychological, social, and cultural factors. In high-vulnerability settings, overcoming fragmented care requires cooperative and transdisciplinary approaches.

The IOC'ENTRO ANLAIDS CheckPoint (Ligurian Section) in Genoa operates through territorial cooperation (Morin, 2000) and inclusive governance (Milani & Nosari, 2022), promoting a syndemic epistemology (Sola, 2024) to address multifaceted health needs and relying on an integrated medical, educational, and psychological care model rooted in transdisciplinarity (Frabboni & Pinto Minerva, 1994).

The present work presents real-world case studies demonstrating the fundamental impact of the Professional Educator in achieving and maintaining therapeutic adherence.

Materials and Methods: This qualitative study analyzes examples of case management conducted between 2024 and 2026. The focus is on healthcare access, antiretroviral therapy (ART) adherence, and the impact of socio-cultural factors on the perception of health and illness.

Results:

- Case 1 (2024): A migrant male living with HIV, who had defaulted on ART due to access barriers, was re-engaged through educational accompaniment to hospital appointments and medication retrieval. Despite language barriers and country of origin socio-political stressors, the intervention facilitated treatment resumption and the achievement of therapeutic autonomy.
- Case 2 (2025): A cisgender woman with a new HIV diagnosis was supported through STI screening and an integrated educational path, ensuring early linkage to care and emotional support.
- Case 3 (2025): a transgender woman maintained high adherence through autonomous service access, monitored via professional feedback loops with hospital health workers.
- Case 4 (2026): A migrant male co-infected with HIV/HBV struggling with diagnostic acceptance is currently undergoing educational counseling. This ongoing case involves community educators and cultural mediators, highlighting how cultural perceptions of illness directly dictate compliance strategies.

Conclusions: Adopting a syndemic approach supports the recognition of the interdependence between medical, pedagogical, and psychological dimensions, to establish a syndemic epistemology (Sola, 2024) founded on dialogical praxis. As evidenced by the case studies, the Professional Educator acts as a "key link" in fostering therapeutic autonomy and self-determination. Integrating educational professionals into community-based screening contexts proves effective in bridging gaps in traditional care models, thereby promoting long-term adherence, continuity of care, and empowerment for PLWH.

Epidemiology, Social Sciences and PROs

P 87 THE THIRD SECTOR IN HIV CARE IN ITALY: MAPPING, VALUE GENERATION AND SUSTAINABILITY CHALLENGES

L. Brogonzoli¹, U. Restelli², M. Cascio^{3,4}, E. Sala¹, S. Silvola², A. d'Arminio Monforte⁵, S. Nozza^{3,6}, N. Policek^{3,7}, S. Lo Caputo^{3,8}, S. Negri^{3,9}, R. Iardino¹

¹The Bridge Foundation, Milan, Italy, ²LIUC Business School, Carlo Cattaneo University – LIUC, Castellanza, Italy, ³HIV Outcomes Italy, Milan, Italy, ⁴EATG (European AIDS Treatment Group), Brussels, Belgium, ⁵Icna Foundation, Milan, Italy, ⁶IRCCS-Ospedale S. Raffaele, Milan, Italy, ⁷NPS Italia Onlus, Milan, Italy, ⁸University of Foggia, A.O.U. Policlinico Foggia, Foggia, Italy, ⁹ANLAIDS Lombardia ETS, Milan, Italy

While HIV is now a chronic condition, challenges remain in terms of comorbidity, access to treatment, and stigma. These challenges underscore the pivotal importance of Third sector organizations, which fill gaps in the healthcare system and reach the most vulnerable groups. For this reason, in 2025 HIV Outcomes Italy conducted research to map these realities and assess the value generated in prevention and support.

For the mapping, a database was created through desk research using websites, areas of action, activities, and contacts of the organizations. Information was updated through a questionnaire and, for non-respondents, via online monitoring. The 22-question questionnaire investigated the organizations' profiles, resources, services, and perceptions of the impact and quality of care for people with HIV. The value of the third sector across social, clinical, psychological, humanistic, and economic domains was assessed by analyzing the number of services delivered and by quantifying the associated reduction in organizational and economic burden on the Italian NHS on the basis of current reimbursement tariffs.

The mapping revealed that of the 184 organizations initially identified, 144 are still active today, providing an up-to-date picture of organizations dealing with HIV in Italy.

An interesting finding is the polarization of economic resources among the organizations, as indicated by their 2024 budgets: 37.3% report a budget of up to €10k, while 40.8% have a budget of over €100k. Regarding sources of funding, private resources slightly prevail (donations and bequests: 59.7%; self-financing: 58.1%). Public contributions remain significant, though not exclusive. The third sector largely relies on local and voluntary resources, and better access to structured and European funds would be helpful. Respondents cited the main difficulties as financial fragility linked to discontinuous funding, a lack of institutional attention to HIV/STI issues, and uncertainty about economic sustainability in the medium to long term. The third sector generates value by reaching hard-to-reach populations through diagnostic services, enabling new diagnoses and reducing late presentation. It also contributes to lowering secondary infections through patient empowerment and improved access to PrEP. Its testing, counselling, psychological support and home care activities produce economic and organizational benefits (yearly estimated avoided costs between 1,000,000 € and 1,700,000 €) including reduced pressure on healthcare facilities, other than benefits related to medication delivery, appointment accompaniment and avoided secondary infections.

The Italian third sector generates measurable clinical, social and economic value within the HIV response. Despite this positive impact, organizations are dealing with problems of long-term sustainability and a lack of attention from institutions, so it is essential to strengthen recognition and dedicated funds.

Epidemiology, Social Sciences and PROs

P 88 THREE-YEAR TRENDS IN CHEMSEX AMONG PREP CLIENTS AND USER-IDENTIFIED NEEDS TO INFORM INTEGRATED RISK-REDUCTION SERVICES

C. Fusetti¹, E. Caruso², S. Lazzarin¹, L. Nekrasova², F. Caruso¹, P. Vinti², V. Iannone¹, R. Repossi², A. Giacomelli^{1,3}, N. Frattini², M.V. Cossu¹, M. Cernuschi², A. Gori^{1,3}, D. Moschese^{1,2}

¹Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ²Milano Checkpoint ETS, Milan, Italy, ³Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy

Background: Chemsex, defined as the use of psychoactive substances to enhance sexual activity, is increasingly reported among GBMSM. In annual surveys conducted within the same PrEP cohort in Milan, chemsex prevalence among PrEP users was 16% in 2024 and 21% in 2025. This study aimed to estimate current chemsex prevalence, compare trends over 3 years, and explore patients' feelings, needs, and preferred chemsex-related support within PrEP services.

Methods: Between January and February 2026, an anonymous online questionnaire was administered at 1 hospital-based and 1 community-based PrEP services in Milan. Data collected included demographics, sexual behaviors, substance use, and chemsex practices over the previous 12 months. Problematic substance use was assessed using the ASSIST score. Additional items explored perceived impact of chemsex and preferred support strategies.

Results: 394 PrEP users participated; 95% were cisgender men, and 99% identified as GBMSM. Median age was 45 years (IQR 32 – 47).

Overall, 29% (115/394) reported substance use. The most frequently used substances were mephedrone (39%), MDMA (35%), cocaine (32%) and GHB/GBL (24%).

Chemsex was reported by 18.5% (73/394), indicating a stable prevalence compared with previous years (16% in 2024; 21% in 2025). Among chemsex users, 41% described stable patterns compared with the previous year and 31% reported an increased use.

Substance use during sex was reported as "always" or "almost always" by 19%, in "more than half of encounters" by 25%, in "less than half" by 25%, and "rarely" by 31%.

Concurrent alcohol use was reported by 40%, and 24% experienced chemsex-related adverse effects. 20% sought for specialist support.

According to ASSIST scores, 27% were classified as low risk and 73% at moderate risk; no participants met criteria for high-risk use.

The perceptions of PrEP users regarding their chemsex practices, and how these impacted their sex, personal and daily lives, were investigated: Figure 1 shows the statements made and the responses given by users.

Overall, 91% of respondents believed that PrEP services should address chemsex-related risk reduction and problematic use. Among chemsex users, preferred support modalities included counselling with trained healthcare professionals (60%), peer support (44%), online information (27%), and dedicated mobile applications (23%).

Conclusions: Chemsex remains consistently prevalent among PrEP users over 3 consecutive years. Although no high-risk substance use was identified, the high proportion of moderate-risk users, alcohol co-use, and reported adverse effects indicate unmet prevention needs within PrEP care. The strong user-driven demand for integrated, face-to-face support highlights an opportunity to embed structured chemsex risk-reduction interventions into routine PrEP services. Scaling provider training and peer-based approaches may enhance early interventions and improve sexual and mental health outcomes.

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Epidemiology, Social Sciences and PROs

P 89 UNDERSTANDING THE “WORRIED WELL” PHENOMENON THROUGH ITALY’S AIDS AND STIS HELPLINE

M. Schwarz, P. Gallo, A. Colucci, E. Fanales Belasio, R. Valli, R. Dalla Torre, C. Gallo, A. D’Agostini

Unità Operativa Ricerca psico-socio-comportamentale, Comunicazione, Formazione - Dipartimento Malattie Infettive, Istituto Superiore di Sanità, Rome, Italy

Background: The fear of having acquired HIV or another sexually transmitted infection (STI), even in the absence of significant risk, is a globally documented phenomenon across diverse cultural, social, and healthcare settings. Helplines such as the Istituto Superiore di Sanità (ISS) AIDS and STIs Helpline offer a valuable observatory of this pattern, commonly defined as the “worried well” (WW). WW individuals experience disproportionate health anxiety and frequently engage in repetitive online searches for medical information, a behavior that tends to exacerbate rather than relieve their concerns. In the field of HIV and STIs, this condition may severely affect daily functioning, work performance, and psychosocial well-being. ISS researchers investigated the WW phenomenon to assess whether the COVID-19 pandemic acted as an amplifying factor and to outline the socio-demographic and behavioral characteristics, as well as the motivations, of repeat callers.

Materials and Methods: Data were extracted from the Helpline’s structured database and analyzed across three consecutive two-year periods: 2018–2019 (pre-pandemic), 2020–2021 (pandemic), and 2022–2023 (post-pandemic). Telephone counselling follows the Communicative-Relational Operating Model, integrating technical-scientific expertise with relational and communication skills to provide tailored responses.

Results: Between 2018 and 2023, 4,703 calls were analyzed. WW users accounted for 8.1% of callers and 7.8% of all questions received. Compared with the overall user population, WW individuals displayed distinctive demographic and behavioral profiles.

The most salient elements in defining the features of the study population were, on the one hand, the number of calls made to the helpline in which the same questions are repeated or only slightly reformulated, and, on the other hand, the evident disproportion between the reported risk profile and the number of tests undertaken. It should also be noted that, compared to the overall population of service users, the WW group exhibits a higher median age and a greater proportion of female users.

Conclusions: Although WW distress is often linked to traumatic or adverse personal experiences shaping sexual perception and behavior, strengthening comprehensive sex education and STI prevention within mandatory school curricula may represent a key strategy to promote health and well-being. Such measures could also mitigate misinformation and misinterpretation of online scientific content, of which the WW phenomenon appears to be a byproduct. While the COVID-19 pandemic may have increased its visibility, the phenomenon seems more deeply rooted in psychological distress and limited health literacy.

Epidemiology, Social Sciences and PROs

P 90 VILLA MARAINI FOUNDATION-CRI: BOOST ACCESS AND QUALITY OF COMMUNITY-BASED COMMUNICABLE DISEASE SERVICES IN ITALY. A PILOT PROJECT

P. Sammarco, D. Masci, G. Rodoquino, N. Gasbarrini, E. Rossi, M. Barra

Villa Maraini Foundation, Italian Red Cross, Rome, Italy

Background: The goal of viral suppression in people living with HIV still seems far away, also due to the increase in late diagnoses over the last decade. At the moment, one of the main reasons for getting tested is the offer of screening initiatives and information campaigns (COA 2025). Therefore, in order to reduce late infections and break down barriers to access to care, it is important to implement good practices focused on vulnerable people, with particular attention to integrated interventions that include screening and linkage to care.

Methods: Villa Maraini Foundation (FVM), National Agency for additions of the Italian Red Cross, promote humanitarian drug policies based on human rights, health-oriented and anti-stigmatizing practices and interventions. Since 1992, FVM has a service for the prevention, treatment and care of HIV/HCV; since 2004, it provides coaching sessions to Red Cross/Red Crescent National Societies on HIV/HCV/STIs prevention, diagnosis and linkage to care, promoting the implementation of testing activities at community level.

Results: In 2025, the FVM participated at the European Project BOOST as center of expertise on drug abuse treatment and care for Italy. Within the project, FVM has trained and assisted four Red Cross local committees (Genoa, Padua, Pisa, Venice) to plan and implement effective Communicable Diseases Action Plans (CDAPs), adapted to the local context. FVM organized a training course in Rome and study visits in each city, involving over 100 Red Cross volunteers. In the four cities, more than 700 people living in marginalized conditions, such as sex workers and PWUD/PWID, were reached and tested for HIV and HCV and received specific counselling. More than half of the people tested (61%) had never been tested for HIV before. There were 6 reactive tests for HIV and 23 reactive tests for HCV. All those with a preliminary positive result were referred to local clinical centers, with whom a fast-track pathway was established.

Conclusions: The work carried out by FVM with the four local Red Cross committees contributed to scale up community-based testing and linkage to care for people living in marginalized conditions. In all four cities, Red Cross Committees were able to establish partnerships with low-threshold services for PWUD/PWID and sex workers and offer voluntary HIV and HCV testing to clients of these services, thereby helping to promote the importance of regular screening and access to care for vulnerable people. Networking with infectious diseases hospitals for referral and linkage to care has facilitated the implementation of integrated, person-centered approaches as a tool for early diagnosis and treatment adherence. In addition, the collaboration with public authorities has ensured the sustainability of the activities, which will continue after the end of the project.

Epidemiology, Social Sciences and PROs

P 91 WHEN COULD IT BE TOO LATE? FACTORS ASSOCIATED WITH DELAYED HIV DIAGNOSIS: A RETROSPECTIVE STUDY

N. Bana¹, G. Cavazza^{1,2}, E. Di Gennaro^{1,2}, L. Luzi^{1,2}, A. Forni^{1,2}, F. Peracchi^{1,2}, L. Rezzonico¹, G. Burastero¹, C. Moiola¹, L. Chianura¹, G. Travi¹, R. Rossotti¹, M. Puoti^{1,2}

¹Department of Infectious Diseases, ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ²School of Medicine and Surgery, University of Milano Bicocca, Milan, Italy

Introduction: Significant improvement has been made over the last years in HIV treatment, prevention and diagnosis. However, despite the number of new diagnosis is overall dropping, more than 50% of them regards late presenter PWH, according with the last ICONA report.

Aim of this study is to find any possible factors associated with higher risk of delayed HIV diagnosis.

Methods: Monocentric observational retrospective study, including all the individuals tested positive for HIV at Niguarda Metropolitan Hospital between January 2019 and December 2024. Participants were stratified in 2 cohorts according to the nadir CD4+ cell count: >200 cells/mm³ vs <200 cells/mm³ (defined as people with advanced HIV disease). Demographic, clinical data and information about any possible social issues were collected for every individual. Descriptive and non-parametric statistics were used to describe study population. Multivariate logistic regression analysis was performed to find any possible factors associated with higher risk of advanced HIV disease at diagnosis.

Results: A total of 203 PLWH were included: 128 (63.1%) with >200 nadir CD4+ and 75 (36.9%) with <200 CD4+. Their main features are shown in Tab.1. No significant difference in new diagnosis trend over time was found, although they tended to increase between 2022 and 2024 (Fig.1). At a multivariate logistic regression analysis (Tab.2), PWH with advanced HIV were older (aOR 1.07 for every year increase, 95%CI 1.03-1.10, p<0.001), while no significant social issue was significantly associated with <200 nadir CD4+. Furthermore, alcohol abuse seemed to be associated with reduced prevalence of delayed HIV diagnosis (aOR 0.03, 95%CI 1.03-1.10, p=0.03), and reported Chems abuse at the time of the diagnosis seemed to be protective, even if at the limit of statistical significance (aOR 0.07, 0.00084-1.13, p=0.06).

Excluding all AIDS-presenters, at a binary regression analysis, testing for HIV due to the presence of any aspecific warning symptoms or clinical signs was significantly associated with higher risk of advanced disease (OR 3.52, 95% CI 1.46-8.50, p=0.005). Even the presence of 2 or more symptoms seemed to be associated with higher risk of delayed diagnosis, although at the limit of statistical significance (OR 2.79; 95%CI: 0.95-8.25; p= 0.06).

The main observed symptoms or signs are summarised in Tab.3.

Conclusion: No significant social issues were associated with increased risk of late presentation while alcohol abuse and Chems practices seemed to be slightly protective, probably reflecting categories of individuals more likely to be tested for HIV. Furthermore, this study showed how PWH with advanced disease were older and testing for HIV only in case of warning signs was associated with higher risk of late presentation: it is important to empower screening strategies to all the population, independently of any risk factors or clinical symptoms, in order to avoid delayed diagnosis.

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Epidemiology, Social Sciences and PROs

P 92 WHEN PREVENTION MEETS STIGMA: MULTILEVEL STIGMA, MENTAL HEALTH, AND PRE-EXPOSURE PROPHYLAXIS USE AMONG MEN WHO HAVE SEX WITH MEN. FINDINGS FROM AN ONLINE ITALIAN SURVEY VIA DATING APPS

G. Cuomo, F. Calandra Buonauro, M. Menozzi, C. Mussini

University Hospital of Modena, University of Modena and Reggio Emilia, Italy

Background: Stigma toward sexual minorities is a multidimensional phenomenon that may be experienced, perceived or internalized, and can extend to HIV prevention such as PrEP. Minority stress theory links stigma to adverse mental health outcomes and barriers to HIV prevention. We explored correlates of different stigma dimensions and their association with PrEP use among MSM in Italy.

Methods: Between September 2025 and February 2026, an anonymous cross-sectional survey was disseminated via MSM-oriented dating apps. Anxiety was assessed with the GAD-7, depression with the PHQ-9, overall quality of life with the WHO-5, and sexual quality of life with the NSSS. Univariate analyses examined stigma dimensions and PrEP use; variables with $p < 0.05$ entered multivariable logistic regression models.

Results: A total of 174 MSM (18–73 years) were enrolled; most were Italian (96.6%), white (96%), cisgender (80.5%), exclusively gay (75%), with medium–high education (91.4%), employed (69%), single (57.5%), and urban residents (58.6%, Table 1).

Over half had disclosed to family, >70% to friends and <50% at work. Experienced stigma was reported by 71.8%, perceived stigma by 94.3% and internalized stigma by 64.4%. At least mild anxiety was present in 52.9% and depression in 19.1%. Overall quality of life was good in over half; sexual quality of life in 64.2%. Twenty-five participants were HIV-positive and 29 reported current or past PrEP use (Table 2).

At univariate analysis ($p < 0.05$) experienced stigma was associated with higher education, non-disclosure (family, friends, work), anxiety and PrEP-related stigma. Perceived stigma was associated only with rural residence. Internalized stigma was associated with importance of religion, exclusive gay orientation, non-disclosure (family, friends, work), depressive symptoms, HIV-positive status and PrEP-related stigma (Tables 3,4,5).

In multivariable models, experienced stigma remained independently associated with anxiety, family non-disclosure and PrEP-related stigma. Internalized stigma remained independently associated with family non-disclosure and PrEP-related stigma (Tables 6-7).

Among non-PrEP users, main reasons for non-use were low perceived risk (39.2%), fear of side effects (25.5%), access difficulties (24.2%), association with promiscuity (15.7%) and fear of judgment (13.1%, Figure 1). Compared with non-users, PrEP users reported higher recreational substance use and higher PrEP-related stigma (Table 8).

Conclusions: Stigma is closely linked to anxiety and disclosure. The independent association between PrEP-related stigma and both experienced and internalized stigma suggests prevention-specific stigma may cluster within broader mechanisms, potentially limiting PrEP uptake. Paradoxically, PrEP users reported higher PrEP stigma, possibly reflecting fear of judgment after engaging in prevention. Multilevel psychosocial and community interventions are needed to reduce stigma and optimize HIV prevention uptake.

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Epidemiology, Social Sciences and PROs

P 93 “WOULD YOU DO IT MORE OFTEN?” A MULTIMEDIA CAMPAIGN AND MOBILE OUTREACH STRATEGY TO PROMOTE HIV/STI TESTING IN CAGLIARI, ITALY

B. Mocci¹, A. Loddo¹, E. Mura^{1,2}, S. Campus¹

¹LILA Cagliari, Italy, ²Dipartimento di Scienze Politiche e Sociali Università di Cagliari, Cagliari, Italy

Background: During 2025 LILA Cagliari (Italian League for the Fight Against AIDS) received funding from the Autonomous Region of Sardinia and, on World AIDS Day developed a multimedia communication campaign combined with the administration of rapid tests for HIV and other sexually transmitted infections. In addition to the testing regularly provided at its headquarters, the service was also delivered on the road through a rented camper van and several mobile outreach events. (Figure 0) This approach enabled direct engagement in popular gathering places, particularly nightlife areas frequented by young people. A visible panel outside the camper van (Figure 1) together with LILA Cagliari staff, invited individuals to undergo testing and receive counseling. The aim of this intervention was to increase awareness of sexual health, promote regular HIV/STI testing and reduce barriers to access through a community-based and destigmatizing outreach approach.

Material and Methods: The communication campaign featured colorful graphics and images of young people (Figure 2) and the slogan “Would you like to do it more often?”, playing on the double meaning between sex and testing while emphasizing regular screening. The campaign was promoted through 6x3 meter billboards in Cagliari (Figure 3) print media, local television and web TV, and disseminated via social networks and online news outlets, including advertising on buses (Figure 4) and bus stop shelters. (Figure 5) Social media were used to encourage message sharing. During outreach activities, rapid tests for HIV, HCV, and syphilis were offered free of charge, anonymously, and voluntarily. Informational materials were distributed, and staff engaged with passersby, including those who did not undergo testing.

Results: During the mobile outreach intervention conducted through the camper unit, a total of 90 rapid tests (HIV, HCV, syphilis) were administered in addition to the routine testing activities carried out at LILA Cagliari's headquarters (Figure 6).

The intervention increased visibility of sexual health issues within the community and promoted regular testing as a preventive strategy. Rather than focusing exclusively on condom use, the intervention addressed the broader population, including individuals who, by choice or circumstance, do not use condoms, with the objective of reducing stigma and encouraging awareness of one's serological status.

Conclusions: The integration of a destigmatizing communication strategy with a mobile outreach testing service facilitated engagement with individuals not previously connected to LILA Cagliari's activities and who might otherwise not have accessed testing.

The mobile setting ensured privacy and anonymity while creating opportunities for informal dialogue and preventive information. This experience highlights the potential of combining community-based communication with low-threshold mobile testing to complement clinic-based services and broaden access to HIV/STI screening.

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Hepatitis/MASLD and other Liver Diseases

P 94 CLINICAL OUTCOMES AFTER SWITCHING FROM TENOFOVIR DISOPROXIL FUMARATE (TDF) TO TENOFOVIR ALAFENAMIDE (TAF) OR ENTECAVIR (ETV) IN CHRONIC HEPATITIS B PATIENTS

F. Cesanelli¹, O. Nozza¹, F. Gottardi¹, F. Mosti¹, G. Tiecco¹, S. Zaltron², A. Spinetti², F. Castelli¹, E. Quiros-Roldan^{1,3}

¹Department of Clinical and Experimental Sciences, Unit of Infectious and Tropical Diseases, University of Brescia and ASST Spedali Civili di Brescia, Brescia, Italy,

²Unit of Infectious and Tropical Diseases, ASST Spedali Civili di Brescia, Brescia, Italy, ³Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden

Background: Tenofovir disoproxil fumarate (TDF) is highly effective for chronic hepatitis B (HBV) but may induce progressive renal impairment and proximal tubular dysfunction. Switching to tenofovir alafenamide (TAF) or entecavir (ETV) may reduce TDF-related nephrotoxicity. This study evaluated renal and metabolic changes before and after switching from TDF to TAF or ETV in a real-world cohort.

Materials and Methods: We conducted a retrospective study including adults with chronic HBV who switched from TDF to TAF or ETV. Inclusion criteria were age ≥ 18 years, had received TDF for at least two years, had undetectable HBV DNA at the time of transition, and had at least one renal assessment following the switch. Exclusion criteria included detectable HBV-DNA, treatment discontinuation, decompensated cirrhosis, or concomitant nephrotoxic drugs. Biomarkers were analyzed from 24 months before to 48 months after switching. Longitudinal trajectories of creatinine, eGFR, serum phosphate, and total cholesterol were estimated using linear mixed-effects models with random intercepts. Time (years) was modeled as a continuous variable. Models were adjusted for baseline covariates, including the baseline value of the outcome.

Results: A total of 102 patients were included (TAF n=82; ETV n=20), mean age 72 ± 10 years, 72% male. During TDF therapy, creatinine increased significantly over time ($\beta \approx +0.017$ mg/dL/year, $p < 0.001$). After switching, the overall slope attenuated ($+0.013$ mg/dL/year, $p < 0.001$) with baseline creatinine being the strongest predictor of longitudinal levels ($\beta \approx 0.39$ mg/dL per SD). In stratified analyses, TAF showed no significant slope change, whereas ETV exhibited a small reduction in creatinine trend. Serum phosphate declined during TDF ($\beta \approx -0.036$ mg/dL/year, $p < 0.001$) and showed a significant increase after switching, with inversion of the temporal trend ($\beta \approx 0.024$ mg/dL/year $p = 0.045$). Total cholesterol increased after switch while the temporal trend remained stable, with no differences between TAF and ETV (Table 1). Observed trajectories were also graphically represented to illustrate biomarker evolution across treatment groups (Figure 1).

Conclusions: Unlike previous studies reporting clear creatinine improvement after switching from TDF, this cohort did not show a significant post-switch reduction in creatinine levels. However, switching to TAF or ETV was associated with attenuation of creatinine progression and recovery of phosphate levels, suggesting mitigation of TDF-related renal and tubular toxicity. No major differences between treatments were observed. Overall, these findings support the clinical benefit of switching to TAF or ETV with heterogeneous individual responses.

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Hepatitis/MASLD and other Liver Diseases

P 95 **DIAGNOSTIC INVISIBILITY OF HBV: A 100% DOMINANT MULTI-MUTANT ESCAPE POPULATION (145R, 144E, 137W, 128V, 124R, 100C) OVERCOMING HBSAG DETECTION LAYERS**

B. Bruzzone¹, B. Galano¹, C. Fraccalvieri¹, S. Varesano¹, M. Mikulska^{1,2}, F. Benvenuto¹, N. Sessarego¹, G. Ubezio¹, F. Grillo^{1,2}, V. Ricucci¹

¹IRCCS Azienda Ospedaliera Metropolitana, Genoa, Italy, ²University of Genoa, Genoa, Italy

Background: The detection of HBsAg is the gold standard for diagnosing HBV infection. However, mutations in the "a" determinant of the S-gene (escape mutants) can lead to conformational changes in the HBsAg, resulting in diagnostic failure by commercial immunoassays. While mixed viral populations (wild-type/mutant) typically yield detectable, albeit weak, signals, a total replacement by mutant strains can lead to complete diagnostic failure, which is particularly critical in immunocompromised patients, where HBV reactivation can occur despite an apparent resolved infection status.

Material and Methods: A 63-year-old male with idiopathic myelofibrosis presented with severe cholestasis and acute hepatitis (ALT 428 U/L, bilirubin 22 mg/dl). Screening for hepatotropic viruses was negative. The patient was known to be HBcAb-positive and HBsAg negative in 2023. Upon admission, overall, four HBsAg commercial assays were consistently negative. HBV-DNA quantification, Sanger Sequencing (SS) and Next Generation Sequencing (NGS) of the S-gene were performed, these last both in plasma and liver tissue, obtained from a liver biopsy executed to investigate hepatitis etiology, including potential extramedullary hematopoiesis.

Results: Liver histology revealed massive extramedullary hematopoiesis (Grade 3/3), together with acute inflammatory damage. Immunohistochemistry for HBsAg on liver tissue was negative. Only 1 out of 5 serological tests yielded a positive HBsAg result, conversely, the molecular analysis detected a HBV-DNA load of 39,800 UI/ml. HBeAg resulted positive (Table 1). SS identified a complex cluster of escape mutations in the S-gene (145R, 124R, 144E, 100C, and 128V) appearing in a homozygous-like pattern, suggesting they represented the dominant viral population. NGS confirmed 100% Variant Allele Frequency in both blood and liver samples for all escape mutants identified (Figure 1). The total absence of wild-type sequences explains the absolute failure of almost all antibody-based detection tests in both serum and tissue.

Treatment with TAF was started upon HBV-DNA detection, and chemotherapy was started the following week. ALT levels were normal 3 weeks later. HBV-DNA rapidly declined (27 UI/ml after 4 weeks of therapy, negative after 2 months). Five months after the onset of chemotherapy, the patient successfully underwent allogeneic stem cell transplant.

Conclusions: This case provides striking evidence of how a 100% dominant multi-mutant HBV population can cause total "sero-clinical" invisibility, misleading both serum and tissue diagnostics. It serves as a definitive warning against laboratory "reflex-testing" policies; had screening relied solely on HBsAg, this life-threatening infection would have remained undetected. In immunocompromised patients, HBcAb and HBV-DNA must remain mandatory first-line investigations to bypass the "blind spot" of modern HBsAg assays. When necessary, the presence of escape mutant can be confirmed by SS or NGS.

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Hepatitis/MASLD and other Liver Diseases

P 96 EVOLUTION OF HBV SEROLOGICAL MARKERS AND REACTIVATION RISK IN PEOPLE LIVING WITH HIV IN THE ERA OF SIMPLIFIED ANTIRETROVIRAL THERAPY: A REAL-WORLD EXPERIENCE

D. Segala^{1,2}, T. Ferroni¹, R. Cultrera^{1,3}

¹University of Ferrara, Ferrara, Italy, ²Azienda Ospedaliero Universitaria di Ferrara, Ferrara, Italy, ³Azienda Unità Sanitaria Locale di Ferrara, Ferrara, Italy

Background: Simplified antiretroviral therapy (ART) effectively manages HIV, yet its long-term hepatic safety is debated. This study evaluates HBV serological evolution and reactivation risks among people living with HIV (PLWH) in Ferrara, focusing on isolated HBcAb management when switching to dual regimens.

Materials and Methods: A single-center, real-world study was conducted at the Ferrara HIV Center, including PLWH with 2025 follow-up visits with HBV serological markers. We aimed to profile the prevalence and fluctuations of HBV markers and reactivation risk in simplified ART, identifying predisposing factors to develop personalized follow-up strategies for optimized hepatic outcomes. Data from HIV diagnosis (T0) and study period (T1) were compared for HBV serological evolution. HBV DNA was tested in HBsAb-/HBcAb+ cases to detect occult reactivation.

Results: We included 544 PLWH, mostly European (82.7%), males (71%), aged 35–65 (74.3%), mean age 54.87, median 57, CDC A2 (32.4%); 41.9% were on simplified ART at T1. We found a dynamic evolution of HBV serological markers from T0 to T1: HBsAg fell (5.5% to 2%), while HBsAb (48.2%) and HBcAb (37.1%) rose significantly. Among the 368 PLWH with paired data, 6% achieved HBsAg loss, suggesting a favorable trend in viral clearance: nearly half (45.5%) of these were receiving HBV-active drugs and were mostly European males (81.8%), aged 35–65 (68.2%), with CDC stage B3 (31.8%), CD4 >500 cells/mm³ (81.8%), and a high HCV coinfection rate (75%), often associated with HBsAg clearance due to viral interference. Conversely, the loss of HBsAb observed in 8.7% of the 355 individuals with complete paired data raises concerns regarding the long-term persistence of humoral immunity; they were mostly males (74.2%), European (87.1%), aged 35–65 years (87.1%), CDC A2-B3 (25.8%-23.6%), CD4 >500 cells/mm³ (87.8%). At T1, 37.1% of the total cohort was HBcAb+, indicating a high prevalence of prior HBV exposure. Among patients on simplified ART, HBsAb negativity reached 45.5%, with 28% presenting an HBsAb-/HBcAb+ profile. HBV reactivation was limited to a single case involving a patient treated with a triple-drug regimen that did not include an HBV-active component.

Conclusions: Our study shows significant HBV serological fluctuations in PLWH. While some achieved HBsAg loss, linked to HBV-active ART and HCV coinfection, the concurrent loss of HBsAb and documented reactivation highlight persistent vulnerabilities, emphasizing the need for rigorous monitoring when switching to simplified regimens lacking HBV coverage. While these patients can still switch to these treatments, HBV DNA monitoring should be integrated into clinical practice, moving beyond occasional testing toward a systematic approach at predefined intervals. Additionally, identifying predictive factors is vital to focus on high-risk cases. Data reinforce the importance of high vigilance and individualized screening to ensure long-term hepatic safety.

Table 1, Table 2

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Hepatitis/MASLD and other Liver Diseases

P 97 HEPATIC HEALTH RESTORATION AND IMMUNE OPTIMIZATION IN ART-NAÏVE PWH STARTING BIC/FTC/TAF: A 96-WEEK MULTICENTER ANALYSIS OF FIB-4 DYNAMICS AND CD4/CD8 RATIO ABSTRACT

S. Spampinato^{1,2,3}, A. De Vito⁴, D. Bivona¹, F. Velardita¹, A. Marino¹, B. Cacopardo¹, B.M. Ceslesia¹, G. Nunnari¹, G. Madeddu⁴

¹Unit of Infectious Diseases, ARNAS "Garibaldi Nesima" Hospital, Department of Clinical and Experimental Medicine, University of Catania, Catania, Italy, ²Department of Biomedical and Biotechnological Sciences, University of Catania, Catania, Italy, ³Unit of Infectious Diseases, "G. Martino" University Hospital, Department of Clinical and Experimental Medicine, University of Messina, Messina, Italy, ⁴Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy

Background: Beyond achieving rapid virologic suppression, modern antiretroviral therapy (ART) aims to reverse systemic damage and organ-specific stress. While the efficacy of BIC/FTC/TAF is well-documented, real-world evidence regarding its capacity to improve liver fibrosis markers (FIB-4) and immune homeostasis (CD4/CD8 ratio) in treatment-naïve cohorts remains a critical clinical endpoint for long-term health optimization.

Methods: We conducted a multicenter observational study of ART-naïve PWH from the SHINE and SHIC cohorts initiating BIC/FTC/TAF with 96-week follow-up. Durability was assessed via Kaplan–Meier estimates. Effectiveness was primarily evaluated through longitudinal changes in hepatic parameters (FIB-4 and liver enzymes) and secondarily through immunological (CD4/CD8 ratio) and metabolic trends. Safety was monitored via adverse event (AE) discontinuations.

Results: A total of 144 PWH were included (median age 43.1 years; 52.1% MSM). Baseline median CD4+ count was 304 cells/mm³ and median HIV-RNA was 168,000 copies/mL (Table 1).

Regarding hepatic health, a significant and progressive improvement in liver enzymes ($p < 0.0027$) and the FIB-4 index was observed over 96 weeks ($p < 0.0001$), suggesting a marked reduction in hepatic stress and potential reversal of early fibrosis risk following ART initiation. This hepatic amelioration was accompanied by profound immunological normalization: the median CD4+ count rose from 306 to 696.5 cells/mm³ ($p < 0.0001$), and the CD4/CD8 ratio significantly increased from 0.35 to 0.75 ($p < 0.0001$), while reaching increasing virological success overtime (Figure 1 and 2).

The regimen demonstrated excellent durability; the cumulative probability of discontinuation was 11.4% at 6 months and 20.9% at 24 months. Notably, the primary driver for discontinuation was treatment simplification (e.g., switch to long-acting CAB/RPV, 8.3%), while no discontinuations due to virological failure were observed. Discontinuations due to AEs were rare (4.3% at 24 months).

Metabolically, the lipid profile remained stable with a favorable increase in HDL cholesterol, while a minor, non-clinically significant increase in creatinine was observed, consistent with the known pharmacodynamics of bictegravir on tubular secretion.

Conclusions: In this 96-week real-world analysis, BIC/FTC/TAF proved to be a powerful driver of systemic health restoration. The significant reduction in FIB-4 scores and liver enzymes highlights a specific benefit for hepatic preservation in naïve patients. Combined with absolute virologic success and robust CD4/CD8 ratio optimization, BIC/FTC/TAF confirms its role as a premier first-line strategy for comprehensive clinical recovery beyond simple viral suppression.

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Hepatitis/MASLD and other Liver Diseases

P 98 HEPATITIS DELTA SCREENING CASCADE IN PEOPLE WITH HIV IN A CENTER IN MILAN

A.R. Raccagni^{1,2}, R. Lolatto¹, H. Hasson¹, E. Messina¹, A. Siribelli¹, T. Clemente¹, M. Ripa^{1,2}, V. Spagnuolo^{1,2}, A. Danise¹, M. Guffanti¹, P. Cinque¹, D. Canetti¹, S. Nozza^{1,2}, A. Castagna^{1,2}

¹IRCCS San Raffaele Scientific Institute, Milan, Italy, ²Vita-Salute San Raffaele University, Milan, Italy

Background: Hepatitis D virus (HDV) infection is associated with accelerated liver disease progression in people with chronic hepatitis B, including people with HIV (PWH), and is recognized as an oncogenic virus. Systematic anti-HDV screening followed by confirmatory HDV RNA testing is required to identify active infection and enable timely linkage to care and treatment. Aim of this study is to assess the HDV testing cascade among PWH with chronic hepatitis B.

Material and Methods: This is a retrospective study including PWH who received care at IRCCS San Raffaele Scientific Institute with chronic hepatitis B (last available HBsAg: positive) and available anti-HDV serology. Among those with anti-HDV positive serology, availability and results of HDV RNA testing were assessed. In people with detectable HDV RNA, treatment uptake with bulevirtide (BLV) was evaluated. Demographic and clinical characteristics by anti-HDV status at last available visit were assessed.

Results: Overall, 161 PWH with positive HBsAg and available anti-HDV serology were included; 33/161 (20.5%) were anti-HDV positive. Overall, 145/161 (90.1%) were male. Characteristics of included PWH according to anti-HDV serology status are presented in Table 1. Among individuals with anti-HDV-positive serology, HDV RNA testing was available for 17/33 (51.5%); 6/17 (35.3%) had detectable HDV RNA (active infection; METAVIR: two F4, three F3 and one F2) and 11/17 (64.7%) were HDV RNA negative. HDV RNA was missing or not performed in 16/33 (48.5%), among whom 12 were lost to follow-up (Figure 1). Among the six individuals with positive HDV RNA, 2/6 (33.3%) initiated bulevirtide with a positive response (improved liver function, overall well-being and no METAVIR worsening), while 4/6 (66.7%) declined treatment primarily due to daily dosing and route of administration (Figure 1).

Conclusions: Anti-HDV seropositivity was moderately frequent among PWH with chronic hepatitis B. However, gaps in confirmatory HDV RNA testing and in treatment uptake among those with active infection were identified. Improvement in systematic HDV screening may boost the HDV cascade in PWH; encouraging and including subjects in treatment remains a challenge.

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Hepatitis/MASLD and other Liver Diseases

P 99 IMMUNOLOGICAL PREDICTIVE FACTORS FOR TREATMENT RESPONSE DURING BULEVIRTIDE THERAPY IN HBV-HDV COINFECTED PATIENTS

C. Taibi, E. Cimmini, G. Grassi, A. Caioli, A. Rianda, F. Cristofanelli, S. Pauciullo, V. Zulian, A.R. Garbuglia, A.M. Geretti, E. Biliotti, G. D'Offizi

National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Background: Chronic Hepatitis Delta (HDV) is the most severe form of viral hepatitis. The entry inhibitor Bulevirdide (BLV) was recently approved for treatment, but validated predictors of treatment response remain limited. HDV replication induces intense activation of innate immunity, with elevated cytokine production and liver inflammation. This study aimed to analyze the inflammatory and pro-fibrotic cytokine profiles of HBV-HDV coinfecting patients to identify potential predictors of response to BLV therapy.

Material and Methods: Twenty-six patients with chronic HBV-HDV hepatitis treated with BLV were consecutively enrolled (April 2022 - May 2024). Biochemical, virological and immunological parameters were evaluated at baseline (T0) and at weeks 4, 12, 24, and 48. Plasma concentrations of IL-6, IL-8, TNF- α , CXCL10 and IFN- γ were quantified using the automated Simple Plex platform. Other parameters included quantification of HBsAg and anti-HBc IgG. A combined BLV treatment response was defined as the concomitant achievement of HDV-RNA suppression (≥ 2 log10 reduction from baseline) and ALT normalization at week 48. Statistical analysis included Principal Component Analysis (PCA) and univariable logistic regression.

Results: Among 26 participants, the median age was 50 years [IQR 47-59], 14 (54%) were female, and 19 (73%) originated from Eastern Europe. Overall, 17 (65%) had compensated cirrhosis, including 4 with esophageal and/or gastric varices (13 Child A5 and 4 Child A6). One patient had a history of resected hepatocellular carcinoma (HCC). At T0 median AST and ALT levels were 72 U/L [48-106] and 88 U/L [56-113], respectively; HDV-RNA was 4.83 log10 cp/mL [3.46-5.76]. After 48 weeks of BLV therapy, 13 (50%) patients achieved a combined response. In univariable analyses, factors associated with a combined response included higher baseline CXCL10 levels (OR 1.12 per 10-unit increase, $p=0.019$) and lower baseline anti-HBc IgG levels (OR 0.88 per 10-unit increase, $p=0.007$) (Table 1). PCA showed that baseline levels of CXCL10, anti-HBc, and IFN- γ were the main characteristics that differentiated responders from non-responders, supporting a distinct immunological profile among responders.

Conclusions: These preliminary findings identify baseline CXCL10 as a potential predictor of response to BLV therapy. Elevated baseline CXCL10 levels characterize a subgroup of patients with an activated interferon-driven immune profile, which may be associated with a higher likelihood of treatment response. Further studies are warranted to validate CXCL10 as a non-invasive biomarker to support personalized therapeutic approaches in chronic HDV.

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Hepatitis/MASLD and other Liver Diseases

P 100 INVITATION-BASED STRATEGY AND HEPATITIS C SCREENING UPTAKE IN TUSCANY, ITALY

S. Moriconi¹, E. De Vita¹, B.R. Porchia², D. Senatore², G. Bianco², R. Gusinu³, S. Del³, P. Mantellini³, P. Ferrante¹, S. Fondelli¹, L. Tivoschi¹

¹Department of Translational Research and New Technologies in Medicine and Surgery, University of Pisa, Pisa, Italy, ²Directorate for Health, Welfare and Social Cohesion, Prevention, Health and Safety and Veterinary Sector, Regione Toscana, Florence, Italy, ³Directorate of the Institute for Cancer Research, Prevention and Clinical Network (ISPRO), Florence, Italy

Background: Hepatitis C virus (HCV) elimination is a global public health priority, with the World Health Organization targeting 90% diagnosis of people living with HCV by 2030. Population-based screening is essential to identify undiagnosed infections and ensure timely linkage to care. In Italy, regional authorities are responsible for implementing HCV screening programmes, resulting in heterogeneous organisational models. In Tuscany, screening has been progressively delivered through multiple channels, including community pharmacies, general practitioners and third-sector organisations. On 6 November 2025, a coordinated invitation campaign based on mailed letters was launched, targeting residents born between 1969 and 1989.

Material and Methods: We conducted a pre-post observational descriptive analysis using regional administrative data on first-level HCV antibody screening tests from July 2025 onwards. Monthly test volumes were analysed overall and stratified by geographical area (Centre, North-West, South-East) and delivery channel. The pre-intervention period (July–October 2025) was compared with the post-intervention period (November 2025–January 2026). In the post-intervention phase, testing volumes were standardised per 1,000 residents in the target birth cohorts to compare screening intensity across areas and assess programme reach.

Results: The mean monthly number of screening tests increased from 624 in the pre-intervention period to 21,377 in the post-intervention period, representing a more than 34-fold increase. A marked rise was observed between November and December (+142%), followed by a decrease in January (–23%), although volumes remained substantially higher than in the initial post-intervention month. Community pharmacies accounted for 82.3% of tests in the post-intervention period, confirming their central role in expanding access. Increased screening activity was observed across all geographical areas, with rates per 1,000 residents of 63.2 in the Centre, 51.8 in the North-West and 68.3 in the South-East.

Conclusions: The introduction of an invitation-based strategy was associated with a substantial and sustained increase in HCV screening uptake, supporting its effectiveness in accelerating case finding within the target population. Community pharmacies emerged as a key access point within a multi-channel delivery model. Geographical differences in screening intensity highlight the importance of local implementation dynamics. Active promotion strategies integrated into regional screening programmes may significantly contribute to progress towards HCV elimination targets.

Hepatitis/MASLD and other Liver Diseases

P 101 METABOLIC-ASSOCIATED LIVER DISEASE IN PEOPLE LIVING WITH HIV: PRELIMINARY RESULTS FROM A LONGITUDINAL OBSERVATIONAL STUDY

G. D'Agati^{1,2}, C. Gioè^{1,2}, C. Mazzola^{1,2}, C. Giordano^{1,2}, S. Urso^{1,2}, C. Conti^{1,2}, G. Valenti^{1,2}, M. Trizzino^{1,2}, L. Pipitò^{1,2}, A. Cascio^{1,2}

¹Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G D'Alessandro", University of Palermo, Palermo, Italy, ²Infectious and Tropical Disease Unit, Sicilian Regional Reference Center for the Fight Against AIDS, AOU Policlinico "P. Giaccone", Palermo, Italy

Background: Metabolic dysfunction-associated steatotic liver disease (MASLD) is highly prevalent among people living with HIV (PLWH) and is an emerging cause of liver-related morbidity in the antiretroviral therapy era. Metabolic factors, HIV-related inflammation, and long-term antiretroviral exposure may contribute to MASLD development and steatosis progression, but long-term longitudinal data using non-invasive tools are limited.

Materials and Methods: We conducted a longitudinal observational study in PLWH followed at the University of Palermo. Clinical, metabolic, virological, and elastographic data (FibroScan®) were collected at baseline (2018–2019) and after a median follow-up of 6–7 years (2024–2026). Hepatic steatosis was assessed by controlled attenuation parameter (CAP) and fibrosis by liver stiffness measurement (LSM) and FIB-4 score. CAP progression was defined as an increase of ≥ 1 or ≥ 2 steatosis classes. Factors associated with MASLD onset and CAP progression were explored by univariate and multivariable analysis.

Results: At baseline, 647 patients were evaluated (73.6% male, median age 49 years). HBV or HCV infection was present in 20.4% of cases. MASLD prevalence was 32.3%, with a median CAP of 234 dB/m; 41.0% had CAP ≥ 248 dB/m, 30.7% ≥ 268 dB/m, and 21.0% ≥ 292 dB/m. Median LSM was 5.0 kPa and median FIB-4 was 0.87.

At follow-up, 60 patients were reassessed (78.3% male, median age 59 years). HBV or HCV was present in 18.3% of cases. MASLD prevalence increased to 48.3%, with a median CAP of 247 dB/m; 48.3% had CAP ≥ 248 dB/m, 43.3% ≥ 268 dB/m, and 23.3% ≥ 292 dB/m. Median FIB-4 increased to 1.14.

At univariate analysis, fasting glucose ≥ 100 mg/dL at follow-up was associated with incident MASLD (OR 6.19, $p=0.004$). Progression of ≥ 1 CAP class was associated with serum creatinine >1.2 mg/dL (OR 4.87, $p=0.024$) and exposure to tenofovir disoproxil fumarate (TDF) for >1 year (OR 7.24, $p=0.048$). Progression of ≥ 2 CAP classes was independently associated with impaired fasting glucose at follow-up (OR 5.0, $p=0.047$) and body mass index ≥ 25 kg/m² at baseline (OR 5.89, $p=0.032$). Viral hepatitis were not significant predictors of MASLD onset or CAP progression. All factors associated with MASLD onset and CAP progression at univariate analysis were confirmed at multivariable analysis.

Conclusions: MASLD prevalence and steatosis severity increased over time in this cohort of PLWH. Steatosis progression was mainly driven by metabolic abnormalities, particularly impaired glucose metabolism and overweight, rather than by viral hepatitis coinfections, in line with current literature. The association with renal dysfunction and prolonged TDF exposure suggests a role of cardio-renal-metabolic interactions and treatment-related factors in selected patients. These findings support integrating systematic metabolic assessment and longitudinal elastographic monitoring into routine HIV care to identify patients at risk of progressive steatotic liver disease.

Hepatitis/MASLD and other Liver Diseases

P 102 OPPORTUNISTIC HOSPITAL SCREENING FOR HCV ELIMINATION IN THE AUTONOMOUS PROVINCE OF TRENTO: EXTENSION TO THE 1948–1989 COHORTS

M. Lanzafame^{1,6}, M. Gottardi¹, D. Fait¹, L. Guella¹, G. Stevanin², C. Pravadelli³, L. Collin⁴, D.A. Ramaroli⁵

¹Unit of Infectious Diseases, Azienda Sanitaria Universitaria integrata trentina, Trento, Italy, ²Provincial Hospital Service Management, Azienda Sanitaria Universitaria integrata trentina, Trento, Italy, ³Unit of Gastroenterology, Azienda Sanitaria Universitaria integrata trentina, Trento, Italy, ⁴Unit of Microbiology, Azienda Sanitaria Universitaria integrata trentina, Trento, Italy, ⁵Department of Prevention, Azienda Sanitaria Universitaria integrata trentina, Trento, Italy, ⁶University of Trento, Trento, Italy

Background: Eliminating HCV as a public health threat by 2030 is one of the World Health Organisation's priority goals. In Italy, Decree-Law 162/2019 introduced free national screening for the 1969–1989 cohorts and key populations. However, the Autonomous Province of Trento did not benefit from dedicated funding, making it necessary to develop sustainable local strategies. Furthermore, recent national data indicate a prevalence of active infection (HCV-RNA+) of 0.1% in the 1969–1989 cohort and 0.9% in the 1948–1968 cohort, suggesting that screening should be extended to those born before 1969.

Methods: Between June 2022 and January 2023, an initial pilot project was conducted on the general population (1969–1989), using a model similar to cancer screening: 4,000 randomised subjects, 819 participants (20.5%), no HCV-RNA+. Subsequently (July 2024–January 2025), opportunistic screening was activated in hospitals in the Infectious Diseases, Internal Medicine and Gastroenterology departments (Trento and Rovereto): 185 eligible subjects, 182 participants (98%), no HCV-RNA+. At the same time, structured activities continued in high-prevalence populations: prisons (547 tested, 23 HCV-RNA+) and SerD (396 tested, 85 HCV-RNA+). Systematic screening was also implemented in asylum seekers (766 tested, 8 HCV-RNA+).

Analysis of hospital discharge volumes over the last three years estimates approximately 11,200 hospitalisations per year in the 1969–1989 cohort and 20,200 in the 1948–1968 cohort. Local serological data show anti-HCV positivity of 1.2% (1969–1989) and 3.4% (1948–1968), suggesting a significantly higher potential diagnostic yield in older cohorts.

Results: In the three years since the start of activities, the targeted approach has confirmed a high diagnostic yield in high-prevalence settings (SerD, prison) and a very low prevalence in the general population 1969–1989. The absence of HCV-RNA+ cases in the two pilot studies on the 1969–1989 cohort, together with national data, highlights a cohort effect with a progressive reduction in prevalence in those born after 1984. The main critical issues include low adherence in active call models and limited availability of laboratory resources.

Conclusions: In a low-prevalence setting and in the absence of dedicated funds, opportunistic hospital screening is a cost-effective strategy with high adherence. Extending screening to the 1948–1968 cohorts, while maintaining active pathways in prisons and SerD, appears consistent with epidemiological evidence and has the potential to increase the identification of active infections, improving the cascade of care and contributing to elimination targets. The new provincial project involves the gradual involvement of all hospitals in Trentino, with centralised management by Infectious Diseases and Gastroenterology, integrating informed consent, inpatient testing and structured linkage to care.

Hepatitis/MASLD and other Liver Diseases

P 103 PERSISTENT INFLAMMATORY SIGNATURE DURING BULEVIRTIDE THERAPY IN PEOPLE WITH CHRONIC HEPATITIS DELTA: ANALYSIS OF IL-37 AND IL-36 CYTOKINES

M. De Sanctis¹, S. Pauciullo¹, R. Sciamanna¹, E. Cimini², P. Del Porto³, A.R. Garbuglia¹, V. Zulian¹

¹Laboratory of Virology, National Institute for Infectious Diseases "Lazzaro Spallanzani" (IRCCS), Rome, Italy, ²Laboratory of Cellular Immunology and Pharmacology, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ³Department of Biology and Biotechnology "Charles Darwin", Sapienza University of Rome, Rome, Italy.

Background: Chronic hepatitis delta represents the most severe form of viral hepatitis and is associated with accelerated progression to cirrhosis and hepatocellular carcinoma. Bulevirtide (BLV) effectively inhibits hepatitis D virus (HDV) entry into hepatocytes. Reliable biomarkers reflecting residual viral activity and immune modulation during BLV treatment remain poorly defined. Cytokines belonging to the interleukin-1 family, including IL-37 and IL-36 isoforms, play key roles in regulating inflammatory responses and may provide insights into persistent immune activation during antiviral therapy.

Material and Methods: Serum samples from 22 people with chronic HBV/HDV coinfection receiving BLV monotherapy (2 mg/day) were analyzed at baseline and after 48 weeks of treatment. Levels of IL-37, IL-36 α , IL-36 β , and IL-36 γ were quantified using Cusabio® ELISA kits and compared with individuals with chronic HBV infection receiving nucleos(t)ide analogue therapy and healthy donors. Associations between cytokine levels, biochemical response (ALT <40 U/L), virological response (≥ 2 log decline or undetectable HDV RNA), and residual HDV RNA levels measured using the AltoStar® HDV RT-PCR Kit (Altona Diagnostics GmbH, Hamburg, Germany) were evaluated.

Results: People with chronic HBV/HDV coinfection showed significantly higher IL-37, IL-36 α , and IL-36 β serum levels compared with control groups at both baseline and week 48 (all $p < 0.05$), regardless of treatment response. IL-36 β levels significantly decreased over time, whereas IL-36 α remained elevated independently of treatment response. IL-36 γ levels were predominantly below the assay's lower limit of detection across all study groups. IL-37 levels demonstrated a significant positive correlation with residual HDV RNA at week 48 ($p = 0.033$; $R^2 = 0.756$). Moreover, lower baseline IL-37 concentrations were observed in individuals achieving virological response at week 96.

Conclusions: Despite effective viral entry inhibition with BLV, chronic hepatitis delta remains characterized by sustained immunological activation. The association between IL-37 and residual viremia suggests a potential role for this cytokine as a complementary biomarker for monitoring low-level viral activity and treatment response, potentially reflecting a compensatory immunoregulatory mechanism aimed at limiting excessive inflammation during antiviral therapy.

Hepatitis/MASLD and other Liver Diseases

P 104 POST-TRANSPLANT COMORBIDITIES AND MASLD DEVELOPMENT IN LIVER RECIPIENTS WITH AND WITHOUT HIV INFECTION

A. Cervo¹, M. Albertini¹, F. Casari¹, J. Milic^{1,2}, B. Catellani⁴, P. Magistri^{2,4}, G. Guerrini⁴, C. Mussini^{1,2}, G. Sebastiani³, F. Di Benedetto^{2,4}, G. Guaraldi^{1,2}

¹Unit of Infectious Diseases, University Hospital of Modena, Modena, Italy, ²Surgical, Medical and Dental Department of Morphological Sciences related to Transplant, Oncology and Regenerative Medicine, University of Modena and Reggio-Emilia, Modena, Italy, ³Division of Gastroenterology and Hepatology, Chronic Viral Illness Service, McGill University Health Centre, Royal Victoria Hospital, Montreal, Canada, ⁴Hepato-Pancreato-Biliary Surgery and Liver Transplantation Unit, University Hospital of Modena, Modena, Italy

Background: Given the growing survival of liver transplant (LT) recipients, non graft-related complications have emerged as major determinants of morbidity. Data on post-transplant comorbidities in LT recipients with HIV infection remain limited, particularly regarding metabolic complications and metabolic dysfunction-associated steatotic liver disease (MASLD).

Methods: This retrospective, propensity score-matched (1:3) case-control study included 87 LT recipients with HIV and 261 without HIV transplanted at the University Hospital of Modena between 2003 and 2024. Matching variables were age, sex, MELD score, hepatocellular carcinoma (HCC), HBV/HCV co-infection, and donor age. Prevalence at LT and incidence rates (IR) post-LT of arterial hypertension, diabetes, dyslipidemia, cardiovascular events (CVE) and MASLD were assessed. MASLD was defined as hepatic steatosis, detected by imaging or histology, in association with at least one cardiometabolic risk factor among overweight/obesity, diabetes, hypertension, dyslipidemia, or insulin resistance.

Results: Of 348 recipients, 17% were females, with median age of 53 years (IQR 47-58) (Table1). Main indications to transplantation were described in Figure1. MASLD-related cirrhosis was the main indication to LT in 4.6% HIV and 5.4% non-HIV recipients ($p=0.780$), whereas alcohol-related cirrhosis was reported in 13.8% HIV and 23% non-HIV recipients ($p=0.067$). At LT, hypertension and dyslipidemia were more prevalent in HIV recipients than non-HIV (38% vs 18% and 26% vs 6%, $p<0.05$), while diabetes prevalence was comparable (21% vs 18%, $p=0.371$). Post-LT dyslipidemia occurred more frequently in HIV recipients [58% vs 35%; IR 1.8 (95%CI 1.3-2.5) vs 0.5 (95% CI 0.4-0.6) per 100PYFU], whereas incidence rates of hypertension and CVE were similar. New-onset diabetes occurred in 15% of HIV and 25% of non-HIV recipients ($p=0.052$) with IR 0.2 (95%CI 0.1-0.4) vs 0.3 (95%CI 0.2-0.4) per 100PYFU (Figure 2a-c). Post-LT overweight/obesity developed in 17% of HIV and 32% of non-HIV recipients ($p=0.053$). Post-LT MASLD was diagnosed in 19.2% of recipients, with similar IR between groups: 3.1 (95%CI 1.9-5.3) in HIV vs 3.2 (95%CI 2.5-4.2) in non-HIV per 100PYFU ($p=0.947$) (Figure 2d). However, a hepatic steatosis index >36 was more frequent in non-HIV recipients (31% vs 21%, $p=0.038$). Post-LT MASLD was not associated with increased risk of HCC recurrence.

Conclusion: Post-LT metabolic comorbidities remain highly prevalent, with dyslipidemia more common in HIV and diabetes in non-HIV recipients. MASLD develops in approximately one-fifth of recipients, apparently without difference per HIV serostatus, underscoring that cardiometabolic dysfunction is a shared and clinically relevant burden after LT. These data highlighted the need of structured surveillance strategies for metabolic syndrome components and MASLD, together with early cardiovascular risk assessment in a context of integrated and multidisciplinary metabolic care after LT.

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Hepatitis/MASLD and other Liver Diseases

P 105 RESULTS OF REAL-WORLD DATA FROM AN OUTREACH PROGRAM FOR HCV DIAGNOSIS AND TREATMENT AMONG KEY POPULATIONS IN BOLOGNA

J.M. Faiella Marsengo, A. Zuppiroli, L. Badia, P. Viale

Infectious Diseases Unit, IRCCS S. Orsola Hospital, University of Bologna, Bologna, Italy

Introduction: PWID represent a major reservoir of HCV infection but often face barriers to conventional hospital-based care. This study evaluated the effectiveness of a street-based outreach program, implemented with the Open Group social cooperative, to improve HCV diagnosis and linkage to treatment among key populations in Bologna.

Methods: We performed a descriptive retrospective analysis of data from an integrated outreach-hospital database. The program used a mobile unit for salivary screening followed by capillary blood molecular confirmation. Pharmacological history, including antiepileptic drugs and potential drug-drug interactions, was collected on site. Eligible individuals were referred weekly for antiviral prescription according to national guidelines, assuming absence of focal liver lesions and non-advanced fibrosis to shorten time to treatment. Patients underwent hospital evaluation including clinical assessment, FibroScan®, DAA prescription, with drug dispensing and follow-up with SVR12 supported by the outreach team. HCV RNA genotyping was performed in suspected reinfections, and patients with advanced liver disease were referred to hepatology care.

Results: The program identified 15 individuals with HCV infection predominantly PWID. The cohort included 12 males and 3 females, with a mean age of 43.4 years (range 31–52). Liver fibrosis staging showed F0–F1 in six patients, F2 in one, and F4 in one, while fibrosis data were unavailable for seven individuals.

Following street-based diagnosis, three patients (20%) did not attend hospital evaluation, whereas twelve (80%) accessed hospital care. According to the Open Group referral system, the interval between referral email and treatment initiation ranged from 2 to 17 days, indicating rapid linkage to care.

Among the 15 diagnosed individuals, eight completed antiviral therapy, four interrupted treatment, one is currently undergoing treatment, and three had no available treatment data. Overall, seven patients achieved SVR12, corresponding to 46.7% of the cohort and 87.5% of those completing therapy.

During follow-up, 6 reinfections (40%) were documented. The interval between referral notification and reinfection treatment ranged from approximately 35 to 65 days. Management proved challenging, as several patients interrupted retreatment, one experienced reinfection after completing therapy, and others have not yet restarted treatment.

Conclusion: This real-world analysis highlights the challenges of achieving HCV micro-elimination among PWID. Although treatment efficacy was high among patients completing therapy, program impact was limited by incomplete linkage to care, treatment interruption, reinfection, and loss to follow-up. Hospital-centered models may represent barriers for vulnerable populations. Decentralized care pathways, community-based treatment delivery, and targeted adherence strategies may improve long-term retention and support micro-elimination in high-risk groups.

Hepatitis/MASLD and other Liver Diseases

P 106 RETROSPECTIVE EVALUATION OF LAMIVUDINE PROPHYLAXIS FOR PREVENTION OF HEPATITIS B VIRUS REACTIVATION IN HEMATOLOGIC PATIENTS UNDERGOING CHEMOTHERAPY (REPLAY): A SINGLE-CENTER EXPERIENCE

S. Resuli¹, V. Severgnini¹, L. Maiocchi¹, P. Sacchi¹, G. Favrin², S. Pedrali², Y. Yudin², V.V. Ferretti³, S. Rattotti⁴, M. Gotti⁴, E. Cappello⁴, A. Parisotto⁴, C. Cavalloni⁴, A. Mazzacane⁴, N. Polverelli⁴, P. Zappasodi⁴, S. Mangiacavalli⁴, D. Ghirardi², L. Arcaini^{2,4}, R. Bruno^{1,5}, M. Varettoni⁴, V. Zuccaro^{1,5}

¹Department of Infectious Diseases, IRCSS Policlinico San Matteo Foundation, Pavia, Italy, ²Department of Molecular Medicine, University of Pavia, Italy, ³Biostatistics and Clinical Trial Center, IRCCS Policlinico San Matteo, Pavia, Italy, ⁴SC Ematologia 1, IRCCS Policlinico San Matteo, Pavia, Italy, ⁵Department of Clinical, Surgical, Diagnostic and Paediatric Sciences, University of Pavia, Italy

The landscape of HBV prophylaxis management in hepatitis B core antibody (HBcAb) positive patients has changed significantly following the publication of the latest international guidelines. These guidelines have led to new recommendations for the use of entecavir (ETV) or tenofovir (TDF) as preferred agents, given lamivudine's (3TC) high resistance rates (20–30% at 1–2 years vs approximately 1% at 5 years with ETV).

This single-center retrospective study aimed to evaluate the real-world effectiveness of 3TC prophylaxis in preventing HBV reactivation (HBVr) in HBcAb positive hematologic patients undergoing chemotherapy and/or immunotherapy. The secondary aims were to identify clinical and virological predictors of treatment failure and assess the safety profile of 3TC in this population. These findings may clarify lamivudine's residual role in current practice and inform optimal HBV prophylaxis strategies in hematologic patients.

We analyzed data from a prospectively maintained database including 380 hematologic patients diagnosed and followed at SC Ematologia IRCCS Policlinico San Matteo. Eligible patients were those who received immunosuppressive therapy and anti-HBV prophylaxis with 3TC between 2002 and 2025 administered 2 weeks before haematologic therapy start and continued for 18 months after its completion. The risk of HBVr was stratified according to the latest European Association for the Study of the Liver (EASL) guidelines.

The patients were stratified into 3 HBVr risk groups (Table 1): high risk (301/380), intermediate risk (77/380), and low risk (2/380). Overall, 10/380 patients (2.6%) experienced HBVr during follow-up. Among these, 6/10 patients were in the high-risk group and 4/10 were in the intermediate-risk group. Among 380 patients included in the study, 8 were HBsAg positive and 367 were HBsAg negative; data were not available for 5 patients. HBVr occurred in 1 of 8 HBsAg-positive patients (12.5%) and in 9 of 367 HBsAg-negative patients (2.45%), corresponding to an approximately 5-fold higher risk in HBsAg-positive individuals (95% CI: 0.73–35.6). Regarding steroid therapy, HBVr was observed in 1 of 9 steroid-treated patients (11.1%) compared with 9 of 364 patients (2.5%) who did not receive steroids. Although it was estimated an increased risk among steroid-treated patients, the association was not statistically significant, likely due to the small sample size and limited number of events. Following reactivation, 7 patients (70%) were treated with ETV, 2 patients (20%) with TDF, and 1 patient (10%) continued 3TC. All patients achieved complete virological response, defined as undetectable HBVDNA.

In this study, 3TC prophylaxis was safe and associated with a low rate of HBVr in HBcAb positive hematologic patients receiving immunosuppressive therapy. Despite guideline preferences for newer antivirals, 3TC appears to remain a reasonable and well-tolerated option, though further studies are needed to confirm its effectiveness.

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Hepatitis/MASLD and other Liver Diseases

P 107 RISK-STRATIFIED HCC SURVEILLANCE IN HIV-HBV/HCV CO-INFECTION: GAPS BETWEEN RECOMMENDATIONS AND CLINICAL PRACTICE

S. Generoso, E. Carriero, V. Bagnoli, M. Menozzi, G. Cuomo, G. Guaraldi, A. Cervo, C. Mussini

Infectious Diseases Clinic, University Hospital Policlinico of Modena, Modena, Italy

Background: Hepatocellular carcinoma (HCC) is a leading cause of liver-related mortality. In people with HIV (PWH), HBV/HCV co-infection accelerates fibrosis progression and increases HCC risk. However, in routine HIV care it is unclear whether HCC surveillance is truly tailored to liver disease severity and validated risk factors, or simply reflects non-systematic, occasional imaging.

This study aimed to evaluate whether HCC surveillance in PWH and HBV and/or HCV co-infection is appropriately implemented according to liver disease severity and validated risk criteria.

Methods: Monocentric retrospective study including PWH with positive HBsAg and/or anti-HCV antibodies in active follow-up (≥ 1 visit after 1st Jan 2025). Virological and biochemical data were collected together with liver status assessment, defined by ultrasound (US), transient elastography (TE) and FIB-4. Advanced fibrosis was defined as liver stiffness measurement (LSM) >8 kPa and >10 kPa in HBV and HCV co-infected PWH, respectively, or FIB-4 >3.25 . Cirrhosis was defined as LSM >11 kPa (in HBV) and >13 kPa (in HCV), or cirrhotic morphology at US. Appropriate surveillance evaluated in the previous 3 years was defined using a risk-stratified model, requiring semiannual US in cirrhosis and in HBV with advanced fibrosis or ≥ 1 risk factor (HDV RNA positivity, family history of HCC, PAGE-B ≥ 10). Annual HBV DNA and quantitative HBsAg defined appropriate virological monitoring.

Results: Among 209 PWH with complete data (74.2% HCV, 20.1% HBV, 5.7% HBV-HCV), 10 (4.8%) had cirrhosis and 64 (30.6%) advanced fibrosis; 16 lacked imaging data. Among those with cirrhosis, 60% had HCV, 30% HBV and 1 HCV-HBV co-infection. Among those with advanced fibrosis, 65.6% had HCV, 25% had HBV and 9.4% had HCV-HBV co-infection. Among those without US or TE, 10 had HCV co-infection with FIB-4 <3.25 and APRI <1 while 6 had HBV with PAGE-B ≥ 10 (Table 1).

Overall, 164 (78.4%) underwent at least one US. All cirrhotic patients had a recent US (in the last median 16 months, IQR 0-50), but only 10% received semiannual surveillance. Among PWH with advanced fibrosis, 58 (90.6%) had at least one US (in the last median 10 months, IQR 0-71), yet of the 22 high-risk HBV individuals no one received while 13.6% received annual surveillance. HBV DNA and quantitative HBsAg were performed annually in 29.7% and 16.7%, respectively. No HCC cases were diagnosed in the last three years.

Conclusion: In this real-world cohort of PWH, despite frequent imaging, risk-adapted HCC surveillance intensity was rarely achieved in cirrhosis and high-risk HBV, revealing a gap between guidelines recommendation and clinically appropriate implementation. Integrating hepatology risk algorithms into HIV care pathways, improving surveillance frequency and strengthening PWH awareness and adherence may improve timely detection of HCC and prevention of liver-related mortality.

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HIV and CNS

P 108 A MULTIDIMENSIONAL SCALE FOR HEALTH NEEDS IN PEOPLE WITH HIV: THE PROSPECTIVE MUSA STUDY

A. Calcagno^{1,2}, E. Sala³, M. Polisenò⁴, M. Mazzitelli⁵, G. Madeddu⁶, B.M. Celesia⁷, G. Marchetti⁸, L. Petrolì¹, M.V. Cossu⁹, P. Cinque¹⁰, S. Di Giambenedetto¹¹, M. Giacomini¹², R. Iardino³, D. Val¹³, L. Brogonzoli³, for the MUSA Research Group

¹Unit of Infectious Diseases, Department of Medical Sciences, University of Turin, Turin, Italy, ²Department of Translational Medicine, University of "Piemonte Orientale", Novara, Italy, ³Fondazione The Bridge, Milan, Italy, ⁴Clinic of Infectious Diseases, DiMePre-J, Università di Bari, Bari, Italy, ⁵Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, ⁶Unit of Immune Deficiency, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ⁷Unit of Infectious Diseases, Garibaldi Hospital, Catania, Italy, ⁸Department of Health Sciences, Clinic of Infectious Diseases, University of Milan, ASST Santi Paolo e Carlo, Milan, Italy, ⁹Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, ¹⁰Unit of Infectious Diseases, San Raffaele Scientific Institute, Milano, Italy, ¹¹Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, Italy, ¹²Department of Informatics, Bioengineering, Robotics and System Engineering (DIBRIS), University of Genoa, Genoa, Italy, ¹³Unit of Psychology, "Psicologia Aziendale", ASL "Città di Torino", Turin, Italy
The MUSA Research Group is composed by the authors and: A. Saracino | Clinic of Infectious Diseases, DiMePre-J, Università di Bari, Bari, Italy, A. Cattelan | Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, A. Gori | Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy, C. Torti | Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, Italy, L. Barbisoni | Infectious and Tropical Diseases Unit, Padua University Hospital, Padua, Italy, M. Strano | Unit of Infectious Diseases, San Raffaele Scientific Institute, Milano, Italy

Background: Despite impressive improvements in the management of HIV infection, people with HIV (PWH) still present a high burden of physical and psychological comorbidities. Identifying health needs in persons under antiretroviral treatment (ART) is critical for improving healthy life expectancy and robust ageing. The Mental Health Group of Coalition HIV developed a multidimensional screening questionnaire, and a prospective study (MUSA) was designed for its validation.

Material and Methods: The screening tool comprises 23 questions covering 12 domains (cognition, functional capacity, depressive and anxiety symptoms, sleep quality, quality of life, biological/nutritional status, socioeconomic factors, stigma, comorbidities, polypharmacy, and alcohol and substance use). It can be completed in about 5 minutes, and participants rated each item on a 1–4 scale (best to worst outcome). The self- or operator-administered confirmatory tools (with the used thresholds) are shown in Table 1. Data are shown as numbers (percentage) or median (interquartile range) and assessed through non-parametric tests.

Results: We enrolled 202 participants. They were mostly male (128, 63.4%) with a median age of 58 years (49-65). They presented a CD4 cell count of 703 cells/mm³ (510-967) and HIV RNA <50 copies/mL in the majority (190, 95%), despite many years of infection (19, 9-30). The domains most commonly identified as altered at the screening test were stigma (138, 70.4%), socioeconomic status (125, 63.8%), and sleep (53, 26.9%). Confirmatory tests identified altered sleep (101, 51.5%), socioeconomic (85, 43.1%), and quality of life (75, 38.1%) domains; no participant had an altered functional domain at the confirmatory test. We observed a significant direct correlation ($p < 0.001$, $R^2 = 0.364$) between the total abnormal domains at screening (2, 2-4) and at confirmatory tests (2, 1-3): the screening test had a sensitivity and specificity of 96.3% and 11.8% in identifying at least one altered domain at confirmatory tests. The performance of the screening tool varied largely according to the domains: it was highly predictive for alterations in depression, anxiety, multimorbidity/polypharmacy, socioeconomic, addictions and stigma, but with varying sensitivity and specificity within each domain (Table 1); cognition and functional domains were not correctly identified.

Conclusions: We developed a new brief screening test that can help identifying patients with higher health needs. A good correlation with the burden of altered domains was found as well as a fair prediction of alterations in depression, anxiety, multimorbidity/polypharmacy, socioeconomic, addictions and stigma. The poor performance in certain domains prompts the need for revising specific screening questions.

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HIV and CNS

P 109 HIGH-RESOLUTION INSIGHTS INTO HIV-1 CNS RESERVOIRS: CLINICAL UTILITY OF NGS-BASED GRT IN CSF WITH VARIABLE MINORITY VARIANT THRESHOLDS

A. Parodi¹, F. Stefanelli², N. Randazzo², V. Ricucci², B. Bruzzzone², M. Giurco¹, L. Costacurta¹, C.A. Bustamante¹, T.E. Ortiz Yupa¹, M. Bassetti^{1,3}, L. Taramasso³, A. Di Biagio^{1,3}

¹Department of Health Sciences, University of Genoa, Genoa, Italy, ²IRCCS Azienda Ospedaliera Metropolitana San Martino Hospital, Genoa, Italy, ³Infectious Diseases Unit, IRCCS Azienda Ospedaliera Metropolitana San Martino Hospital, Genoa, Italy

Background: Characterizing HIV-1 drug resistance mutations (RAMs) in the cerebrospinal fluid (CSF) is critical for managing people with HIV (PWH) with suspected viral escape. Standard genotypic resistance testing (GRT) often fails to capture complexity of viral populations in both plasma and CSF. This study assesses the feasibility of Next-Generation Sequencing (NGS) in paired CSF and plasma samples, exploring if different detection thresholds impact the identification of RAMs revealing hidden compartmentalization.

Materials and Methods: Paired CSF and plasma samples from PWH (collected 2022-2025) with a clinical indication for lumbar puncture (e.g., cognitive decline, confusion or viral escape screening) were analyzed. Viral RNA was extracted using automated platforms. NGS-based GRT targeted Protease (PI), Reverse Transcriptase (NRTI/NNRTI), and Integrase (INSTI) regions using the Illumina iSeq 100 platform. Bioinformatic analysis was performed to identify RAMs at three different sensitivity cut-offs for minority variants: 5%, 10%, 20%. Demographic and clinical data were extracted from electronic medical records.

Results: Seven PWH were included, 2 were treatment-naïve and 5 had discontinued antiretroviral therapy. HIV-RNA was detectable in all compartments (CSF: 33 to 1.0×10^6 copies/mL; plasma: 1.0×10^2 to 2.2×10^6 copies/mL). All PWH had subtype B, except one CRF02_AG. Using a 20% cut-off, CSF and plasma resistance profiles were largely concordant in both compartments in 5 out of 7 participants, although the relative frequencies were not always identical. Among these, two harbored wild-type virus and three had at least one major RAM (PWH ID 1, 4, 5, 6, and 7; Table 1). With threshold reduced to 10%, PWH ID 3 showed evidence of compartmental relevant NNRTI discordance. Specifically, while the RAMs 101E, 103N, 106I, and 138K were present in plasma, 101E and 106I were detected in CSF only as minority variants and would have been missed at higher cut-offs. At the 5% threshold, PWH ID 2 exhibited the PI mutation 32I at 6% in CSF, whereas it was present at only 4% in plasma. Although the relevance of this minority variant may be debated, the same virus also harbored the PI mutation K43T in plasma (68%), suggesting possible transmission of a PI-experienced virus. Overall, applying the 5% threshold increased the detection of minority variants in 2 of 7 cases, providing a more detailed characterization of the CSF viral reservoir.

Conclusions: NGS-based GRT in CSF is feasible and offers greater resolution than standard methods. The RAMs detected in CSF, even at low threshold, were all significantly represented in plasma, suggesting that the use of lower detection thresholds (5–10%) may be clinically relevant for identifying minority variants that could precede virological escape. Integrating NGS into CSF diagnostics supports precision medicine in PWH with CNS involvement and highlights the need for standardized bioinformatic thresholds in routine practice.

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HIV and CNS

P 110 NEUROSymptomatic CSF HIV ESCAPE IN A WOMAN ON DUAL THERAPY

M. Munarini, A. Zuppiroli, R.D. Barison, F. Baggio, S. Babini, L. Calza, G. Fasulo, P. Viale

Infectious Diseases Unit, IRCCS S. Orsola Hospital, University of Bologna, Bologna, Italy

Background: Neurosymptomatic cerebrospinal fluid (CSF) HIV escape is usually defined by detectable CSF HIV RNA with undetectable plasma or by CSF HIV RNA ≥ 1 log than plasma. Emerging data suggest a continuum of CNS-compartmentalized replication in which neurologic symptoms may occur even when this strict virologic threshold is not fulfilled.

Material and Methods: We describe a 62-year-old woman with long-standing HIV infection, no prior AIDS-defining events and stable virological suppression on ART, recently simplified to DTG/3TC. Clinical, laboratory, CSF and neuroimaging data were collected during hospitalization for suspected encephalitis, together with plasma and CSF HIV RNA and resistance testing.

Results: The patient presented with high-grade fever, severe headache and marked gait ataxia with cerebellar signs; CT and MRI showed only mild small-vessel disease without acute lesions. CSF analysis revealed lymphocytic pleocytosis, elevated protein and low glucose; multiplex PCR and cultures for common neurotropic pathogens, as well as an autoimmune encephalitis panel, were negative. HIV-1 RNA was 37.113 cp/mL in plasma and 127.734 cp/mL in CSF, indicating clear compartmentalized replication, although the CSF–plasma gradient was <1 log and therefore below the conventional escape definition. Empirical acyclovir and ampicillin were discontinued after negative workup, and ART was intensified by switching from DTG/3TC to DRV/c/FTC/TAF, with rapid improvement of neurological symptoms and recovery of a safe gait, leaving only a mild residual intentional tremor at discharge. Plasma genotypic resistance testing showed no relevant resistance mutations, while CSF resistance testing is still ongoing.

Conclusions: This case supports a pragmatic interpretation of neurosymptomatic CSF HIV escape, where severe neurologic manifestations, inflammatory CSF changes, evidence of compartmentalized CNS replication and a clear ex iuvantibus response to ART intensification justify the diagnosis even when the classical >1 -log CSF–plasma threshold is not met. These observations align with existing reports of CSF escape under dual regimens, where CNS-driven dysfunction consistently improves after ART optimization.

In patients on simplified ART who develop acute neurologic symptoms, prompt CSF evaluation and early regimen intensification (switch to PIs) should be considered when discordant CNS replication is detected.

HIV and CNS

P 111 NEUROSYPHILIS AND OCULAR SYPHILIS: CLINICAL SPECTRUM, LABORATORY PROFILE AND OUTCOME IN A 15-YEAR RETROSPECTIVE COHORT AT IRCCS SAN RAFFAELE SCIENTIFIC INSTITUTE

C. Candela¹, N. Capra¹, R. Lolatto¹, C. Tassan Din¹, M. Ranzenigo¹, S. Del Fabbro², G. Catalano³, P. Cinque^{1,3}, A. Castagna^{1,3}, S. Nozza^{1,3}, E. Miserocchi^{2,3}

¹Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy, ²Ophthalmology Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy, ³Infectious Diseases Unit, Vita-Salute San Raffaele University, Milan, Italy

Background: Neurosyphilis results from central nervous system involvement by *Treponema pallidum* and may occur at any stage of infection, ranging from asymptomatic cerebrospinal fluid (CSF) abnormalities to overt neurological or ocular disease. We described demographic, clinical, laboratory features of neurosyphilis cases managed at our centre.

Materials and Methods: Retrospective study including adults diagnosed with neurosyphilis at IRCCS San Raffaele Scientific Institute, Milan, Italy (January 2010–July 2025). Diagnosis required suggestive clinical presentation, reactive nontreponemal and treponemal serology, and CSF abnormalities. Data were collected from electronic medical records. Clinical outcome at 3 months was described as improved, stable, or worsened based on changes in neurological/ocular manifestations after treatment. Relapse was defined as recurrence of symptoms or new increase in nontreponemal titres after initial response. Continuous variables are reported as median (interquartile range, IQR) and categorical variables as percentage.

Results: Overall, 92 cases of neurosyphilis were diagnosed, but complete data were available for 61 (Table1). Median age was 54 years (IQR 43–63), 49 (80.3%) were male. People with HIV (PWH) were 23 (37.7%, Table2). Systemic symptoms were described in 22 (36%). Neurological involvement occurred in 25 (41%) and ocular involvement in 41 (67.2%), respectively. Eight people (13.1%) manifested both neurological and ocular manifestations (Figure 1). Serum rapid plasma reagin (RPR) titres were $\geq 1:32$ in 65.6%, *Treponema pallidum* haemagglutination assay (TPHA) titres were $\geq 1:5120$ in 83.6%. CSF analysis (n=46) showed mild pleocytosis (11 cells/mm³, IQR 5–22), moderately elevated protein levels (57 mg/dL, IQR 39–79), preserved glucose concentration (58 mg/dL, IQR 53–65). CSF TPHA was positive in 40 cases, fluorescent treponemal antibody absorption (FTA-ABS) in 22, and Venereal Disease Research Laboratory (VDRL) in 13. Neuroimaging (n=55) revealed abnormalities in 36 (65.5%), mainly nonspecific. Intravenous therapy lasted a median of 14 days (IQR 14–14), with penicillin being administered to 35 (57.4%) and ceftriaxone to 26 (42.6%). Within 3 months, clinical improvement was observed in 43 (70.5%) cases, 16 (26.2%) were stable, 1 (1.6%) worsened due to retinal necrosis, 1 (1.6%) died for other reason. Improvement rates were similar in PWH (ocular 90.9%/neurological 81.3%) and HIV-negative individuals (ocular 83.3%/neurological 82.6%). Relapse occurred in 5 (8.1%) within 12 months.

Conclusions: In our cohort, neurosyphilis showed heterogeneous neurological and ocular manifestations, high plasma treponemal titres and relatively mild CSF inflammation. Neuroimaging abnormalities were nonspecific. Although appropriate therapy achieved positive overall outcomes, more than one-quarter didn't improve, likely reflecting delayed diagnosis or irreversible neurological/ocular damage at presentation, underlying the substantial burden of persistent deficits.

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HIV and CNS

P 112 STIGMA AS A BARRIER TO ART ADHERENCE: A CASE OF ADVANCED CEREBRAL TOXOPLASMOSIS FOLLOWING TREATMENT INTERRUPTION

V. Blevé¹, L. Bortolani¹, A. Falletta¹, A. Impellizzeri¹, L. Moretti¹, S. Rubino¹, E. Casali², M.R. Cuomo², C. D'Agostino², V. Mauro², G. Siccardi², C.M. Mastroianni¹, G. d'Ettore¹

¹Department of Public Health and Infectious Diseases, Sapienza University of Rome, Policlinico Umberto I, Rome, Italy, ²Infectious Diseases Unit, Azienda Ospedaliero Universitaria Policlinico Umberto I, Rome, Italy

Background: Despite the effectiveness of antiretroviral therapy (ART), HIV-related stigma remains a barrier to disengagement from care. Internalized stigma, fear of disclosure, and perceived judgment within healthcare settings continue to undermine adherence and timely diagnosis, particularly among socially vulnerable individuals and migrants.

Case Presentation: A 45-year-old man diagnosed with HIV in 2014 in Argentina relocated to Italy in 2022. Soon after migration, he voluntarily discontinued ART (EFV/FTC/TDF) despite no adverse events or medical contraindications. Treatment interruption was mainly driven by internalized stigma, difficulty disclosing his HIV status in a new social environment, and fear of judgment.

In December 2025, he presented with progressive headache, nausea, vomiting, photophobia, marked asthenia, and recent onset of visual disturbances. Multiple emergency department evaluations failed to identify an acute etiology. Upon admission to the Infectious Diseases Unit, he was in poor general condition, with left conjunctival hyperemia and nystagmus-like ocular movements, without focal neurological deficits. Immunovirological assessment revealed advanced immunosuppression (CD4+ T-cell count 64 cells/ μ L; CD4/CD8 ratio 0) and high-level viremia (HIV RNA 757,056 copies/mL), secondary to prolonged ART discontinuation. Laboratory tests showed leukopenia. Cerebrospinal fluid (CSF) analysis demonstrated xanthochromic appearance, monocytic pleocytosis, hyperproteinorrachia, and hypoglycorrhachia. Contrast-enhanced brain magnetic resonance imaging identified multiple supra and infratentorial ring-enhancing lesions compatible with multifocal abscess. CSF polymerase chain reaction was positive for *Toxoplasma gondii*, confirming cerebral toxoplasmosis. Targeted therapy with trimethoprim-sulfamethoxazole (TMP/SMX) and adjunctive systemic corticosteroids was initiated. ART was reintroduced with BIC/TAF/FTC after exclusion of contraindicating opportunistic infections, with good tolerability and the patient achieved virological suppression. Structured psychological support was integrated into the management plan during hospitalization.

Conclusions: This case highlights the preventable consequences of ART discontinuation driven by HIV-related stigma. Rapid virological rebound and CD4+ depletion led to AIDS-defining cerebral toxoplasmosis. Migration represented a critical stressor amplifying stigma and contributing to treatment abandonment. Furthermore, delayed recognition of advanced HIV infection across repeated healthcare encounters raises concerns about persistent structural stigma within healthcare settings. Beyond virological control, comprehensive HIV care must address psychosocial determinants, ensure stigma-free healthcare environments, and integrate psychological support to prevent avoidable AIDS-defining events.

HIV and CNS

P 113 SUCCESSFUL USE OF FOSMANOGEPIX IN RELAPSING CRYPTOCOCCAL MENINGITIS IN A PWH

V. Brogna^{1,2}, N.B. Bana², A. Forni^{1,2}, L. Luzi^{1,2}, F. Peracchi^{1,2}, A. Repishti^{1,2}, M. Chiamenti², G. Travi², M. Vecchi², M. Puoti², P. Bonfanti¹, R. Rossotti²

¹University of Milano-Bicocca, Milan, Italy, ²ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy

Background: Although amphotericin B-based regimens plus flucytosine have improved survival in cryptococcal meningitis among people with HIV (PWH), treatment is frequently complicated by poor tolerability and toxicity. Refractory cases and relapses remain a major challenge, highlighting the need for alternative antifungal therapies.

Case presentation: A 36-year-old man from Kosovo living in Italy for 18 years was diagnosed with HIV infection in September 2024 (HIV-RNA 166,000 copies/mL; CD4+ count 197 cells/ μ L). Combination antiretroviral therapy (cART) was started but discontinued after two weeks due to fever, vomiting, worsening headache and a cryptococcal antigen of 1:1024. He was admitted and diagnosed with disseminated cryptococcosis and meningitis due to *Cryptococcus neoformans*.

Induction therapy with liposomal amphotericin B (L-AMB) plus flucytosine was started and cerebrospinal fluid (CSF) parameters improved after 14 days, although microscopy remained positive. Gastrointestinal intolerance to flucytosine and L-AMB-related hypokalemia prompted transition to consolidation with fluconazole after 3 weeks. cART was resumed after 6 weeks, fluconazole was reduced to secondary prophylaxis at 12 weeks.

During week 14 of prophylaxis, after a brief interruption of fluconazole, he developed worsening headache and vomiting. CSF revealed pleocytosis (277 cells/ mm^3) with negative cultures but detectable HIV-RNA (2,910 copies/mL) despite systemic virological control. He was readmitted in May 2025 with relapsing cryptococcal meningoencephalitis. Antiretroviral therapy was optimized for CNS penetration and L-AMB plus high-dose fluconazole were reintroduced; but renal function deteriorated, requiring L-AMB discontinuation. Two weeks later, CSF pleocytosis persisted (285 cells/ mm^3) with negative microscopy and cultures. Ongoing headache, vomiting and a generalized seizure occurred. Corticosteroid treatment led to rapid symptomatic improvement, suggesting an inflammatory component consistent with late Immune Reconstitution Inflammatory Syndrome.

Given toxicity to standard antifungal regimens, compassionate use of Fosmanogepix was initiated (intravenous loading dose followed by oral therapy), combined with fluconazole. There were no significant adverse events. Corticosteroids were discontinued, maintaining clinical stability. Serial lumbar punctures showed marked reduction in CSF cellularity with persistently negative microscopic and cultural findings, while brain MRI demonstrated substantial reduction of leptomeningeal enhancement.

Conclusions: Fosmanogepix has demonstrated strong in vitro activity against *Cryptococcus* species, but there are no clinical data supporting its use in cryptococcosis. In this case, it was associated with sustained clinical, radiological and microbiological improvement without additional safety concerns. These findings support further investigation of Fosmanogepix as a potential salvage therapy in cryptococcal meningitis.

HIV and CNS

P 114 WHEN MOOD MEETS COGNITION: UPDATING MENTAL AND COGNITIVE HEALTH OF PLWH IN THE CONTEXT OF HAND

G. Del Duca, A. Lener, G. Frate, M. Maresca, V. Mazzotta, R. Gagliardini, I. Mastrosera, A. Antinori, C. Pinnetti

National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Background: Anxiety, depression, and HIV-associated neurocognitive disorders (HAND) frequently coexist in people living with HIV (PLWH), even though their independent and interrelated contributions remain unclear. We investigated the relationship between affective symptoms and HAND in a real-world cohort of PLWH receiving ART, with the aim of assessing and updating mental and cognitive health over time.

Methods: We conducted a longitudinal analysis on PLWH who underwent neuropsychological assessment at baseline (T0) and at one-year follow-up (T1) from January 2018 and March 2025. Anxiety and depression were assessed using the Beck Anxiety Inventory (BAI) and Beck Depression Inventory-II (BDI-II). HAND diagnosis was established according to the standard Frascati's criteria. Demographic, clinical, and HIV-related variables were collected. Paired Wilcoxon tests and regression models were performed.

Results: A total of 181 participants were included (median age 56 years, IQR 46–63; 85.6% male). Overall, 32% had normal cognition, 61.9% were diagnosed with ANI/MND, and 6.1% were HAND-unclassifiable (Table 1). ANI/MND was strongly associated with clinically significant anxiety (OR 11.42, 95% CI 5.38–24.24; $p < 0.001$), as was unclassifiable impairment (OR 11.51, 95% CI 2.71–48.88; $p = 0.001$) (Table 2). In multivariable analysis, female sex and Efavirenz-based ART were independently associated with higher odds of both anxiety and depression. Older age was associated with a lower likelihood of anxiety, whereas no additional variables showed a significant independent association with depression after adjustment (Table 2). No significant association emerged between HAND and depressive symptoms. From T0 to T1, 12.7% improved, 6.7% remained stable, and 4.4% worsened in BAI scores; for BDI-II, 14.4% improved, 12.2% remained stable, and 7.7% worsened (Table 3).

Conclusion: Anxiety seems to be a significant correlate of neurocognitive impairment in PLWH, whereas depressive symptoms do not show a similar association. Female sex and Efavirenz-based ART were independently associated with higher odds of both anxiety and depression, while older age appeared protective against anxiety. The longitudinal variability of affective symptoms suggests that emotional burden is dynamic and potentially modifiable. Further studies are needed to clarify causal pathways and their implications for prognosis and quality of life.

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Immunocompromised host: Infections and Therapy

P 115 CRYPTOCOCCAL ANTIGENEMIA AND MULTIPLE DRUG HYPERSENSITIVITY IN A “LATE PRESENTER”: A MANAGEMENT CHALLENGE

L. Abbate, T. Tiberio, A. Zuppiroli, S. Tedeschi, M. Munarini, L. Calza, P. Viale

Infectious Diseases Unit, IRCCS S. Orsola Hospital, University of Bologna, Bologna, Italy

Background: In People Living with HIV (PLWH) with advanced immunosuppression ($CD4^+; 100 \text{ cells/mm}^3$), screening for serum cryptococcal antigen (CrAg) is recommended in order to identify subclinical infection and prevent progression to cryptococcal meningitis.

Case presentation: A 42-year-old man, who had remained untreated by personal choice since his HIV diagnosis in 2010, came at the attention of our clinic as an outpatient in May 2025 to establish clinical follow-up and begin therapy. Baseline laboratory tests showed an HIV-RNA of 1,052,203 copies/mL and a CD4 count of 99 cells/mm³ (9%). In the absence of any neurological or systemic symptoms, ART (B/F/TAF) and cotrimoxazole prophylaxis were promptly initiated. Baseline serum CrAg screening returned positive, despite the patient being asymptomatic. Consequently, ART was temporarily withheld, and the patient was hospitalized to exclude disseminated disease. Lumbar puncture ruled out CNS involvement (CSF CrAg negative). Chest CT showed nonspecific micronodules; bronchoscopy with bronchoalveolar lavage was negative for fungal elements.

Pre-emptive fluconazole was initiated but discontinued after 48 hours, together with cotrimoxazole, due to a diffuse rash suggestive of drug hypersensitivity. A subsequent cutaneous reaction to atovaquone further limited prophylactic options.

Meanwhile, ART was resumed with good tolerance. Remarkably, despite the early cessation of fluconazole, a follow-up serum CrAg performed only 8 days after the initial positive test was negative. Good therapy adherence led to a rapid virological response ($>2\text{Log}$ decrease in less than a month, undetectable by November 2025) and early immune recovery, with CD4 counts rising to 148 cells/mm³ in June and 365 cells/mm³ by January 2026. During follow-up, no opportunistic infections or immune reconstitution inflammatory syndrome (IRIS) occurred.

Discussion and conclusions: This case highlights a significant therapeutic challenge: managing CrAg positivity when the gold-standard treatment, fluconazole, is contraindicated due to hypersensitivity.

Given the short duration of fluconazole exposure, a decisive antifungal effect seems unlikely. While rapid antigen clearance may reflect a low initial fungal burden, the prompt virological suppression and subsequent immune reconstitution following ART initiation likely played a central role in controlling the subclinical infection.

The clinical course emphasizes the role of the CD4 T-cell recovery as a primary mechanism in controlling early-stage fungal dissemination when pharmacological options are exhausted. In carefully monitored patients with rapid immune reconstitution, favorable outcomes may occur even when antifungal therapy cannot be fully administered. Nevertheless, current guideline-recommended management remains the standard of care.

Immunocompromised host: Infections and Therapy

P 116 HHV-8-ASSOCIATED MULTICENTRIC PLASMACYTIC CASTELMAN DISEASE IN A TREATMENT-NAÏVE PATIENT WITH LLV

A. Del Villano¹, A. Masiello², V. Iodice², A.G. Iodice², A. Salzillo², F. Simeone², F. Colucci², G. Di Caprio², F.P. Fabozzi¹, R. Marmo¹, G. Falzarano¹, A. Corrente¹, G.M. Bottino¹, C. Sagnelli^{1,2}

¹Department of Mental, Physical, and Preventive Health, Infectious Diseases Section, University of Campania "Luigi Vanvitelli", Naples, Italy, ²University-Directed Infectious and Tropical Diseases Unit, AORN Sant'Anna e San Sebastiano, Caserta, Italy

Castleman's disease (CD) comprises a heterogeneous group of lymphoproliferative disorders diagnosed histologically on excised lymph nodes. Three patterns are recognized: hyaline vascular, plasma cell, and the more recently described plasmablastic variant. Based on the extent of lymphadenopathy, CD is classified as unicentric (UCD) or multicentric (MCD). MCD is a systemic disorder characterized by fever, anemia, and multifocal lymphadenopathy, and is currently most frequently observed in PLWH. Nearly all HIV-associated MCD cases and about 50% of HIV-negative cases are linked to HHV-8. Conventional strategies including surgery, ART, interferon- α , foscarnet, ganciclovir, and anti-IL-6 antibodies have shown limited efficacy, while chemotherapy in HIV-positive individuals is burdened by toxicity and suboptimal outcomes. The introduction of the anti-CD20 monoclonal antibody rituximab has significantly improved prognosis, leading to sustained remissions, radiologic responses, and normalization of hematologic and biochemical parameters. Early diagnosis is essential to initiate appropriate therapy, improve survival, and prevent progression to aggressive disease or lymphoma.

We observed a 53-year-old man admitted in July 2024 for intermittent fever, progressive asthenia, superficial lymphadenopathy lasting two months, cough, leukopenia, and anemia. Initial laboratory evaluation revealed newly diagnosed HIV infection with HIV RNA 3,894,480 copies/mL, CD4+ 588 cells/mm³ (23%), CD8+ 744 cells/mm³, ratio 0.74, and high HHV-8 DNA levels (178,550 copies/mL). ART with BIK/TAF/FTC was started. T-b CT scan was performed, revealing diffuse lymphadenopathies above and below diaphragm, for which, after hematology consultation, a lymph node biopsy was performed. The histological examination showed presence of "monotypic plasmablasts, lambda-restricted, infected by HHV-8 (LANA-positive), primarily located in mantle zones and adjacent to the germinal centers, consistent with MCD.

PET-CT revealed multiple hypermetabolic lymph node foci above and below the diaphragm. Treatment with rituximab plus valganciclovir was initiated. Complete radiologic remission was achieved in October, and maintenance therapy was started, temporarily suspended in February due to fever and resumed in April for four months. At last follow-up, the patient was clinically stable. Immunologic assessment showed CD4+ 556 cells/mm³ (24%), CD8+ 1276 cells/mm³ (55%), r: 0.43, but persistent low-level viremia (>200 copies/mL) not attributable to DDI, RAMs, adherence issues or concomitant chronic infections.

This case underscores the importance of a multidisciplinary approach in late-presenting PLWH and highlights diagnostic timeliness and therapeutic appropriateness as key prognostic determinants. It also reflects the ongoing challenge of managing persistent low-level viremia in advanced treatment-naïve patients, a relevant issue in contemporary HIV care.

Immunocompromised host: Infections and Therapy

P 117 IMMUNO-MODULATION OF INNATE AND ADAPTIVE IMMUNE RESPONSE IN PATIENTS WITH SEPSIS

M. Antonacci¹, M.A. Zingaropoli¹, P. Pasculli¹, F. Dominelli¹, G. Galardo², E. Petrillo², R. Renna², G. Imbimbo², C.M. Mastroianni¹, M.R. Ciardi¹

¹Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ²Medical Emergency Unit, Sapienza University of Rome, Policlinico Umberto I, Rome, Italy

Introduction: Clinical flow cytometry has revealed that sepsis elicits a multifaceted and time-dependent immune response characterized by the simultaneous activation of pro- and anti-inflammatory pathways. This technology has enabled the identification of immune dysfunction patterns and the development of immunostimulatory approaches, thereby offering new insights into sepsis pathophysiology and allowing for a refined delineation of immune trajectories in affected patients.

Materials and Methods: Whole-blood samples were obtained from patients presenting to the emergency department with clinical features of sepsis or septic shock. Based on blood culture results, patients were classified into confirmed sepsis (c-SEP) or no sepsis (n-SEP) groups. Flow-cytometric immunophenotyping was performed to investigate the percentage of subpopulations of innate (monocytes, neutrophils, dendritic cells) and adaptive (T-cell) immune cell subsets. Age- and sex-matched healthy donors (HDs) served as controls.

Results: A total of 55 patients (30 c-SEP, 25 n-SEP) and 12 HDs were enrolled. Among c-SEP cases, 53% (16/30) were positive for Gram-negative pathogens, with *Escherichia coli* being the most common isolate (23% [7/30]). Compared with HDs, patients demonstrated increased immature neutrophils ($p=0,0097$) and decreased plasmacytoid dendritic cells ($p=0,0143$). Significant reductions in CD3⁺ ($p=0,0036$) and CD4⁺ T cells ($p=0,0121$), but not CD8⁺ T cells, were observed. Within the CD8⁺ compartment, naïve ($p=0,0121$) and central memory cells ($p=0,0005$) were reduced, whereas effector ($p=0,0030$) and effector memory ($p=0,0105$) subsets were increased.

When stratified by microbiological results, n-SEP and c-SEP patients shared similar immunological trends. However, effector-memory CD4⁺ T cells ($p=0,0492$) tended toward greater reductions in c-SEP, whereas naïve CD4⁺ T cells were significantly increased in this group ($p=0,0196$).

Discussion: In conclusion, the present findings indicate that sepsis may induce immune dysregulation, suggesting concomitant immunoparalysis and inflammation, likely driven by persistent activation and cellular depletion. This finding underscores the necessity for targeted immunomodulatory strategies in patients with sepsis.

Immunocompromised host: Infections and Therapy

P 118 IMPACT OF ANTI-CD20 THERAPY ON T-FOLLICULAR HELPER AND CXCR5+ CD8+ T-CELL SUBSETS IN MULTIPLE SCLEROSIS: A PRELIMINARY LONGITUDINAL STUDY

F. Dominelli¹, M.A. Zingaropoli^{1,2}, P. Pasculli¹, M. Antonacci¹, F. Ciccone¹, M. Proietti¹, M. Lichtner³, G. Ferrazzano⁴, C.M. Mastroianni¹, A. Conte⁴, M.R. Ciardi¹

¹Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ²Microbiology and Virology Unit, Policlinico Umberto I, Sapienza University of Rome, Rome, Italy, ³Department of Neurosciences, Mental Health, and Sense Organs, NESMOS, Sapienza University of Rome, Rome, Italy, ⁴Department of Human Neurosciences, Sapienza University of Rome, Rome, Italy

Introduction: Anti-CD20 monoclonal antibodies are highly effective in multiple sclerosis (MS) but may impact T-cell immunity, potentially increasing susceptibility to herpesvirus reactivation, opportunistic infections, and suboptimal control of respiratory viruses. Specifically, follicular helper T-cells (Tfh) are instrumental for germinal centre development and memory B-cells generation. While T-cell expansions are reported during treatment, data on Tfh and CXCR5+ CD8+ T-cells, which share transcriptional profiles with Tfh and aid viral control, remain limited. This study characterized these subsets longitudinally during anti-CD20 therapy.

Materials and Methods: Anti-CD20 eligible people with MS (pwMS) and healthy donors (HD) were enrolled. Peripheral blood samples were collected prior to the commencement of treatment (T0), following 6 and 12 months from start, corresponding to the second (T1) and third (T2) infusion/injection. Through flow cytometry T-cell subsets were characterized as follows: naïve (CD45RO-CD27++), central memory (CD45RO+CD27+), effector memory (CD45RO+CD27-), effector (CD45RO-CD27-), and intermediate (CD45RO-CD27+), as well as Tfh (CXCR5+CD45RO+) and CXCR5+ CD8+ T-cell.

Results: 8 pwMS and 7 HD. In the observational year, no infectious events were reported by pwMS that started anti-CD20 treatment. Looking at the T-cell subsets, when comparing the T-cell subpopulation between the two groups, we observed at T0, high percentages of naïve CD4+ and CD8+ T-cell (CD45RO-CD27+) in pwMS when compared to HD ($p=0.0199$; $p=0.0246$). On the other hand, a tendency toward a low percentage of central memory CD8+ T-cell (CD45RO+CD27+) was seen in pwMS ($p=0.0787$). While a low percentage of effector memory CD4+ T-cell (CD45RO+CD27-) was seen in pwMS compared to HD ($p=0.0336$), as well as low percentage of CXCR5+ CD8+ T-cell at T0 ($p=0.0226$). At T1, we observed a persistence in high percentage of naïve CD4+ T-cell ($p=0.0729$) and low percentages of central memory CD8+ T-cell ($p=0.0124$), effector memory CD4+ T-cell ($p=0.0166$) and CXCR5+ CD8+ T-cell ($p=0.0250$) in pwMS when compared to HD. Finally, at T2, the reoccurrence of high percentage of naïve CD4+ T-cell ($p=0.0335$) and low percentage of CXCR5+ CD8+ T-cell ($p=0.0503$) was seen in pwMS. Furthermore, low percentage of CD4+ Tfh (CXCR5+CD45RO+) was seen at T2 in pwMS when compared to HD ($p=0.0836$) (Table 1).

Conclusion: Anti-CD20 treatment can cause long-lasting changes to T-cell compartments, particularly a reduction in memory CD8+ and CXCR5+ T-cells. As CXCR5+ CD8+ T-cells contribute to viral control and B-cell help, their reduction suggests a potential compromise in T-B cell collaboration and cytotoxic support. Although this immune remodelling is therapeutic for MS, it may impair host defence mechanisms, potentially increasing susceptibility to infections and reducing vaccine efficacy. Therefore, long-term immunological monitoring is advised for people undergoing anti-CD20 treatment.

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Immunocompromised host: Infections and Therapy

P 119 ITB SCREENING AND TREATMENT IN IATROGENICALLY IMMUNE-DEPRESSED PATIENTS: A MONOCENTRIC RETROSPECTIVE EXPERIENCE (2021-2024)

M. Ticozzelli^{1,2}, L. Pezzati², F. Bassani², G. Canavesi², M. Rigoni^{1,2}, M.P. Bissanti^{1,2}, A.M. Tshishimbi^{1,2}, D. Bernacchia², S. Rusconi^{1,2}, G. Paganì²

¹Università degli Studi di Milano, Milano, Italy, ²SC Malattie Infettive, ASST Ovest Milanese, Ospedale di Legnano, Legnano, Italy

Background: In recent years, the use of immunodepressants or immunomodulators, in particular monoclonal antibodies, has expanded into a broad spectrum of immune-mediated inflammatory diseases.

Due to their efficacy and safety profile, these therapies are commonly used as a first or second-line therapy. Their novelty and widespread use bring new challenges for infectious disease experts, both in screening and prophylaxis strategies, and in the management of breakthrough infections. These specificities require a tailored clinical approach, prioritizing individual risk factors, type and duration of therapy, potential drug-drug interactions, and specific underlying medical needs.

Therefore, a specialized outpatient clinic dedicated to iatrogenic immunosuppression (ID) was opened in 2021, mainly focusing on immunological and pharmacological prophylaxes and tubercular infection (TBI) treatment.

Material and Methods: The objective of our study was to describe and evaluate pharmacological interventions in iatrogenically immunocompromised patients. We retrospectively enrolled all patients followed up from the start of the outpatient clinic (August 2021) to the end of 2024. For each patient, we recorded demographics, characteristics of the underlying disease and treatment history, risk factors for TBI, vaccines, prophylaxis, and treatment suggested by our clinic, and laboratory follow-up. Data were analyzed using standard methods; continuous variables are presented as median and IQR, discrete variables as N (%).

Results: During the study period, 78 outpatients were followed in our clinic (Table 1).

Six patients (8%) were not previously screened for TBI at baseline and underwent TB screening only after initiating immunomodulatory/immunosuppressive treatment (Table 2).

Two patients developed active tubercular disease during the period of our study: one had a previously negative IGRA test and had a possible contact with an active tuberculosis while on adalimumab, while the other had not been tested previously due to immunosuppression.

Data also indicate that TBI prophylaxis is well-tolerated: among 34 treated patients, common adverse events (AE) were mild-moderate (Grade 1 or 2, n=15; 44.1%), with four treatment discontinuations (elevated transaminases and gastrointestinal intolerance), with complete resolution upon treatment withdrawal. We recorded no severe (grade ≥3) AEs during the period of our study.

Conclusions: This study identifies a remaining gap in applying TBI screening among high-risk patients who are eligible for immunosuppression. Universal screening should be mandatory for all ID subjects, regardless of geographical origin or previously known risk factors. Annual re-evaluation should be considered for high-risk patients and treatment should be proactively recommended unless contraindications are present, given the high tolerability profile.

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Immunocompromised host: Infections and Therapy

P 120 MARIBAVIR BEYOND REFRACTORY/RESISTANT CMV INFECTION: A MONOCENTRIC EXPERIENCE

L. Loiacono, I. Abbate, E. Cimini, R. Lionetti, E. Biliotti, F. Iacomì, F. Maggi, G.P. D'Offizi

INMI L. Spallanzani, Rome, Italy

Background: Cytomegalovirus (CMV) infection is the main infectious complication that negatively affects the outcome of solid organ transplantation. While ganciclovir/valganciclovir (GCV/VGCV) and foscarnet (FOS) represent the standard first-line therapies, their clinical utility is frequently limited by significant toxicities, specifically myelosuppression and nephrotoxicity. Maribavir (MBV) is a recently approved UL97 kinase inhibitor indicated for refractory or resistant CMV infections. Due to its superior tolerability profile, MBV also emerges as a valuable off-label therapeutic option for patients experiencing clinical intolerance to conventional first-line agents.

Methods: We performed a retrospective analysis of CMV reactivation/infection in liver transplant recipients at INMI L. Spallanzani (January 2023 – July 2025). A preemptive prevention strategy for CMV infection/reactivation was adopted. Patients requiring a switch from first-line GCV (initiated at viral loads of at least 10,000 IU/mL) to MBV due to toxicity were analyzed in depth.

Results: A total of 107 patients were included in the analysis median age 60 (IQR 55-65); 83% male. Pre-transplant CMV-IgG positivity was present in 89.7% of recipients, and 82% received grafts from CMV-IgG-positive donors. Post-transplant CMV replication occurred in 56% of patients, mainly due to reactivations (90%). No severe CMV-related disease was observed. All patients were receiving standard immunosuppressive therapy, including steroids. GCV/VGCV were used as initial therapy. Four cases (6.6%) were treated off-label with MBV due to intolerance to first-line drugs, rather than for the presence of resistance or refractoriness as per the technical indication. Among patients receiving MBV (Table 1), 2 were CMV serologically matched (D+/R+) and 2 were mismatched (D+/R-) with their donors; 2 patients experienced rejection, 1 patient had gram-negative sepsis, and 1 patient had both rejection and gram-negative sepsis. Patients with rejection needed steroid therapy at high doses. I.V GCV was used in three patients and oral VGC in one and all of them developed severe myelosuppression with neutropenia (<1000 cells/mm³), unresponsive to growth factors. MBV was started at a median CMV DNA of 4159 (IQR 2596-9345) IU/ml and led to effective viral control and hematological recovery. One relapse after MBV discontinuation was successfully retreated with VGC.

Discussion: GCV/VGCV-induced neutropenia frequently complicates CMV management, potentially exacerbating the risk of graft rejection and secondary infections. Liver transplant recipients are particularly vulnerable due to hypersplenism-related myelosuppression. In this high-risk cohort, MBV's favorable hematological profile suggests its role as a proactive alternative to conventional therapy, potentially mitigating treatment-limiting toxicities beyond current regulatory labeling. These findings warrant validation through prospective, multicenter studies.

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Immunocompromised host: Infections and Therapy

P 121 PNEUMOCYSTIS JIROVECII PNEUMONIA IN THE ART ERA: DIFFERENCES BETWEEN HIV AND NON-HIV IMMUNOCOMPROMISED PATIENTS IN A REFERRAL CENTER

S. De Giorgi¹, G.M. Leanza¹, B. Allegretti¹, L. Lucarelli¹, M. Chiuchiarelli², F. Frondizi², R. Torelli³, B. Fiori³, A. Sanfilippo⁴, A. Cingolani^{1,2}, C. Torti^{1,2}

¹Dipartimento di Sicurezza e Bioetica-Sezione di Malattie Infettive, Università Cattolica del Sacro Cuore, Roma, Italy, ²UOC Malattie Infettive-Dipartimento Scienze Mediche e Chirurgiche, Fondazione Policlinico Universitario A.Gemelli IRCCS, Roma, Italy, ³Dipartimento di Scienze di Laboratorio ed Ematologiche, Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma, Italy, ⁴Dipartimento di Scienze Biotechnologiche di Base, Cliniche Intensivologiche e Perioperatorie, Università Cattolica del Sacro Cuore, Roma, Italy

Background: In the antiretroviral therapy (ART) era, *Pneumocystis jirovecii* pneumonia (PJP) has become uncommon among people living with HIV (PWH) receiving effective treatment, while its burden has progressively shifted toward patients with non-HIV-related immunosuppression. This epidemiological transition challenges HIV reference centers, which increasingly manage opportunistic infections across a broader spectrum of immunodeficiency.

Methods: We conducted a single-center retrospective observational cohort study including all adult patients with microbiologically confirmed *Pneumocystis jirovecii* pneumonia (PJP) diagnosed between 2021 and 2024 at a tertiary referral center. Demographic characteristics, type of immunosuppression, comorbidities, clinical severity at diagnosis, treatment strategies, and in-hospital outcomes were collected and compared between PWH and non-HIV immunocompromised patients. Clinical severity was assessed using the SOFA score and oxygen requirement at diagnosis. Univariate and multivariate logistic regression analyses were performed to identify factors independently associated with in-hospital mortality.

Results: A total of 127 patients were included; 18% were PWH and 82% had non-HIV-related immunosuppression. Almost all PWH were ART-naïve at PJP diagnosis, with a median CD4 count of 16 cells/mm³. Compared with PWH, non-HIV patients were significantly older (median age 63 vs 44 years, $p < 0.001$) and had a higher burden of comorbidities, including hematologic malignancies, solid organ or stem cell transplantation, autoimmune diseases, and chronic corticosteroid exposure. Disease severity at presentation was markedly greater in the non-HIV group, with higher SOFA scores (median 7 vs 4, $p < 0.001$), greater oxygen requirements, more frequent need for invasive mechanical ventilation, and higher ICU admission rates. Overall in-hospital mortality was 39%, significantly higher among non-HIV patients compared with PWH (38% vs 4.3%). At multivariate analysis, SOFA score >3 was independently associated with increased mortality (OR 42.0, 95% CI 5.26–336.1, $p < 0.001$), whereas adjunctive corticosteroid therapy was independently protective (OR 0.27, 95% CI 0.10–0.67, $p = 0.005$).

Conclusions: In this cohort, non-HIV immunocompromised patients with PJP had higher in-hospital mortality than PWH. However, non-HIV status was not independently associated with in-hospital mortality after multivariate adjustment. SOFA score was the main predictor of adverse outcome, while adjunctive corticosteroids were independently protective, supporting their role in reducing mortality also in non-HIV patients. These data stress the need for early recognition and optimized care, particularly in non-HIV patients.

Table 1, table 2

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Immunocompromised host: Infections and Therapy

P 122 RETROVIRUSES 2.0: UNMASKING HIV-1/HTLV-1 COINFECTION IN A WOMAN WITH AIDS-DEFINING CONDITIONS AND ELEVATED CD4+ COUNTS. INSIGHTS FROM BRAZIL

G. Catalano¹, J. Souza Silva², L. Batista³, F. Carmo³, A. Castagna^{1,4}, P. Cinque⁴, J.E. Vidal^{2,5}

¹Vita-Salute San Raffaele University, Milan, Italy, ²Neurology Service, Emílio Ribas Institute of Infectology, São Paulo, Brazil, ³Emílio Ribas Institute of Infectology, São Paulo, Brazil, ⁴IRCCS San Raffaele Scientific Institute, Milan, Italy, ⁵Hospital das Clínicas, Faculty of Medicine, University of São Paulo, São Paulo, Brazil

Background: Human immunodeficiency virus (HIV) and human T-lymphotropic virus (HTLV) are related retroviruses sharing transmission routes and targeting CD4 T cells, causing depletion and clonal proliferation, respectively. This report describes the case of a woman living with HIV who discontinued antiretroviral therapy (ART) and was hospitalized for AIDS-defining conditions despite presenting with long-term elevated CD4 cell count.

Case Presentation: A 40-year-old woman living in São Paulo, Brazil has been HIV-positive since 2014. Despite poor adherence to ART with tenofovir disoproxil fumarate, lamivudine, and ritonavir-boosted darunavir (TDF/3TC/DRV/r) and detectable viral loads (median of 45,448 copies/mL), her CD4 counts remained elevated (median 1,268 cells/mm³). [Table 1] In September 2025, she was hospitalized at the Emilio Ribas Infectious Disease Hospital in São Paulo, Brazil, for dyspnea, fever, 15 kg weight loss, dysphagia, night sweats, psychomotor slowing, and disorientation. At admission, CD4 cell count resulted 1,046 cells/mL and HIV viral load 527,000 copies/mL; cryptococcal antigen, syphilis, hepatitis B, and C serologies resulted negative, and plasmatic CMV DNA was 83 copies/mL. The physical examination revealed severe wasting syndrome, extensive oral candidiasis and diffuse skin lesions, initially treated empirically for Herpes Zoster infection which later on were unmasked as severe scabies. Concerning the pulmonary symptoms, negative sputum smear and rapid molecular test for Mycobacterium tuberculosis resulted negative; community-acquired pneumonia was diagnosed and successfully treated. Brain imaging revealed multiple cortico-subcortical lesions with eccentric contrast enhancement, consistent with active cerebral toxoplasmosis for which she received specific antiparasitic treatment with corticosteroids and resumed ART. A control neuroimaging showed unequivocal improvement of initial brain lesions. Given the elevated CD4 count despite severe AIDS-defining illness and considering the local epidemiology, HTLV-1 infection was suspected; serology was performed and confirmed by western blot. HTLV-1 proviral load was 1 cell/10⁶ peripheral blood mononuclear cells (PBMC) and lymphocyte basal proliferation was 3.3% (reference range 0.9–4.4%). After clinical stabilization, she was discharged on ART and secondary prophylaxis.

Conclusions: HIV-1/HTLV-1 coinfection can cause artificially elevated CD4 counts, complicating timely immunological assessment, prophylaxis, and treatment. Given its association with reduced survival and increased mortality, systematic retroviruses screening and prompt ART are essential both in endemic and non-endemic settings, particularly given global mobility. Despite low HTLV-1 proviral load and limited basal lymphocyte proliferation, additional mechanisms likely contributed to immunosuppression. Reliable biomarkers are needed to accurately monitor immune function and guide management in this population.

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Immunology and Inflammation

P 123 CAN ROUTINE HEMOCYTOMETRIC INDICES BE USED AS PROXIES FOR IMMUNE ACTIVATION MARKERS IN PEOPLE LIVING WITH HIV?

S. Vita¹, M. Guardiani², A. Carraro², A. Gasperin³, M.A. Zingaropoli², L. Ansaldo³, G. Mancarella³, F. Dominelli², F. Mengoni², C.M. Mastroianni², R. Marocco³, C. Del Borgo³, M. Lichtner¹

¹Department of Neurosciences, Mental Health, and Sense Organs, NESMOS, Sapienza University of Rome, Rome, Italy, ²Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ³Infectious Diseases Unit, SM Goretti Hospital, Sapienza University of Rome, Latina, Italy, ⁴Department of Molecular Medicine, Sapienza University of Rome, Rome, Italy

Background: In people living with HIV (PLWH), hematological inflammation indexes derived from routine blood counts—such as the Systemic Immune-Inflammation Index (SII), neutrophil-to-lymphocyte ratio (NLR), and platelet-to-lymphocyte ratio (PLR)—reflect persistent immune activation despite effective antiretroviral therapy [Madzime 2021]. Elevated NLR has been associated with increased mortality and cardiovascular risk, while PLR and SII have also been linked to adverse clinical outcomes [Quiros-Roldan 2016; Sun 2025]. These inexpensive and widely available biomarkers may therefore help improve inflammatory risk stratification in PLWH [Obeagu 2024].

Methods: This observational study included 47 unique PLWH. Demographic and treatment characteristics were calculated using one record per patient, while laboratory parameters represented repeated measurements obtained from the same individuals at different time points over one year. Systemic inflammation indexes (SII, SIRI, NLR, PLR, MLR) were calculated from routine blood counts. Immune activation was assessed by CD38 and HLA-DR co-expression on CD4⁺ and CD8⁺ T cells (CD4DR38 and CD8DR38), while immunosenescence was evaluated through CD28/CD57⁺ expression on CD4⁺ and CD8⁺ T-cell subsets. Associations between inflammation indexes and immunological parameters (CD4, CD8, CD4/CD8 ratio, activation and senescence markers) were analyzed using Spearman's rank correlation (rs), with Benjamini–Hochberg false discovery rate correction (FDR).

Results: Forty-seven PLWH receiving effective ART were included (Table 1). A total of 180 laboratory samples were analyzed. Significant associations were mainly observed with CD8 T-cell counts. Inverse correlations were found between CD8 and multiple inflammation indexes, including PLR (rs = -0.358), SII (rs = -0.294), MLR (rs = -0.290), NLR (rs = -0.287), and SIRI (rs = -0.217), all remaining significant after FDR correction. No significant correlations were observed between inflammation indexes and absolute CD4 counts or CD4/CD8 ratio after adjustment.

Modest positive correlations were detected between SII (rs = 0.209, p = 0.0049) and NLR (rs = 0.191, p = 0.010) and CD4 activation (CD4DR38), both retaining statistical significance after FDR correction. No consistent associations were observed with CD8 activation markers or with immunosenescence markers (CD28/CD57⁺ subsets). Overall, the magnitude of correlations was modest (all rs < 0.40).

Conclusions: Systemic inflammation indexes derived from routine blood counts are associated with CD8 T-cell levels and markers of immune activation in PLWH, whereas no relationship was observed with immunosenescence markers. Although modest, these findings suggest that such indexes may reflect ongoing immune activation in treated HIV infection. Given their availability and low cost, they may represent complementary tools alongside established immunological parameters but cannot replace them in routine clinical practice.

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Immunology and Inflammation

P 124 DIFFERENT CLINICAL AND VIRO-IMMUNOLOGICAL EVOLUTION OF HIV-1 INFECTION IN TWO LONG-TERM NON-PROGRESSOR PATIENTS WHO SHARED THE SAME VIRUS

L. Salmoni¹, S. Martini¹, A. Russo^{1,2}, N. Cuomo³, A. Raddi³, M. Starace¹, C. Minichini¹, M. Pisaturo¹, N. Coppola¹

¹Department of Mental and Physical Health and Preventive Medicine, University of Campania "Luigi Vanvitelli", Naples, Italy, ²Department of Life Science, Health, and Health Professions Link Campus University, Rome, Italy, ³UOC Microbiologia e Virologia, Azienda Ospedaliera Speciaistica dei Colli Monaldi-Cotugno-C.T.O., Napoli, Italy

Background: Long-Term Non-Progressors (LTNP) are a rare category of patients, characterized by a stable CD4+ count and persistently low levels of HIV-RNA in the absence of antiretroviral therapy. The factors determining the maintenance or loss of such an immuno-virological balance are not yet fully understood. We present the case of a heterosexual couple in which both partners are HIV+ LTNP. The two patients, although infected with the same virus (as shown by phylogenetic analysis), have shown over time a divergent clinical and viro-immunological evolution.

Methods: Clinical, virological, and immunological data were collected retrospectively. The following were analyzed: biochemical and metabolic parameters, plasma viremia values (HIV-RNA), CD4+ count, comorbidities, and clinical course. Furthermore, genotyping was performed by PCR, as well as phylogenetic analysis and evaluation of HIV-DNA with Sanger sequencing of the pol gene.

Results: The couple, initially followed regularly with check-ups every four months, discontinued follow-up three years ago due to moving abroad, without undergoing further investigations or taking antiretroviral therapy. Upon returning to our center at the beginning of 2025, a different viro-immunological trend was observed in the two patients: the man still showed stable CD4+ values (545 cells/ μ L; 16.2%; CD4/CD8 ratio 0.2) and low viremia, while the woman presented with a high viral load and a marked reduction in CD4+ (61 cells/ μ L; 14%; CD4/CD8 ratio 0,3). During subsequent investigations, the woman was also diagnosed with breast cancer and thyroid carcinoma. At this point, we promptly initiated antiretroviral therapy in both patients. The woman was treated with a triple combination of bicitgravir/emtricitabine/tenofovir alafenamide, and the man with a dual therapy of dolutegravir/lamivudine. In both, a rapid suppression of viral replication and a progressive immunological recovery were observed, although slower in the woman, who started from lower CD4+ levels, as was predictable.

Discussions: The case demonstrates incontrovertibly that the same virus had different dynamics over time in the two LTNP patients observed, and that the evolution of the disease depends on an unstable balance between HIV and the immune system.

Immunology and Inflammation

P 125 DOWNREGULATION OF CD8+CD38+DR+ EXPRESSION ON T CELL AFTER 10-YEAR OF PERSISTENT AND FULLY SUPPRESSIVE HIV THERAPY

D. Ripamonti¹, L. Castellani², L. Comi¹, S. Venturelli¹, G. Cavazza³, N. Galizzi¹, D. Valenti⁴, F. Zoboli¹, A. Paganì⁵, F. Crippa¹, A. Francavilla⁴

¹Infectious Diseases Unit, ASST Papa Giovanni XXIII, Bergamo, Italy, ²Immunohematology and Transfusion Medicine. Department of Transfusion Medicine and Hematology, ASST Papa Giovanni XXIII, Bergamo, Italy, ³School of Medicine and Surgery, University of Milan, Milan, Italy, ⁴Bergamo Hospital Research Foundation – ETS (FROM), Bergamo, Italy, ⁵Servizio Farmacia, ASST Papa Giovanni XXIII, Bergamo, Italy

Background: Despite the significant treatment-related immune recovery in people with HIV (PWH), immune activation persists even after long term effective therapy. We explored the effect of HIV treatment on the downregulation of the co-expression of HLA-DR and CD38 on CD8+ T-lymphocytes, as markers of immune activation and disease progression, after 10 years of optimal virological control.

Methods: Retrospective study at a single centre in Northern Italy, in ART-naïve PWH who achieved plasma HIV RNA persistently <50 copies/ml (tested at least once per year, with blips <200 c/ml allowed) for 10 consecutive years since starting. The determination of CD4+, CD8+ counts and the percentage of CD8+CD38+HLA-DR+ T-lymphocyte were performed at least yearly by automated flow cytometry carried out on fresh peripheral blood. Demographic data, blood tests and HIV regimens were retrieved from the electronic database. Adherence to ARVs was assessed by refill pharmacy reports. Cox regression was used to assess factors associated to CD8+CD38+DR+ T-cell percentages reduction below 10% at year 10.

Results: A total of 218 PWH naïve to ARVs were enrolled in the study. Males were 173 (79%), median (IQR) age was 51 (47-60) years, 206 (94%) were Caucasians. Median (IQR) baseline CD4+, CD8+ and CD4+/CD8+ ratio were 379 (237-498) cells/ml, 1069 (668-1583) cells/ml and 0.32 (0.22-0.49), while median (IQR) baseline HIV RNA was 42,150 (10,390-157,000) copies/ml, respectively. At study entry, median (IQR) CD8+CD38+DR+ percentage was 32 (23-44). One or more comorbidities were present in 138 (63%) subjects. HBsAg+, HBeAb+ and HCMV+ were present in 7, 20 and 70%, respectively. Initial regimens were NNRTI-, PI- or INSTI-based in 53, 27 and 20%, respectively. At year 10, median (IQR) CD4+ and CD4+/CD8+ ratio increased to 934 (719-1209) cells/ml and 0.97 (0.7-1.35), respectively, while median (IQR) CD8+ and CD8+CD38+DR+ T-cell were 935 (703-1277) cells/ml and 10 (7-15) percentages, respectively. Such percentages increased to year 10, after the initial decline over the first 5 years. Among baseline HIV RNA and CD4 count, current age and number of comorbidities, CMV IgG+, HBeAb+ and statin use, only initial high CD8+CD38+DR+ percentages were associated to a lower probability to achieve values below 10% at year 10.

Conclusions: In subjects with full virological control over 10 years, CD8+CD38+DR+ T cell percentages decreased significantly since baseline, although they tended to re-increase from year 5 to year 10, confirming the ongoing immune-activation as a major gap of persistent effective therapy.

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Immunology and Inflammation

P 126 EXTRACELLULAR VESICLES FROM ACTIVATED V δ 2 T CELLS INHIBIT VIRAL REPLICATION AND ENHANCE ADAPTIVE ANTIVIRAL IMMUNITY IN IMMUNOCOMPROMISED HOSTS

V. Bordon¹, F. Guarracino¹, F. Marocco², L. Quattrocchi², A. Lorusso¹, A. Minutolo³, S. Garbo², C. Matteucci³, D. Pagliara¹, F. Galaverna¹, C. Battistelli¹, P. Merli¹, F. Locatelli¹, C. Agrati¹

¹Bambino Gesù Children's Hospital, IRCCS, Rome, Italy, ²Sapienza University of Rome, Rome, Italy, ³University of Rome Tor Vergata, Rome, Italy

Introduction: V δ 2 T cells are promising immunotherapy candidates for approaches of immunotherapy due to their unique pleiotropic functions; they were recently shown to enhance antiviral protection in hematopoietic stem cell transplantation (HSCT) recipients via innate effector activity and modulation of virus-specific adaptive T-cell response. Extracellular Vesicles (EVs) have recently attracted growing scientific interest due to their potential wide clinical applications as carriers of immunomodulatory and antitumor activity. This study was aimed to investigate the antiviral function of EVs released by activated V δ 2 T cells (V δ 2-EVs).

Methods: The direct antiviral activity was measured quantifying the frequency of MRC5-CMV infected cells pretreated with V δ 2-EVs by flow cytometry. The immunomodulatory antiviral activities of V δ 2-EVs were evaluated by in vitro assays in healthy donors and HSCT recipients, quantifying the IFN γ production and proliferation of CMV-specific T cells by Elispot and flow cytometry respectively. Moreover, the molecular cargo of V δ 2-EVs was characterized through miRNA sequencing. Validation of miRNA target genes was performed by qRT-PCR in CMV-MRC5 -infected cells as well as in monocytes cells pre-treated with V δ 2-EVs.

Results: V δ 2-EVs efficiently inhibit in vitro CMV replication, reducing the frequency of CMV-infected cells (% decrease, V δ 2-EVs median= 14% (IQR 5-39) vs control-EVs, median= 0.8 (IQR 0-3). Moreover, V δ 2-EVs are taken up by myeloid cells and were able to activate antigen-presenting cells, leading to an increased frequency of CMV-specific T cells, as measured by IFN- γ production (n=6, p < 0.05). Priming of peripheral blood from pediatric HSCT recipients with V δ 2-EVs enhanced the expansion capacity of CMV-specific T cells (n=10, p < 0.05), suggesting their potential to support the proliferation of virus-specific T cells even in immunocompromised patients (% CD3+Ki67+ after CMV stimulation, V δ 2-EVs median= 15.3% (IQR 3-26) vs control, median= 7.8 (IQR 1-24). Finally, the analysis of miRNA content in V δ 2-EVs highlighted the enrichment of several miRNAs targeting genes involved in key processes of antiviral response such as SOCS1.

Conclusions: Altogether, this study provides new insights into the antiviral functions of V δ 2-EVs and underscores their potential as modulators of antiviral immunity in both healthy and immunocompromised hosts, providing a proof of concept for their potential clinical application.

Immunology and Inflammation

P 127 IL-6 AS A POTENTIALLY USEFUL MARKER IN THE MANAGEMENT OF PEOPLE LIVING WITH HIV: LINKS TO IMMUNE ACTIVATION AND INFLAMMATION

A. Gallicchio¹, A. Bianchi¹, A.M. Carleo², F.M. Fusco³, A. Guida², A. Marocco¹, V. Rizzo², M. Sardo¹, E. Manzillo¹

¹UOC Malattie infettive dell'immunodepresso dell'immigrazione, ²UOC Malattie infettive dell'immunodepresso e medicina di genere, ³UOC Malattie infettive dell'immunocompromesso, Ospedali dei Colli Cotugno, Napoli, Italy

Background: Persistent immune activation and inflammation contribute to non-AIDS morbidity in people living with HIV (PLWH) despite durable viral suppression. Interleukin-6 (IL-6) is an upstream mediator of chronic inflammation and predicts non-AIDS events. We explored whether IL-6 could help recognize a clinically relevant inflammatory phenotype in routine care.

Methods: We conducted a single-center retrospective observational study (Jan 2023–Jan 2026) including 849 PLWH in follow-up. Participants were stratified by IL-6 (≤ 6 vs >6 pg/mL, IL-6 >20 pg/mL was explored within IL-6 >6). Clinical, demographic, metabolic and HIV-related variables were collected, including C reactive protein (CRP), soluble IL-2 receptor (sIL-2R), fibrinogen, D-dimer, homocysteine, Framingham risk score and carotid ultrasound evidence of endothelial damage.

Results: IL-6 was >6 pg/mL in 175/849 (20.6%) and >20 pg/mL in 21/849 (2.5%). Viral suppression and ART coverage were high across strata, suggesting that IL-6 elevations occurred despite optimal virological control (Table1). The IL-6 >6 group clustered with features consistent with an “inflammaging” profile: older age, longer time since diagnosis and lower CD4 counts, together with higher sIL-2R, fibrinogen and D-dimer. In parallel, cardiometabolic risk markers (homocysteine and Framingham score) were higher and carotid endothelial damage was more frequent (61.9% vs 53.2%), supporting a link between IL-6–driven inflammation and vascular injury (Table1). Notably, median CRP did not differ across groups, indicating that IL-6 may detect inflammatory activity not reflected by CRP (Table1). Individuals with IL-6 >20 showed a further step-up in inflammatory markers, suggesting a potentially higher-risk subset.

Conclusions: In this real-life cohort, IL-6 stratification identified a distinct low-grade inflammatory phenotype not detected by CRP and associated with biomarkers of immune activation, coagulation and vascular damage. IL-6 may therefore complement standard labs to refine inflammation-related risk profiling and to prompt a more focused assessment of non-AIDS comorbidities (e.g. cardiovascular evaluation) in PLWH with durable viral suppression. Prospective studies should clarify clinical cut-offs, longitudinal trajectories and whether IL-6–guided strategies improve outcomes.

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Immunology and Inflammation

P 128 IMPACT OF STING1 VARIANTS ON IMMUNE RECOVERY AND METABOLIC BURDEN IN OLDER PEOPLE LIVING WITH HIV ON LONG-TERM ANTIRETROVIRAL THERAPY

I. Zanella^{1,2}, C. Fornari³, F. Cesanelli^{1,2}, G. Tiecco^{1,2}, E. Zacchi^{1,2,4}, C. Bouros^{1,2,4}, S. Codenotti¹, R.M. Ferraro⁵, A. Franzani¹, S. Giliani^{1,5,6}, E. Quiros-Roldan^{1,2,7}

¹Università degli Studi di Brescia, Brescia, Italy, ²ASST Spedali Civili di Brescia, Brescia, Italy, ³CIMEC, University of Trento, Rovereto, Italy, ⁴University of Bologna, Bologna, Italy, ⁵Angelo Nocivelli Institute for Molecular Medicine, Università degli Studi di Brescia, Brescia, Italy, ⁶National Center for Gene Therapy and Drugs Based on RNA Technology-CN3, Brescia, Italy, ⁷Karolinska Institutet, Stockholm, Sweden

Background: Persistent innate immune activation under long-term antiretroviral therapy (ART) contributes to heterogeneous immune recovery and metabolic burden in people living with HIV (PLWH). The STING1/TMEM173 pathway regulates type I interferon signaling and may differentially modulate immune tone. We investigated whether common STING1 variants independently influence long-term immuno-metabolic phenotypes in older PLWH on ART.

Methods: We conducted a cross-sectional study including 60 PLWH aged >50 years, on ART for ≥10 years, with stable virological suppression. Exclusion criteria included psychiatric disorders, use of anticholinergic/psychotropic drugs, and high alcohol intake. Participants were genotyped for STING1 HAQ and R232H variants. Detailed clinical and laboratory data were collected. Multiple hierarchical comparisons were performed: WT/WT vs any polymorphism; HAQ/AQ/A carriers vs WT; H232 carriers vs WT; and HAQ/AQ-only vs H232-only carriers. Parametric or non-parametric tests and ANCOVA adjusted for HIV disease duration were used.

Results: Overall, 32% of PLWH were heterozygous for the HAQ haplotype and 21.7% for the R232H variant. Genotype prevalences are shown in Table 1. No significant differences emerged when comparing WT/WT versus carriers of any polymorphism. Compared to WT/WT, HAQ/AQ/A carriers had fewer comorbidities ($p=0.016$) and lower prevalence of dyslipidemia ($p=0.009-0.020$), with lower mean CD4⁺ T-cell counts ($p=0.010$). In contrast, H232 carriers showed significantly higher CD4⁺ T-cell counts when compared to ... ($p=0.006-0.028$). A trend toward increased comorbidity burden was observed ($p=0.061$). [GT3.1]HAQ/AQ-only carriers had significantly lower CD4⁺ counts ($p=0.002$) but fewer comorbidities ($p=0.044$) and lower dyslipidemia prevalence ($p=0.026$) when compared to H232-only carriers. The H232/H232 subject maintained spontaneous viral control for >30 years without ART, with high CD4⁺ counts (656 cells/mL in November 2025), CD4/CD8 ratio > 1 into advanced age. Conversely, the HAQ/HAQ individual exhibited moderate CD4⁺ counts (477 cells/mL and CD4/CD8 0.85 in November 2025) and infectious susceptibility in early disease but limited long-term metabolic burden under ART. [GT4.1]Main findings are displayed in Table 2.

Conclusions: STING1 variability differentially shapes long-term immune and metabolic phenotypes in ART-treated PLWH. H232 carriers are associated with better immune control yet a possible increased metabolic burden[GT5.1], while HAQ/AQ/A carriers show lower CD4 levels with a protected metabolic profile. The absence of differences in global WT vs carrier comparisons indicates that STING1 variability does not define a uniform clinical category. Homozygous cases further support this pattern of immune-metabolic balance. These findings support a role for host innate immune genetics as an independent modulator of long-term ART response and clinical heterogeneity.

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Immunology and Inflammation

P 129 VIROLOGICAL, IMMUNOLOGICAL, AND METABOLIC CHARACTERISTICS OF WOMEN LIVING WITH HIV: THE CD4/CD8 RATIO AS A MULTIDIMENSIONAL BIOMARKER OF HEALTH

S. Spampinato^{1,2,3}, G. Scuderi⁴, E. Castro^{1,2}, M. Di Rosa⁵, A. Marino^{1,2}, E. Venanzi Rullo³, M. Paternò Raddusa¹, R. Bruno¹, N. Villari¹, G. Bruno¹, A. De Vito⁶, G. Madeddu⁶, B. Cacopardo^{1,2}, B.M. Celesia¹, P. Fagone⁴, G. Nunnari^{1,2}

¹ARNAS Garibaldi Hospital, Unit of Infectious Diseases, Catania, Italy, ²University of Catania, Department of Clinical and Experimental Medicine, Catania, Italy, ³University of Messina, Department of Clinical and Experimental Medicine, Messina, Italy, ⁴Department of Biomedical and Biotechnological Sciences, University of Catania, Catania, Italy, ⁵Department of Biomedical and Biotechnological Sciences, Human Anatomy and Histology Section, School of Medicine, University of Catania, Catania, Italy, ⁶Infectious Diseases Unit, University of Sassari, Sassari, Italy

Background: In the ART era, the clinical focus for women living with HIV (WLWH) has shifted toward aging and the management of non-AIDS-defining comorbidities. The CD4/CD8 ratio is an integrative biomarker reflecting immune activation and exhaustion. This retrospective study on WLWH evaluated the associations between the CD4/CD8 ratio, residual viremia, and metabolic health.

Material and Methods: This is a retrospective, cross-sectional, descriptive-analytical study involving a cohort of 187 consecutive WLWH followed at the Infectious Diseases Unit of the ARNAS Garibaldi Nesima Hospital (Catania, Italy). The ethic committee approved the SHiNe-SHiC study. All participants provided written informed consent. Clinical, social, epidemiological and laboratory data were analyzed. The Kruskal-Wallis test was used for group comparisons, followed by Bonferroni post-hoc tests. Spearman's rank correlation evaluated the clinical-laboratory associations. Statistical significance was set at $p < 0.05$.

Results: The current mean CD4+ T-cell count was 700.3 ± 361 cells/ μ L (range: 40–2008), the mean CD8+ count was 714.1 ± 326 cells/ μ L (180–2002). The average CD4/CD8 ratio was 1.13 ± 0.6 (range: 0.05–3.68) (Table 1). 18.7% of WLWH had a ratio < 0.5 , 25.1% between 0.5 and 1.0, and 56.1% had normalized their ratio (> 1.0). A ratio < 0.5 was significantly associated with a lower CD4 nadir ($p = 0.002$) (Fig. 1), higher viral Zenith ($p < 0.001$) (Fig2). Triglyceride levels were significantly higher in the low-ratio group (134 ± 78 mg/dL) compared to those with a ratio > 1.0 (92 ± 50 mg/dL, $p = 0.013$). Similarly, the atherosclerotic index (Total Chol/HDL) was more unfavorable in the < 0.5 group (4.8 ± 1.2 vs. 3.6 ± 0.9 , $p = 0.008$) (Fig3). Creatinine levels were significantly higher in patients with a ratio < 0.5 (0.84 ± 0.2 mg/dL) compared to those with a normalized ratio (0.72 ± 0.14 mg/dL, $p = 0.046$).

The cohort was stratified into 5 viral load groups. G1 VL not detectable (55.9%), G2 VL < 20 copies/mL (23.1%), G3 VL 20–50 copies/mL (10.2%), G4 VL 50–200 copies/mL (4 5.9%), G5 VL > 200 copies/mL (4.8%). WLWH with CD4/CD8 ratio below 0,5 had higher viral loads compared to those with CD4/CD8 ratio > 0.5 and > 0.1 and CD4/CD8 ratio > 1 ($p < p = 0.0001$) (Fig4). WLWH with residual viremia (20–200 cps/mL) showed a significantly lower CD4 nadir ($p = 0.002$). The CD4 nadir also showed significant differences ($p = 0.002$), with lower values in patients belonging to the categories with higher viremia.

Conclusion: CD4/CD8 ratio $< 0,5$ is a valuable tool for identifying WLWH at higher risk for cardiovascular and renal diseases. Of note, CD4/CD8 ratio $< 0,5$ correlates with higher current VL, viral Zenith and low CD4 Nadir. The latter also correlated with higher residual viremia.

WLWH with CD4/CD8 ratio $< 0,5$ not only have an unfavorable immunological profile and higher viral loads but also an increased risk of metabolic related conditions, requiring a strict clinical, pharmacological and laboratory control.

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Long Acting and new therapeutic scenarios

P 130 96-WEEK METABOLIC AND IMMUNOLOGICAL OUTCOMES OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN TUSCANY: REAL-WORLD DATA FROM LAHIV

F. Lagi¹, M. Maruotto², M. Piccica³, G. Sarteschi⁴, A. Pampaloni⁵, B. Menichini⁶, B. Rossetti⁷, M. Sambo⁸, S. Costarelli⁹, C. Bianco¹⁰, M. De Gennaro¹¹, S. Modica¹¹, P. Corsi¹, M. Pozzi¹, M. Turco¹², M. Tumbarello⁸, S. Trevisan², C. Costa³, B. Adriani⁵, C. Nencioni⁷, D. Messeri⁶, D. Tacconi¹⁰, S. Sanf⁹, A. Vincenti⁴, L. Pisano¹², F. Bartalesi³, A. Bartoloni^{1,2}

¹SOD Malattie Infettive, Azienda Ospedaliero-Universitaria Careggi, Università degli Studi di Firenze, Italy, ²Dipartimento di medicina sperimentale e clinica, Università degli Studi di Firenze, Italy, ³SOC Malattie Infettive, Ospedale Santa Maria Annunziata, USL Toscana Centro, Italy, ⁴UO Malattie Infettive, Nuovo Ospedale Apuane, USL Toscana Nord-Ovest, Italy, ⁵UO Malattie Infettive, Azienda Ospedaliera Prato, USL Toscana Centro, Italy, ⁶SOS Malattie Infettive, Azienda Ospedaliera Pistoia, USL Toscana Centro, Italy, ⁷UO Malattie Infettive, Azienda Ospedaliera Grosseto, USL Toscana Sud-Est, Italy, ⁸Azienda Ospedaliero-Universitaria Siena, Università degli Studi di Siena, Italy, ⁹UO Malattie Infettive, Azienda Ospedaliera Livorno, USL Toscana Nord-Ovest, Italy, ¹⁰UOC Malattie Infettive, Azienda Ospedaliera Arezzo, USL Toscana Sud-Est, Italy, ¹¹UO Malattie Infettive, Azienda Ospedaliera Lucca, USL Toscana Nord-Ovest, Italy, ¹²Section of Dermatology, Health Sciences Department, University of Florence, Florence, Italy

Background: Following its approval in Italy in June 2022, the long-acting intramuscular combination of cabotegravir (CAB) and rilpivirine (RPV), administered every two months, became the first long-acting regimen available for the maintenance of virological suppression in people living with HIV-1. This study aimed to assess longitudinal changes in renal, metabolic, and immunological parameters—specifically creatinine, total cholesterol, triglycerides, CD4 count, and CD4/CD8 ratio—from baseline to week 96 after switching to CAB+RPV

Methods: We performed a multicenter, observational study involving 11 HIV centers across Tuscany, encompassing both academic referral centers and non-academic HIV clinics, in order to reflect routine real-world clinical practice. Eligible participants were virologically suppressed adults (≥ 18 years; HIV-RNA < 50 copies/mL) who initiated CAB +RPV and had available measurements of creatinine, total cholesterol, triglycerides, and CD4 parameters at baseline and during follow-up. Individuals with incomplete laboratory data or inadequate follow-up were excluded. Dyslipidemia was defined as total cholesterol > 200 mg/dL and/or triglycerides > 150 mg/dL.

Results: At week 96, 72 people living with HIV were included in the analysis. The majority were male ($n=59$, 81.9%), with a median age of 52 years (IQR 42–59). At baseline, approximately 40% of participants met criteria for dyslipidemia, although only 27.8% were receiving statin therapy. Four participants started statin therapy during follow-up. Over 96 weeks of follow-up, no significant variations were detected in total cholesterol, triglyceride levels, CD4 count, or CD4/CD8 ratio (Figure 1). A statistically significant reduction in serum creatinine was observed; however, the magnitude of change was small and unlikely to be clinically meaningful. Among the cohort, 28 individuals presented with a CD4/CD8 ratio < 1 at the time of switching, despite a long history of antiretroviral therapy (median duration 10 years, IQR 7–13 [7–16]). In this subgroup, a modest but statistically significant increase in the CD4/CD8 ratio was noted at week 96 (mean increase $+0.03$; 95% CI 0.05–0.15; $p=0.049$). No comparable change was observed in participants with a baseline CD4/CD8 ratio > 1 .

Conclusion: These real-world data, collected over a two-year follow-up, suggest that switching to long-acting CAB +RPV is associated with a metabolically neutral profile in virologically suppressed individuals managed in routine clinical practice. A modest but statistically significant improvement in the CD4/CD8 ratio was observed among participants with a ratio < 1 at baseline, in line with findings from recent real-world reports [1]. Larger studies with longer follow-up are needed to confirm these results and to better identify patient subgroups that may derive greater immunological benefit from long-acting antiretroviral therapy.

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Long Acting and new therapeutic scenarios

P 131 BACK TO ORAL: IMMUNOVIROLOGICAL STABILITY AFTER LONG-ACTING CAB/RPV INTERRUPTION

C. Grillo, A. Narducci, F.R.P. Ieva, S. Ferrara, I.F. Bottalico, A. Vergori, S. Lo Caputo

Infectious Diseases Unit, A.O.U. Policlinico Foggia, University of Foggia, Foggia, Italy

Background: Long-acting cabotegravir/rilpivirine (CAB/RPV LA) represents an important advance in HIV management by reducing daily pill burden and supporting adherence. However, real-world data on immunovirological outcomes after virological failure (VF) or treatment discontinuation (TD) are still scarce. We evaluated immune and virological outcomes following CAB/RPV LA interruption in a real-life cohort.

Materials and Methods: We conducted a retrospective analysis of 84 people with HIV (PWH) receiving CAB/RPV LA followed at our clinic. PWH experiencing VF or TD were included. Immunological parameters (CD4, CD8, CD4/CD8 ratio), genotypic resistance testing at VF were collected. The cumulative probability of VF/TD was assessed by Kaplan–Meier analysis. VF was defined as two consecutive HIV RNA measurements >200 copies/mL or a single value >1000 copies/mL after prior virological suppression (VS).

Results: Among 84 PWH [71.4% male; median age of 52.5 (IQR 43.8–61.0)], median CD4 at switch was 856 cells/mm³ and CD4/CD8 1.11. Heterosexual intercourse was the most frequent transmission risk factor (42.4%); median BMI was 25.5 kg/m² (22.2–28.8) (Table 1).

9/84 (10.7%) PWH experienced VF (n=4) or TD (n=5) with a median duration of CAB/RPV LA of 8 months (5–18).

In TD cases, immunological parameters remained stable through follow up (FU); all maintained VS and switched to oral ART (DTG/3TC, n=3; ABC/3TC/DTG, n=1; BIC/F/TAF, n=1) (Table 2).

In VF cases, median CD4 at failure was 715 cells/mm³ (609–814), CD4/CD8 ratio was 0.69 (0.28–1.12), and HIV-RNA 4.89 log₁₀ copies/mL (3.92–5.52). A non-significant immunological change was observed at last FU.

Overall, mean changes from VF/TD to last FU were +163.8 CD4 cells/mm³ (95% CI –109.8 to +437.4) and +0.25 in CD4/CD8 (95% CI +0.03 to +0.47).

All VF cases (subtype B) had no prior INSTI/NNRTI failure; emergent resistance mutations occurred in three, involving NNRTI and/or INSTI. After switch to oral therapy (BIC/F/TAF, n=3, DRV/c/F/TAF, n=1) all achieved viral re-suppression within a median of 4 months (3.25–4.5) (Table 3).

No correlation emerged between LA duration and time to re-suppression ($p=0.00$; $p=1.000$). The cumulative probability of VF/TD was 1.4% at 6 months, 5.8% at 12 months, and 8.9% at 24 months (Fig.1).

Conclusions: In this real world cohort, CAB/RPV LA interruption was not associated with meaningful immunological change and VF/TD events were infrequent.

With resistance-informed management, viral re-suppression after switch to oral ART was consistently achieved. Although limited by small numbers, these findings suggest that carefully monitored transition back to oral therapy after CAB/RPV LA can be managed without major immunovirological compromise.

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Long Acting and new therapeutic scenarios

P 132 CARDIOMETABOLIC OUTCOMES AND BODY COMPOSITION IN PWH SWITCHING TO LA-CAB/RPV VS. ORAL 2DR REGIMENS

F. Calandra Buonauro¹, J. Milic¹, S. Generoso¹, E. Delmonte¹, U. Calvi¹, F. Buffagni¹, M. Menozzi², G. Cuomo², G. Mancini², M. Menozzi², C. Mussini¹, G. Guaraldi¹

¹Modena HIV Metabolic Clinic, University of Modena and Reggio Emilia, Modena, Italy, ²Infectious Diseases Clinic, Azienda Ospedaliero-Universitaria Policlinico of Modena, Modena, Italy

Background: Real-world data on cardiometabolic changes in people with HIV (PWH) switching to long-acting cabotegravir + rilpivirine (LA CAB+RPV) are still limited. The objective of the study was to explore cardiometabolic outcomes and body composition in PWH switching to LA or remaining on oral two-drug regimens (2DR).

Methods: This was a retrospective longitudinal cohort study including antiretroviral therapy (ART)-experienced PWH. PWH were divided into two groups (LA CAB+RPV) and oral dual therapy (2DR). Inclusion required at least one pre- and post-switch evaluation in the LA group or at least two evaluations in oral 2DR group. 2DR regimens included the following combinations: DTG/3TC, DTG/RPV, DOR + DTG, DOR + RAL, RPV + RAL. PWH receiving boosted protease inhibitors or obsolete regimens such as EFV or ETR based therapies were excluded. Baseline was the last visit before switch and follow-up the last available post-switch visit. The primary outcome was change in body composition including visceral adipose tissue (VAT), lean mass, fat mass, and femoral and lumbar bone mineral density (BMD). Secondary outcomes included waist-to-height ratio, body mass index (BMI), insulin resistance assessed with HOMA-IR, and liver steatosis measured with CAP.

Results: A total of 617 people with HIV were included, 69 in the LA CAB+RPV group and 548 in the oral 2DR group. Median age was 53 years (IQR 47–60) in the LA group and 58 years (IQR 52–62) in the oral 2DR group. Most participants were male, accounting for 81% in the LA group and 72% in the oral 2DR group, while females represented 19% and 28%, respectively. At baseline, cardiometabolic parameters including BMI, waist circumference, lipids, HOMA-IR, VAT, liver steatosis, and SCORE2 were overall comparable between groups, with no major differences observed. Median follow-up time was 18 months (Q1, Q3: 4.5, 24.1). Changes from baseline to follow-up were largely comparable between groups (Table 1). No significant between-group differences were observed in BMI, waist circumference, HOMA-IR, HbA1c, lipid profile, visceral adipose tissue, total fat mass, total lean mass, femoral BMD, SCORE2, CAP, or liver stiffness (all $p > 0.05$). A greater reduction in lumbar spine BMD was observed in LA-CAB + RPV group compared with oral 2DR ($\Delta -0.01 \pm 0.04$ vs 0 ± 0.06 , $p = 0.043$). Overall, cardiometabolic and body composition trajectories were similar between groups over follow-up.

Conclusions: Switching to LA CAB+RPV showed a cardiometabolic profile comparable to oral 2DR, with no meaningful differences in adiposity, metabolic parameters, or liver outcomes. The small reduction in lumbar spine BMD observed with LA therapy was statistically significant but of limited magnitude. Overall, these real-world data support LA CAB+RPV as a metabolically neutral switch strategy in ART-experienced PWH.

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Long Acting and new therapeutic scenarios

P 133 DURABILITY IN REAL LIFE: THERAPEUTIC PERSISTENCE AND INJECTION ADHERENCE WITH LONG-ACTING CABOTEGRAVIR/RILPIVIRINE

C. Conti¹, M. Trizzino^{1,2}, C. Gioè^{1,2}, G. D'agati¹, S. Urso¹, A. Cascio^{1,2}

¹Università degli Studi di Palermo, Italy, ²Unità di Malattie Infettive e Tropicali, AOU Policlinico "P. Giaccone", Palermo, Italy

Background: Long-acting (LA) antiretroviral therapy with cabotegravir and rilpivirine represents a paradigm shift in the management of people living with HIV. Beyond virological efficacy, a key aspect in the evaluation of LA regimens is durability, defined as the ability of a therapeutic strategy to maintain virological suppression over time while remaining clinically manageable, well tolerated, and persistently adopted by patients in real-world settings. In LA regimens, durability also encompasses adherence to scheduled injections and the organizational sustainability of care pathways.

Materials and Methods: Observational cohort study of people living with HIV (PLWH) receiving cabotegravir and rilpivirine, followed at the outpatient clinic of the UOC Infectious and Tropical Diseases, AOU "P. Giaccone", Palermo. To evaluate the durability of LA cabotegravir/rilpivirine, viro-immunological parameters were collected every 6 ± 2 months from a clinical database to assess maintenance of virological suppression, while adherence to injection appointments was monitored using Google Calendar to quantify punctuality and delays relative to the prescribed dosing windows.

Results: In our experience LA regimens demonstrated high durability over time, with sustained virological suppression in the majority of patients. Two consecutive measurements of viremia >200 copies/mL were documented in a single case, followed by re-establishment of virological suppression. Among 112 patients who initiated LA cabotegravir/rilpivirine, only 11 (9,8%) returned to their previous oral therapy, primarily due to injection site reactions (n = 9) or logistical challenges (n = 2). Adherence to injection schedules was generally high: among the 1005 injections administered during follow-up, 966 (96.11%) were performed within the ±7-day dosing window; only one case required repetition of the booster dose due to a 53-day delay, without clinically significant impact on virological outcomes (Figure 1). The low discontinuation rate and maintained suppression illustrate that the regimen is durable in real-world conditions, integrating patient adherence, tolerability, and clinical management.

Conclusions: Over a three-year observation period, long-acting cabotegravir/rilpivirine demonstrates high durability, evidenced by persistent therapy, low discontinuation, and sustained virological suppression. These data highlight that, with appropriate clinical and organizational support, LA therapy offers a sustainable and effective long-term treatment option, confirming its potential to improve both patient experience and long-term adherence in real-world HIV care.

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Long Acting and new therapeutic scenarios

P 134 ESCALATING TO "TARGET NOT DETECTED": A LONGITUDINAL ANALYSIS OF ENHANCED VIROLOGIC DEPTH, RENAL DYNAMICS, AND IMMUNOLOGICAL RECOVERY IN PWH SWITCHING TO CAB/RPV

S. Spampinato^{1,2,3}, A. De Vito⁴, D. Bivona¹, G. Migliazzo¹, A. Marino¹, R. Fontana del Vecchio⁵, A. Franco⁵, A. Montineri⁶, C. Fasca⁶, S. Sofia⁷, G. Pantò⁷, C. Calì⁸, R. Bruno¹, N. Villari¹, C. Iacobello⁶, B. Cacopardo¹, B.M. Celasia¹, A. Albanese⁹, G.F. Pellicano³, E. Venanzi Rullo³, G. Madeddu⁴, G. Nunnari¹

¹Unit of Infectious Diseases, ARNAS "Garibaldi Nesima" Hospital, Department of Clinical and Experimental Medicine, University of Catania, Catania, Italy, ²Department of Biomedical and Biotechnological Sciences, University of Catania, Catania, Italy, ³Unit of Infectious Diseases, "G. Martino" University Hospital, Department of Clinical and Experimental Medicine, University of Messina, Messina, Italy, ⁴Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ⁵Unit of Infectious Diseases, Umberto I Hospital, ASP, Siracusa, Italy, ⁶Unit of Infectious Diseases, "G. Rodolico-S. Marco" University Hospital, University of Catania, Catania, Italy, ⁷Unit of Infectious Diseases, AOE "Cannizzaro", Catania, Italy, ⁸Unit of Infectious Diseases, ASP Ragusa, Ragusa, Italy, ⁹Unit of Infectious Diseases, "Papardo" Hospital, Messina, Italy

Background: Long-acting injectable antiretroviral therapy with cabotegravir and rilpivirine (CAB/RPV) represents a novel treatment strategy for people with HIV (PWH), offering an alternative to daily oral therapy. Real-world data on its effectiveness, safety, and metabolic impact remain limited, particularly in heterogeneous clinical cohorts

Methods: We conducted a retrospective observational analysis of the SHINE and SHIC cohorts, including all PWH who initiated CAB/RPV. Baseline demographic, clinical, and laboratory characteristics were collected. Continuous variables were reported as median and interquartile range (IQR), while categorical variables were expressed as frequencies and percentages. Longitudinal changes in laboratory parameters between baseline and follow-up at 6 and 12 months were assessed using the Wilcoxon signed-rank test for paired samples. Statistical significance was defined as a two-sided p-value <0.05.

Results: A total of 201 individuals were included. Median age was 49.6 years (IQR 38.4–56.5), with a median duration of HIV infection of 10 years (IQR 6–17). Median nadir CD4 count was 385 cells/mm³ (IQR 214–560), and median zenith HIV RNA was 51,100 copies/mL (IQR 7,910–195,000). The majorities of participants were male (84.6%), and most were men who have sex with men (52.7%). 94.5% were of Italian nationality.

Dyslipidemia (35.3%) and hypertension (25.9%), anxiety (17.4%) and depression (13.9%) were the main comorbidities. Regarding smoking status, 46.3% were current smokers and 6.5% former smokers (Table 1).

Prior antiretroviral regimens were dolutegravir-based (24.9%) and bictegravir-based regimens (23.4%). 81.0% of PWH were receiving an integrase inhibitor (16.4% oral induction).

During follow-up, treatment discontinuation was rare (n=5), mainly due to CNS adverse events (40%), transfer of care (40%), and virological failure (20%).

Creatinine levels significantly decreased from baseline at both time points (p<0.001). The CD4/CD8 ratio significantly increased (p<0.001 at both time points). CD8 cell counts significantly decreased over time (p=0.027 at 6 months and p=0.013 at 12 months). HDL cholesterol increased significantly at 12 months (p=0.001), whereas glucose levels showed a modest increase at 12 months (p=0.027). No significant changes were observed in lipid profile, liver enzymes, glucose levels (Table 2).

Target Not Detected status (TND) was achieved by a substantial 79.1% of PLWH at 12 months, a significant increase from the baseline of 69.6% (Fig 1).

Conclusions: In conclusion, switching to CAB/RPV significantly improved virologic outcomes over 12 months, with the proportion of patients reaching TND increasing from 69.6% to 79.1%. This virologic success was accompanied by robust immunological recovery, evidenced by an improved CD4/CD8 ratio, and a favorable metabolic profile characterized by higher HDL levels and reduced creatinine.

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Long Acting and new therapeutic scenarios

P 135 HBV REPLICATIVE ACTIVITY BY HIGHLY-SENSITIVE DROPLET-DIGITAL-PCR IN PWH SWITCHING TO CAB/RPV-LA THERAPY: PRELIMINARY RESULTS FROM THE OBILART STUDY

A. Magnapera¹, G. Piromalli², I. Grossi¹, M. Ranzenigo², E. Messina², S. D'Anna¹, R. Lolatto², T. Clemente², L. Piermatteo¹, S. Bagaglio², R. Salpini¹, M.A. Pisaturo⁴, V. Svicher¹, H. Hasson^{2,3}, A. Castagna^{2,3}

¹University of Rome Tor Vergata, Department of Biology, Rome, Italy, ²Unit of Infectious Diseases, IRCCS, Ospedale San Raffaele, Milan, Italy, ³Vita-Salute San Raffaele University, Milan, Italy, ⁴Department of Mental and Physical Health and Medicine prevention, University of Campania L. Vanvitelli Naples, Italy

Background: With the rising adoption of TDF/TAF-sparing long-acting (LA) regimens, accurate identification of anti-HBc-positive/HBsAg-negative PWH who can safely switch therapy is crucial. This study evaluates the kinetics of highly sensitive serum HBV markers to assess viral replication risks and optimize clinical management within this specific participant population.

Material and Methods: The OBILART study (NCT06728917) is an ongoing prospective multicentre study that has so far included 8 anti-HBc-positive/HBsAg-negative PWH treated with FTC/3TC/TAF-containing therapy for >12 months and switching to LA-therapy (CAB/RPV-LA) (48 Weeks). Highly-sensitive droplet-digital-PCR (ddPCR) was used to quantify cryptic HBV-DNA (ranging between 1 and 10 IU/ml) and HBV-RNA (LLOQ: 2 IU/ml) at the time of starting LA (T0) (N=8) and at week 12 (N=5) (T1). HBV reactivation was defined as an HBV-DNA >10 IU/ml during LA treatment. Clinical and demographic characteristics at baseline were expressed as median and interquartile range (IQR), frequency (%) and showed in Table 1. HIV-RNA undetectability was defined as <50 copies/ml.

Results: Eight subjects who had started therapy with long-acting HIV drugs that were not active against HBV were enrolled in the study. Observation of PWH at week 12 did not detect hepatitis B virus reactivation (HBV-DNA<10 IU/ml) and all subjects showed HIV-RNA levels < 50 copies/ml.

At T0, despite FTC/3TC/TAF-containing therapy pressure, 3 out of 8 (37.5%) participants showed evidence of HBV replicative-activity, as attested by positivity to cryptic HBV-DNA (1, 1.9 and 4.9 IU/ml), while all PWH were negative to HBV-RNA. Conversely, negativity to HBV-DNA (suggesting a silent HBV reservoir) was detected in 62.5% (5/8) of PWH. Among the 5 PWH with a sample available at T1, 2/4 (50%) with a silent HBV-reservoir at T0 resulted positive to HBV-DNA or -RNA, suggesting the acquisition of an active HBV-reservoir after FTC/3TC/TAF-containing therapy withdrawal. In particular, one acquired positivity to both HBV-DNA and RNA (1.3 and 3.3 IU/ml), while the other increased HBV-DNA up to 9.6 IU/ml. Furthermore, one PWH maintained signs of HBV replicative activity also at T1, indicating persistent HBV replication (albeit minimal).

Conclusions: Preliminary results showed that HBV replicative activity, detected by ddPCR, may occur under FTC/3TC/TAF-containing therapy and after switching to CAB/RPV-LA therapy.

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Long Acting and new therapeutic scenarios

P 136 IS ISOLATED HBcAb A CONTRAINDICATION TO SWITCHING TO LONG-ACTING CABOTEGRAVIR/RILPIVIRINE?

L. Pagnucco¹, R. Bruno^{1,2}, R. Gulminetti¹

¹Infectious Diseases Unit, Medical Department, Fondazione IRCCS Policlinico San Matteo University of Pavia, Pavia, Italy, ²Department of Medicine, Surgical, Diagnostic and Pediatric Science, University of Pavia, Pavia, Italy

Background: Cabotegravir/rilpivirine (CAB/RPV) is the first injectable combination antiretroviral therapy (cART) approved for clinical use. Although chronic hepatitis B virus (HBV) infection (HBsAg-positive) is a contraindication to this regimen, its use in individuals who are hepatitis B core antibody (HBcAb) positive only has raised concerns regarding the potential risk of HBsAg reactivation.

Isolated anti-HBc positivity, defined by the absence of hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (HBsAb) in the presence of HBcAb, is recognized as a potential risk factor for occult HBV infection and for de novo HBV reactivation, reflecting two distinct pathogenic mechanisms. In the first scenario, HBsAg loss occurs following antiviral therapy or spontaneous viral clearance, without subsequent seroconversion to HBsAb. In the second scenario, HBsAb are initially detectable but later decline to levels below the threshold of assay detection.

Material and Methods: PWH attending the Outpatients Infectious Diseases Clinic in Pavia are routinely screened for HBV and, if not immune, vaccination is offered.

In subjects eligible for CABO/RPV switch, HBV serology and ALT and, in the case of isolated HBcAb-positivity, HBV-DNA were performed at baseline. In subjects with HBcAb+, HBV-DNA was monitored at months 1, 3, 5, and then every 6 months during routine blood sampling.

Results: Among the 172 PWH who switched to CABO/RPV, 55 were HBV vaccinated at baseline, 54 were not immune to HBV, 33 had serology compatible with previous exposure (HBsAb+, HBcAb+) with a protective HBsAb titer (>10), and 30 were HBcAb+. Of the HBcAb subjects, 24 were receiving anti-HBV drugs (8 TAF/FTC and 24 3TC) and 8 were not.

All HBcAb subjects had negative HBV DNA at baseline, and no cases of HBV reactivation were documented during follow-up.

Conclusions: The presence of isolated HBcAb does not constitute a contraindication to switching to cabotegravir/rilpivirine; however, subjects should undergo careful clinical and virological evaluation prior to the switch.

In HBcAb-positive subjects with no data on the course of HBV in the past medical history, the assessment of additional virologic markers, such as HBV-RNA, can further support clinical decision-making and increase confidence when considering a switch to CAB/RPV.

Long Acting and new therapeutic scenarios

P 137 LONG-ACTING ANTIRETROVIRAL THERAPY IN FRAGILE PWH FOLLOWED IN THE HOME CARE ASSISTANCE: REAL-LIFE EXPERIENCE IN A HIGHLY CLINICALLY COMPLEX COHORT

C. De Vivo¹, S. Colaiuda¹, G. Lenzi¹, F. Lombardi^{1,2}, G. Cucinotta¹, F. La Fata¹, A. Carbone¹, L. Spina¹, P.F. Salvo^{1,2}, G. Baldin^{1,2}, C. Torti^{1,2}, S. Di Giambenedetto^{1,2}

¹Dipartimento di Sicurezza e Bioetica, Sezione di Malattie Infettive, Università Cattolica del Sacro Cuore, Rome, Italy, ²Dipartimento di Scienze Mediche e Chirurgiche, UOC Malattie Infettive, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy

Background: Poor adherence to oral antiretroviral therapy remains a major challenge in the management of people with HIV (PWH), particularly among those with high clinical and social frailty, where multiple comorbidities and polypharmacy increase the risk of failure and loss to follow-up.

In this context, Long-acting therapy with cabotegravir and rilpivirine (LA-CAB/RPV) could determine an advantage. This therapy, when delivered by Home Care Assistance (HCA), could represent an optimal strategy in improving adherence and virological control in complex and vulnerable PWH. This study evaluates the effectiveness and durability of LA-CAB/RPV in a cohort of frail PWH followed by HCA.

Methods: This monocentric, retrospective observational study includes suppressed PWH who switched to LA-CAB/RPV and followed over time by our HCA. We described demographic and clinical characteristics and evaluated any treatment discontinuation (TD), including virologic failures (VF) (i.e. two consecutive HIV-RNA >50copies/mL or a single HIV-RNA >200copies/mL).

Results: The study included 18 PWH (Table 1): 50% (9/18) were male and 83% (15/18) Caucasian, with sexual transmission reported in 44% (8/18) of them. Median age was 59.5 (IQR 48–70) years and 66% (12/18) of them had a CD4 cell count <200 cells/mm³ at diagnosis.

All participants presented high clinical frailty due to comorbidities and polypharmacy, 28% (5/18) had a history of injecting drug use and 44% (8/18) experienced at least one previous VF.

In a median follow-up period of 14 (IQR 7–37) months, 88% (16/18) of PWH maintained virologic suppression: among them, 19% (3/16) experienced virologic blips at very low copies (<56 HIV-RNA cps/mL). TDs occurred in 50% (9/18) of PWH: 33% (3/9) due to clinician's decision, 22% (2/9) due to VF and 44% (4/9) due to death. All deaths were HIV-unrelated and reflected the underlying clinical frailty of the cohort.

In a subgroup of PWH who reached 1 year of follow-up (n=14), when comparing the median CD4 cell count at baseline and after 1 year, no significant variation was observed (p=0.245). Specifically, 57% (8/14) showed an increase of CD4 cell count of at least 10%, the remaining 43% (6/14) did not: among these, 66% (4/6) experienced a median decline of 27%.

Conclusions: In clinically complex PWH, traditionally underrepresented in clinical trials, LA-CAB/RPV demonstrated a relatively good rate of virologic suppression and overall immunologic stability.

Despite the high-risk profile of this cohort, when integrated into a structured home-based care model, LA-CAB/RPV could be an effective and innovative strategy to address adherence barriers, management difficulties and clinical challenges in vulnerable PWH at risk of TD and loss to follow-up.

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Long Acting and new therapeutic scenarios

P 138 MANAGEMENT OF ACUTE HBV INFECTION DURING LONG-ACTING ANTIRETROVIRAL THERAPY: A CLINICAL CASE OF SUCCESSFUL ORAL BRIDGE THERAPY AND RESUMPTION AFTER HBSAG SEROCONVERSION

C. Parrotta, A. Zuppiroli, M. Giglia, L. Calza, P. Viale

Infectious Diseases Unit, IRCCS S. Orsola Hospital, University of Bologna, Bologna, Italy

Background: Long-acting (LA) cabotegravir plus rilpivirine (CAB+RPV) has transformed HIV clinical management. However, its lack of anti-HBV activity represents a significant vulnerability, particularly in the context of rising Sexually Transmitted Infections (STIs) among people living with HIV (PLWH). Currently, the use of this injectable regimen in the presence of active HBV infection is considered off-label, as its clinical indications are restricted to patients without chronic or acute hepatitis B. Consequently, there is a lack of standardized clinical pathways for managing incident HBV acquired while on LA therapy and for defining the criteria to safely resume injections after the acute phase.

Material and Methods: We report the clinical course of a 40-year-old virologically suppressed male who developed acute HBV as an incident STI four months after switching to CAB+RPV LA. Notably, the patient had been offered HBV vaccination and it was undergoing. Clinical monitoring included HIV-RNA, HBV-DNA, transaminases, and serological markers (HBsAg, HBeAg, anti-HBs). We evaluated the efficacy of a temporary switch to an oral regimen and the feasibility of returning to LA therapy following HBsAg loss.

Results: The patient started CAB+RPV LA in April 2024. In July 2024, acute HBV was diagnosed (HBsAg+, HBeAg+, HBV-DNA 1,524,714 IU/mL, ALT 455 U/L). Upon notification of the HBV infection, the patient was immediately transitioned from the injectable regimen to oral bridge therapy with bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) to ensure both HIV suppression and potent anti-HBV activity. Under the new INSTI based regimen, the patient maintained HIV suppression and achieved complete HBV-DNA clearance. By January 2026, stable HBsAg loss and anti-HBs seroconversion (>10 mIU/mL) were documented, representing a "functional cure"; notably the early introduction of nucleoside analogues in acute HBV is sometimes debated due to its potential to reduce the probability of spontaneous HBsAg seroconversion. On January 26, 2026, the patient successfully resumed CAB+RPV LA. No virological failure or hepatic flares were observed during the treatment transitions. **Conclusions:** This case demonstrates that incident HBV as an STI does not necessarily preclude the long-term use of injectable ART, though it highlights the critical importance of vaccine uptake in at-risk populations. A dynamic management strategy incorporating a temporary ART regimen with anti-HBV activity ensures virological safety during the acute phase. Stable HBsAg seroconversion serves as a definitive milestone for the safe re-introduction of NRTI-sparing LA regimens, effectively reconciling clinical safety with patient quality-of-life preferences.

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Long Acting and new therapeutic scenarios

P 139 OUTCOMES OF DUAL ANTIRETROVIRAL THERAPY (ART) REGIMENS IN ANTI-HBC CARRIERS: A COMPARATIVE ANALYSIS

A. Zuppiroli, M. Giglia, J.M. Faiella Marsengo, M. Munarini, L. Calza, P. Viale

Infectious Diseases Unit, IRCCS S. Orsola Hospital, University of Bologna, Bologna, Italy

Background: People living with HIV (PLWH) with isolated anti-HBc positivity who switch from triple-drug regimens containing anti-HBV agents (tenofovir, lamivudine) to dual ART lacking them present a theoretical risk of HBV reactivation (HBVr). This study compares immuno-virological, hepatic, and metabolic outcomes in anti-HBc carriers initiating either long-acting injectable dual ART (CAB/RPV) or comparable oral dual regimens.

Material and Methods: We conducted a retrospective study of anti-HBc positive outpatients switching between 2021 and 2024 from anti-HBV active regimens to dual therapy (INSTI + NNRTI). Exclusion criteria included prior liver transplantation or discontinuation of long-acting (LA) therapy within two weeks of initiation. The cohort was divided into injectable and oral groups. Baseline (T0) and follow-up data (T1: 6 months; T2: 12 months) were assessed. Primary endpoints were HBVr incidence and sustained virological suppression (HIV-RNA <50 copies/mL); changes in hepatic, renal, and metabolic parameters were also evaluated.

Results: A total of 47 participants were included (median age 56 years; 85.1% male; median BMI 24.8 kg/m²). Median time since HIV diagnosis was 21 years (CD4 nadir: 215 cells/μL); 19.1% had a prior AIDS-defining event. Baseline characteristics were homogeneous, except for switch motivation: 100% of the injectable group switched for personal choice, 19.2% of the oral group switched due to clinical toxicity or renal disease.

After 24 weeks (T2), renal function was the only parameter showing a statistically significant difference in variation between the two groups (p=0.0398). In the CAB+RPV group, mean creatinine decreased slightly by 0.04 mg/dL. Conversely, the oral therapy group showed a mean creatinine increase of 0.05 mg/dL, more pronounced in those switching for clinical reasons (baseline creatinine: 1.35 mg/dL).

Immune function remained stable in both cohorts. All patients remained virologically suppressed. The injectable group showed a mean CD4 increase of 1.70 cells/mm³ (CD4/CD8 ratio: +2.03), while the oral group showed a mean CD4 increase of 9.07 cells/mm³ (CD4/CD8 ratio: +1.33).

Metabolic/hepatic parameters showed no significant changes (p>0.05). Total cholesterol increased by 0.80 mg/dL in the CAB+RPV group, with a 13.93 mg/dL decrease in the oral group (p=0.1042). No patients experienced HBV reactivation: no HBsAg reappearance, HBV DNA elevation, or significant ALT increases occurred. Hepatic markers remained stable, with mean Fib-4 variations of -0.05 and -0.04 respectively.

Conclusions: In this cohort, switching to dual ART without anti-HBV components was safe regarding HBVr risk and ensured optimal virological control. The higher creatinine levels in the oral group reflect baseline clinical profiles rather than a treatment-related decline. These findings confirm that both long-acting and oral dual therapies are viable and safe maintenance strategies for anti-HBc positive PLWH.

Long Acting and new therapeutic scenarios

P 140 REAL-WORLD EFFECTIVENESS AND TREATMENT PERSISTENCE OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN WOMEN LIVING WITH HIV

L. Pagnucco¹, M.V. Cossu², M. Matone², C. Mariani², R. Solidoro², M.A. Muslimani¹, A. Riva^{2,3}, R. Gulminetti¹

¹Infectious Diseases Unit, Medical Department, Fondazione IRCCS Policlinico San Matteo University of Pavia, Pavia, Italy, ²Department of Infectious Diseases - ASST FBF SACCO, Milan, Italy, ³DIBIC Luigi Sacco, University of Milan, Italy

Background: Long-acting injectable antiretroviral therapy with cabotegravir plus rilpivirine (CAB/RPV LA) represents a paradigm shift in the management of HIV-1 infection. Although phase III studies demonstrated non-inferiority compared with daily oral regimens, women remain underrepresented, limiting sex-specific conclusions. Considering that approximately 40,000 women are living with HIV in Italy, real-world data are essential to evaluate effectiveness, safety, and acceptability in this population. We evaluated virological outcomes and tolerability of CAB/RPV LA among women in routine clinical practice.

Materials and Methods: We conducted a multicenter retrospective cohort study including adult women living with HIV who switched from a stable oral antiretroviral regimen (Table 1) to CAB/RPV LA between October 2022 and December 2025. Eligible participants had documented viral suppression (HIV-1 RNA <50 copies/mL) for at least 6 months prior to switch. Demographic, clinical, and laboratory data were extracted from electronic medical records. Outcomes included maintenance of viral suppression, incidence of virological failure, treatment discontinuations and reasons for discontinuation. Treatment discontinuations were defined as permanent interruption of CAB/RPV LA for clinical or patient-related reasons; transfers of care were censored and not included in discontinuation analyses.

Results: A total of 122 women were included, with a median age of 51 years; a substantial proportion had BMI ≥ 30 kg/m² (Table 2). At week 48, 94.9% maintained virological suppression. Confirmed virological failure occurred in one participant, with no consistent association with BMI; but she successfully re-suppressed the virus by switching back to oral therapy with BIC/TAF/FTC. Excluding transfers of care, 17 women (13.9%) discontinued treatment. The most frequent reason for discontinuation was injection-site reactions (n=8), followed by HBsAg positivity (n=2), logistical challenges (n=1), patient preference (n=1), desire for pregnancy (n=1), and other causes (n=3). Two women became pregnant during follow-up and decide to continue CAB/RPV LA; they delivered while maintaining virological suppression, with no adverse maternal outcomes.

Conclusions: In this real-world multicenter cohort, long-acting CAB/RPV demonstrated high rates of virological maintenance, favourable tolerability, and good persistence among women. Effectiveness was consistent with pivotal trial data. Viral suppression was maintained in the two pregnancies observed during follow-up, providing preliminary real-world data in this setting. These findings reinforce the importance of generating sex-specific real-world evidence and support CAB/RPV LA as a valuable therapeutic option for women living with HIV.

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Long Acting and new therapeutic scenarios

P 141 REAL-WORLD ELIGIBILITY AND UPTAKE OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN A STRUCTURED SCREENING PROGRAM

L. De Martino, A. Lazzaro, L. Maddaloni, C. Falvino, R.C. Carafa, L. Santinelli, C. M. Mastroianni, G. d'Ettorre

Dipartimento di Sanità Pubblica e Malattie Infettive, Sapienza Università di Roma, Rome, Italy

Background: Long-acting cabotegravir/rilpivirine (CAB/RPV LA) is an alternative to daily oral antiretroviral therapy for virologically suppressed people living with HIV (PLWH). In routine practice, eligibility may depend not only on virological criteria but also on clinical history and practical factors. We report updated data from our structured screening program.

Methods: All virologically suppressed PLWH were evaluated for potential switch to CAB/RPV LA according to current guidelines. Clinical history, resistance profile, HBV serology, BMI, drug-drug interactions, ART regimen, and adherence were assessed before eligibility.

Results: A total of 107 PLWH were screened and 30 (28.0%) initiated CAB/RPV LA. At data cut-off, 27 (25.2%) remained on treatment. Confirmed virological failure occurred in 1 individual (0.9%), persistent low-level viremia requiring switch to BIC/TAF/FTC in 1 (0.9%), and treatment discontinuation due to injection-site pain in 1 (0.9%). Four individuals (3.7%) were scheduled to start therapy and four (3.7%) were still undergoing screening.

Baseline demographic, immunological, and virological characteristics were comparable between initiators and non-initiators (Table 1). No significant differences were observed in duration of HIV infection, CD4 parameters, HIV-RNA levels, BMI, HBV/HCV serostatus, or ART regimen at screening.

The most frequent reasons for non-initiation were personal or work-related deferral (n=36, 33.6%) and suboptimal adherence (n=16, 15.0%). Clinical exclusion criteria were identified in 17 individuals (22.1%), including resistance-associated mutations, persistent negative HBsAb despite vaccination, BMI >30 kg/m², and one relevant drug-drug interaction (Table 2).

Conclusions: In this real-world screening program, fewer than one in three screened PLWH initiated long-acting therapy. Uptake was mainly associated with adherence and practical considerations rather than immunovirological parameters. Careful evaluation of resistance history and patient motivation remains essential to optimize long-acting therapy implementation in routine clinical practice.

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Long Acting and new therapeutic scenarios

P 142 REAL-WORLD LONG-TERM OUTCOMES OF CABOTEGRAVIR/RILPIVIRINE Q8W WITH EXTENDED FOLLOW-UP

M.V. Cossu¹, D. Moschese¹, M. Matone¹, A. Giacomelli^{1,2}, P. Olimpia¹, A. Riva^{1,2}, A.L. Ridolfo¹, C. Gervasoni¹, A. Gori^{1,2,3}

¹Department of Infectious Diseases - ASST FBF SACCO; Milan, Italy, ²DIBIC Luigi Sacco, University of Milan; Milan, Italy, ³Centre for Multidisciplinary Research in Health Science (MACH), University of Milan, Milan, Italy

Background: Long-acting injectable cabotegravir/rilpivirine (CAB/RPV LAI) administered every 8 weeks (Q8W) is an established maintenance strategy for virologically suppressed people with HIV (PWH). While clinical trials have demonstrated sustained efficacy through 152 weeks, real-world data with longer follow-up remain limited. We evaluated long-term treatment persistence, injection adherence, and virological outcomes in routine clinical practice.

Methods: We conducted a retrospective observational study including virologically suppressed PWH who initiated CAB/RPV LAI Q8W at our center between October 2022 and September 2023, with follow-up through December 1, 2025. Treatment durability was assessed using Kaplan–Meier survival analysis, with treatment-related discontinuation as the event of interest. Transfer of care, pregnancy planning, and non-treatment-related deaths were censored. Injection adherence was evaluated by comparing observed versus expected dosing intervals. Virological outcomes included rates of viral suppression, virological blips, and confirmed virological failure.

Results: A total of 227 PWH were included (median age 51 years [IQR 42–60]; 24.7% female), with a median follow-up of 163 weeks (IQR 152–168); 213 patients (93.8%) reached ≥144 weeks of observation.

Treatment Persistence: Treatment-related discontinuation occurred in 20/227 patients (8.8%) (Table 1). Kaplan–Meier analysis showed sustained treatment persistence over time, with an estimated probability of remaining on therapy of 92.1% at week 144. Discontinuations were primarily driven by adverse events (n=8), injection fatigue (n=4), and clinical reassessment or other patient-related reasons (n=8).

Injection Adherence: Across 5,252 completed dosing intervals, 95.2% were administered within the protocol-defined window (±7 days from scheduled date). The remaining 4.8% (252) were delayed beyond this window: 4.3% by 8–14 days and only 0.5% by more than 14 days. No temporal deterioration in injection timing was observed.

Virological Outcomes: Virological suppression remained high, with 99.5% of patients suppressed at both week 96 (n=218) and week 144 (n=206). Twenty-four virological blips were documented in 20 individuals (8.8%); most were transient and did not require treatment modification. Two confirmed virological failures occurred (incidence rate: 0.4/100 person-years).

Conclusions: Over a median follow-up exceeding three years, CAB/RPV LAI Q8W demonstrated sustained treatment persistence, high adherence to injection schedules, and durable virological suppression in routine clinical practice. These real-world findings support the long-term feasibility and effectiveness of CAB/RPV LAI Q8W beyond clinical trial settings and confirm its durability in unselected patient populations.

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Long Acting and new therapeutic scenarios

P 143 SWITCHING TO LONG-ACTING CABOTEGRAVIR/RILPIVIRINE VERSUS MAINTAINING ORAL THERAPY IN VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV: A MULTICENTRE, REAL-LIFE COMPARISON

A. Palomba^{1,2}, M. Maccarrone², P.F. Salvo^{3,4}, A. Borghetti^{1,2}, A. Carbone⁴, M. Polidori^{1,2}, G. Baldin³, R. Cinelli^{1,2}, M. Falcone^{1,2}, S. Di Giambenedetto^{3,4}

¹Infectious Diseases Unit, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy, ²Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy, ³Dipartimento di Scienze Mediche e Chirurgiche, UOC Malattie Infettive, Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma, Italy, ⁴Dipartimento di Sicurezza e Bioetica, Sezione Malattie Infettive, Università Cattolica del Sacro Cuore, Roma, Italy

Background: Randomized trials demonstrated the non-inferior efficacy of long-acting cabotegravir plus rilpivirine (LA) versus oral regimens (OR), but comparison data from real-life are lacking.

Methods: This was a retrospective, observational study, including people with HIV (PWH) followed at two University Hospitals, who were offered LA after reaching viral suppression, and either agreed (study group) or refused (control group) this option. Other inclusion criteria were: negative HBsAg+ serostatus, written documentation of LA proposal and at least one HIV-RNA measurement after baseline (BL, i.e. the date of LA proposal for OR group, or the date of first LA assumption for LA group). We compared LA and OR concerning: 1) time to virological failure (VF, defined by either: one HIV-RNA $\geq$ 1000 cp/ml, 2 consecutive HIV-RNA $\geq$ 200 cp/mL or emergent resistance to study drugs at any HIV-RNA value) and time to treatment discontinuation for any cause (TD), assessed by Kaplan-Meier and log-rank test; 2) risk of detecting an HIV-RNA $>$ 50 copies/mL at 6, 12, 18 and 24 months after BL, estimated by pooled logistic regression; 3) trend in CD4-to-CD8 ratio at 6 and 12 months, evaluated by linear mixed models. An inverse-probability of treatment weight approach was used to adjust the effect of LA versus OR for the 2nd and 3rd study objective.

Results: Two hundred and twenty-one PWH were evaluated, 165 (74.7%) switching to LA, 56 (25.3%) refusing LA (mainly for logistic barriers). The two groups were comparable for most BL characteristics, as reported in table 1. During 8 months of median follow-up time, 4 and 0 VFs occurred with LA and OR (log-rank $p=0.292$), respectively, with an estimated probability of VF with LA of 2.3% at 12 months (95% CI 0.9-8.7). The only available genotypic test at VF revealed the E138K mutations to rilpivirine and no major mutations to integrase inhibitors. No differences emerged in rate of TD, with a probability of 9.7% (95% CI 5.4-17.2) and 7.3% (95% CI 2.8-17.3) with LA and OR, respectively (log-rank $p=0.875$). Of note, only 2 TD occurred for VFs in the LA, while other reasons were: death for unrelated cause (1), injection site reactions (2), toxicities (6), preference for oral therapy (1), unknown (1). All PWH discontinuing OR (4) switched to LA. The probability of detecting HIV-RNA $>$ 50 cp/mL over time was not different in the LA versus the OR group (weighted OR: 2.45, 95% CI 0.27-22.5; $p=0.428$). The CD4-to-CD8 ratio was stable in the OR group over 12 months, whereas a trend for increase at 12 months was evident in the LA group (time-treatment interaction B: +0.10, 95% -0.01; +0.22; $p=0.073$), that reached statistical significance in the group of PWH with BL CD4-to-CD8 in the lowest 50th centile (<1.1 ; time-treatment interaction B: +0.14, 95% CI 0.00-0.28; $p=0.049$).

Conclusions: LA was as effective as OR in virologically suppressed PWH. In the LA group, an improvement in CD4-to-CD8 ratio was also evidenced, that deserves further investigation.

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Long Acting and new therapeutic scenarios

P 144 SWITCHING TO LONG-ACTING REGIMENS IN PEOPLE WITH HIV: REAL-WORLD EXPERIENCE AND ANALYSIS OF THE 2023-2025 PERIOD IN AN ITALIAN HOSPITAL

M. D'Auria¹, N. Papa², V. Mattera Iacono², T. Di Caprio², M. Spatarella²

¹Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy, ²AORN - Ospedali dei Colli, Naples, Italy

Background: Long-Acting (LA) antiretroviral therapy represents a promising approach in the management of HIV infection, aiming to improve quality of life, reduce stigma, and foster adherence compared to daily oral therapy. This therapeutic strategy involves switching from an oral regimen to the bimonthly injectable combination of cabotegavir/rilpivirine. The present work evaluates retention in care and the efficacy of this switch, aiming to provide data to support its consolidation in clinical practice.

Materials and Methods: Data from patients on LA therapy, collected between December 2022 and September 2025, were extracted from the hospital pharmacy management system. Concurrently, in collaboration with six Infectious Diseases Units, the corresponding medical records were reviewed. A dedicated and secure database was created in compliance with current regulations to collect demographic (age, sex) and clinical variables, in order to evaluate baseline oral regimens, comorbidities, and the tolerability of the new treatment.

Results: A total of 164 patients (155 males, 9 females) with a mean age of 51 years were identified. The baseline oral regimens consisted of the following combinations: bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF); dolutegravir/lamivudine (DTG/3TC); dolutegravir/rilpivirine (DTG/RPV); and doravirine/lamivudine/tenofovir disoproxil (DOR/3TC/TDF). Specifically, 40% of People with HIV (PWH) switched from BIC/FTC/TAF, 34% from DTG/3TC, 18% from DTG/RPV, and 8% from DOR/3TC/TDF (Figure 1). The main reported comorbidities included: metabolic and nutritional disorders (49.3%), musculoskeletal conditions (10%), vascular diseases (11%), and coinfections with CMV, syphilis, and salmonellosis (26.7%). Psychiatric disorders were among the least represented comorbidities. Out of 164 PWH, 151 (92%) are currently still receiving LA treatment, whereas 13 (8%) discontinued the therapy (Figure 2). Specifically: 5 (3%) discontinued therapy due to adverse drug reactions (ADRs), 4 (2.4%) due to therapeutic failure, and 4 (2.4%) due to voluntary withdrawal. The ADRs leading to discontinuation were primarily injection site reactions (ISRs). Isolated episodes of transient post-injection systemic vasovagal reactions were also reported.

Conclusions: Real-world data demonstrate that LA therapy represents a highly effective and safe option in the treatment of HIV infection. A retention in care of 92%, coupled with a low therapeutic failure rate of 2.4%, supports the clinical robustness of this approach. Furthermore, LA therapy is associated with good compliance and tolerability among PWH. In conclusion, LA drugs for HIV emerge as a valid alternative to daily oral therapy, highlighting that careful patient selection and adequate follow-up are key factors in optimizing clinical outcomes.

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Long Acting and new therapeutic scenarios

P 145 THE ROLE OF RESISTANCE TESTING OF HIV-DNA IN PBMC WHEN SWITCHING TO LONG ACTING (LA) THERAPY: WHAT GUIDES CLINICAL DECISION?

S. Lerta^{1,2}, L. Pagnucco², G. Sangaletti^{1,2}, V.A. Villano^{1,2}, R. Gulminetti²

¹University of Pavia, Department of Clinical-Surgical, Diagnostic, and Pediatric Sciences, Pavia, Italy, ²Fondazione IRCCS Policlinico San Matteo, Division of Infectious Diseases, Department of Medical Science, Pavia, Italy

Background: Assessing eligibility for LA in PLWH without historical genotypic resistance data and clear ART history can be challenging. Genotypic resistance testing of HIV-1 DNA in peripheral blood mononuclear cells (PBMC) may be used to guide the decision in virologically suppressed PLWH.

Material and Methods: We conducted a retrospective analysis of adult PLWH attending our clinic between 1st October-29th November 2024, evaluating the proportion who met clinical criteria for LA therapy candidacy, and assessed the impact of resistance test (GRT) on PBMC-DNA on the decision-making process.

Results: Out of 403 PLWH attending our clinic, 216 (54%) lacked historical genotypic data about resistances. Of those, 164 (76%) met clinical criteria for LA therapy candidacy. GRT on PBMC-DNA was performed in 19 (11%): 3 PLWH (16%) exhibited resistance-associated mutations relevant to cabotegravir or rilpivirine, leading to contraindication to LA therapy. In the remaining 16 people (84%) without detected resistances, 3 changed their mind and didn't switch therapy.

Of 145 PLWH eligible for LA therapy who lacked both historical genotypic data and PBMC-DNA resistance test, 34 (23%), in absence of history of virological failure, started LA therapy anyways, 71 (49%) declared lack of interest in switching to LA, and 40 (28%) may be reevaluated in the following appointments.

On the other hand, 12 people who had old historical genotypic tests showing unfavorable genotypic mutations repeated PBMC-DNA assessment, resulting in a change in favor of eligibility in 3 cases.

Conclusions: According with DHHS 2025 guidelines, PBMC-DNA GRT, also considering the time elapsed since the last plasma RNA GRT exceeding 10 years, convinced us to start LA in these PLWH, albeit with careful virological monitoring. DNA GRT, although not recommended in routine clinical practice, could guide clinical decisions in virologically suppressed PLWH who consider switching to LA, especially in absence of historical data on resistance and with unknown therapeutic history.

Long Acting and new therapeutic scenarios

P 146 VIROLOGICAL FAILURE OR TRANSIENT VIREMIA? SPONTANEOUS RESUPPRESSION IN PATIENTS RECEIVING LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN THE ODOACRE MULTICENTRE COHORT

L. Bortolani¹, E. Altavilla¹, V. Racolta¹, A. Ciccullo³, G. Balducci², P.F. Salvo², M.V. Cossu⁴, A. Giacomelli⁴, A. Cervo⁵, G. Madeddu⁶, M. Fabiani⁷, F. Lagi⁸, F. Bassani⁹, C. Mussini⁵, S. Di Giambenedetto², G. d'Ettorre¹

¹Sapienza University of Rome, Rome, Italy, ²Cattolica University of Rome, Rome, Italy, ³Ospedale San Salvatore, L'Aquila, Italy, ⁴Ospedale Luigi Sacco, Milano, Italy, ⁵AOU di Modena, Modena, Italy, ⁶AOU di Sassari, Sassari, Italy, ⁷AOU Senese, Siena, Italy, ⁸AOU Careggi, Firenze, Italy, ⁹Nuovo Ospedale di Legnano, Legnano, Italy

Background: The introduction of long-acting injectable cabotegravir/rilpivirine (CAB/RPV LA) has expanded therapeutic options for people living with HIV (PLWH). However, uncertainties remain regarding the clinical significance and management of detectable viremia, particularly low-level events. We aimed to characterize virological trajectories after detectable viremia to guide monitoring and identify patients at risk of persistent failure.

Methods: We conducted a post-hoc descriptive analysis within the ODOACRE multicentre cohort including PLWH receiving CAB/RPV LA. Confirmed virological failure at the 50 copies/mL threshold (CVF-50) was defined as either one HIV-RNA determination ≥ 200 copies/mL or two consecutive HIV-RNA measurements ≥ 50 copies/mL during follow-up (low-level events group). For each event, we evaluated time to first HIV-RNA ≥ 50 copies/mL, peak viral load, subsequent virological course, treatment modification, and reason for discontinuation. Baseline demographic and clinical characteristics were compared descriptively between groups.

Results: Among 490 PLWH receiving CAB/RPV LA in the ODOACRE cohort, 15 CVF-50 events were identified. Of these, 46.7% were single determinations ≥ 200 copies/mL while 53.3% were classified as low-level events. Baseline characteristics were largely comparable between groups and are summarized in Table 1.A. The mean time to first HIV-RNA ≥ 50 copies/mL was 11.5 months. Peak viral load ranged from 51 to 24,111 copies/mL. Overall, 46.7% of individuals achieved subsequent virological resuppression. Resuppression occurred in 62.5% of low-level events compared with 28.6% of ≥ 200 rebound cases. Notably, 3 of the 5 resuppressions observed in the low-level group occurred without treatment intensification. CAB/RPV LA was discontinued in 73.3% of CVF-50 cases. Among discontinuations, 81.8% were due to treatment intensification, while one case was related to HBV reactivation and one to pregnancy. When categorized by clinical trajectory, 33.3% of events represented transient low-level viremia with resuppression, 20.0% persistent low-level viremia, 13.3% ≥ 200 rebound with resuppression, and 33.3% ≥ 200 rebound without resuppression. Results are summarized in Table 1.B.

Conclusions: In our analysis, nearly half of CVF-50 events were followed by virological resuppression, particularly among low-level events. A substantial proportion of participants with low-level viremia regained viral suppression without treatment modification, suggesting that immediate intensification may not always be required. These findings support a stepwise clinical approach based on close monitoring and contextual assessment rather than systematic regimen escalation. Larger prospective studies are warranted to identify predictors of persistent failure versus spontaneous resuppression and to optimize clinical management while avoiding unnecessary switches.

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Metabolic and other non-communicable diseases

P 147 **CARDIOVASCULAR RISK STRATIFICATION IN A COHORT OF ADOLESCENTS AND YOUNG ADULTS WITH VERTICALLY ACQUIRED HIV: APPLICATION OF THE 2025 ESC FOCUSED UPDATE**

M. Stracuzzi¹, F. Marinacci¹, C. Coppola¹, V. Giacometti^{1,2}

¹Pediatric Infectious Diseases, Luigi Sacco Hospital, ASST FBF SACCO, Milan, Italy, ²Dipartimento di Scienze Biomediche e Cliniche "Luigi Sacco", Università degli Studi di Milano, Italy

Background: Lifelong HIV and ART exposure drive premature vascular aging. This study applies the 2025 ESC framework to identify early metabolic derangement in a cohort followed at Luigi Sacco Hospital.

Methods: We conducted a retrospective observational study involving patients with vertically acquired HIV followed at the Pediatric Infectious Disease Unit of the Luigi Sacco Hospital in Milan. All included patients were receiving stable antiretroviral therapy (ART). The cohort of 33 patients was stratified into two age-based groups: adolescents (12–18 years, n=4) and young adults (>18 years, n=29). Comprehensive clinical assessments included Body Mass Index (BMI), Waist Circumference (WC), and standardized blood pressure (BP) measurements. A complete fasting lipid profile was obtained, including Total Cholesterol (TC), LDL-C, HDL-C, and Triglycerides (TG). In the adult subgroup, CV risk was stratified according to 2025 ESC SCORE2 algorithms, integrating HIV infection as a specific "risk enhancer" justifying more aggressive lipid-lowering targets.

Results: Adolescents (12–18 years): This group showed a mean ART exposure of 14.0 years with a 100% virological suppression rate (HIV-RNA <20 copies/mL). Anthropometric data revealed a mean BMI of 18.1 kg/m² (range 17.5–19.0) and a mean WC of 69.5 cm. Metabolic parameters remained within optimal ranges: mean BP was 110/75 mmHg, TC was 165 mg/dL, LDL-C was 92 mg/dL (range 82–101), HDL-C was 54 mg/dL, and TG were 68 mg/dL. Despite the long-term HIV history, 100% (n=4) of adolescents were classified as Low Risk due to the absence of additional metabolic or hemodynamic alterations.

Young Adults (>18 years): This group had a mean ART exposure of 25.0 years with 93.1% virological suppression. Mean BMI was 23.8 kg/m² (range 18.2–31.0) and mean WC was 81.2 cm (range 71–104), with 20.6% of subjects exceeding abdominal obesity thresholds. Metabolic assessment revealed a mean BP of 124/81 mmHg (range 95/70–140/100), TC of 182 mg/dL, and a significant trend toward elevated LDL-C (mean 118 mg/dL, range 68–162). Mean HDL-C was 48 mg/dL and mean TG were 105 mg/dL. Active smoking was a major modifiable factor, reported by 24.1% of patients.

According to the 2025 ESC risk categories, 13.8% (n=4) were classified as Very High Risk (meeting the new Class I recommendation for patients over 40 with chronic infection), 27.6% (n=8) as High Risk, 34.5% (n=10) as Moderate Risk, and 24.1% (n=7) as Low Risk. The progression to higher risk classes was primarily driven by the synergy between smoking, hypertension, and long-term ART-related metabolic shifts.

Conclusions: Early metabolic alterations in young adults with vertically acquired HIV necessitate proactive cardiovascular screening and aggressive prevention well before standard age thresholds. Early pharmacological intervention should be considered to mitigate the cumulative effect of lifelong viral and ART exposure.

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Metabolic and other non-communicable diseases

P 148 CHANGES IN BODY WEIGHT AND METABOLIC PARAMETERS IN PEOPLE LIVING WITH HIV STARTING AN INITIAL REGIMEN WITH TENOFOVIR DISOPROXIL FUMARATE/LAMIVUDINE/DORAVIRINE OR TENOFOVIR ALAFENAMIDE EMTRICITABINE/ BICTEGRAVIR OR LAMIVUDINE/DOLUTEGRAVIR (WEINF STUDY)

L. Calza¹, M. Giglia¹, A. Zuppiroli¹, D. Marzolla¹, D. Rigamonti¹, S. Cretella¹, I. Bon², P. Viale¹

¹Unit of Infectious Diseases, IRCCS S.Orsola Hospital, University of Bologna, Bologna, Italy, ²Unit of Microbiology, IRCCS S.Orsola Hospital, University of Bologna, Bologna, Italy

Background: To date, there is no a direct comparison about changes in body weight, metabolic parameters and inflammatory markers across antiretroviral therapy-naïve people living with HIV (PWH) starting bictegravir/emtricitabine/tenofovir alafenamide (BIC/F/TAF), dolutegravir/lamivudine (DOL/3TC) or doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF).

Methods: We performed a prospective, observational, cohort study on adult PWH who started as initial ART the single tablet regimen BIC/F/TAF, DOL/3TC or DOR/3TC/TDF. Physical and laboratory parameters were evaluated during a 12-month follow-up. Patients with baseline HIV RNA >500,000 copies/mL or genotype resistance testing showing reduced sensitivity to >1 of the prescribed antiretroviral drugs were excluded.

Results: Study inclusion criteria were met by 120 patients who were enrolled into the study: 40 subjects started DOR/3TC/TDF, 40 BIC/F/TAF, and 40 DOL/3TC. Median age was 45.2 years and 91 patients (75.8%) were males. The median baseline log₁₀ HIV RNA was 5.18 copies/mL, median baseline CD4⁺ lymphocyte count was 363 cells/mm³, and 29 patients (24.2%) had one or more comorbidities. Baseline characteristics of study patients exhibited a general homogeneity across all groups. Twelve months after the initiation of ART, a significantly higher increase in median value of body weight was observed in the BIC/F/TAF group (+2.66 Kg) and in DOL/3TC group (+2.41 Kg) compared to DOR/3TC/TDF one (+1.17 Kg) ($p=0.017$ and 0.033 , respectively). Moreover, the increase in median value of waist circumference was significantly greater in the BIC/F/TAF group (+2.11 cm) and in DOL/3TC group (+1.92 cm) compared to DOR/3TC/TDF one (+0.56 cm) ($p<0.001$). At month 12, changes in median values of all evaluated inflammatory and coagulation markers were comparable across all groups and no significant variations for each marker were reported in comparison with respective baseline values. During the 12-month follow-up, a significantly greater elevation in median concentrations of total cholesterol was reported in the BIC/F/TAF group (+34 mg/dL) than in the DOR/3TC/TDF (+6 mg/dL; $p<0.001$) and 3TC/DOL (+13 mg/dL; $p=0.042$) groups. After 12 months, the proportion of patients with HIV RNA <50 copies/mL was comparable in all groups: 90% (36/40) in the DOR/3TC/TDF group, 87.5% (35/40) in the BIC/F/TAF group, and 85% (34/40) in the DOL/3TC group. Treatment discontinuations were very uncommon and the incidence of adverse events was very low and comparable in subjects treated with DOR/3TC/TDF, BIC/F/TAF, or DOL/3TC.

Conclusions: In our study, initial antiretroviral regimen with DOR/3TC/TDF led to a significantly lower increase in body weight in comparison with BIC/F/TAF and DOL/3TC after a 12-month follow-up, and to a significantly lower elevation in total cholesterol in comparison with BIC/F/TAF, while no significant differences were reported with regard to other metabolic parameters and serum inflammation markers.

Metabolic and other non-communicable diseases

P 149 DUAL AND TRIPLE ANTIRETROVIRAL THERAPIES: THE EFFECT ON GUT MICROBIOME

C. Papalini, S. Marchianò, M. Albagini, S. Fiorucci, G. De Socio

University of Perugia, Department of Medicine and Surgery, Perugia, Italy

Background: High life quality and comorbidities prevention are the new goal for antiretroviral therapy (ART). The main disease affecting people living with HIV (PLWH) is the cardiovascular one. Gut microbiome can influence cardiovascular risk and can be influenced by ART.

The aim of this study is to investigate gut microbiome differences in PLWH in dual or triple ART correlating with cardiovascular risk.

Material and Methods: We analysed viral suppressed PLWH assuming 3TC/DTG or TAF/FTC/BIC for at least 3 years. We took in consideration viral, immunological and metabolic parameters and calculated cardiovascular risk according to ASCVD score. On stool samples 16S rRNA sequencing was performed.

Results: Sixty-1 patients were enrolled: 83% males, 52% with CD4 nadir <200 cells/ μ l, 70% with CD4 count >500/ μ l at the last visit, 37% smoking, 52% overweight, 75% with high cardiovascular risk. Patients taking TAF/FTC/BIC were 33 while those in 3TC/DTG were 28 whose 50% had been exposed to ABC previously. These 14 individuals resulted at higher cardiovascular risk. Comparing TAF/FTC/BIC and 3TC/DTG groups we noticed prevalence of Actinobacteria and Bifidobacteriaceae in the first one and of Firmicutes and Enterobacteriaceae in the second one. No statistically relevant differences about metabolic parameters and cardiovascular risk emerged between the 2 groups.

Conclusions: Taxa considered beneficial in literature were more frequent in PLWH assuming TAF/FTC/BIC. Further studies are required to assess the influence of previous regimens and to understand if the abundance of unfavorable taxa in 3TC/DTG group is related to the actual therapy or to the exposition to ABC.

Metabolic and other non-communicable diseases

P 150 EFFICACY AND SAFETY OF BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE IN PEOPLE LIVING WITH HIV-1 WITH CHRONIC RENAL DISEASE

L. Calza¹, M. Giglia¹, A. Zuppiroli¹, S. Babini¹, F. Baggio¹, J.M. Faiella¹, A. Alai¹, P. Viale¹

¹Unit of Infectious Diseases and ²Unit of Microbiology, IRCCS S.Orsola Hospital, University of Bologna, Bologna, Italy

Introduction: Renal disease is one of many complications that can occur in people living with HIV (PWH), who are at higher risk for developing chronic kidney disease (CKD) than the general population.

Methods: Retrospective cohort study evaluating records from antiretroviral therapy (ART)-naïve or -experienced PWH with G3 CKD who started Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/F/TAF) between January 2022 and December 2024. Eligible patients were PWH with baseline estimated glomerular filtration rate (eGFR) ranging between 30 and 60 mL/min/1,73m², 48 weeks of follow-up data and no known resistance mutations for bictegravir, emtricitabine and tenofovir. The primary endpoints were change in eGFR and albumin-to-creatinine ratio (ACR), safety and virological efficacy at week 48.

Results: Inclusion criteria were met by 42 patients: 4 naïve and 38 experienced. Mean age was 66.2 years (range, 59-82), 92% were men, and 94% were Caucasian. In naïve patients, mean CD4+ T lymphocyte count was 302 cells/mm³, mean log₁₀ HIV RNA was 4.31, and two (4.7%) had an AIDS diagnosis. In experienced patients, mean CD4+ T lymphocyte count was 479 cells/mm³, 35 (83%) had HIV RNA <50 copies/mL, and previous antiretroviral regimen included two nucleoside/nucleotide analogues (NRTIs) plus one non-nucleoside reverse transcriptase inhibitor in 25 (59.5%), and two NRTIs plus one integrase inhibitor in 9 (21.4%) patients. Before the start of BIC/F/TAF, the mean eGFR was 48.2 mL/min/1,73m², and the mean ACR was 105.4 mg/g; 14 subjects (33.3%) had an eGFR of 30-45 mL/min/1,73m² and 6 (14.3%) had an ACR >300 mg/g. After 12 months of treatment with BIC/F/TAF, changes in mean values of eGFR and ACR were not significant: mean variations were -0.48 mL/min/1,73m² for eGFR (p=0.166) and +8.5 mg/g for ACR (p=0.331). The number of subjects with an eGFR of 30-45 mL/min/1,73m² and an ACR >300 mg/g was unchanged (14 and 6, respectively). After 12 months, 38 patients (90.5%) had HIV RNA <50 copies/mL: 4 (100%) naïve and 34 (89.5%) experienced. Four patients (9.5%) discontinued BIC/F/TAF: one for virological failure and three for adverse events. A genotype resistance testing did not show any resistance mutations in the unique case of virological failure. Treatment-related adverse events occurred in 10 (23.8%) patients (all grade 1-2). At month 12, mean change in CD4+ T lymphocyte count was +148 cells/mm³ in naïve patients and +44 cells/mm³ in experienced patients. Overall, mean variations in total cholesterol, LDL cholesterol, triglycerides and glucose were not significant. At month 12, mean change in body weight was +2.59 Kg (p=0.043) in naïve patients and +1.09 Kg (p=0.291) in experienced patients.

Conclusion: In this real-world cohort, BIC/F/TAF was associated with a good renal safety in PWH with chronic renal impairment (G3 CKD), without significant changes in renal function and proteinuria after 12 months of treatment, in addition to a high effectiveness.

Metabolic and other non-communicable diseases

P 151 EXTREME CARDIOVASCULAR RISK AND LDL-C TARGET ACHIEVEMENT IN PEOPLE WITH HIV

A. Giacomelli^{1,2}, A.L. Ridolfo¹, L. Oreni¹, G. Carrozzo¹, M.V. Cossu¹, D. Moschese¹, G. Pozza¹, V. Iannone¹, A. Poloni¹, A.P. Maggioni³, A. Gori^{1,2,4}, C. Gervasoni¹

¹Department of Infectious Diseases, ASST Fatebenefratelli Sacco, Luigi Sacco Hospital, Milan, Italy, ²Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milan, Italy, ³ANMCO Research Center, Heart Care Foundation, Florence, Italy, ⁴Centre for Multidisciplinary Research in Health Science (MACH), Università degli Studi di Milano, Milan, Italy

Background: People with HIV (PWH) have an increased burden of atherosclerotic cardiovascular disease (ASCVD). The 2025 ESC/EAS dyslipidaemia guidelines introduced the category of “extreme cardiovascular risk” (established ASCVD plus either recurrent vascular events despite lipid-lowering therapy [LLT] or extensive multivessel arterial disease involving at least two arterial territories [coronary, cerebral, or peripheral]), recommending an intensified LDL-cholesterol (LDL-C) target of <40 mg/dL. We assessed the proportion of PWH meeting criteria for extreme cardiovascular risk and evaluated attainment of guideline-recommended LDL-C targets in routine care.

Materials and Methods: We conducted a retrospective observational study at the HIV outpatient clinic of Luigi Sacco Hospital, Milan, Italy. All adults attending at least one follow-up visit between June and December 2025 were included. Demographic characteristics, HIV-related parameters, cardiovascular risk factors, ASCVD history, lipid profiles, and LLT were extracted from electronic medical records. Individuals with established ASCVD were classified as very high or extreme cardiovascular risk according to the 2025 ESC/EAS guidelines. The most recent fasting LDL-C value was used to assess target achievement: <55 mg/dL for very high-risk and <40 mg/dL for extreme-risk individuals.

Results: Among 2,955 PWH attending follow-up visits during the study period, 202 (6.8%) had established ASCVD. Of these, 55 (27.2%) fulfilled criteria for extreme cardiovascular risk: 14 (25.4%) due to extensive multivessel arterial disease and 41 (74.5%) due to recurrent vascular events. A total of 297 events were recorded: 157 myocardial infarctions, 45 coronary revascularizations or bypass procedures, 61 ischemic strokes, 12 symptomatic peripheral artery disease cases, 11 peripheral revascularizations, and 11 carotid revascularizations (Figure 1). PWH at extreme risk were older (median age 67 [IQR 64–73] vs 64 [59–70] years, $p=0.001$) and more frequently had a history of AIDS-defining events (41.8% vs 22.4%, $p=0.008$) (Table 1). Combination LLT was used in 43.6% (88/202), whereas PCSK9 inhibitors and bempedoic acid were rarely prescribed. Additionally, 9.4% received no lipid-lowering therapy. LDL-C targets were frequently unmet: 79.6% of very high-risk and 72.7% of extreme-risk individuals had LDL-C above 55 mg/dL. Only 10.9% of extreme-risk PWH achieved LDL-C <40 mg/dL.

Conclusions: More than one quarter of PWH with established ASCVD meet criteria for extreme cardiovascular risk. LDL-C target achievement, use of combination LLT and the access to new LLT, such as PCSK9 and bempedoic acid, remain markedly inadequate. Bridging the gap between updated lipid guidelines and clinical practice is crucial to reduce recurrent ASCVD in PWH.

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Metabolic and other non-communicable diseases

P 152 FACTORS ASSOCIATED WITH HEPATIC STEATOSIS IN PEOPLE LIVING WITH HIV WITH ASSESSMENTS OF METABOLIC DISORDERS, TYPE OF ANTIRETROVIRAL REGIMEN, POSSIBLE INTIMA-MEDIA THICKNESS AND GENETIC PREDISPOSITION

L. Salmoni¹, S. Martini¹, A. Russo^{1,2}, G. Ricciardiello¹, F. Laguardia¹, M. Russo¹, M. Starace¹, C. Minichini¹, M. Pisaturo¹, N. Coppola¹

¹Department of Mental Health and Public Medicine, Section of Infectious Diseases, University of Campania Luigi Vanvitelli, Naples, Italy, ²Department of Life Science, Health, and Health Professions Link Campus University, Rome, Italy

Introduction: The widespread implementation of combination antiretroviral therapy (ART) has dramatically improved survival among people living with HIV (PLWH), transforming HIV infection from a fatal disease into a chronic condition. Therefore, metabolic comorbidities have emerged as a central concern. Our aim is to evaluate incidence of steatosis and its correlation with other elements, such as metabolic disorders, type of antiretroviral regimen, carotid intima-media thickness and genetic polymorphisms.

Methods: We retrospectively analyzed a cohort of 75 patients living with HIV-1, who had undergone at the same moment transient elastography (FibroScan®) to evaluate liver steatosis and fibrosis; Carotid eco-color Doppler ultrasound to assess carotid intima-media thickness (cIMT) and presence of atherosclerotic plaques; Genetic polymorphisms related to dislipidemia, using Qiagen-based DNA extraction and an Aria Dx (Agilent) real-time platform.

Results: A total of 75 patients were included in the analysis. Moderate/severe steatosis was significantly associated with age >50 years ($p=0.019$), lower HDL levels ($p=0.015$), and higher triglycerides ($p=0.001$).

In the enrolled population, 27 (36%) of the 75 patients had steatosis. Various factors related to steatosis were analyzed (figure 1).

TSA Doppler revealed an incidence of atheromatous plaques in the steatotic group of 29.6% vs. 18.8% in the non-steatotic group ($p = 0.42$).

Regarding the PI-based regimen, it was more commonly used in patients with steatosis (48.1% vs. 29.2%, $p = 0.16$).

The evaluation of genetic polymorphisms was not particularly predictive, as they were evident in both the steatotic and non-steatotic groups (44% vs. 30%, $p = 0.67$).

Regarding the lipid profile, hypercholesterolemia was statistically correlated with steatosis (70.4% vs. 43.75%, $p = 0.04$).

Liver stiffness values (kPa) increased according to steatosis severity ($p=0.050$), suggesting a link between steatosis and fibrosis progression. Carotid atherosclerosis was significantly associated with hepatic fibrosis ($p=0.023$), particularly for right-sided plaques (75% vs. 15.3%; $p=0.022$). Fibrosis was also associated with increased right common carotid artery intima-media thickness (median 0.85 mm vs. 0.48 mm; $p=0.046$). Genetic analysis showed that 20% of the cohort carried at least one polymorphism involved in lipid metabolism and steatosis development.

Conclusions: Our study shows that steatosis appears more evident in patients with a higher incidence of carotid plaques, a history of PI therapy, hypercholesterolemia and a positive genetic test for steatosis polymorphism. This may encourage clinicians to study more extensively patients with steatosis in order to also investigate the possible correlation with atheromatous plaques, that are associated with greater cardiovascular risk.

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Metabolic and other non-communicable diseases

P 153 LIFESTYLE FACTORS ASSOCIATED WITH OVERWEIGHT AND OBESITY IN PEOPLE LIVING WITH HIV ON STABLE ART

B. Zanini¹, G. Gilberti¹, S. Marconi¹, M. Salvi², M. Rota³, F. Donato⁴, G. Tiecco², I. Scarvaglieri², F. Castelli², E. Quiros-Roldan² on behalf of LIFEH Collaboration Group*

¹Department of Clinical and Experimental Sciences, University of Brescia, Brescia, Italy, ²Department of Clinical and Experimental Sciences, Unit of Infectious and Tropical Diseases, University of Brescia and ASST Spedali Civili General Hospital, Brescia, Italy, ³Department of Molecular and Translational Medicine, University of Brescia, Brescia, Italy, ⁴Department of Medical-Surgical Specialties, Radiological Sciences and Public Health, University of Brescia, Brescia, Italy

*LIFEH Collaboration Group: A.M Della Vedova¹, M. Castellano¹, E. Focà²

Background: Following ART initiation, metabolic shifts may contribute to weight gain in PLWH. While early weight gain has been linked to integrase inhibitors (INSTIs), the relative impact of long-term stable ART versus modifiable lifestyle factors remains unclear. The LIFEH study investigated lifestyle associated with overweight/obesity (OO) vs normal weight (NW) in PLWH on stable suppressive ART.

Material and Methods: We performed a cross-sectional analysis of LIFEH study. Adult PLWH (18–65 years) on stable ART with HIV-RNA <20 copies/mL for ≥24 months, followed at a tertiary center in Northern Italy (2023–2024), were enrolled. Individuals with metabolic/cardiovascular disease, cancer, opportunistic infections, substance abuse, or prescribed diets were excluded. Lifestyle factors were assessed using validated tools (24-hour recall diet, MediLite, IPAQ-SF, CAGE). OO was defined as BMI ≥25 kg/m². Multivariable logistic regression identified independent factors associated to OO.

Results: Among 176 participants (median age 51 years; 22% female; median HIV duration 17 years), OO prevalence was 52.8%, slightly higher than that reported in the Italian general population (43%). Thirty percent had BMI ≥25 kg/m² at HIV diagnosis; 39.8% of initially normal-weight individuals developed OO over time, while 83% of those overweight/obese at diagnosis remained in the same BMI category at study entry.

HIV-RNA at diagnosis was higher in OO vs NW (p=0.043), with similar current immunovirological parameters.

OO vs NW participants had lower fiber intake (14 vs 17 g/day; p=0.007) and lower Mediterranean diet adherence (MediLite 10 vs 11; p=0.009). Beer and aperitif consumption were more frequent in OO (p=0.022; p=0.002). Physical activity was comparable between groups. In multivariable analysis, BMI ≥25 kg/m² at HIV diagnosis was strongly associated with current OO (OR 7.61, 95% CI 3.27–19.6; p<0.01). Conversely, each 1-point increase in MediLite score was independently associated with lower odds of OO (OR 0.80, 95% CI 0.67–0.94; p<0.01). ART regimen (INSTI-based or dual vs triple therapy) did not increase risk of current OO.

Conclusions: In PLWH on long-term stable ART, overweight and obesity appear more strongly associated with modifiable lifestyle factors than with ART regimen. Integrating structured nutritional and lifestyle interventions into routine HIV care may be crucial to prevent metabolic complications.

Figure 1

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Metabolic and other non-communicable diseases

P 154 LOW-LEVEL VIREMIA IS ASSOCIATED WITH INCIDENT DIABETES IN OBESE PEOPLE WITH HIV

L. Costacurta¹, L. Taramasso², E. Ricci³, N. Squillace⁴, G. Orofino⁵, G.F. Pellicano⁶, G.V. De Socio⁷, B. Menzaghi⁸, S. Ferrara⁹, P. Maggi¹⁰, E. Pontali¹¹, S. Piconi¹², E. Sarchi¹³, G. Madeddu¹⁴, P. Bonfanti¹, A. Di Biagio^{1,2}

¹Department of Health's Sciences, University of Genoa, Genoa, Italy, ²Infectious Diseases Unit, IRCCS Azienda Ospedaliera Metropolitana, Genoa, Italy, ³Fondazione ASIA Onlus, Buccinasco (MI), Italy, ⁴Infectious Disease Unit, Fondazione IRCCS San Gerardo dei Tintori, Monza, University of Milano-Bicocca, Monza, Italy, ⁵Division I of Infectious and Tropical Diseases, ASL Città di Torino, Italy, ⁶Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, AOU Policlinico G. Martino, Messina, Italy, ⁷Clinic of Infectious Diseases, Department of Medicine and Surgery, University of Perugia, Italy, ⁸Unit of Infectious Diseases, ASST della Valle Olona – Busto Arsizio (VA), Italy, ⁹Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy, ¹⁰Infectious Diseases Unit, AORN Sant'Anna e San Sebastiano, Caserta, Italy, ¹¹Department of Infectious Diseases, Galliera Hospital, Genoa, Italy, ¹²Unit of Infectious Diseases, A. Manzoni Hospital, Lecco, Italy, ¹³Infectious Diseases Unit, S. Antonio e Biagio e Cesare Arrigo Hospital, Alessandria, Italy, ¹⁴Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Italy

Background: The prevalence of obesity is increasing among people with HIV (PWH), which has significant implications for cardiometabolic health. This study aims to identify which factors are associated with the development of diabetes mellitus (DM) in obese PWH, including the role of antiretroviral treatment (ART), which is still debated in PWH and has never been studied specifically in obese PWH.

Methods: This was a multicentre, prospective, observational study that enrolled obese PWH in two Italian multicentre cohorts: The Overweight and Obese People with HIV (OBHIV) Cohort and the Surveillance Cohort Long-Term Toxicity Antiretrovirals (SCOLTA) Cohort. Participants were enrolled from 2014 onwards, provided they had at least one follow-up visit and were not diagnosed with DM at enrolment. Factors associated with the onset of DM were estimated using a Cox proportional hazards model. Variables were included in the multivariate model through a forward model selection with p value set at 0.2. We defined low-level viremia as an HIV-RNA value between 50 and 199 copies/mL.

Results: Three hundred and fourteen obese PWH were enrolled, with a mean BMI of 33.3 kg/m² (SD+/-3.7). The mean age was 49 years (SD +/- 11.4) and 70.4% were male. Among study participants, 8% were ART-naïve at enrolment, and 15% were in CDC stage C. Twenty-three developed DM during a mean follow-up of 24 months (IQR 11-38), with an estimated incidence of 3.1/100 PYFU (95%CI 2.0-4.6). Participants with incident diabetes had higher baseline values of blood glucose (p<0.0001), triglycerides (p=0.0003), and ALT (p=0.03) and lower HDL cholesterol (p=0.01). According to the multivariable analysis, incident diabetes was more probable in PWH with higher BMI (aHR 1.11 per each kg/m², 95%CI 1.003;1.24) and with low-level viremia at the time of DM occurrence, (aHR 4.12, 95% CI 1.5-11.42). Sex and statin use were not correlated to DM incidence in this population, as well as the type of ART (Table).

Conclusions: The presence of low-level viremia was strongly associated with the occurrence of DM in this cohort. These results underline a possible interplay between residual inflammation in uncontrolled low-level HIV replication and the risk of diabetes in obese people. No correlation was found between incident DM and exposure to different ART classes.

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Metabolic and other non-communicable diseases

P 155 METABOLIC CHANGES AFTER SWITCH TO LONG-ACTING CABOTEGRAVIR/RILPIVIRINE: IMPLICATIONS FOR CARDIOVASCULAR RISK IN PLWH

V. Kelmendi¹, A. Carraro¹, R. Marocco², L. Ansaldo², G. Mancarella², M. D'Achille², C. Del Borgo², M. Lichtner³

¹U.O.C Malattie Infettive, Azienda Ospedaliero-Universitaria Sant'Andrea, Sapienza Università di Roma, Italy, ²U.O.C Malattie Infettive, Ospedale Santa Maria Goretti, Polo Pontino, Sapienza Università di Roma, Latina, Italy, ³Dipartimento di Neuroscienze, Salute Mentale e Organi di Senso NESMOS, Sapienza Università di Roma, Italy

Background: As life expectancy increases, optimizing cardiovascular health has become a central objective in HIV care. People living with HIV (PLWH) have an increased burden of cardiovascular disease related to chronic inflammation and antiretroviral-associated metabolic alterations. Weight gain and lipid changes observed with certain integrase inhibitors and tenofovir alafenamide (TAF)-based regimens have raised concerns regarding cumulative cardiovascular risk. We evaluated metabolic changes after switching to long-acting cabotegravir/rilpivirine (CAB/RPV LA) in a real-world cohort.

Methods: This prospective observational study was conducted between June 2023 and June 2025 at the AIDS Reference Center of the Infectious Diseases Unit, Santa Maria Goretti Hospital, Latina (Sapienza University of Rome). Thirty-nine virologically suppressed PLWH switched to CAB/RPV LA and were followed for 52 weeks; nineteen PLWH continuing oral ART served as controls.

Median age was 48 years (IQR 35–56) in the LA group and 56 years (IQR 36–60) in the control group. In the LA group, 13/39 (34.2%) were female and 26/39 (65.8%) male; 38/39 were Caucasian and 1/39 Black. In the control group, 6/19 (31.6%) were female and 13/19 (68.4%) male; all 19 participants were Caucasian.

All participants had BMI <30 kg/m². Two subjects in the LA group had type 2 diabetes mellitus, one had a history of ischemic heart disease, and four had dyslipidemia. Concomitant statin therapy was not modified.

Longitudinal assessments included body weight, waist circumference, systolic blood pressure, and lipid profile (total cholesterol, LDL-C, HDL-C, triglycerides). Data are expressed as median (IQR). Repeated measures were analyzed using the nonparametric Friedman test.

Results: At week 52, 92% of participants maintained virologic suppression in the LA group.

Body weight (T0: 76 kg [45–98] vs T52: 74 kg [48.3–103]), waist circumference (T0: 93.5 cm [70–108] vs T52: 93 cm [72–110]), and systolic blood pressure (T0: 120 mmHg [100–160] vs T52: 120 mmHg [100–150]) remained unchanged.

Total cholesterol decreased from 199 mg/dL [113–286] at baseline to 188 mg/dL [125–295] at week 52 (p=0.04), with an early reduction observed at week 28; this decrease was not observed in the control group. LDL cholesterol showed a downward trend (T0: 122 mg/dL [66–193] vs T52: 120 mg/dL [61–208]; p=0.057), without reaching statistical significance. Triglycerides progressively declined (T0: 93 mg/dL [40–357] vs T52: 84 mg/dL [27–376]; p=0.053), while HDL cholesterol remained stable.

In the control group, no significant longitudinal changes were observed in anthropometric or lipid parameters.

Conclusions: Switching to CAB/RPV LA was associated with a modest improvement in atherogenic lipid parameters over 52 weeks, without weight gain or blood pressure increase. Long-acting injectable ART may represent a metabolically favorable strategy contributing to cardiovascular risk mitigation in virologically suppressed PLWH.

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Metabolic and other non-communicable diseases

P 156 METABOLIC IMPACT AND CARDIOVASCULAR RISK AFTER SWITCHING TO BIC/FTC/TAF VS DOR/3TC/TDF IN A REAL-WORLD COHORT OF VIROLOGICALLY SUPPRESSED PLWH

S. Colaiuda¹, C. De Vivo¹, G. Lenzi¹, G. Cucinotta¹, F. La Fata¹, L. Spina¹, A. Carbone¹, P.F. Salvo^{1,2}, F. Lombardi^{1,2}, G. Balzin^{1,2}, C. Torti^{1,2}, S. Di Giambenedetto^{1,2}

¹Dipartimento di Sicurezza e Bioetica, Sezione di Malattie Infettive, Università Cattolica del Sacro Cuore, Rome, Italy, ²Dipartimento di Scienze Mediche e Chirurgiche, UOC Malattie Infettive, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy

Background: In people living with HIV (PLWH), the choice of antiretroviral regimen should take into account not only the maintenance of antiviral efficacy, but also long-term metabolic impact. Although highly effective, integrase strand transfer inhibitor (INSTI)-based regimens have been associated with weight gain and metabolic alterations. Regimens based on Doravirine (DOR), a newer-generation non-nucleoside reverse transcriptase inhibitor (NNRTI), have shown a favorable lipid profile in clinical trials, but comparative real-world data after switching to DOR/3TC/TDF versus BIC/FTC/TAF remain limited. The aim of this study was to assess changes in lipid profile at 48 and 96 weeks.

Methods: This is a retrospective single-center observational study including treatment-experienced PLWH virologically suppressed (HIV-RNA <50 copies/mL), switching either to BIC/FTC/TAF (BIC) or DOR/3TC/TDF (DOR) between 2019 and 2025, and followed up to week 48 (48W) and for a smaller proportion to week 96 (96W). We assessed change in lipid profile and blood glucose over time. We also evaluated probability of experiencing virological failure (VF, i.e. two consecutive HIV-RNA ≥ 50 copies/mL or a single HIV-RNA ≥ 1000 copies/mL), the rate of treatment discontinuation (TD) and change in both CD4 cell count and CD4/CD8 over time. A repeated-measures mixed model was used to evaluate the dynamic of parameters over time. Time to VF and TD were assessed by survival analysis.

Results: We enrolled a total of 519 PLWH, of whom 429 switched to BIC and 90 to DOR. Baseline characteristics including lipid parameters were similar between groups, but participants in BIC were younger ($p=0.005$) with higher zenith HIV-RNA ($p=0.048$) and higher CD4 cell counts ($p=0.002$) (Table 1). At 48W, a significant decrease in both total cholesterol and LDL was observed (-7.9 and -6.0 , respectively, both $p<0.001$), with no significant differences between regimens ($p=0.764$ and 0.364 , respectively). At 96W, the reduction in LDL cholesterol persisted (-5 , $p=0.003$), while no significant changes were observed in the other metabolic parameters. At both 48W and 96W, triglycerides and blood glucose showed no variation in either group. Regarding immunological profile, CD4 cell count significantly increased at 48W ($+39$, $p=0.020$), with a greater rise in the DOR group than in the BIC group ($p<0.001$); overall no significant variations were observed at 96W, however a greater gain was found in the DOR group ($p<0.001$). The probability of virological failure was similar between the groups (6.1% vs 4.4% , $p=0.881$), while TD was more frequent with DOR (13.1% vs 18.9% , $p=0.044$).

Conclusions: Both BIC/FTC/TAF and DOR/3TC/TDF were effective switch options in virologically suppressed PLWH, ensuring durable virological control and favorable lipid effect up to 96W. These findings support their use in clinical practice, particularly when metabolic profile is a relevant consideration.

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Metabolic and other non-communicable diseases

P 157 PRESERVING HEALTH BEYOND INFECTION CONTROL: FRAILITY, WEIGHT, AND COGNITION IN OPAT PATIENTS

B. Catania^{1,2,3}, G. Coniglione⁴, G. Pipitone¹, G. Ciusa¹, C. Imburgia¹, M.G.L. Marsala⁵, P. Scordo⁴, A. Albanese⁴, A. Cascio^{2,3}, G. Guaraldi⁶, C. Iaria¹

¹Infectious and Tropical Diseases Unit, A.R.N.A.S. Civico-Di Cristina-Benfratelli, Palermo, Italy. ²Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G D'Alessandro", University of Palermo, Palermo, Italy. ³Infectious and Tropical Disease Unit, AOU Policlinico "P. Giaccone", Palermo, Italy. ⁴Infectious Diseases Unit, Hospital Papardo, Messina, Italy. ⁵Quality and Clinical Risk Management Unit, A.R.N.A.S. Civico-Di Cristina-Benfratelli, Palermo, Italy. ⁶Modena HIV Metabolic Clinic, Department of Surgical, Medical, Dental and Morphological Sciences, University of Modena and Reggio Emilia, Modena, Italy

Background: Outpatient Parenteral Antimicrobial Therapy (OPAT) is a validated alternative to inpatient care for complicated infections, ensuring clinical efficacy, safety, and cost-effectiveness. However, its impact on patient-centered outcomes such as nutritional status, frailty, and cognitive well-being has rarely been studied.

Methods: We conducted a multicentric retrospective observational study of patients treated with OPAT between April 2024 and July 2025 in two tertiary care hospitals. Baseline demographics, comorbidities, weight, frailty status (Rockwood Clinical Frailty Scale (CFI)), and infection-related variables were collected. Follow-up assessments evaluated body weight, frailty, and subjective cognitive status. Clinical outcomes, adverse events, and hospital readmissions were recorded.

Results: Of 139 patients treated with OPAT, 119 were included in the analysis (56% male, median age 67 years). Common comorbidities were ischemic heart disease (33%), diabetes mellitus (29%), chronic pulmonary disease (22%), and solid tumors (19%). The most frequent infections were urinary tract infections (UTIs) (29%), osteomyelitis (25%), and pneumonia (17%). Multidrug-resistant (MDR) organisms were isolated in 66% of cases. Clinical recovery occurred in 82.5% of patients, while 16% required readmission in the next 30 days; no deaths were reported. Body weight (median 73 vs. 73.0 kg at baseline, $p = 0.43$) and frailty index (median 2.5 vs. 2.4, $p = 0.16$) remained stable. Cognitive status was unchanged in 85.6%, declined in 5.9%, and improved in 8.5% (fig. 1).

Conclusions: OPAT was confirmed to be clinically robust and well tolerated, with additional potential benefits in preserving weight, frailty status, and cognitive well-being. These findings suggest that OPAT not only ensures infection control but may also protect against hospitalization-related functional decline. Prospective studies incorporating standardized geriatric and cognitive assessments are needed to confirm these preliminary findings and define OPAT's broader role in holistic patient care.

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Metabolic and other non-communicable diseases

P 158 PREVALENCE AND DETERMINANTS OF LIVER STEATOSIS, FIBROSIS, AND CARDIOVASCULAR RISK IN HIV-MONOAFFECTED PATIENTS ON ART: STEAT-HIV STUDY

G. Quartini¹, C. Di Giulio¹, L.M. Saraca¹, L. Capogrossi¹, E. Svizzeretto¹, G. Genga¹, G. Proietti¹, M. Cordoni¹, F. Gentili², P. Fiore², G.V.L. De Socio³, C. Ucciferri^{1,3}

¹Infectious Disease Clinic, S. Maria Hospital Terni, Italy, ²Hepatology, gastroenterology and digestive endoscopy structure, S. Maria Hospital Terni, University of Perugia, Italy, ³Infectious Disease Clinic, Department of Medicine and Surgery, University of Perugia, Perugia, Italy

Background and Aims: Hepatic steatosis and fibrosis are increasingly recognized as major comorbidities among in people living with HIV (PLWH), even without of viral coinfections or metabolic syndrome. Chronic immune activation, metabolic dysfunction, and long-term antiretroviral therapy (ART) exposure contribute to progressive liver injury. The STEAT-HIV study aimed to assess the prevalence and determinants of hepatic steatosis and fibrosis using non-invasive tools and to explore their associations with metabolic and therapeutic variables.

Methods: A retrospective and prospective cohort study (2021–2022) was conducted at the Infectious Diseases Clinic in Terni (Italy).

Liver stiffness (LSM) and controlled attenuation parameter (CAP) were measured using FibroScan®. Biochemical (transaminases, lipids), anthropometric, and cardiovascular (ASCVD, SCORE) data were analyzed. Correlation and multivariate regression analyses were performed ($p < 0.05$).

Results: A total of 258 patients were analyzed, 115 PLWH on stable ART after excluding HBV/HCV coinfections, diabetes, alcohol abuse, and recent diagnoses (< 6 months) were enrolled.

Median age was 52 years (IQR 46–59), 73% were male, with median BMI 24.3 kg/m² (IQR 22.8–26.7) and HIV duration 14 years (IQR 10–19).

ART regimens included 38% protease inhibitor (PI), 42% integrase inhibitor (INSTI), 15% Doravirine, and 5% two-drug regimens (2DR).

Hepatic steatosis (CAP > 248 dB/m) was observed in 42.6% (49/115), and significant fibrosis (LSM > 7 kPa) in 18.9% (22/115).

CAP correlated with total cholesterol ($r = 0.31$; $p = 0.002$), triglycerides ($r = 0.34$; $p < 0.001$), and ASCVD score ($p = 0.02$).

Patients receiving PI-based regimens had higher CAP (285 dB/m, IQR 260–310) and LSM (7.4 kPa, IQR 6.1–8.8) compared to those on Doravirine or 2DR (CAP 245 dB/m, IQR 230–260; $p < 0.01$).

FibroScan® parameters showed stronger correlations with metabolic indices than serum-based scores (FIB-4, APRI; $p < 0.001$).

Conclusions: Hepatic steatosis and fibrosis are highly prevalent in HIV-monoinfected patients, closely linked to metabolic dysregulation and ART exposure, particularly PI-based regimens.

FibroScan® with CAP effectively identifies early hepatic injury and outperforms serum indices in this population.

Integrating non-invasive liver assessment into PLWH care could enhance early detection guide selection of metabolically favorable ART regimens, and prevent long-term hepatic and cardiometabolic complications.

Metabolic and other non-communicable diseases

P 159 PREVALENCE OF SEXUAL DYSFUNCTION IN WOMEN LIVING WITH HIV: RESULTS FROM SENSE STUDY

V. Brogna^{1,2}, M. Bani¹, D.P. Bernasconi¹, M.G. Strepparava¹, B. Menzaghi³, T. Bini⁴, S. Piconi⁵, V. Rochira⁶, P. Bonfanti^{1,2}, N. Squillace²

¹University of Milano-Bicocca, Milan, Italy, ²Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy, ³ASST Valle Olona, Varese, Italy, ⁴San Paolo Hospital, Milano, Italy

⁵"Alessandro Manzoni" Hospital, Lecco, Italy, ⁶University of Modena and Reggio Emilia, Modena, Italy

Background: Sexual health in women living with HIV (WLWH) remains underexplored despite its relevance to overall well-being and quality of life. We aimed to estimate the prevalence and describe the main domains of sexual dysfunction in WLWH with sustained virological suppression.

Materials and Methods: We conducted a cross-sectional analysis of a subsample from the multicenter Sexual Satisfaction and Sexual Dysfunctions Among People with HIV (SENSE) quantitative study. This analysis included women living with HIV (WLWH) aged ≤50 years who had an HIV viral load <50 copies/mL. Women with premature menopause or severe treatment-resistant depression were excluded.

To assess their mental, sexual, and overall well-being, participants completed a set of validated questionnaires, including the Female Sexual Function Index (FSFI), the Generalized Anxiety Disorder-7 (GAD-7), the Patient Health Questionnaire-9 (PHQ-9), and the Internalized HIV Stigma Scale (IA-RSS).

Sociodemographic and clinical data were also collected. Results are presented as medians with interquartile ranges (IQR) or frequencies (%).

Results: A total of 58 WLWH were enrolled (see Table 1 for the main characteristics). The median age was 43 years (IQR 39.3–45.8), and most participants were Italian (82%). The majority were in a stable relationship (79.3%).

The median FSFI total score was 27.65 (IQR 23.40–30.90). Using the validated cut-off (<26.55), 21 women (37.5%) met criteria for sexual dysfunction. Domain-specific analysis revealed lower median scores in the desire and arousal domains (3.60 and 3.90, respectively), suggesting that hypoactive sexual desire and reduced arousal may represent the most affected dimensions in WLWH.

Mild anxiety and depressive symptoms were present in 63.8% and 39.7% of participants, while moderate-to-severe symptoms were reported by 11 (19%) and 10 (17.2%) women, indicating a substantial psychological burden despite virological suppression.

In our cohort, the level of internalized stigma experienced by WLWH was moderate (IA-RSS median score 3 on a 0–6 scale).

Conclusions: In this cohort of virologically suppressed WLWH aged ≤50 years, more than one-third met the criteria for sexual dysfunction, particularly in the desire and arousal domains, alongside a relevant burden of anxiety, depressive symptoms, and internalized stigma.

Our observed prevalence of sexual dysfunction (37.5%) aligns with a recent finding from an Italian cohort showing a 36% prevalence using the same FSFI cut-off.

These findings indicate that sexual health concerns persist despite optimal virological control and highlight the need to routinely address sexual health during HIV care to ensure comprehensive and gender-sensitive management.

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Metabolic and other non-communicable diseases

P 160 REVERSIBILITY OF TUBULAR RENAL DAMAGE AFTER SWITCHING FROM TDF TO TAF IN A REAL-WORLD SETTING: THE IMPACT OF AGING AND BASELINE VULNERABILITIES

M. Trizzino¹, A. Cicero^{1,2}, C. Gioè¹, M. Tamiglio², L. Pipitò^{1,2}, C. Conti^{1,2}, C.V. Mazzola^{1,2}, A. Cascio^{1,2}

¹Infectious and Tropical Diseases Unit, Sicilian Regional Reference Center for the Fight Against AIDS, AOU Policlinico "P. Giaccone", Palermo, Italy, ²Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G D'Alessandro", University of Palermo, Palermo, Italy

Background: Cumulative exposure to tenofovir disoproxil fumarate (TDF) is a well-established risk factor for renal tubular damage in people living with HIV (PLWH). As the PLWH population ages, managing this legacy toxicity becomes crucial. This study aimed to evaluate the clinical impact of switching to tenofovir alafenamide (TAF) on tubular damage markers (UPCR) and bone metabolism, investigating the potential limiting role of aging alongside other baseline vulnerabilities, such as viral coinfections and historical antiretroviral exposure.

Material and Methods: We conducted a retrospective cohort study on 389 virologically suppressed PLWH who received TDF for at least 96 weeks before switching to a TAF-based regimen for 48 weeks. Evolution of urine protein-to-creatinine ratio (UPCR), serum creatinine, calcium, and phosphate levels was assessed using the Wilcoxon signed-rank test for paired data. The impact of potential baseline confounders, primarily older age (≥ 55 years), along with HBV/HCV coinfections and previous protease inhibitor (PI) use, on UPCR recovery post-switch was evaluated through Mann-Whitney U test and multivariate linear regression.

Results: The paired analysis (N=167-239) included an aging real-world cohort (median age 55 years, IQR 40-55; 70.6% male) with a substantial history of TDF exposure. At 48 weeks post-switch, we observed a statistically significant reduction in median UPCR (from 0.103 to 0.088 g/g, $p=0.002$), with 54.2% of patients showing clinical improvement. While UPCR improved, we observed a statistically significant, albeit mild, increase in serum creatinine ($p<0.001$), consistent with the known benign inhibition of tubular creatinine secretion associated with modern regimens. Serum calcium showed a significant recovery ($p<0.001$), although hypophosphatemia remained stable ($p=0.369$). Subgroup analyses revealed that historical vulnerabilities did not hinder tubular recovery. Surprisingly, older patients (≥ 55 years) demonstrated a tendency toward better and more consistent UPCR normalization compared to younger individuals (0.174 vs 0.225 g/g, $p=0.604$). Other legacy factors, including previous PI use (UPCR post-TAF: 0.213 vs 0.175 g/g in non-PI, $p=0.717$) and viral coinfections did not limit the benefit. Multivariate regression ($R^2=0.003$, $p=0.973$) confirmed that tubular improvement was driven exclusively by the switch to TAF, regardless of age or comorbidities.

Conclusions: Switching from TDF to TAF leads to a rapid, significant improvement in tubular proteinuria and renal function. The most striking finding from our cohort is universal nature of this benefit: advanced age does not preclude reversibility, challenging the paradigm of "irreversible" tubular damage in older PLWH. Although limited by the retrospective design and the lack of dual-energy X-ray absorptiometry (DEXA) scans and specific metabolic comorbidity data, our real-world evidence strongly supports the renal safety profile of TAF across all age groups.

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Metabolic and other non-communicable diseases

P 161 SEXUAL DYSFUNCTIONS IN MEN WITH HIV AND QUALITY OF LIFE: THE RESULTS OF SENSE STUDY

N. Squillace¹, V. Cogliandro¹, V. Brogna^{1,2}, D.P. Bernasconi³, M. Bani⁴, G. Lapadula^{1,2}, A. Soria¹, M.G. Strepparava^{4,5}, B. Menzaghi⁶, T. Bini⁷, S. Piconi⁸, V. Rochira⁹, P. Bonfanti^{1,2}

¹Clinic of Infectious Diseases, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy, ²University of Milano-Bicocca, Monza, Italy, ³Bicocca Bioinformatics Biostatistics and Bioimaging Centre, University of Milano-Bicocca, Milan, Italy, ⁴School of Medicine and Surgery, University of Milano-Bicocca, Monza, Italy; ⁵Clinical Unit "Psicologia Clinica", Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy, ⁶Unit of Infectious Diseases, ASST della Valle Olona, Busto Arsizio, Italy, ⁷Clinic of Infectious Diseases, San Paolo Hospital, ASST Santi Paolo e Carlo, Department of Health Sciences, University of Milan, Milan, Italy, ⁸Unit of Infectious Diseases, Alessandro Manzoni Hospital, ASST Lecco, Lecco, Italy, ⁹Endocrinology, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Modena, Italy

Background: Sexual dysfunctions, including erectile dysfunction (ED) and decreased sexual desire are frequent but under-recognised comorbidities in men with HIV (MWH) despite modern antiretroviral therapy and good viro-immunological control. These disturbances can interact with internalised stigma and relationship factors, potentially worsening overall and quality of life.

Methods: We performed a cross-sectional analysis of the male subsample of the multicenter Sexual satisfaction and sexual dysfunctions among people with HIV (SENSE) quantitative study, which enrolled (MWH) aged <50 years old in stable antiretroviral treatment (ART) and HIV-VL<50 copies/ml followed in four Italian infectious disease clinics and completing a comprehensive sexuality and QoL battery including the International Index of Erectile Function-15 (IIEF-15) and the HIV-Dependent Quality of Life (HIVDQoL). The scores are multiplied to give a Weighted Impact (WI) score. WI scores for applicable items are summed and divided by the number of applicable items to produce an average weighted impact score (AWI).

Results: Among 181 men (median age 43 years see table 1), three quarters identified as men who have sex with men (MSM 75.1%) and one quarter as men who have sex with women (MSW 24.9). Moderate-severe ED was present in 14.4% (26/181; 95% CI 9.6–20.3), while any degree of ED (mild-severe) affected 41.4% (75/181; 95% CI 34.2–49.0), with similar patterns in MSM and MSW and frequent additional disturbances of sexual desire and satisfaction. In the overall male SENSE population, the median total HIVDQoL AWI was approximately -0.95 (IQR -1.92 to -0.30), indicating a moderate overall negative impact of HIV on QoL, with domains such as sex life, self-confidence, feelings about the future and the past among the most negatively weighted aspects. When stratified by erectile function, men with any ED showed more frequent reporting of non-good general present QoL (overview item) and tended to have slightly more negative HIVDQoL AWI scores than those without ED, although differences in the total AWI were modest and confidence intervals largely overlapped. Nevertheless, item-level analyses indicated that men with ED more often endorsed that, without HIV, their sex life, self-confidence and feelings about the past would be "much" or "extremely" better, suggesting a concentrated negative impact of HIV in sexuality-related domains rather than a global QoL collapse.

Conclusions: In this male SENSE cohort, ED and other sexual dysfunctions were highly prevalent despite good HIV control and were accompanied by a measurable, domain-specific worsening of HIV-dependent quality of life, especially regarding sex life and self-related perceptions. These findings support assessment of sexual function and use of HIVDQoL in male HIV care to identify patients with hidden sexual distress and to target integrated interventions aimed at improving both sexual health and overall quality of life.

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Metabolic and other non-communicable diseases

P 162 SIGNIFICANT WEIGHT REDUCTION AND METABOLIC IMPROVEMENT WITH TIRZEPATIDE IN A PERSON LIVING WITH HIV ON LONG-ACTING CAB/RPV

S.G. Rizzello, R. Ferri, E. D'Arcangelo, K. Falasca, J. Vecchiet

Clinic of Infectious Diseases, "G. d'Annunzio" University of Chieti-Pescara, Italy

Background: Cardiometabolic comorbidities increasingly affect long-term outcomes in people living with HIV (PLWH), despite effective antiretroviral therapy (ART). Obesity, type 2 diabetes mellitus (T2DM) and metabolic-associated liver dysfunction contribute to residual cardiovascular (CV) risk. Tirzepatide, a dual GIP/GLP-1 receptor agonist, has demonstrated substantial weight loss and metabolic benefit in the general population; however, data in PLWH remain limited, particularly regarding virological safety and CV risk estimation in patients receiving long-acting ART.

Materials and Methods: We report a 51-year-old male diagnosed with HIV in 2004, on long-acting cabotegravir/rilpivirine (CAB/RPV), with hypertension and T2DM. In May 2025, tirzepatide 5 mg weekly was initiated for class II obesity (weight 120 kg; BMI 37 kg/m²). Clinical, metabolic, hepatic, renal and viro-immunological parameters were collected at baseline and during 8 months of follow-up.

Results: At baseline, fasting glucose was 135 mg/dL, triglycerides 229 mg/dL, LDL 112 mg/dL, AST/ALT 58/43 U/L. HIV-RNA was undetectable.

After 8 months of tirzepatide therapy, body weight decreased to 104 kg (-16 kg; -13.3%), representing clinically meaningful weight reduction. This was accompanied by marked metabolic improvement: triglycerides decreased to 96 mg/dL (-58%) and fasting glucose to 104 mg/dL. Liver enzymes normalized (AST 24 U/L; ALT 28 U/L). Renal function remained stable.

Virologically, HIV-RNA remained persistently undetectable and CD4+ T-cell count increased to 978 cells/mm³, with no evidence of virological rebound or interaction with long-acting CAB/RPV.

Conclusions: In this PLWH receiving long-acting CAB/RPV, tirzepatide was associated with substantial weight loss (-13.3% at 8 months) and significant metabolic and hepatic improvement, without compromising virological control. Incretin-based therapies may represent a safe and effective adjunct strategy to address obesity and metabolic burden in aging PLWH.

Metabolic and other non-communicable diseases

P 163 SUBCLINICAL ATHEROSCLEROSIS AND HEPATIC FIBROSIS IN PEOPLE LIVING WITH HIV: A MULTIVARIABLE ANALYSIS OF CLINICAL, METABOLIC, AND VIRO-IMMUNOLOGIC FACTORS

M.S. Paternò Raddusa¹, S. Spampinato^{2,3,4}, G. Scuderi⁵, B.S. Cacopardo^{2,3}, B.M. Celesia², A. Marino^{2,3}, G. Bruno¹, C. Giarratana¹, C. Gullotta⁶, P. Fagone⁵, P. Maggi⁷, G. Nunnari^{2,3}

¹Gravina Hospital, Caltagirone (Catania), Italy, ²ARNAS Garibaldi Hospital, Unit of Infectious Diseases, Catania, Italy, ³University of Catania, Department of Clinical and Experimental Medicine, Catania, Italy, ⁴University of Messina, Department of Clinical and Experimental Medicine, Messina, Italy, ⁵Department of Biomedical and Biotechnological Sciences, University of Catania, Catania, Italy, ⁶Umberto I Hospital, Siracusa, Italy, ⁷University "Kore" of Enna Department of Medicine and Surgery, Enna Italy

Background: People living with HIV (PLWH) have an increased cardiometabolic risk not fully explained by traditional risk factors. Chronic inflammation, immune activation, and antiretroviral therapy may contribute to vascular remodeling and hepatic fibrosis. Carotid intima-media thickness (IMT) and non-invasive fibrosis scores are validated markers of subclinical organ damage, but the role of viro-immunologic determinants and the relationship between vascular and hepatic involvement remain unclear.

Methods: We conducted a cross-sectional study of 160 PLWH followed at the Garibaldi Nesima center of Catania (July 2023–March 2025). Carotid color-Doppler ultrasonography assessed IMT; outcomes were FINAL IMT (≥ 1 mm vs < 1 mm) and FINAL BIL (bilateral IMT ≥ 1 mm). Hepatic fibrosis was evaluated using FIB-4 and the NAFLD Fibrosis Score (NFS). Generalized linear models estimated independent associations adjusting for clinical, metabolic, and virological covariates (age, sex, infection/therapy duration, CD4 nadir, CD4/CD8 ratio, viral-load metrics including zenith and current VL, smoking, diabetes, ASCVD, obesity, lipids, lipid-lowering therapy, HBV/HCV, protease-inhibitor exposure). Partial correlations assessed vascular-hepatic relationships. The SHiNe-SHiC project adheres to ethical standards consistent with the Declaration of Helsinki. The relevant ethics committee approved the study. All participants provided written informed consent to partake in the study.

Results: Mean age was 53.0 ± 10.9 years; 77% were male. FINAL IMT was observed in 67% of participants (fig.1) and was associated with age ($p=0.048$), zenith VL ($p=0.010$), and LDL ($p=0.005$). FINAL BIL was observed in 71% of FINAL IMT group (fig.2); FINAL BIL was also associated with obesity ($p=0.031$), protease-inhibitor exposure ($p=0.041$), age ($p=0.015$), and LDL ($p=0.006$); current VL ($p=0.057$) and CD4/CD8 ratio ($p=0.054$) approached significance. Higher NFS was predicted by age ($p<0.001$) and obesity ($p=0.026$). FIB-4 increased with age ($p<0.001$), zenith VL ($p=0.042$), and current VL ($p=0.014$). Modest inverse correlations were observed between vascular and hepatic indices (IMT with FIB-4: $r=-0.204$, $p=0.036$; MONOBIL with NAFLD strata: $r=-0.207$, $p=0.033$), while FINAL IMT and FINAL BIL were strongly concordant ($r=0.888$, $p<0.001$) (fig.3).

Conclusions: In treated HIV infection, vascular remodeling is mainly related to age, LDL, and viro-immunologic activity, with a specific contribution of protease-inhibitor exposure to bilateral IMT. Hepatic fibrosis is driven by age and metabolic burden and tracks with viral-load dynamics. Vascular and hepatic trajectories appear partially uncoupled, supporting integrated cardio-hepatic surveillance alongside durable viral suppression. Larger longitudinal studies are warranted.

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Metabolic and other non-communicable diseases

P 164 SWITCHING TO DTG/3TC OR FTC/TAF/BIC IN PEOPLE LIVING WITH HIV ALREADY ON A STABLE TAF INCLUDING REGIMEN DOES NOT CHANGE WEIGHT AND LIPID PROFILE

N. Squillace¹, L. Taramasso², E. Ricci³, B. Menzaghi⁴, A. Gidari⁵, G. Orofino⁶, B.M. Cesia⁷, E. Sarchi⁸, S. Piconi⁹, G. Pellicano¹⁰, G. Madeddu¹¹, S. Ferrara¹², L. Attala¹³, A. Di Biagio², P. Bonfanti¹, for the CISAI Study Group

¹Infectious Diseases Unit Fondazione IRCCS, San Gerardo dei Tintori-University of Milano-Bicocca, Monza, Italy, ²Infectious Diseases, San Martino Hospital Genoa, University of Genoa, Genoa, Italy, ³Fondazione ASIA Onlus, Buccinasco (MI), Italy, ⁴Unit of Infectious Diseases, ASST della Valle Olona – Busto Arsizio (VA), Italy, ⁵Department of Medicine and Surgery, Clinic of Infectious Diseases, "Santa Maria della Misericordia" Hospital, University of Perugia, Perugia, Italy, ⁶Division I of Infectious and Tropical Diseases, ASL Città di Torino, Italy, ⁷Unit of Infectious Diseases, Garibaldi Hospital, Catania, Italy, ⁸Infectious Diseases Unit, S. Antonio e Biagio e Cesare Arrigo Hospital, Alessandria, Italy, ⁹Unit of Infectious Diseases, A. Manzoni Hospital, Lecco, Italy, ¹⁰Infectious Diseases, G. Martino Hospital -University of Messina, Messina, Italy, ¹¹Unit of Infectious Diseases, Department of Medicine, Surgery, and Pharmacy, University of Sassari, Sassari, Italy, ¹²Unit of Infectious Diseases, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy, ¹³Unit of Infectious Diseases, Santa Maria Annunziata Hospital, Florence, Italy

Background: Our aim was to investigate the role of switching from Emtricitabine/Tenofovir Alafenamide (TAF) based regimen to a dolutegravir and lamivudine (DTG) vs BIC/FTC/TAF (TAF) on metabolic parameters.

Material and Methods: Consecutive people living with HIV infection (PWH) enrolled in a multicenter observational cohort (SCOLTA) project, on a stable FTC/TAF based regimen with a HIV-RNA<50 copies/ml were included. Changes from baseline (T0) to follow-up (T1, week 24 and T2, week 36) were analyzed.

Results: Five hundred and twenty PWH met the inclusion criteria, 408 (78.5%) were males, 298 (57.3%) were on a previous Cobicistat including regimen (COBI-IR).

At T0 main characteristics were (mean $\pm$ standard deviation [SD]): age 49.7 $\pm$ 11.9 years, weight 75.9 Kg $\pm$ 13.9, body mass index (BMI) 25.7 $\pm$ 4.1 kg/m², total cholesterol (TC) 192 $\pm$ 41 mg/dL, LDL-cholesterol (LDL-c) 114 $\pm$ 36 mg/dL, CD4+ cell count median value was 680 cell/ μ L (interquartile range [IQR] 498-908), triglycerides (TGL) 113 mg/dL (IQR 82-158). Median time of observation was 32 months (IQR 16-48).

PWH switching to DTG differed significantly by TAF for: INSTI and NNRTI in previous regimen (65.9% vs 81.0% and 25.4% vs 5.3% respectively; $p < 0.001$), risk factor for HIV infection (Intravenous Drug users 6.3% vs 18.3%, sexual 87.3% vs 66.5%, other/unknown 6.4% vs 15.2%, $p < 0.0001$), HCV coinfection (7.9% vs 18.3%, $p < 0.0001$), baseline CD4 (median 772 [IQR 585-978] and 656 [IQR 469-882], $p = 0.0005$), CDC stage C (10.3% vs 18.3%, $p = 0.001$), years of Antiretroviral Therapy (median 6.9 [IQR 3.1-13.3] vs 8.6 [IQR 3.8-17.1], $p = 0.01$) and previous COBI-IR (33.3% in 2DR vs 65.9% in TAF, $p < 0.0001$). PWH with previous COBI-IR had higher levels of TC (210 $\pm$ 39 mg/dl vs 196 $\pm$ 41 mg/dL, $p = 0.046$) at enrollment. PWH on statin therapy were 11.1% in DTG vs 18.0% in TAF group ($p = 0.07$). In a multivariate model adjusted for initial value of the variable, previous regimen class (with or without Cobicistat), CDC stage, statin use and HCV-coinfection, no significant differences were found between DTG and TAF group as regards weight, BMI and lipid profile (see table 1).

On the entire sample, TC reduced significantly in DTG group at T1 (-9 mg/dl [95% confidence interval -18 to -1], whereas at T2 the levels were still lower than T0 but not statistically significant. At T2 LDL-Cholesterol (LDL-c) showed a further decrease, both in DTG and TAF (-12 mg/dl [95% CI -23 to -2] and -9 mg/dl [95% CI -17 to -0] respectively) with no differences between the two groups.

In PWH on previous COBI-IR we observed significant declines in TC and LDL-C both at T1 and T2 with no differences between DTG and TAF.

Conclusions: In PWH already on TAF, stopping TAF does not have an impact on lipid profile and BMI. Switching to DTG+3TC or BIC/FTC/TAF is associated with TC and LDL reduction independently of previous regimen. Weight and BMI were not influenced by switching TAF or COBI.

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Metabolic and other non-communicable diseases

P 165 THE DARK SIDE OF DIETARY SUPPLEMENTS (DS) IN PEOPLE WITH HIV (PWH)

F. Abrescia, A. Narducci, C. Grillo, F.R.P. Ieva, S. Ferrara, A. Vergori, S. Lo Caputo

Infectious Diseases Unit, Department of Clinical and Surgical Sciences, University of Foggia, Foggia, Italy

Background: People with HIV (PWH) often rely on dietary supplements (DS) but real-world data on patterns use, source of information and awareness of potential drug-drug interactions remain limited. We aimed to describe the prevalence and characteristics of DS use and evaluate awareness of potential interaction risks in a cohort of PWH.

Material and Methods: We conducted a cross-sectional study including 210 PWH followed at our center. Clinical and laboratory data were extracted from medical records. DS use was assessed (Jan-Feb 2026) through a structured questionnaire on type, frequency, timing of intake relative to ART, motivations, source of advice and awareness of potential interaction risk. Descriptive analysis was performed.

Results: The study included 210 PWH (median age 54 years, IQR 44-61; 32.8% female), with long-standing HIV infection and high rates of comorbidities (table 1).

Overall, 79.5% of PWH reported DS use. Vitamin and mineral supplements were the most frequently used products, particularly vitamin D (74.4%), vitamin C (69.7%), and B complex (60.5%) [Fig. 1]. DS targeting lipid and cardiovascular health were used by 30.5% [Fig. 2] and herbal products by 38.3%.

Among users, 52.7% reported daily intake and 49.7% current use, mainly to improve quality of life [Fig. 3].

Although many purchased DS in pharmacies and followed medical advice, a notable proportion reported online purchase (19.8%), self-medication (25.1%) and internet-based information (15%) [Fig. 4]. Awareness of potential interactions with ART was low: 78.4% were unaware and only 30.5% informed their HIV specialist [Fig. 5]; the main reason for no-disclosure is the perception of low clinical relevance (78.4%). Regarding timing of intake, 40.7% space DS more than two hours from ART, while 18.6% take them concomitantly.

Only one virologic failure meeting the predefined criteria was observed. In this case, no resistance mutations were detected; the patient was temporarily switched to DRVb/F/TAF while awaiting genotypic results and was subsequently returned to BIC/F/TAF. Another patient experienced a single viral blip that resolved promptly without any modification of ART, occurring during the intake of an herbal supplement containing *Bacopa monnieri* and *Withania somnifera* (ashwagandha).

(table 2).

Conclusions: DS use is highly prevalent among PWH and frequently includes autonomous use, sometimes connected also to fads, while awareness of potential interaction risks remains scarce. Proactive clinicians' inquiry and education are warranted to optimize ART safety.

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Metabolic and other non-communicable diseases

P 166 ULTRASOUND-GUIDED EVALUATION OF METABOLIC HEALTH IN A COHORT OF MIDLIFE WOMEN WITH HIV: THE URSULA STUDY

M. Poliseño¹, D. Capruzzi¹, A. Cianciaruso¹, N. Colavito¹, F. Dalitto², V. Giliberti¹, V. Lobalsamo¹, G. Metrangolo¹, M. Noviello², A. Vigna¹, M. Zarcone³, F. Di Gennaro¹, V.O. Palmieri², A. Saracino¹

¹Clinic of Infectious Diseases, Department of Regenerative and Precision Medicine and Jonian Area (DiMePre-J), University of Bari, Bari, Italy, ²Clinic of Internal Medicine, AOUC Policlinico di Bari, Bari, Italy, ³Palermo and Province Cancer Registry, Clinical Epidemiology Unit with Cancer Registry, Azienda Ospedaliera-Universitaria Policlinico "Paolo Giaccone", University of Palermo, Palermo, Italy

Background: Women with HIV (WoWH) show increased risk of metabolic impairment, especially in midlife, due to several biological, hormonal, cultural, and social factors. However, metabolic health is not always routinely assessed in this population.

Methods: Between April 1 and July 31, 2025, all WoWH aged ≥ 40 years under stable antiretroviral treatment (ART) followed up in our HIV outpatient Clinic were offered a comprehensive clinical and laboratory metabolic assessment, as well as an abdominal and carotid Doppler ultrasound (US). Hepatic steatosis (HS) was evaluated and classified according to a semi-quantitative visual scale from 0 (no steatosis) to 3 (severe steatosis), based on established echogenicity criteria. Atherosclerotic plaques, carotid intima-media thickness (cIMT), and visceral, extra-hepatic fat thickness were assessed. Demographic, clinical, immunovirological and therapeutic data were collected and summarized according to the presence of at least grade 1 HS. Metabolic syndrome (MetS) was diagnosed according to NCEP-ATP III criteria. Cox regression analyses were performed to identify predictors of increased risk of HS. Spearman's correlations estimated the associations between HS and abnormal visceral fat distribution. Receiver operating characteristic (ROC) curves were used to assess the accuracy of NCEP-ATP III criteria in identifying also WoWH at higher risk of HS.

Results: Overall, 98/282 eligible WoWH consented to participate in the study, mainly Italians (93%) of mean (56 ± 7) years. Among them, 55 (56%) had at least grade 1 HS. Atherosclerotic plaques were detected in 35 WoWH (36%) with no differences according to HS. Other detailed US findings are reported in Table 1. MetS was diagnosed in 24 WoWH (25%) with higher prevalence among those with HS (40% vs 7%, $p < 0.001$). High insulin [$10.5 (\pm 4.40)$ vs $16.1 (\pm 13.3)$, $p = 0.02$] and lower HDL-Chol levels [$62.9 (\pm 12.4)$ vs $54.9 (\pm 16.0)$, $p = 0.01$] were also observed in the latter group. At multivariable analysis including age, menopausal status, BMI, lifestyle habits, history of ART treatments, baseline immune virological assessment, viral hepatic coinfections, MetS was the main risk factor for HS (aOR 13.94, 95% C.I. 2.99-85.78). Progressive HS severity was significantly associated with retroperitoneal, subcutaneous, and epicardial fat thickness increasing and exceeding the normal ranges ($p = 39.3$, $p = 0.0001$, $p = 27.7$, $p = 0.005$, and $p = 31.2$, $p = 0.002$, respectively), but not with increased cIMT. NCEP-ATP III criteria showed only limited accuracy in identifying patients at risk for HS (AUC = 0.67) (Figure 1).

Conclusions: In the URSULA cohort, hepatic steatosis – largely driven by MetS – was highly prevalent and associated with abnormal visceral fat distribution. Dedicated metabolic surveillance strategies are urgently needed in this population. In this context, US may represent a highly cost-effective, rapid and non-invasive preventive tool.

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Metabolic and other non-communicable diseases

P 167 VITAMIN D DEFICIENCY AMONG WOMEN AGED >50 YEARS LIVING WITH AND WITHOUT HIV: PREVALENCE, PREDICTORS, AND ASSOCIATIONS WITH METABOLIC DISEASES

M. Polisenò, R. Starace, D. Capruzzi, A. Cianciaruso, N. Colavito, V. Giliberti, V. Lobalsamo, A. Vigna, G. Romita, F. Di Gennaro, A. Saracino
Clinic of Infectious Diseases, Department of Regenerative and Precision Medicine and Jonian Area (DiMePre-J), University of Bari, Bari, Italy

Background: The immunomodulatory and osteoprotective effects of vitamin D (VitD) have been widely investigated in women living with and without HIV; however, its potential role in metabolic disorders - now affecting a large proportion of this population - remains poorly understood. This study aimed to assess the prevalence and predictors of VitD deficiency in a cohort of women with HIV (WoWH), to explore its potential association with metabolic syndrome (MetS) and its individual components, and to evaluate differences compared with an age- and menopausal status-matched HIV-negative control group.

Material and Methods: From April 1, 2025 to January 31, 2026 all WoWH aged >50 years followed at our HIV Clinic were evaluated for serum VitD levels. MetS was defined according to NCEP-ATP III criteria. Serum VitD levels of 15–30 ng/mL and <15 ng/mL defined moderate and severe deficiency, respectively. Similar data were collected from voluntary, HIV-negative, age-matched women attending the Clinics of Internal Medicine and Infectious Diseases during the same period. Descriptive statistics were performed. Cox regression analysis identified predictors of VitD deficiency in the overall population and stratified by HIV status. The association between moderate/severe VitD deficiency and MetS and/or its components was assessed using the chi-square test and confirmed by logistic regression analysis.

Results: Two hundred fifty-four women were enrolled, including 204 WoWH. Median (IQR) age was 59 (55–64) years; 90% were menopausal, with no difference between groups. Although 154 reported VitD supplementation, 47% still had at least moderate deficiency. Overall, moderate and severe VitD deficiency were observed in 118 (46%) and 31 (12%) women, respectively, with similar prevalence by HIV status.

At multivariable analysis, longer menopause duration and BMI >30 were independent predictors of VitD deficiency in the overall population, whereas HIV status was not associated. Among HIV-negative women, only BMI >30 was associated with a sixfold increased risk of deficiency. In WoWH, longer menopause duration and prior AIDS diagnosis were associated with increased risk (Table 1).

MetS prevalence was overall high (81 women, 32%), with no significant difference by HIV status (42% vs 29%, $p=0.08$). Moderate VitD deficiency was not associated with MetS or its components. Conversely, severe deficiency was associated with a fourfold increased risk of MetS and with higher odds of hyperglycemia and abdominal circumference and reduced HDL cholesterol levels, irrespective of HIV status (Table 2).

Conclusions: VitD deficiency was highly prevalent in this cohort, despite supplementation and regardless of HIV status. Given the observed association between severe VitD deficiency and MetS, monitoring and optimizing VitD levels may be crucial in menopausal women, particularly in the presence of additional metabolic risk factors.

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Pharmacology

P 168 COMPREHENSIVE PHARMACOGENETIC, PHARMACOKINETIC AND CLINICAL ASSESSMENT OF BULEVIRTIDE IN CHRONIC HEPATITIS D PATIENTS

J. Cusato¹, M. Antonucci², A. Palermi¹, A. Manca¹, S. Perosino², F. Onelia², A. De Nicolò¹, C. Quarta², A. D'Avolio¹, S. Bonora², G. Di Perri², L. Marinaro²

¹University of Turin, Turin, Italy, ²Amedeo di Savoia Hospital, Turin, Italy

Background: Bulevirdide represents the first authorized entry inhibitor indicated for the management of chronic hepatitis D (CHD), exerting its antiviral activity by blocking the sodium taurocholate co-transporting polypeptide (NTCP). Although clinical results have been promising, marked variability among patients in drug exposure and therapeutic effectiveness has been reported. So far, limited evidence has explored the variability in bulevirdide plasma concentrations and the potential role of genetic polymorphisms. The present study sought to evaluate bulevirdide plasma levels, along with biochemical and virological markers at different time points, and to investigate the impact of NTCP gene variants on clinical outcomes, taking into account virological and biochemical responses at week (W) 60.

Material and Methods: patients with CHD treated with bulevirdide were included in the study. Bulevirdide plasma levels, together with biochemical and virological markers, were measured at baseline and at weeks (W) 4/12/24/36/48 and 60 using liquid chromatography-mass spectrometry. The pharmacogenetic evaluation targeted NTCP genetic variants (rs8011311-rs2296651), analyzed through PCR genotyping.

Results: Seventeen patients were initially recruited; five were later excluded due to incomplete follow-up and inadequate adherence to therapy. Among the twelve patients included in the final analysis, 75% were male. Median age was 51.5 years and median BMI was 24.5 kg/m²; cirrhosis was present in 50% of cases. At baseline, median ALT level was 80.5 IU/L and median HDV RNA was 5.3 Log. Liver stiffness significantly decreased at week 48 compared with baseline (p=0.041, figure 1). Lipid parameters were not affected by treatment, while a slight, non-significant increase in bile acids was observed. No adverse events were reported.

At week 60, virological response was achieved in 4 patients (33.3%), biochemical response in 4 (33.3%), and a combined response in 3 (25%).

Median plasma bulevirdide concentration was 0.4 ng/mL (IQR 0.3–0.5) at W4, 0.9 ng/mL (IQR 0.4–1.9) at W12, 0.6 ng/mL (IQR 0.3–1.6) at W24, 1.0 ng/mL (IQR 0.5–1.3) at W36, 1.2 ng/mL (IQR 0.5–7.2) at W48, and 0.7 ng/mL (IQR 0.3–2.1) at W60. Concomitant medications did not appear to influence bulevirdide exposure, whereas liver stiffness values >12 kPa were associated with differences in drug levels, particularly at week 12 (p=0.026).

Regarding pharmacogenetic findings, patients carrying the NTCP rs8011311 GC/CC genotype exhibited lower bulevirdide concentrations compared with those with the GG genotype at week 4 (p=0.047).

Conclusions: This exploratory study is the first to describe bulevirdide plasma concentrations in patients undergoing 60 weeks of treatment and to investigate the influence of genetic factors, although sample size was limited. Larger-scale studies are needed to support the development of individualized dosing approaches aimed at optimizing efficacy and safety in patients with HDV infection.

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Pharmacology

P 169 THE SUPPLEMENT IS THE CULPRIT: A CASE OF VIROLOGICAL FAILURE DUE TO UNEXPECTED INTERACTIONS

S. Pagano, M. Maffezzoni, A. Dessilani, I. Baldisserotto, P.A. Grossi

Circolo Hospital and Macchi Foundation, Varese, Italy

Background: The use of dietary supplements (including vitamins and minerals) is common among people living with HIV (PLWH) receiving antiretroviral therapy (ART), but is often unknown to prescribing physicians. Some drug-supplement combinations may result in clinically significant interactions with ART, sometimes reducing its absorption.

Case Description: We report the case of a 31-year-old woman living with HIV, diagnosed in 2012, with no previous virological failures. She has been receiving antiretroviral therapy with dolutegravir (DTG) plus emtricitabine/tenofovir alafenamide (FTC/TAF) since 2020 and has maintained stable viral suppression since then.

She was also affected by tuberculous spondylodiscitis, diagnosed in April 2022 and treated with specific therapy for a total of 12 months, together with B6-containing supplement to prevent neurological side effects caused by isoniazid.

In November 2024, an elevated viral load was detected (HIV-RNA 4,964 copies/mL), confirmed on subsequent testing (4,887 copies/mL). During the infectious disease consultation, the patient firmly denied any interruption of antiretroviral therapy. She also denied starting new medications and reported no recent infections or vaccinations.

After further investigation, the patient admitted to continued use of a dietary supplement containing B vitamins, phosphoserine, and glutamine concomitantly with antiretroviral therapy. One month after discontinuation of the supplement, viral load testing was repeated and showed suppression below 30 copies/mL.

Genotypic resistance testing performed on the viral load of 4,887 copies/mL using next-generation sequencing revealed no resistance-associated mutations (RAMs) to the antiretroviral drugs taken by the patient. After six months, the patient remained stably virologically suppressed.

Conclusions: Unexpected drug interactions between non-conventional products and antiretroviral therapy may lead to virological failure. Clinicians should maintain a high level of vigilance regarding all substances used by patients.

PrEP

P 170 **BREAKING BARRIERS: LONG-ACTING CABOTEGRAVIR FOR HIV PREP IN AN ITALIAN ADOLESCENT**

C. Coppola¹, M. Stracuzzi¹, R. Caiazza¹, M.S. Valentino¹, A. D'Avolio², D. Moschese³, V. Giacomel¹

¹Pediatric Infectious Disease Unit, Luigi Sacco Hospital, University of Milan, Milan, Italy, ²Department of Medical Sciences; University of Turin - ASL 'Città di Torino' Laboratory of Clinical Pharmacology and Pharmacogenetics; Amedeo di Savoia Hospital, Turin, Italy, ³I Division of Infectious Diseases, ASST Fatebenefratelli Sacco, Luigi Sacco Hospital, Milan, Italy

Background: The approval of long-acting injectable cabotegravir (CAB-LA) for HIV pre-exposure prophylaxis (PrEP) represents a paradigm shift in HIV prevention, particularly for adolescents who often face challenges with daily oral adherence and stigma. While clinical trials (HPTN 084) demonstrated high efficacy, real-life data in the European pediatric setting are still extremely limited. We describe the first Italian experience of CAB-LA in an adolescent, integrating therapeutic drug monitoring (TDM) and patient-reported outcomes (PROs).

Material and Methods: A 16-year-old male (weight 69 kg, height 173 cm, BMI 23.5 kg/m²) presented to our Adolescent STI Clinic for PrEP. Baseline screening showed optimal health status with normal hepatic (ALT/AST) and renal (Creatinine/eGFR) functions. He started CAB-LA (600 mg IM at week 0, 4, and then every 8 weeks). TDM was performed at mid-interval between the 3rd and 4th dose (4 weeks after the previous injection) using UPLC-MS/MS. PROs were assessed via the IATA (Injected Adherence and Tenability Assessment) scale and a Visual Analogue Scale (VAS) for satisfaction and pain.

Results: The transition to CAB-LA was successful with excellent clinical and psychological tolerability. TDM at mid-interval revealed a CAB plasma concentration of 1642 ng/mL (1.64 µg/mL), which is approximately 10-fold higher than the protein-adjusted 90% inhibitory concentration (PA-IC₉₀ = 0.166 µg/mL), confirming robust and stable drug exposure during the maintenance phase. Local injection site reactions were negligible (VAS 2/10). The patient reported a significant reduction in "pill-burden" anxiety and perceived stigma, highlighting the benefit of "treatment invisibility." No HIV seroconversions or laboratory abnormalities were observed during follow-up.

Conclusions: This case provides clinical and pharmacological reassurance for the use of CAB-LA in the adolescent population. The high drug exposure at mid-interval and the positive impact on quality of life suggest that CAB-LA is a key tool for sustainable prevention in youth at high risk of HIV acquisition, effectively overcoming the main psychosocial barriers to oral PrEP.

PrEP

P 171 CLINICAL AND ECONOMIC IMPACT OF PRE-EXPOSURE PROPHYLAXIS (PrEP) FOR HIV PREVENTION IN ITALY

C. Bini¹, V. Mazzotta², S. Nozza³, M. Paoletti¹, V. Scansetti¹, P. Sciattella¹

¹Economic Evaluation and HTA (EEHTA) - CEIS, Faculty of Economics, University of Rome "Tor Vergata", Rome, Italy, ²Clinical Infectious Diseases Department, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ³Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy; Vita-Salute San Raffaele University, Milan, Italy

Background: Infection with the human immunodeficiency virus (HIV) remains a major public health challenge even in high-income countries. In Italy, despite high levels of treatment coverage, HIV is associated with a significant clinical and economic burden, further exacerbated by the ageing of the HIV-positive population and the increasing prevalence of comorbidities. In this context, pre-exposure prophylaxis (PrEP) represents an effective tool for primary prevention. This study aims to assess the clinical and economic impact of PrEP in a subgroup of population at high risk of HIV transmission (men who have sex with men - MSM).

Material and Methods: A Cost-Consequence Analysis (CCA) based on a Markov model was conducted to simulate the pathway of a closed hypothetical cohort of 1,000 MSM with and without PrEP over a 20-year time horizon. In the scenario including PrEP, the hypothetical cohort was assumed to reflect current patterns of use in Italian clinical practice, with 85% of individuals receiving oral PrEP with tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) and the remaining 15% receiving long-acting injectable PrEP with lenacapavir. Epidemiological data, resource use, and associated costs were obtained through an exploratory literature review, consultation of data from major institutional websites, and input from clinicians with national-level expertise in the management of HIV infections. Efficacy data for oral and injectable PrEP were derived, respectively, from the ANRS PREVENIR cohort and the PURPOSE-2 clinical trial.

Results: The simulation of a cohort of 1,000 MSM showed that the use of PrEP could lead to a reduction in cumulative HIV infections over 20 years of approximately 69% compared with the no-PrEP scenario. This reduction in infections was also associated with a decrease in cumulative direct costs for the management of new HIV cases of approximately €32.8 million.

Conclusions: The adoption of PrEP in the MSM population could result in a significant reduction in new HIV infections, with a consequent favourable impact on the sustainability of the healthcare system through a decrease in costs related to clinical management and treatment of the infection.

PrEP

P 172 EVOLUTION OF INTEGRATED HIV CARE: THE FERRARA PREP CENTER EXPERIENCE

D. Segala^{1,2}, C. Magagnoli¹, P. Mori², C. Sartori², R. Cultrera^{1,3}

¹University of Ferrara, Ferrara, Italy, ²Azienda Ospedaliero Universitaria di Ferrara, Ferrara, Italy, ³Azienda Unità Sanitaria Locale di Ferrara, Ferrara, Italy

Background: Pre-Exposure Prophylaxis (PrEP) reliably prevents HIV, yet barriers and rising Sexually Transmitted Infections (STIs) require analyzing experiences to identify challenges and optimize care pathways for improved preventive service delivery.

Methods: A single-center, retrospective, real-life study was conducted at the Ferrara PrEP Center and included adult subjects who received at least one PrEP prescription between November 2018 and June 2025. The aim was to profile Ferrara PrEP users for personalized care and evaluate drug safety/efficacy. Additionally, we analyzed STI incidence/prevalence and socio-demographic correlations, while assessing adherence and discontinuation reasons to improve long-term patient compliance. Demographic, clinical, and laboratory data (HIV, hepatitis A/B/C, T. pallidum, Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG) were collected at baseline and follow-up. Comparative analyses were performed between STI-positive/negative subjects and those retained in care versus those lost to follow-up. Categorical variables were analyzed using the Chi-squared test or the Fisher-Freeman-Halton exact test, while quantitative variables were assessed using the Mann-Whitney U test (significance level set at $\alpha=0,05$).

Results: We enrolled 107 PrEP users (99.07% male at birth, 85.05% Italian-born; median age 33, IQR 27–43). At baseline, 32.7% had prior STIs and 6.54% prior PEP use. HBV vaccination was 70.1%, with limited monkeypox coverage. Enrollment peaked in 2024 (37.38%) and 2022 (21.50%). Dosing regimens were 57.01% on-demand and 28.04% continuous, with 14.02% switching modalities. Median follow-up was 10 months (IQR 1–20) over 4 visits (IQR 1–5); 52.33% discontinued or were lost to follow-up. Overall, 30.8% tested positive for at least one STI (9.09% multiple pathogens), with no HIV seroconversions or acute viral hepatitis. Most frequent STIs were gonorrhea (18.84%), chlamydia (14.5%), and syphilis (14.02%). Rectal CT prevalence was 68.75% and oropharyngeal NG was 60%. No significant renal alterations occurred. Comparative analysis showed significant differences in follow-up duration, visit frequency, and prior STI history between positive and negative subjects for syphilis, CT/NG, and overall STIs (reimbursement subgroup). Significant differences between those lost to follow-up and retained in care emerged regarding PrEP initiation year, dosing, reimbursement, follow-up metrics (Tables 1-4).

Conclusions: Findings confirm PrEP efficacy and safety for HIV prevention. Despite the need for broader minority representation, increased access post-reimbursement provides a robust foundation for future implementation. The Ferrara experience shows an integrated prevention model combining vaccination, counseling, and STIs management, that promotes patient empowerment through tailored care pathways. PrEP is not merely a drug but a vital public health tool safeguarding the physical, sexual, and psychological well-being of users.

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PrEP

P 173 HOW PREP IMPACTS PSYCHOLOGICAL, SEXUAL, AND RELATIONAL WELL-BEING: A LONGITUDINAL EVALUATION

G. Del Duca, A. Caioli, M. Maresca, R. Esvan, A.C. Brita, G. Micheli, G. Terracini, A. Giacinta, V. Barchi, D. Farinacci, R.J. Steiner, A. Antinori, V. Mazzotta

National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Background: Access to pre-exposure prophylaxis (PrEP) may both reflect and influence users' psychological, sexual, and relational characteristics. This study aimed to assess and longitudinally track factors related to the psychological and sexual well-being of individuals initiating PrEP.

Material and Method: The "VAMOS-PrEP Study" enrolled PrEP-naïve users who completed three psychological questionnaires (PQ) at baseline (T1), six months (T2), and twelve months (T3): the Sex Relation Evaluation Schedule Assessment Monitoring (SESAMO) for sexual functioning, the Symptom Checklist-90-R (SCL-90-R) for psychological status, and the Sex Addiction Screening Test (SAST) for compulsive sexual behaviors. Analyses were performed on standardized z-scores. The impact of PrEP at T2 was assessed using Cohen's d and Wilcoxon signed-rank tests. Mixed-effects linear regression models with random intercepts for patients and PQ items were used to evaluate the effects of PrEP and other covariates on SAST and SCL-90-R scores.

Results: 92 PrEP users performed PQ: 90 (98%) identified as male, with a median age of 36 (IQR 30-45). At follow-up, 49 (53%) completed T2 and 18 (20%) T3. Regression on standardized SAST scores showed that younger age ($\beta = -0.02, 95\%CI: -0.04 - -0.01, p = 0.010$) and chemsex ($\beta = 0.42, 95\%CI: 0.10 - 0.73, p = 0.010$) were associated with higher compulsive sexual behaviors. On SCL-90-R, older age ($\beta = -0.02, 95\%CI: -0.03 - 0.00, p = 0.009$), PrEP use ≥ 6 months ($\beta = -0.06, 95\%CI: -0.12 - 0.00, p = 0.046$) and stable relationships ($\beta = -0.23, 95\%CI: -0.39 - 0.06, p = 0.006$) were associated with better psychological status. A comparison between T1 and T2 SESAMO scores (Fig. 1) revealed a significant worsening in the contraception area ($d = 0.5, p = 0.04$) for single users. Imaginative eroticism was more dysfunctional after 6 months in both couples ($d = 0.4, p = 0.32$) and single users ($d = 0.4, p = 0.07$), but not statistically significant.

Conclusion: Among PrEP users, younger age and chemsex are associated with increased compulsive sexual behaviors, while longer PrEP use and stable relationships support better psychological well-being. Over time, modest increases in sexual activity were observed in both singles and couples. These findings can inform tailored interventions addressing the psychological and sexual needs of PrEP users.

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PrEP

P 174 INTEGRATING COMPREHENSIVE VACCINATION STRATEGIES INTO PREP CLINICAL CARE: REAL-WORLD DATA ON UPTAKE AND BARRIERS (2021–2026)

A. Çekrezi¹, D. Zacc¹, A. Morgante¹, R.A. Cavasio¹, N. Braccialarghe¹, F. Nina¹, L. Coppola², L. Campogiani², M. Iannetta^{1,2}, V. Malagnino^{1,2}, L. Sarmati^{1,2}

¹Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy, ²Infectious Diseases Unit, University Hospital Tor Vergata, Rome, Italy

Background: HIV pre-exposure prophylaxis (PrEP) provides regular clinical follow-up, which represents an opportunity to improve vaccination coverage against preventable sexually transmitted infections. We evaluated vaccination uptake among PrEP users and described associated variables in a tertiary care center.

Methods: We conducted a retrospective study including individuals receiving PrEP at Tor Vergata University Hospital (Rome, Italy) from January 2021 to January 2026. Demographic and behavioral data were collected. Vaccination status for hepatitis B virus (HBV), hepatitis A virus (HAV), human papillomavirus (HPV), for meningococcal B (MenB), baseline data for MenB were unavailable, and only post-PrEP initiation data were evaluated. Mpox vaccination status was also documented.

Results: A total of 285 individuals were included (median age 35 years, IQR 31–43) (table 1). Most participants were single (77.3%); 5% reported chemsex practices.

Before PrEP initiation, 247/280 individuals (88.2%) had been vaccinated against HBV; among them, 45 had received a booster dose. At PrEP initiation, 178/264 individuals (67.4%) had protective anti-HBV antibody titers. Following PrEP start, 56 individuals received HBV vaccination.

Regarding HAV, 74/271 individuals (27.1%) had been vaccinated before PrEP initiation, while 22 additional individuals were vaccinated after starting PrEP.

The proportion of individuals who had received at least one dose of HPV vaccine significantly increased from 81/264 (30.7%) before PrEP initiation to 197/264 (74.6%) after PrEP initiation ($p = 0.04$); among these, 167 individuals completed the full vaccination schedule.

Mpox vaccination was documented in 88/270 individuals (32.6%). However, this vaccine was not directly administered at our center, representing a significant barrier to uptake.

After PrEP initiation, 138/276 individuals (50.0%) received at least one dose of MenB vaccine, with 104/276 (37.7%) completing the two-dose schedule. Before vaccination, 20/116 individuals (17.2%) tested positive for *Neisseria gonorrhoeae*, compared with 10/110 (9.1%) after vaccination ($p = 0.40$) (Figure 1).

HPV vaccination was initiated before PrEP in 30% (81/280) and during follow-up in 47.4% (128/270), resulting in an overall coverage of 77.3%.

Overall, vaccination coverage was high for HBV and HPV, while HAV and MenB vaccination uptake remained suboptimal.

Conclusions: PrEP services represent an important platform to enhance preventive care beyond HIV protection. Structured integration of vaccination strategies within PrEP clinics may improve coverage forecommended vaccines in high-risk populations.

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PrEP

P 175 NURSE-LED FOLLOW-UP PREP AND STI CLINIC TO ADDRESS GROWING PREP ENROLMENTS

S. Venturelli¹, A. Crovetto², A. Bresciani³, L. Comi¹, F. Borghi¹, E. Nespoli⁴, G. Ghilardi⁴, D. Ripamonti¹, F. Crippa¹

¹Infectious Diseases Unit, ASST Papa Giovanni XXIII, Bergamo, Italy, ²Surgery Department, ASST Papa Giovanni XXIII, Bergamo, Italy, ³Department of Corporate Management for Healthcare and Social Professions, ASST Papa Giovanni XXIII, Bergamo, Italy, ⁴School of Medicine and Surgery, University of Milano-Bicocca, Monza, Italy

Background: Nurse-delivered sexual health and PrEP clinic models are well-established and widely adopted internationally. The WHO recognises that task-sharing with nurses involvement can be applied to support scaling-up of PrEP service. In Italy, the Multidisciplinary Centre for Sexual Health (Ce.Mu.Ss.) in Turin has implemented a nurse-led STI clinic for asymptomatic patients showing sustained effectiveness in clinical practice. The progressive increase in PrEP user enrolment at our centre, with quarterly STI screening, encouraged us to explore service implementation strategies. In April 2025, we established a nurse-led STI and PrEP clinic.

Methods: A retrospective observational study was performed to evaluate the type of activity carried out at the nurse-led clinic and the appointment slot occupancy rate from its opening on 16th April 2025 through to the end of December 2025. Thirteen slots per week were planned.

Results: In 2025, 150 new PrEP users were enrolled at our centre, bringing the total enrolments since programme start in 2018 to 611, with 461 in regular follow-up at the end of 2025. During the same period, 153 gonorrhoea infections and 31 syphilis were diagnosed among PrEP users, all requiring attendance for intramuscular treatment. Since its opening, 327 patients were booked at the nurse clinic, with 20 no-shows. In the first quarter following service launch, the slot occupancy rate was 53%, attributable to quarterly PrEP follow-up visits already scheduled at the medical-led clinic and to the initial set-up phase. In the final quarter (October–December 2025), the occupancy rate reached 96%. Among the persons assessed, 183 (60%) were seen for PrEP follow-up visits, 49 (16%) for gonorrhoea treatment, 41 (13%) for syphilis treatment and 34 (11%) for asymptomatic STI screening in non-PrEP patients. All treatment prescriptions, including PrEP prescriptions, were issued by a physician prior to the visit, following allergy verification. Benzylpenicillin injections were administered in the nurse clinic only to patients who had previously received at least one dose. A same-day parallel medical-led clinic was maintained and patients found to be unexpectedly symptomatic at the time of nursing assessment were promptly referred to the medical clinic. The nurse clinic was well accepted by all patients, with good engagement and high levels of satisfaction reported. Collaboration between medical and nursing staff remained consistently excellent.

Conclusions: Our experience demonstrates that a nurse-led clinic represents a feasible and efficient strategy to support expansion of PrEP and STI services. Saturation of the nurse clinic is anticipated and further expansion is under evaluation. Structured and continuous training for nursing staff should be implemented and formally endorsed by national policies in order to enhance the nurse role in PrEP services and to address the growing PrEP demand.

PrEP

P 176 ONE-YEAR OUTCOMES OF LONG-ACTING CABOTEGRAVIR PREP AT A SINGLE ITALIAN CENTRE

A.R. Raccagni^{1,2}, R. Lolatto², N. Capra², E. Bruzzesi^{1,2}, G. Loi¹, V. Lovato², L. Della Torre², M. Di Gerardo², R. Puzifferri², C. Ferri², A. Castagna^{1,2}, S. Nozza^{1,2}

¹Vita-Salute San Raffaele University, Milan, Italy, ²IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: Long-acting injectable cabotegravir (CAB-LAI) for HIV pre-exposure prophylaxis (PrEP) may overcome adherence barriers of oral PrEP. Aim is to present real-world 12-month persistence and follow-up outcomes in an Italian center.

Material and Methods: Prospective cohort at IRCCS San Raffaele Scientific Institute, Milan, Italy (NCT06418048). Adults initiating CAB-LAI for PrEP since November 2024 who completed the month-11 follow-up visit were included (freezing date January 2026). CAB-LAI was administered according to international guidelines; HIV testing was conducted at each injection with HIV Ag/Ab and HIVRNA. Baseline individuals' characteristics were collected. Follow-up data included injection timing, discontinuations, HIV testing and bacterial sexually transmitted infections. Injection site reactions (ISRs) and systemic adverse events were assessed at each injection with a survey. Persistence was estimated with Kaplan-Meier; STI incidence rates (IR) were expressed per 100 person-years (PY).

Results: A total of 79 participants were included (98.7% MSM; median age 41.2 years), mostly oral PrEP-experienced (94.9%) and with previous STI history (86.1%) (Table 1). Median follow-up was 12.2 months (IQR 11.8–13). Reasons for starting CAB-LA PrEP are presented in Table 2; the most common clinical reasons were oral PrEP adherence issues and chemsex. Six (7.6%) participants discontinued CAB-LAI after a median of 6.1 months (IQR 4–7); 12-month persistence was 92.4% (95%CI 83.9–96.5) (Figure 1). Discontinuation reasons are detailed in Table 3; 4/6 (66.6%) resumed oral PrEP with FTC/TDF. ISRs were common but generally mild and overall improved over time; systemic adverse events were infrequent. Among 473 maintenance CAB-LA injections, 450 (95.1%) were administered within ± 7 days of the scheduled date and two with a delay >10 days; one person required loading dose given the administration delay (Figure 2). Overall, 54 STI episodes occurred (IR 68.3/100 PY, 95%CI 51.3–89.2), including 28 gonorrhea (IR 24.05, 95%CI 14.48–37.55), 19 chlamydia (IR 35.44, 95%CI 23.55–51.22) and 7 syphilis (8.86, 95%CI 3.56–18.25). Two cases of acute HBV infection were observed in non-responders to HBV vaccination; one resulted in discontinuation of CAB and start of FTC/TDF. In both cases, HBsAg cleared within study period. Overall 480 HIV tests were performed (median per user 6, IQR 6–7), with no evidence of breakthrough infections.

Conclusions: In this real-world experience, largely composed of oral-PrEP-experienced MSM, CAB-LAI PrEP showed high 12-month persistence and excellent adherence to the recommended injection window. However, discontinuation was not negligible, with heterogeneous underlying reasons. Tolerability was favorable: injection-site reactions were frequent but mostly mild, with few discontinuations related to ISRs. No breakthrough HIV infections were detected, while bacterial STIs were common and two cases of acute HBV infection were observed.

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PrEP

P 177 POLITICAL AND STRUCTURAL OBSTACLES IN ITALY ARE DRIVING THE RISE OF PREP SAUVAGE?

S. Mattioli¹, S. Cecere¹, L. Badia², S. Maugeri¹, P. Morabito¹, M. Degli Esposti¹, G. Spreafico¹

¹Plus - Rete Persone LGBT+ Sieropositive - aps, Bologna, Italy, ²Azienda USL di Imola, Malattie Infettive, Imola, Italy

Background: Authorized by AIFA in Italy in October 2017, oral pre-exposure prophylaxis (PrEP) with TDF/FTC has seen a significant increase, especially after the introduction of reimbursement in May 2023. Data from the PrIDE (Prevention ICONA Dedicated Ensemble) cohort show an increase in PrEP users from approximately 11,300 in 2023 to over 16,220 in 2024, a percentage increase of 43.22% nationwide. The regions with the highest number of users are Lombardy, Lazio, and Emilia-Romagna, which together account for approximately 76% of the total. But, according to ECDC data, still less than in other EU Countries like Spain, France or UK. This small study seeks to understand whether some local laws introduced after 2023 have succeeded in hindering access to PrEP, leading to an increase in the use of "do-it-yourself" PrEP.

Methods: All users who leave our PrEP Point (PPP) Service are asked to complete the Lost Follow-up Questionnaire. We examined the reasons reported from 2018 to 2025 in general, and also examined whether external obstacles influenced the decision to no longer be followed by PrEP Point, stratifying the data based on:

- Application Note no. 3/2023 from the Emilia-Romagna Region, which limits PrEP's prescription to ID specialists only and only in clinics, and drug's dispensing to hospital pharmacies only.
- Memorandum no. 43774/2025, which prohibits the dispensing of the drug to non-residents of the Region.

For these two application notes, we considered data from 07/2023 to 12/2025.

Results: In the period considered, 174 users have left the PrEP Point Plus service, 159 (91.38%) of whom responded to the questionnaire clarifying the reason (table 1).

Out of this, 27 (17.65%) declare to be still on PrEP but not followed by a clinical center (table 2).

Conclusions: Further studies are needed but, considering that in a similar study(1) conducted before 2023, the percentage of our former users still on PrEP but not followed by a clinic was 10%, it appears that structural, logistical and regulatory barriers are hindering access to PrEP and encouraging users to withdraw from clinical care.

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PrEP

P 178 PREP EXPERIENCE FROM A SINGLE PIEDMONT REFERRAL MEDICAL CENTRE IN TURIN: A CASE OF HIV SEROCONVERSION

V. Ranotti¹, G. Maffei¹, A. Sau¹, F. Donato¹, P. Crosasso¹, A. Lucchini², M. Tutone², M. Ferrara³, S. Bonora³

¹S.D.S Infectious Diseases Hospital Pharmacy, Amedeo di Savoia Hospital, ASL City of Turin, Turin, Italy, ²S.D.S. Multidisciplinary Center for Sexual Health, Prevention Department, ASL City of Turin, Turin, Italy, ³Unit of Infectious Diseases, Department of Medical Sciences, University of Turin, Turin, Italy

Background: Pre-exposure prophylaxis (PrEP) with Emtricitabine/Tenofovir Disoproxil Fumarate (FTC/TDF) represents a cornerstone of contemporary HIV prevention strategies. In Italy, its integration into the National Health Service was formalized through AIFA Resolution 349/23, which established full reimbursement criteria and standardized follow-up requirements. Adherence and dosing modality are recognized as primary determinants of prophylactic efficacy. The report aims to characterize prescribing trends and real-world implementation focusing on dosing modality, comparing continuous daily versus on-demand regimens and the impact on adherence and prophylactic efficacy.

Methods: A retrospective observational analysis was conducted on PrEP prescriptions dispensed through the Hospital Pharmacy of a Piedmont Referral Center from June 2023 to February 2026. A database was developed to collect study population characteristics including age, gender, date of initiation, dosing regimen and number of days between drug refills. Clinical collaboration enabled the additional evaluation of a case of HIV seroconversion occurring during active PrEP use.

Results: During the observation period, 1,622 individuals received PrEP. The cohort was predominantly male (98%), with a median age of 39 years. On-demand dosing represented 73% of prescriptions and was exclusively adopted by men who have sex with men (MSM), whereas 27% of individuals received a continuous daily regimen. Among 334 recorded PrEP discontinuations, two prophylactic failures occurred to on-demand dosing: one related to discontinuation for gastrointestinal intolerance, and the other due to non adherence to standard medical visits and exams. This individual, 29 yrs old, MSM, was diagnosed with HIV in January 2026 after having received three packs of TDF/FTC from the hospital pharmacy in June 2024. He did not attend subsequent follow-up visits nor repeat HIV serological testing, which had been negative at the time of PrEP prescription. Seroconversion during FTC/TDF use is mainly associated with poor adherence or acute infection at initiation, potentially selecting resistance mutations such as M184I/V and less frequently K65R, without compromising INSTI-based regimens.

Conclusions: The prescription pattern observed in the Piedmont cohort is consistent with European trends, with on-demand PrEP representing the predominant modality among MSM. Mandatory quarterly screening linked to PrEP delivery likely enhances the detection of otherwise asymptomatic sexually transmitted infections. Continuous pharmacovigilance, structured adherence support, and nucleic acid testing before initiation in high-risk individuals are essential to optimize preventive efficacy and to minimize both prophylactic failure and the emergence of drug resistance within comprehensive PrEP programs.

PrEP

P 179 PREP IMPLEMENTATION IN THE LOMBARDY REGION: COVERAGE, ADHERENCE HETEROGENEITY, AND IMPLICATIONS FOR HIV PREVENTION

D. Moschese¹, S. Nozza², N.B. Bana³, G. Ancona⁴, D. Bernacchia⁵, A. Pandolfo⁶, S. Venturelli⁷, E. Focà⁸, C. Fornabaio⁹, D. Radrizzani¹⁰, L. Pagnucco¹¹, A. Muscatello¹², L. Corsico¹³, G. Del Castillo¹⁴, M. Maffeo^{1,14}, D. Cereda¹⁴

¹ASST Fatebenefratelli Sacco, Milan, Italy, ²Vita-Salute San Raffaele University, Milan, Italy, ³ASST GOM Niguarda, Milan Italy, ⁴ASST Santi Paolo e Carlo, Milan, Italy, ⁵ASST Ovest Milanese, Legnano, Italy, ⁶ASST Lecco, Lecco, Italy, ⁷ASST Papa Giovanni XXIII, Bergamo, Italy, ⁸ASST Spedali Civili di Brescia, Brescia, Italy, ⁹ASST Cremona, ¹⁰ASST Valle Olona, Busto Arsizio, Italy, ¹¹Fondazione IRCCS Policlinico San Matteo, Pavia, Italy, ¹²Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, ¹³Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy, ¹⁴Directorate General for Health – Lombardy Region, Milan, Italy

Background: This study aimed to describe pre-exposure prophylaxis (PrEP) for HIV use in the Lombardy Region, quantifying users, outlining their demographic characteristics, and exploring patterns of use.

Material and Methods: Administrative data on antiretroviral (ARV) drugs prescribed through NHS were used to identify PrEP users, defined as individuals receiving TDF/FTC. To avoid including people with HIV (PWH) or post-exposure prophylaxis, users were censored at the first prescription of another ARV. Data from 1 June 2023 to 31 December 2025 were included for patients aged ≥ 18 years. Age, sex, and place of birth were recorded at PrEP initiation. Daily vs on-demand use was explored by calculating the medical refill ratio (MRxR), defined as the total number of tablets dispensed divided by the number of days between the first and last visit. Linear regression was used to assess the association between age and MRxR. Number of infections in PrEP users is systematically recorded from July 2025.

Results: A total of 6,938 PrEP users were identified; 98% were male, 84% were born in Italy, and the median age was 36 years (IQR 30–44). Overall, 3,951 (57%) resided in the Milan metropolitan area. PrEP initiation was recorded for 2,502 users in 2023, 2,348 in 2024, and 2,088 in 2025.

Figure 1 presents the cumulative distribution of individuals according to MRxR. Among the 5,396 users with at least two prescriptions, 24.5% had an MRxR ≥ 0.85 , corresponding to approximately six tablets per week. No meaningful association was observed between age and MRxR ($R^2 = 0.09\%$). Among the 6,938 users who started PrEP, 5,601 (80%) were dispensed at least one tablet in 2025. Six new HIV infections were reported among individuals using PrEP from July 2025 onward. Of these, one reported ≥ 6 tablets/week, two daily use with unknown or low adherence, and three on-demand use.

Conclusions: Since reimbursement was introduced, PrEP uptake in the Lombardy Region has increased; however, individuals recorded as new users in 2023 were likely already receiving PrEP out-of-pocket. Refill patterns show marked heterogeneity, and unfortunately, administrative data cannot distinguish between appropriate on-demand use and suboptimal adherence.

Using as a proxy denominator the 5,601 individuals who received at least one tablet in 2025, six new HIV infections were recorded from July 2025 onward (0.1%). Only one occurred in a person who self-reported consistent daily use. Although few infections were observed, potential gaps in protection may persist, and continued monitoring is warranted to better understand this phenomenon.

Current PrEP scale is unlikely to be sufficient to substantially impact HIV incidence. The Lombardy Region has a strategic responsibility in consolidating integrated surveillance, expanding equitable access to PrEP, and strengthening adherence support to maximize the population-level impact of HIV prevention.

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PrEP

P 180 PREP IN REGIONAL PREVENTION PLANS: A MISSED OPPORTUNITY FOR INTEGRATION INTO NATIONAL PREVENTION PLAN

G. Dessì¹, C. Sardu², E. Mura^{1,3}

¹Lila Cagliari OdV, Cagliari, Italy, ²Dipartimento di Scienze Mediche e Sanità Pubblica, Università degli studi di Cagliari, Cagliari, Italy, ³Dipartimento di Scienze Politiche e Sociali, Università degli Studi di Cagliari, Cagliari, Italy

Background: Since 2010, the Italian Ministry of Health and Regions have periodically defined a National Prevention Plan (NPP) and 21 Regional Prevention Plans (RPPs). RPPs implement PNP Predefined Programs (PPs) and may include Free Programs (FPs). This study analyzes PrEP within the 2020-2025 NPP and RPPs. Adopting a "One Health" approach aligned with SDGs, the NPP emphasizes multidisciplinary and community-centeredness. The NPP identifies six Macro-Objectives (MO). MO 6 rationale (Priority Infectious Diseases) mentions HIV and STIs but ignores PrEP. However, in the logical framework, PrEP appears as Strategic Objective (SO 6.23), limited to "implementing protocols according to current guidelines on selected populations." Its strategic line focuses on "pharmacological interventions: prevention strategies on antiretroviral drugs," yet indicators only refer to protocol mapping and monitoring. Although the NPP requires Regions to adopt ten PPs, PrEP is entirely absent from these programs.

Material and Methods: The 2020-2025 NPP and RPPs were analyzed (22 documents; 9,620 pages). Regions were categorized into three groups based on their FPs: no HIV actions, HIV actions without PrEP, and specific PrEP actions. Finally, planned PrEP interventions across regions were compared.

Results: Regions were categorized into three groups: six had no HIV actions in their FPs (Bolzano, Liguria, Molise, Sicily, Veneto, Valle d'Aosta); six had HIV actions but no PrEP actions in their FPs (Abruzzo, Basilicata, Calabria, Friuli VG, Marche, Trento); and nine included PrEP-related actions (Campania, Emilia-Romagna, Lazio, Lombardy, Piedmont, Puglia, Sardinia, Tuscany, Umbria). These nine regions prioritize protocol definition for PrEP implementation. Campania, already having a protocol, aims to establish a regional network of referral clinics for PrEP and PEP. Emilia-Romagna, Lombardy, Piedmont, Puglia, Sardinia, Tuscany, and Umbria emphasize standardizing PrEP access through unified protocols. Puglia and Sardinia focus on establishing a regional PrEP protocol, with concise and—in Sardinia's case—contradictory actions.

Conclusions: The study highlights an undervaluation of PrEP as a manageable HIV prevention tool within RPPs. There is a lack of vision and no provision for developments through 2025, such as the 2023 oral drug reimbursement or future Long-Acting authorization. Despite its efficacy, PrEP requires wider dissemination for epidemiological impact: currently, <50% of high-risk and <5% of moderate-risk individuals use PrEP in Europe. The French OMaPrEP study on PLWH (diagnosed <6 months) confirms a "missed opportunity," as 91% were PrEP-eligible but lacked access. While NHS regionalization allows for tailored services, collaboration with NGOs is essential.

PrEP

P 181 PREP USERS, SEXUALLY TRANSMITTED INFECTIONS AND VACCINES: THE EXPERIENCE OF CENTRO IST MUGGIÒ

A. Ranzani¹, L. Corsico¹, V. Cogliandro¹, P. Columpsi¹, E. Pollastri¹, S. Limonta¹, N. Squillace¹, G. Lapadula^{1,2}, P. Bonfanti^{1,2}

¹S.C. Malattie Infettive, IRCCS San Gerardo dei Tintori, Monza, Italy, ²Università degli Studi Milano-Bicocca, Italy

Background: Pre-exposure prophylaxis (PREP) has been demonstrated to be a highly effective intervention for preventing HIV acquisition, and its use has been increasing over time. Aim of this study was to describe the characteristics of PREP users in Monza and Brianza and the incidence of sexually transmitted infections (STI) in this population.

Methods: In February 2026, we conducted a retrospective review of the medical records of all PREP users at Centro IST Muggiò (IRCCS San Gerardo, Monza). Data was collected on demographics, PREP schedule, STI diagnoses and vaccinations. STI screening in PREP users is offered every 3 to 4 months, according to national guidelines, and includes HIV, HCV and syphilis serology and nucleic acid amplification test (NAAT) for chlamydia, gonorrhoea and M. genitalium on urine sample, pharyngeal and rectal swab. Vaccination for HBV, HAV, HPV and mpox is offered onsite.

Results: Overall, 453 people have received PREP since 2019 at our clinic; of them, 316 (69.8) were still on treatment when the analysis was performed and were enrolled in the study (table 1). Most of them were male (299/316, 94.6%), mainly men-who-have sex-with-men (291/316), and the median age was 36 years (IQR 31-47). The median time of observation per patient was 18 months (IQR 5-31). The most common schedule chose by PREP users was on demand (217/316, 68.7%). Nineteen (6%) patients reported a previous use of post-exposure prophylaxis for HIV, while 147 (46.5) had at least a previous diagnosis of a STI. Considering vaccination coverage, 94.3% of patients were immune for HBV (298/316), 80.4% for HAV (254/316) and HPV (219/316, 69.3%), while the rate was lower for mpox vaccine, that was available in limited time frames (135/316, 42.7%).

One-hundred and thirty-eight PREP users (43.7%) received at least one diagnosis of STI during the observations period, ranging from one infection in 73 people (52.9%) to 12 STI in 1 person. The median time from PREP introduction to the 1st diagnosis of a STI was 8 months (IQR 4-16). Overall, we identified 273 STIs (table 2), with an incidence rate of 44.2 per 100 person-years. The most frequent infection was gonorrhoea (154/273, 56.4%), followed by chlamydia (76/273, 27.8%) and syphilis (33/273, 12.1%); however, most of the infections diagnosed with NAAT were asymptomatic (182/238, 76.5%). We did not observe any HIV seroconversion.

Conclusion: The characteristics of PREP users in Monza and Brianza are similar to those reported by other Italian studies. The rate of asymptomatic infections reinforces the growing debate on whether repeated screening should be carried out in this population. On site vaccine availability promotes vaccination coverage.

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PrEP

P 182 REAL-WORLD IMPLEMENTATION OF PREP IN CENTRAL ITALY: USERS' RISK PROFILE FROM A TERRITORIAL HIV PREVENTION CLINIC

G. Picchi^{1,2}, A. Emiliozzi¹, R. Preziosi¹, S. Farinelli¹, S. Necozione², V. Cofini²

¹UOC Malattie Infettive, Ospedale S.Rosa ex Belcolle, Viterbo, Italy, ²Dipartimento di Medicina clinica, sanità pubblica, scienze della vita e dell'ambiente, Università degli Studi dell'Aquila, L'Aquila, Italy

Background: Since FTC/TDF free availability as Pre-Exposition Prophylaxis (PrEP) in Italy in 2023, PrEP request increased also in small cities, and sexually-transmitted infections (STIs) prevention services has been implemented. We report activity of a newly opened PrEP service in Central Italy.

Material and Methods: We conducted a retrospective review of all individuals accessing PrEP clinic. Demographic characteristics, sexual behaviour, prevention strategies (including Post-Exposition-Prophylaxis, PEP), and clinical data were extracted. All patients were screened for common STIs according to guidelines. Continuous variables are presented as mean, median and range; categorical variables as frequencies and percentages.

Results: A total of 61 individuals were included. The majority were male (90.2%), with 4.9% female and 4.9% transgender individuals. Median age was 39 years (mean 39.5±9.5; range 22–68). Most participants were non-heterosexual (91.8%), and 18% were non-Italian, mainly coming from Central-South America. Unemployed or students were 13%, health workers were 13% and 2 transgender women were sex workers. More than 70% lived in small towns surrounding the city.

Access was predominantly self-referred (73.7%), while 18% were addressed by other services. A partner living with HIV was reported by 9.8%, and 11.5% accessed the clinic for a recent STI. Previous PrEP use was documented in 16.4%, and prior PEP in 11.5%.

Chemsex was reported by 12.7% (n=55), 26.7% reported being in an open relationship and accessed the clinic as couple, while 59% reported one or more previous STIs. Condom use was scarce: 26.9% reported never using, 26.9% mostly not using, and 44.2% mostly using it.

Among individuals with available data (n=52), the mean monthly number of sexual intercourse referred was 4.1 (median 4; range 0–17), with a mean of 3.9 different partners (median 3.5; range 0–17). Almost all participants reported using dating apps.

Basal screening detected 42.6% positivity for at least one STIs, mainly syphilis (84.6%) followed by Chlamydia (7.7%) and Mycoplasma (3.8%); overall 19.6% were evaluated as active and treated. One subject's HIV test was positive and antiretroviral therapy was promptly started. All subjects were addressed to vaccination services for HPV, meningococcus, HBV and/or HAV according to serology.

Fifty-one PrEP regimens were prescribed, 66.7% of these were continuous while 33.3% were on-demand. Non-prescriptions were motivated by risk abolition, logistic difficulties or refusal. Clinic activity increased strongly over time (fig. 1).

Conclusions: PrEP demand is increasing, especially in young population with instable use of condom and high frequency of STIs. Free PrEP availability is an important opportunity to develop and strengthen STIs prevention also in territories far from big cities, allowing STIs information, early diagnosis and therapy in a safe and dedicated setting, and implements vaccine coverage.

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PrEP

P 183 REAL-WORLD PRE-EXPOSURE PROPHYLAXIS (PrEP): SAFETY, RETENTION AND SEXUALLY TRANSMITTED INFECTIONS IN AN ITALIAN SINGLE-CENTER COHORT

T. Ascione, R. Ferri, J. Vecchiet, K. Falasca

Clinic of Infectious Diseases, SS. Annunziata Hospital - "G. d'Annunzio" University of Chieti-Pescara, Italy

Background: Pre-exposure prophylaxis (PrEP) has emerged as a cornerstone of combination HIV prevention strategies, showing high efficacy in reducing HIV acquisition across diverse high-risk populations. Following its implementation in routine clinical practice, attention has increasingly shifted from efficacy under trial conditions to real-world effectiveness, long-term safety, adherence patterns, and retention in care. Moreover, concerns have been raised about potential changes in sexual behavior and the associated burden of sexually transmitted infections (STIs) among PrEP users.

Methods: We conducted a retrospective observational analysis of a cohort of individuals receiving PrEP at the Division of Infectious Diseases, SS. Annunziata Hospital, CH, Italy. Demographic characteristics, PrEP regimen (daily vs on-demand), follow-up data, adverse events, renal function parameters, HIV and viral hepatitis serology, and STI screening results were collected. Continuous variables were described as median (IQR) or mean $\pm$ standard deviation (SD), and categorical variables as number (%).

Results: A total of 39 male patients (100%) were included, with a median age of 38 years (IQR 32–48.5) and a mean age of 39.6 ± 11.0 years. PrEP was administered on-demand in 18/39 patients (46.2%) and as a daily regimen in 6/39 (15.4%); regimen data were unavailable for 15/39 (38.5%). Twenty-four patients (24/39; 61.5%) remained in follow-up, whereas 15/39 (38.5%) were lost to follow-up, including one patient (2.6%) transferred to another center and one (2.6%) who discontinued PrEP due to increased serum creatinine. Among patients with available baseline and follow-up creatinine measurements ($n=18$), no significant changes were observed (mean $\Delta -0.012$ mg/dL; $p=0.667$). Adverse events were reported in 9/39 patients (23.1%), mainly gastrointestinal (7/39; 17.9%: vomiting/diarrhea in six cases and abdominal pain in one) and headache in 2/39 (5.1%). No HIV seroconversions were observed among patients with available follow-up

testing (0%). 6 microbiological positive results were detected during routine screening (6/39; 15.4%): *Mycoplasma genitalium* in 1/39 (2.6%), *Mycoplasma hominis* in 3/39 (7.7%; two co-infected with *Ureaplasma urealyticum*), and isolated *Ureaplasma urealyticum* infection in 1/39 (2.6%); all were treated with doxycycline. 1 case of recent syphilis (1/39; 2.6%) and 1 new diagnosis of hepatitis B virus infection (1/39; 2.6%) were recorded. 4 patients (10.3%) reported a stable HIV-positive partner on antiretroviral therapy, and 1 (2.6%) reported occasional sexual contact with an HIV-positive partner.

Conclusions: In this real-world cohort, PrEP was overall well tolerated, with no observed HIV seroconversions and no evidence of clinically significant renal impairment. The occurrence of STIs and the proportion of patients lost to follow-up highlight the need for regular microbiological screening and targeted strategies to improve retention in care within PrEP programs.

PrEP

P 184 RELATIONAL DETERMINANTS OF CHOOSING THE ON-DEMAND REGIMEN IN PREP: REAL-WORLD EXPERIENCE FROM A CENTER IN SOUTHERN ITALY

P. Congedo, G. Manco Cesari, G. Metrangola, A. De Girolamo, A. Marignone, A.M. Maci

Clinic of Infectious Diseases, Vito Fazzi Hospital, Lecce, Italy

Background: Pre-exposure prophylaxis (PrEP) is a highly effective tool in preventing HIV infection. In real-world settings, the choice between continuous and on-demand regimens can be influenced by behavioral and relational determinants as well as clinical ones. Identifying these factors is essential for optimizing personalized counseling. The PrEP clinic of the Infectious Diseases Unit at the “V. Fazzi” Hospital in Lecce is a regional reference center integrated with the HIV clinic.

Methods: Single-center descriptive-analytical observational study. All patients actively treated in 2025 with at least one visit were included.

At the first visit, socio-demographic data, relationship status, number of partners, previous STIs, and substance use (chemsex) were collected, followed by clinical evaluation and drug prescription. Follow-up was set at 12 weeks. Primary outcome: use of on-demand regimen.

Analysis: descriptive statistics, Welch's t-test, χ^2 /Fisher and multivariate logistic regression (covariates: age, relationship status, chemsex; $p < 0.05$). Chemsex data were available for 69/121 patients (57.0%); multivariate analysis was performed on complete cases ($n=69$).

Results: A total of 121 patients (98.3% male) were included, with a mean age of 37.9 ± 9.9 years. The cohort is characterized by a high level of education (49.6% university degree; 25.6% high school diploma) and job stability (19.0% white-collar workers; 15.7% freelancers), suggesting a population with good health literacy. The average number of visits in 24 months was 1.40 ± 0.83 (median 1; IQR 1–2) and was not associated with the treatment regimen ($p=0.330$). The on-demand regimen was adopted by 65.3% (Graph 1).

Relationship status was significantly associated with the regimen ($p=0.012$). Patients in open relationships were more likely to use on-demand (adjusted OR 3.96; 95% CI 1.22–12.88; $p=0.022$) (Graph 2). Age and chemsex were not significantly associated in the model ($n=69$).

Chemsex was reported by 23/69 patients (33.3% of respondents; 19.0% of the entire cohort).

Eighty percent of patients were residents of the province of Lecce; 9.9% came from outside the region, suggesting moderate extra-regional attractiveness. Access was predominantly peer-driven (64.5%).

Only one case of new HIV infection (0.8%) was observed, in a patient with documented irregular dispensing.

Conclusions: In our real-world cohort in southern Italy, the on-demand regimen is the predominant mode of PrEP use and is independently associated with open-couple status. The territorial data and the peer-driven access model confirm the role of community dynamics in the spread of PrEP. The systematic integration of relational assessment into clinical counseling could improve the personalization of the preventive pathway, maintaining high efficacy and low incidence of seroconversion.

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PrEP

P 185 ROUTINE CHEMSEX SCREENING IN HIV AND PREP CARE IDENTIFIES DISTINCT SUBSTANCE-USE RISK PROFILES: A REAL-WORLD OBSERVATIONAL STUDY

A. Pastena¹, G. Bozzi¹, B. Mariani¹, N. Iannotti¹, V. Castelli¹, A. Maccaro¹, A. Gaviraghi¹, S. Roda¹, G. Renisi¹, M. Pernich¹, A. Muscatello¹, A. Bandera^{1,2}

¹Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano, Milan, Italy, ²UniMi, Università degli Studi di Milano, Milan, Italy

Background: Chemsex, the intentional use of psychoactive substances before or during sexual activity, is increasingly reported among gay, bisexual and other men who have sex with men (GBMSM). We implemented routine chemsex screening among people living with HIV (PLWH) and in individuals attending our PrEP outpatient clinic to characterize substance use risk profiles and inform targeted interventions.

Material and Methods: Monocentric retrospective observational study analysing routinely collected clinical data from consecutive outpatients attending our HIV and PrEP services in February 2026. Individuals without language barriers underwent routine chemsex screening as part of standard care. Participants reporting chemsex were further evaluated using the Italian version of the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) in line with EACS recommendations. ASSIST scores of 3–26 prompted brief intervention, whereas scores ≥ 27 triggered referral to an addiction service. Between group comparisons were performed using chi-square or Fisher's exact test.

Results: Among 181 screened individuals (36 PLWH and 145 PrEP users), 21 (11.6%) reported chemsex and 9 (5.0%) reported current use (past 3 months): 3/36 (8.3%) PLWH and 6/145 (4.1%) PrEP users (ns). Stimulants and GHB/GBL were the most frequently reported substances, followed by crystal methamphetamine and mephedrone; no injection drug use was reported.

PLWH showed higher median ASSIST scores than PrEP users (19 vs 4.5) and clustered in moderate-to-high risk categories, whereas PrEP users mainly showed low-risk profiles ($p=0.088$).

Chemsex was more frequent in PLWH aged >49 years and PrEP users aged 29–40 years.

STI history was common (52/181, 28.7%). Current chemsex use was strongly associated with STI diagnosis in the previous year (7/9 vs 45/172, $p=0.002$), with consistent trends in PLWH (2/3 vs 10/33, ns) and PrEP users (5/6 vs 35/139, $p=0.0018$).

Conclusions: Routine chemsex screening in HIV and PrEP care is feasible and reveals distinct substance-use risk phenotypes. The overall prevalence (11.6%) aligns with European estimates and supports systematic screening to enable risk stratification, integrated care pathways and targeted harm-reduction strategies.

PrEP

P 186 SELF-PERCEIVED HIV RISK IS ASSOCIATED WITH HIGHER RETENTION IN PREP CARE COMPARED WITH PHYSICIAN-DRIVEN REFERRAL: A REAL-WORLD COHORT STUDY FROM COTUGNO HOSPITAL, NAPLES, 2023-2025

F.M. Fusco¹, C. Camaioni¹, F. Borrelli¹, O. Tambaro¹, N. Sangiovanni¹, I.P. Ferrara¹, R. Falanga¹, N. Papa², V. Mattera², D. Ardolino², M. Spatarella², V. Sangiovanni¹, R. Viglietti¹

¹UOC Malattie Infettive dell'Immunodepresso; Ospedale "D. Cotugno", Azienda Ospedaliera dei Colli, Naples, Italy, ²UOSD Farmacovigilanza; Farmacia Ospedaliera, Ospedale "D. Cotugno", Azienda Ospedaliera dei Colli, Naples, Italy

Background: Retention in pre-exposure prophylaxis (PrEP) care is a critical determinant of HIV prevention effectiveness. Little is known about whether the pathway of access to PrEP influences retention in PrEP care. In particular, individuals starting PrEP after medical recommendation (e.g., following post-exposure prophylaxis, PEP) may differ from those who autonomously seek prevention services based on their perceived risk.

Methods: We conducted a single-centre observational cohort study including all individuals initiating daily oral PrEP at an HIV clinic between September 2023 (when free distribution of PrEP started at study site) and December 2025. Participants were classified according to access pathway: self-driven access (individuals spontaneously requesting PrEP) or physician-driven access (PrEP recommended by a clinician, mainly following PEP).

Retention in PrEP care was evaluated at 3, 6 and 12 months after PrEP initiation. Discontinuation of PrEP care was defined as failure to attend follow-up visits and obtain prescription renewal within 3 months after expected pill exhaustion. Individuals without sufficient follow-up were censored at last available visit. Kaplan–Meier analysis was used to compare retention between groups.

Results: A total of 291 individuals initiated daily PrEP in the study period: 208 (71.5%) through self-driven access and 83 (28.5%) through physician-driven referral. The population was almost entirely male (99%) and predominantly Italian (97%). Median age was 37 years (IQR 30–45) in the self-driven group and 34 years (IQR 27.5–40.5) in the physician-driven group.

Persistence in PrEP differed markedly between groups from the earliest follow-up visit.

At 3 months, 93.3% of self-driven users remained in PrEP compared with 72.3% of physician-driven users.

At 6 months, persistence was 77.9% vs 50.6%, and at 12 months 48.6% vs 26.5%, respectively. Differences between groups were statistically significant ($p < 0.001$ at all timepoints). Kaplan–Meier analysis showed early and sustained separation of survival curves, with most discontinuations in the physician-driven group occurring within the first six months after initiation (see Figure).

Conclusions: Persistence in PrEP care was substantially higher among individuals who autonomously sought PrEP compared with those starting PrEP following medical recommendation after PEP. These findings suggest that self-perceived HIV risk appears to be a stronger determinant of sustained engagement in prevention care than clinician-assessed risk.

Consequently, strategies facilitating direct, low-threshold access to PrEP and supporting individual risk awareness may be essential to maximize real-world effectiveness of PrEP services.

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PrEP

P 187 “TELEPREP”: BRIDGING THE GAP IN HIV PREVENTION AND NAVIGATING SYSTEMIC BARRIERS IN ITALY

L. Cosmaro¹, F. Falzetta¹, S. Penon¹, V. Walsh¹, A.R. Raccagni^{2,3}, C. Candela^{2,3}, S. Nozza^{2,3}

¹Fondazione LILA Milano ETS, Milan, Italy, ²Vita-Salute San Raffaele University, Milan, Italy, ³Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: The introduction of PrEP reimbursement in Italy by the National Health System (SSN) increased national uptake, although structural and regional barriers endure. TelePrEP is an exclusively online PrEP service launched in April 2023 through a collaboration between community health workers and infectious disease specialists. This study aims to analyze PrEP user's territoriality and motivations to understand how TelePrEP might address systemic shortcomings and support individuals who cannot access the Italian SSN.

Material and Methods: TelePrEP is an ongoing fully remote service which provides PrEP prescription and care through an integrated ePlatform for consultations, prescriptions, and test result exchanges. Counseling is delivered via Zoom calls, fostering user-provider trust. Clients' demographic/behavioral data are collected in a dedicated database for monitoring and evaluation purposes. Beyond clinical management, the service supports enrollment at territorial centers, by facilitating referrals and bridging prolonged waiting lists until access is secured. PrEP users enrolled between April 2023 and December 2025 were considered; geographical distribution of users is described considering the number of existing territorial PrEP centers.

Results: A total of 562 people contacted TelePrEP, with 121 referred directly to existing territorial centers (Fig. 1-2). Data analysis reveals significant regional trends and barriers:

- Regional Disparities: high demand was observed in Northern Italy (Lombardy, Veneto) despite a higher density of PrEP centers (Fig. 3), likely reflecting community-driven awareness in the absence of public PrEP campaigns. In 2025, requests notably increased in Central Italy and the Islands (Fig. 4).
- Systemic Shortcomings: 50% of users accessed TelePrEP due to institutional barriers, with 25.1% reporting long waiting lists (36.8% in Lombardy, Fig. 5) and 25.1% geographical distance (17.5% in Piedmont, 10.5% in Calabria, Fig. 6).
- Negative experiences and lack of access to the SSN: 4% of users felt uncomfortable within the public health system, 5.3% lacked an Italian health card, making TelePrEP their primary or only access point, and 8.4% preferred TelePrEP to protect their privacy (Fig. 7).
- Referrals: 42% of discontinuations occurred after accessing a local public PrEP center.

Conclusions: While PrEP reimbursement is a landmark achievement, universal access remains hindered by geographical disparities, administrative barriers, and avoidance of the SSN among users seeking clinical privacy or reporting negative experiences with institutional care. Our data show that TelePrEP complements the public sector by supporting individuals who might otherwise fall through the cracks of the SSN. By providing a low-threshold entry point and facilitating referrals and access, TelePrEP highlights the value of community-led digital health models in advancing health equity and national HIV prevention goals.

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PrEP

P 188 WHY ARE CISGENDER WOMEN NOT INTERESTED IN PREP? RISK PERCEPTION AND PREVENTION GAPS IN A COMMUNITY-BASED SETTING

L. Nekrasova¹, E. Caruso¹, L. Cavallero¹, D. Zagato¹, R. Repossi¹, I. Gotti¹, P. Russo¹, P. Vinti¹, D. Moschese^{1,2}, V. Iannone^{1,2}, R. Rossotti^{1,3}, M. Cernuschi^{1,4}, N. Frattini¹

¹Milano Checkpoint ETS, Milan, Italy, ²ASST Fatebenefratelli-Sacco, Milan, Italy, ³ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ⁴San Raffaele Scientific Institute, Milan, Italy

Background: Despite representing a substantial proportion of new HIV diagnoses globally, cisgender women remain underrepresented in PrEP programs. Low PrEP uptake in this population may reflect perceived low HIV risk, yet the alignment between perceived protection and reported behaviors is unclear. We assessed self-reported reasons for declining PrEP and their concordance with self-reported HIV-related risk behaviors in a community-based setting.

Materials and Methods: We conducted a cross-sectional study among cisgender women reporting no interest in PrEP at a community-based HIV/STI testing center (April–December 2025). Data were collected during peer-led counseling using the COBATEST platform and an additional ad-hoc survey. Reasons for PrEP were grouped into three non-mutually exclusive domains: (i) perceived adequate risk control, (ii) gendered/misinformation-based beliefs, and (iii) medical/pharmaceutical concerns. Possible HIV exposure was quantified as the number (0–8) of related risk factors reported in the previous 12 months (prior STIs, ≥ 2 sexual partners, group sex, recreational drug use, irregular STI testing, inconsistent condom use, sex work, cisgender male sexual partners). Higher vulnerability was defined as ≥ 3 concurrent factors. Concordance between perceived protection and reported exposure was assessed descriptively, and associations were tested using chi-square.

Results: Among 194 women not interested in PrEP, perceived adequate risk control was the most commonly reported group (75.8%), followed by gendered/misinformation beliefs (35.1%) and medical/pharmaceutical concerns (21.6%). Overall, 72.2% demonstrated ≥ 3 cumulative risk indicators, suggesting clustering of multiple behavioral exposures. Higher vulnerability was similarly prevalent among women endorsing perceived protection and those who did not (72.5% vs 71.1%; $p=0.857$). Substantial discordance was commonly observed. Among women citing condom use as a reason for declining PrEP (13.9%), 40.7% reported a condomless last intercourse and/or inconsistent condom use. Among those reporting “only one partner” (22.2%), 62.8% reported ≥ 2 partners or non-monogamy in the previous year. Overall, 55.7% of participants reported no interest in PrEP due to self-perceived low HIV risk, while demonstrating a higher behavioral vulnerability (Table 1).

Conclusions: Despite substantial cumulative HIV risk indicators, most women who declined PrEP reported low self-perceived HIV risk. This misalignment between the perceived protection and reported behaviors suggests that inaccurate or incomplete risk appraisal may limit PrEP uptake, highlighting the importance of accessible, evidence-based information on risks and prevention, and targeted strategies to enhance PrEP engagement among cisgender women.

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Reservoir/Cure

P 189 ONE YEAR-CHANGE IN TOTAL PROVIRAL HIV-DNA IN A COHORT OF VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV SWITCHING TO LONG-ACTING CABOTEGRAVIR/RILPIVIRINE

A. Borghetti^{1,2}, F. Saladini³, M. Fabbiani^{3,4}, A. Palomba^{1,2}, L. Fiaschi³, M. Sambo^{3,4}, M. Maccarrone², N. Bartolini³, E. Morelli^{3,4}, L. Del Bono^{1,2}, L. Di Gasparro^{3,4}, R. Iapoce^{1,2}, M. Falcone^{1,2}

¹Infectious Diseases Unit, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy, ²Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy, ³Department of Medical Biotechnologies, University of Siena, Siena, Italy, ⁴Infectious and Tropical Diseases Unit, Azienda Ospedaliero-Universitaria Senese, Siena, Italy

Background: Proviral HIV-DNA in peripheral blood mononuclear cells may predict viral rebound in virologically suppressed people with HIV (PWH) on antiretroviral therapy. We analysed changes in total proviral HIV-DNA in a cohort of PWH starting cabotegravir plus rilpivirine (CAB/RPV).

Material and Methods: PWH switching to CAB/RPV from 2 University hospitals underwent yearly blood sampling for HIV-DNA quantification and sequencing on proviral DNA. Individuals were eligible if they were virologically suppressed (i.e. HIV-RNA < 50 copies/ml) at the time of CAB/RPV start (baseline, BL), had no contraindications to long-acting therapy (as per information leaflet), and had ≥ 52 weeks of follow-up (FU). Total HIV-DNA at BL and 1 year of FU was quantified by digital PCR using a home-made protocol targeting the HIV-1 LTR region, and results were expressed as log₁₀ HIV-DNA copies/10⁶ leucocytes. Next-generation sequencing at BL and after 1 year was used to detect resistance mutations (RAMs) in the pol gene.

The 1-year change in HIV-DNA was assessed by non-parametric signed-rank test and predictors of this change were evaluated by linear regression. Secondary outcome was to evaluate the association of HIV-DNA with detectable HIV-RNA (TD, including viral load below the limit of quantification) at BL, 4, 12, 20, 28, 36, 44 and 52 weeks, through multivariable pooled logistic regression.

Results: Twenty-six PWH were included, 84.6% were male, median age was 53 years. Table 1 summarizes characteristics of study population. No PWH had RAMs to RPV or CAB on historical genotypic resistance test (GRT) on HIV-RNA. However, BL GRT identified 4 PWH with at least one RAM conferring resistance to RPV (E138K, M230MI) and/or CAB (N155NS, G140GS). Of note, one participant had HIV-1 subtype A6.

HIV-DNA did not vary over time (mean difference in log₁₀ copies/10⁶ leucocytes between 1 year and BL values: -0.12, 95% CI -0.51; +0.26; sign-rank test p=0.760) and no predictor of 1-year change was identified.

Over 189 HIV-RNA determinations, 27 (14.3%) TD were shown (of which 4 HIV-RNA > 50 copies/ml). BL proviral HIV-DNA (upper versus lower 50th percentile, OR 2.76, 95% CI 1.14-6.66; p=0.024) predicted TD at univariable analysis, but the association was not maintained (aOR, 1.38, 95% CI 0.49-3.90; p=0.538) after adjusting for nadir CD4 count and previous AIDS events. BL RAMs did not predict TD; of note, none of the BL RAMs to RPV was detected at FU GRT on DNA, but new RPV RAMs (E138EA, G190GE and M230MI, the latter two likely APOBEC-mediated) were noticed in 3 different PWH; concerning RAMs to CAB, G140GS persisted while N155NS was not confirmed; a new accessory RAM (L74I) was detected in a different individual.

Conclusions: No significant change in proviral HIV-DNA was evidenced in this cohort of PWH on CAB/RPV long-acting therapy. Nor BL HIV-DNA nor RAMs on HIV-DNA were predictive of TD.

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Reservoir/Cure

P 190 PERSISTENT APOBEC ACTIVITY IN CHILDREN WITH LONGSTANDING HIV INFECTION: CHARACTERIZATION AND CORRELATION WITH CLINICAL OUTCOME

L. Colagrossi¹, C. Dell'Angelo², C. Artini², R. Scutari², G. Lorenzetti³, V. Fini¹, V. Fox², V.C. Di Maio¹, L. Coltella¹, S. Ranno¹, G. Linardos¹, L. Gentile¹, C. Russo¹, S. Bernardi², C.F. Perno¹

¹Microbiology and Diagnostic Immunology Unit, Bambino Gesù Children's Hospital, IRCCS; Rome, Italy, ²Unit of Immune and Infectious Disease, University Department of Pediatrics DPUO, Bambino Gesù Children's Hospital, Rome, Italy, ³Multimodal Research Area, Microbiology and Diagnostics of Immunology Unit, Bambino Gesù Children Hospital IRCCS, Rome, Italy

Background: This study aims to characterize APOBEC-associated mutational patterns in individuals with longstanding HIV infection and prolonged exposure to antiretroviral therapy, and to assess their potential associations with clinical outcomes.

Methods: A total of 47 individuals with childhood-acquired HIV infection were enrolled and HIV-DNA samples were collected between March 2021 and July 2025 at Bambino Gesù Children's Hospital (Rome, Italy). Next-generation sequencing (NGS) was performed with DeepChek® HIV Full PR/RT/INT Drug Resistance kit (ABL Diagnostics) on the MiSeq platform (Illumina). The prevalence of drug resistance mutations (DRMs) and signature APOBEC-related mutations (APO-Ms) (frequency higher than 5%) was evaluated through the DeepChek and HIVdb Stanford tools.

Results: Participants had a median age of 19 years (IQR: 14-25) and were mainly male (53.2%). Among them, 41 cases (87.2%) acquired the HIV-1 infection through vertical transmission. The most frequent HIV-1 subtype was BF (15;32%), followed by subtypes C and A1 (8;17% each one). Overall, 19 (40.4%) had undetectable HIV-RNA, 14 (29.8%) showed <40 copies/mL and 14 (29.8%) >40 copies/mL, with a median viremia of 170 copies/mL (IQR: 142–17,133). While the median (IQR) HIV-DNA level was 551(181–1340) copies/10⁶ CD4+T-cells. Among the 47 PWH, 26 (55.3%) had received early therapy, defined as initiation within the first year of life and an AIDS event was observed in 34%(16/47) individuals.

Notably, early-treated individuals had a significantly lower HIV reservoir compared with those treated later, as reflected by lower median total HIV-DNA levels (387 [123–697] vs 1262 [367–1712] copies/10⁶ CD4+ T cells; p=0.027).

Overall, 57.4%(27/47) of individuals harboured at least one HIV-1 DRMs; in particular the NRTI, NNRTI and PI resistance were present in 19.1%, 38.3% and 8.5% of cases, respectively. 30/47 individuals (64%) showed at least one APOBEC-related mutation, mainly in the INSTI region (22; 73%), while 21/47 (45%) with at least one APOBEC-related stop codon.

No significant differences were observed in APOBEC-associated mutations, when stratifying by early treatment initiation (38.5% vs 57.1%, p=0.163) and AIDS-defining events (56.2% vs 41.9%, p=0.893). Similar results were observed for stop codon frequency, both by early treatment (42.3% vs 47.6%; p=0.472) and AIDS events (43.8% vs 45.2%; p=0.587).

Conclusions: HIV-DNA sequencing revealed a significant prevalence of drug resistance mutations, as well as APOBEC-related mutations, particularly in the INSTI region.

Early antiviral treatment was associated with significantly smaller HIV reservoir. The frequency of APOBEC-related mutations or stop codons seems not different in this relatively small cohort, yet their stable presence over the years in these young individuals without clinical progression suggests that studies with larger settings are required to define whether their presence affects the progression of the disease.

Reservoir/Cure

P 191 RESERVOIR PERSISTENCE MEASURED AS UNINTEGRATED HIV-DNA IN A REAL-WORLD COHORT OF PEOPLE LIVING WITH HIV

C. Orlandi^{1,2}, B. Canovari³, F. Barchiesi^{3,4}, M. Magnani⁵, M.B.L. Rocchi⁶, A. De Maria^{7,8}, A. Casabianca^{2,9}

¹Department of Biomolecular Sciences, Section of Biochemistry and Biotechnology, University of Urbino Carlo Bo, Fano (PU), Italy, ²Laboratorio Covid, University of Urbino Carlo Bo, Fano (PU), Italy, ³Unit of Infection Diseases, San Salvatore Hospital, AST Pesaro Urbino, Pesaro, Italy, ⁴Department of Biomedical Sciences and Public Health, Marche Polytechnic University (UNIVPM), Ancona, Italy, ⁵Department of Biomolecular Sciences, Campus Scientifico Enrico Mattei, University of Urbino Carlo Bo, Urbino, Italy, ⁶Department of Biomolecular Sciences, Service of Biostatistics, University of Urbino Carlo Bo, Urbino, Italy, ⁷Department of Health Sciences, University of Genova, Genova, Italy, ⁸S. C. Malattie Infettive, Azienda Sociosanitaria del Levante n. 5, Regione Liguria, Sarzana (SP), Italy, ⁹Department of Pure and Applied Sciences, Section of Chemistry, Environment, and Materials, University of Urbino Carlo Bo, Urbino, Italy

Background: HIV-1 cannot be eradicated even with suppressive antiretroviral therapy (ART) because it persists in infected cells as a stable integrated genome and more labile linear and episomal unintegrated DNA forms (uDNA), creating a long-term viral reservoir. The detection of uDNA forms signals recent events of infection and uncontrolled replication below plasma RNA detection limits.

The purpose of this study was to evaluate the performance of an assay to measure uDNA in the blood of person with HIV (PWH) under therapy with the intent of characterizing those with undetectable uDNA and identifying the possibly associated factors.

Methods: Total and unintegrated HIV-DNA levels were simultaneously quantified by real-time qPCR in whole blood samples from 87 chronically treated PWH.

The data are presented as medians and interquartile ranges (IQRs, 25th to 75th percentiles) and expressed as copies/10⁴ CD4⁺. Pearson correlation test was used to assess correlations between variables and uDNA levels. For multivariate analysis, logistic regression was used to assess factors associated with undetectable uDNA.

Results: Total HIV-DNA was detected in all the samples. In 68% of the samples (59/87) HIV-DNA levels were quantified > QL of the assay (2 copies/PCR) (range: 0.8-147; median [IQR] 3.7 [2-8.5] copies/10⁴ CD4⁺), while in 32% (28/87) were <2 copies (range 0.4-2; median [IQR] 0.6 [0.4-0.8]). The uDNA was quantified in 11/87 (13%) samples (range: 1.3-10.5; median [IQR] 3.8 [2.9-8.6]), was detected <2 copies in 52/87 (60%) (range: 0.3-6.1, median [IQR] 0.6 [0.5-1]), and undetectable in 24/87 (28%). The uDNA accounting for 17% [0-36] of total HIV-DNA. Unintegrated HIV-1 DNA levels showed a positive correlation with total HIV-DNA ($r=0.67$, $p<0.0001$) and were associated with immunological parameters (CD4⁺ nadir, CD4⁺ counts, CD4⁺ %, CD4/CD8, r from -0.20 to -0.50).

Undetectable uDNA was associated with higher CD4⁺ T-cell nadir, higher current CD4⁺ T-cell counts, and lower total HIV-1 DNA levels and in multivariable analysis, CD4⁺ T-cell nadir was the only factor independently associated with uDNA undetectability ($p=0.001$).

Conclusion: This study provides evidence of the viral reservoir persistence, not only as total HIV-DNA but also as unintegrated HIV-DNA, a form of reservoir that has been previously underestimated but measured in 72% of our real-world cohort. Moreover, in multivariable analysis emerged that the CD4⁺ T-cell nadir was the sole independent factor associated with uDNA undetectability.

Prospective studies are needed to further explore the possible relevance of quantifying this side of the reservoir in routine clinical practice.

STI

P 192 ACCEPTABILITY AND VALIDITY OF HR-HPV ANAL SELF-SAMPLING FOR ANAL CANCER SCREENING

E.N. Cavallari¹, M.A. Zingaropoli², A. Lazzaro¹, L. Bortolani³, G.B. Tassone⁴, M. Ridolfi¹, F. Alessi¹, Xh. Xhuli⁴, C.M. Mastroianni³, O. Turriziani⁴, G. d'Ettore³

¹Department of Infectious Diseases, AOU Policlinico Umberto I, Rome, Italy, ²Department of Microbiology, AOU Policlinico Umberto I, Rome, Italy, ³Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ⁴Department of Molecular Medicine, Sapienza University of Rome, Rome, Italy

Background: Screening for anal cancer should be a standard of care for high-risk populations such as people living with HIV (PLWH), women with HPV-related gynecological cancer and precancer and solid organ transplant recipients. Most of these high-risk groups are under screened due to a lack of screening access as well as a lack of screening acceptance. Anal high-risk HPV (HR-HPV) test is a baseline screening tool for anal cancer. We aim to evaluate anal self-sampling for high-risk HPV (HR-HPV) as a tool to expand anal cancer screening.

Material and Methods: From January 2026 we started offering an additional self-collected (SC) anal swab to all patients attending our anal cancer screening ambulatory who underwent a clinician collected (CC) anal swab for HR-HPV. The SC-swab was obtained as the first sample using a dacron swab kit licensed for HR-HPV cervical self-screening, while the CC-swab was collected as the second sample using a cytobrush.

Participants autonomously decided to collect the swab while standing or laying on their left side. To avoid the risk of bias, participants were alone in the room while performing the SC-swab.

Data on easiness and discomfort/pain were collected for both swabs referring to a 1 to 10 scale with 1 meaning "extremely hard" and "no discomfort at all" and 10 "extremely easy" and "intense pain". The presence of anatomical factors causing potential difficulties (hemorrhoids, anal skin tags, anal fistula, anal papillae, anal/rectal prolapse) were noted. Here we present the results from the first 54 individuals enrolled.

Results: 25.5% of our study population was represented by women, 74.5% were men. Median age of participants was 50.5±15.4 for women and 50±11.1 for men. Among men, all but 1 enrolled subject were men who have sex with men (MSM). 15% of women and 74% of men were LWH.

The upright position was preferred by 43% of participants and the left side decubitus by 57%.

Median reported easiness of SC-swab was 9±1.62. No differences were observed between women and men (8±1.44 vs. 9±1.60; p=0.791), between the upright or left lateral position (9±1.13 vs. 8±1.86; p=0.153) and in respect to the presence or absence of anatomical difficulties (8±1.85 vs. 9±1.50; p=0.241).

Discomfort/pain was lower for SC-swab than CC-swab (median 1±1.65 vs. 6±2.72; p<0.01). SC-swab discomfort/pain was not affected by sex (1±1.68 vs. 1±1.39; p=0.401), position (1±1.65 vs. 1±1.68; p=0.842) and anatomical difficulties (1±1.22 vs. 1±1.82; p=0.832). No differences were observed in respect to the above-mentioned variables for CC-swabs.

SC-swabs gave a valid result in 93% of participants while CC-swabs in 89% of cases.

78.5% of participants would have chosen SC-swab for future screening if available, 13.7% CC-swab and 7.8% expressed no preference.

Conclusion: In consideration of the observed easiness and validity rate, anal self-sampling for HR-HPV is a promising tool to expand anal cancer screening in under screened high-risk populations.

STI

P 193 ACUTE CHOLESTATIC HEPATITIS AS THE FIRST MANIFESTATION OF SECONDARY SYPHILIS IN A PATIENT LIVING WITH HIV AND PSORIASIS: A DIAGNOSTIC CHALLENGE

L. Pisano¹, M. Turco², J. Farini², A.L. Rapaccini¹

¹Centro MTS, S.C. Dermatologia, Ospedale Piero Palagi, Firenze, Italy, ²Università degli Studi di Firenze, Firenze, Italy

Background: Syphilitic hepatitis is a rare manifestation of secondary syphilis, typically presenting with transient cholestatic jaundice that may precede the characteristic skin rash by weeks or months. We report a case occurring in a patient living with human immunodeficiency virus (HIV) and psoriasis.

Materials and Methods: A 46-year-old Italian man, self-identifying as a man who has sex with women, was diagnosed with HIV in May 2024 (nadir CD4+ count 213 cells/μl; HIV-RNA 102,000 copies/mL) and started bicitgravir/tenofovir alafenamide/emtricitabine, achieving viral suppression and CD4+ recovery (~600 cells/μl) within one year.

In June 2025, he presented with acute jaundice, low-grade fever, diffuse myalgia and arthralgia, vomiting, right upper quadrant abdominal pain, pale stools, and dark "marsala-colored" urine. Laboratory tests showed marked cholestasis with moderate transaminase elevation. Abdominal contrast-enhanced CT excluded hepatic or biliary obstruction, showing only mild intrahepatic bile duct dilatation, a hyperemic and edematous ampulla of Vater, splenomegaly, and diffuse lymphadenopathy. Ampulla biopsy ruled out neoplasia. The patient improved rapidly with supportive therapy and was discharged with a diagnosis of acute cholestatic jaundice of unknown origin. Extensive infectious, autoimmune, and toxicological investigations were negative, including viral hepatitis, opportunistic infections, autoantibodies, and hepatotoxic exposures; mild Epstein-Barr virus reactivation was considered clinically insignificant. Approximately three months later, he presented with erythematous, scaly palmar lesions suggestive of secondary syphilis (Figure 1). Serology showed VDRL >1:256 and TPHA >1:10.240. Retrospective review revealed early seroconversion (TPHA 1:160, VDRL non-reactive) around March 2025, preceding the hepatic episode but initially unrecognized. The patient also recalled pruritic, erythematous, scaly lesions on the trunk and upper limbs, which he had misattributed to his longstanding psoriasis and treated with topical steroids.

Results: A diagnosis of secondary syphilis was established, and the prior self-limiting acute cholestatic hepatitis was interpreted as syphilitic hepatitis. The patient received six intramuscular injections of benzathine penicillin G, leading to complete resolution of skin lesions. At six-month follow-up, VDRL titers declined to 1:16, while TPHA remained stable, consistent with a serological scar.

Conclusions: This case underscores the importance of including syphilis in the differential diagnosis of acute hepatitis of unknown etiology, particularly in people living with HIV. HIV coinfection may contribute to atypical presentations and delay seroconversion on serologic tests, complicating timely diagnosis. Furthermore, syphilis can mimic other dermatological conditions, such as psoriasis flares, highlighting the crucial role of the dermatologist-venereologist in establishing an accurate differential diagnosis.

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STI

P 194 ADAPTING OUTREACH STRATEGIES TO IMPROVE ACCESS FOR VULNERABLE POPULATIONS: THE EXPERIENCE OF A COMMUNITY-BASED HIV SCREENING SERVICE IN NORTHWEST ITALY

L. Ferrari^{1,5}, A. Ferrari^{1,3}, I. Schenone^{1,2}, G. Notore^{1,4}, G. Manzi^{1,4}, A. Amoretti^{1,4}, F. Cucchetti^{1,4}, F. Tatta^{1,4}, F. Fadda^{1,4}, E. Pontali^{1,5}

¹ANLAIDS Sezione Liguria, Genoa, Italy, ²IRCCS AOM Ospedale Policlinico San Martino, Genoa, Italy, ³University of Antwerp, Antwerp, Belgium, ⁴University of Genoa, Genoa, Italy, ⁵Ente Ospedaliero Ospedali Galliera, Genoa, Italy

Background: Community-Based Voluntary Counseling and Testing (CBVCT) services are pivotal in reaching key populations. This study assesses pre-post changes in user profiles and risk behaviors at the Anlaids Liguria IOC'ENTRO Checkpoint in Genoa, Italy, after the expansion of outreach activities through local partnerships.

Materials and Methods: We conducted a retrospective descriptive pre-post analysis of individuals attending the checkpoint between December 2021 and 2025. While outreach progressively expanded through several collaborations, the initiation of HIV/syphilis testing sessions conducted twice a month at a low-threshold drop-in center for people experiencing housing instability and substance use (June 2024) was used as the reference point for the analysis. Sociodemographic and behavioral data were collected during counselling using the standardized COBATEST Network questionnaire.

Results: A total of 1,211 rapid HIV tests and 388 syphilis tests (since Nov 2024) were performed, identifying 7 (0,6%) new reactive cases for HIV and 4 (1%) for syphilis. After a pilot phase in 2021 (n=11), annual attendance increased from 242 in 2022 to 359 in 2025 (+48.3%). Within our cohort, most represented age groups were 25-39 years (53.0%) and 18-24 years (33.8%). The majority were cisgender men (56.4%) and women (39.9%), followed by non-binary people (1.9%), transgender women (0.9%) and men (0.7%). 294 (23.9%) men had sex with men, and 97 (7.9%) women had sex with women.

Following the initiation of a structured collaboration with a drop-in service (152 HIV and syphilis tests conducted since June 2024), the proportion of users belonging to socially vulnerable groups rose substantially (Figure 1). Foreign-born individuals and individuals reporting substance use increased from 11.0% to 22.2% (+11.2%) and from 3.0% to 21.5% (+18.5%), respectively. The proportion of sex workers (SW) or individuals reporting sex with SW also showed a slight increase, from 3.8% to 4.6%. Independently, the proportion of non-cisgender individuals increased from 2.0% to 4.8%, reflecting sustained presence at annual LGBTQ+ Pride events (63 tests in 2022 vs 116 in 2025).

Conclusions: After four years of activity, Anlaids IOC'ENTRO Checkpoint transitioned from a generalist screening point into a network-oriented service, embedded within local community and harm-reduction infrastructures. Through the systematic decentralization of testing activities, the service diversified its user profile and expanded access to foreign-born individuals and people who use substances. Future development will focus on further reducing structural barriers to testing by strengthening outreach to sex workers and other populations at higher risk of sexually acquired HIV infection.

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STI

P 195 ANAL HPV PERSISTENCE IN AN ITALIAN COHORT OF PEOPLE WITH HIV: RISK FACTORS AND CLINICAL IMPLICATIONS

D. Leoni¹, B. Bragato¹, A. De Rossi², E. Vania¹, A. Ferrari¹, E. Franchin³, S. Gardin¹, S. Cavinato¹, L. Sasset¹, A. Cattelan¹

¹Azienda Ospedaliera Università di Padova - UOC Malattie Infettive e Tropicali, Padua, Italy, ²Azienda Ospedaliera Università di Padova - UOC Psichiatria Clinica, Padua, Italy, ³Azienda Ospedaliera Università di Padova - UOC Microbiologia e Virologia, Padua, Italy

Background: Human papillomavirus (HPV) infection is highly prevalent among people with HIV (PWH). Impaired clearance of oncogenic anal HPV infection represents a critical risk factor for anal malignancy in this population.

Methods: We retrospectively reviewed data from adult PWH screened via anal swabs for HPV-DNA at our outpatient HIV clinic. The study included individuals with follow-up testing between 2022 and 2025 (T2) and a prior assessment performed at least two years earlier (T1). Descriptive demographics and HPV genotypes were analyzed; logistic regression models were employed to evaluate associations between HPV genotype persistence and clinical variables.

Results: A total of 98 PLWH were included: 93 men (94.9%) and 5 women (5.1%). Among men, 79 (84.9%) were MSM and 14 (15.1%) were heterosexual. The median age was 46 years (IQR: 40-54), with a median interval between tests of 8 years (IQR: 4-9). Overall, 73 participants (74.5%) were vaccinated against HPV (Table 1). High-risk HPV (HR-HPV) genotypes were detected in 72 subjects (73.5%) at T1 and in 54 (55.1%) at T2. Genotype-specific persistence was documented in 50 individuals (51%). Anal HPV-DNA clearance was observed in 5 PWH (5.1%), while acquisition was documented in 5 others. Among the persistent high-risk strains, HPV16 was the most frequent (16.6%), followed by HPV51 and HPV52 (both 13.3%). In the multivariate model, HPV-DNA genotype persistence was significantly associated with HR-HPV carriage (OR 8.06, 95% CI: 2.24, 29.03; p=0.001), female sex (OR 34.25, 95% CI: 1.44, 818.15; p=0.03), and MSM status (OR 6.56, 95% CI: 1.17, 36.98; p=0.03) (Table 2). Age (OR 1.04, 95% CI: 0.99, 1.09; p=0.08) showed a trend toward association.

Conclusions: In this cohort, high rates of anal HPV-DNA persistence were observed, confirming a prolonged interaction between the virus and the host immune system in PWH. Carriers of high-risk genotypes were significantly more prone to viral persistence, potentially increasing their long-term risk for anal malignancy. Notably, women living with HIV, despite their limited representation in our cohort, and aging individuals emerged as groups at higher risk for persistent positivity, highlighting the need for targeted screening and prevention strategies. Further large-scale studies are warranted to validate these findings and evaluate whether such persistence directly correlates with increased anal dysplasia incidence.

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STI

P 196 ASSESSING THE RISK FACTORS FOR SEXUALLY TRANSMITTED INFECTIONS AMONG CISGENDER WOMEN IN ITALY. INSIGHTS FROM THE WOMANIST STUDY AND IMPLICATIONS FOR PREVENTION

G. Canavesi¹, M. Rigoni^{1,2}, L. Pezzati¹, M. Ticozzelli^{1,2}, M.P. Bissanti^{1,2}, A. M. Tshishimbi^{1,2}, S. Rusconi^{1,2}

¹SC Malattie Infettive, ASST Ovest Milanese, Legnano (MI), Italy, ²DIBIC, University of Milan, Italy

Background: Sexually transmitted infections (STIs) represent a major public health concern. Among women, STIs constitute a challenging topic due to their insidious nature, frequent asymptomatic presentation, and potential for severe long-term complications. STIs remain a relevant issue that primarily affects female reproductive health. Evidence on STIs risk factors among cisgender women in high-income countries remains limited. In Italy, women are routinely tested for STIs only during pregnancy, and systematic preventive strategies are lacking.

Methods: WomanIST is a monocentric, retro-perspective study, approved by Ethics Committee, designed to investigate sexual habits, condom use, risks and prevalence of all STIs in cisgender women who came to the Female Sexual Health Clinic in Legnano Hospital (Milan, Italy). In an inclusive space, a dedicated questionnaire was proposed to all patients. Information regarding demographics, sexual orientation, partners and condom use, combined with serological tests (HIVAg/Ab, HCVAb, HBsAg, and T. pallidum Ab) were collected. Nucleic Acid Amplification Tests (C. trachomatis, N. gonorrhoeae, Mycoplasma and Ureaplasma spp) on endocervical swabs were performed. A descriptive, univariate and multivariate analysis were conducted in order to find a correlation between current STIs diagnosis and sexual habits.

Results: From January 2024 to February 2026, 296 women were enrolled. We found 137 infections including HIV, HBV, HCV, syphilis, C. trachomatis, N. gonorrhoeae and urogenital mycoplasmas. We detected one new HIV- 1 infection and 9 latent syphilis, with a prevalence of 0,3% and 3%, respectively. There were no new diagnosis of viral hepatitis. From cervical swabs we identified 7% C. trachomatis, 3% N. gonorrhoeae, 3,3% M. genitalium, 12,5% M. hominis, 4,4% U. urealyticum, 12,5% U. parvum. We observed 32 co-infections. In the univariate analysis, we observed a significant correlation with current STIs diagnosis and inconsistent use of condom, use of hormonal contraceptive methods, previous STIs and use of "morning after pill", at least once. We confirmed the role of these parameters in the multivariate analysis.

Conclusions: If compared with European data, the WomanIST Study showed a higher STIs prevalence among Italian cisgender women which may reflect an emerging trend of increased STI risk. Strengthened screening strategies are required to prevent serious complications in this neglected population. Promoting female empowerment through tailored prevention and sexual education is crucial to support women in making mindful choices about their health.

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STI

P 197 BARRIERS TO HIV PREVENTION IN ADOLESCENTS: A CASE SERIES AND THE PIVOTAL ROLE OF SPECIALIZED PEDIATRIC STI CLINICS

C. Coppola¹, M. Stracuzzi¹, R. Caiazza¹, M.S. Valentino¹, D. Moschese², V. Giacometti¹

¹Pediatric Infectious Disease Unit, Luigi Sacco Hospital, University of Milan, Milan, Italy, ²Division of Infectious Diseases, ASST Fatebenefratelli Sacco, Luigi Sacco Hospital, Milan, Italy

Background: Despite the global effort to end the HIV epidemic, adolescents remain a vulnerable population with significant gaps in accessing Biomedical Prevention (PEP and PrEP). In Italy, structural barriers, legal uncertainties regarding minors' autonomy, and a lack of standardized emergency protocols in non-specialized settings often result in missed opportunities. We aim to analyze diverse clinical pathways within a dedicated Pediatric Infectious Disease (PID) unit to identify systemic failures and successful management models.

Material and Methods: We conducted an analysis of paradigmatic cases managed at our dedicated Adolescent STI Clinic in Milan between 2025 and 2026. Clinical records were reviewed to evaluate: timing of access to care, referral sources, barriers encountered (administrative, cultural, or legal), and clinical outcomes of prevention strategies (PEP/PrEP).

Results: We present three paradigmatic cases managed at our Adolescent STI Clinic in Milan:

1. The Delayed Referral: A 15-year-old male sought urgent assistance at a local family counseling center following a high-risk encounter with a sex worker. Due to protocols and the counselor's insistence on a preliminary parental psychological interview before medical referral, the patient reached our unit 21 days later. This administrative and cultural delay resulted in the loss of the 72-hour window for PEP efficacy, leaving the minor at risk and causing significant psychological distress.
2. The Emergency Gateway: A 16-year-old female was referred by her parents for emergency screening after her first unprotected sexual encounter. This case highlights how a "low-threshold" access point, perceived as a safe and expert environment by families, can facilitate early STI screening and prevent the complications of untreated infections, serving as an entry point for sexual health education.
3. The Proactive Transition: A 16-year-old male, initially presenting for PEP, was successfully transitioned to a PrEP program. Given the high-risk profile and adherence concerns with daily pills, he was started on Long-Acting Cabotegravir (CAB-LA). This transition demonstrates that an emergency visit can be transformed into a sustainable, long-term prevention strategy through a multidisciplinary approach involving pediatric ID specialists and psychologists.

Conclusions: The case of the missed PEP underscores a critical training gap in primary care and counseling centers. To bridge the gap between risk and prevention, it is essential to establish specialized adolescent-friendly STI clinics. These units must provide immediate medical access, bypassing bureaucratic delays, and offering the specific legal and psychological framework required to protect minors' health rights.

STI

P 198 BRIDGING THE GAP IN STIS PREVENTION. MISSED OPPORTUNITIES IN HIV AND STIS SCREENING IN CISGENDER WOMEN: INSIGHTS FROM THE WOMANIST COHORT

M. Rigoni^{1,2}, G. Canavesi¹, L. Pezzati¹, M. Ticozzelli^{1,2}, M.P. Bissanti^{1,2}, A.M. Tshishimbi^{1,2}, D. Bernacchia¹, S. Rusconi^{1,2}

¹SC Malattie Infettive, ASST Ovest Milanese, Legnano, Italy, ²DIBIC, University of Milan, Milan, Italy

Background: In women, STIs are frequently asymptomatic and can lead to several complications such as infertility, ectopic pregnancy and PID. In the last few years, female empowerment has led to significant changes in women's sexual habits. Despite this, women remain a neglected population in early STIs diagnosis. In Italy, women get tested systematically for STIs primarily during pregnancy and there is no proper prevention. In 2024, we tried to solve this gap and opened the WomanIST clinic at Legnano General Hospital. We performed a complete STIs screening including serological test for HIV, HCV and syphilis, along with vaginal and endocervical NAAT swabs for *C. trachomatis*, *N. gonorrhoeae* and urogenital mycoplasma. Additionally, we designed a specific questionnaire to investigate social and sexual behaviors of patients attending the clinic.

Material and Methods: We made a descriptive analysis of questionnaire data focusing on sexual behaviors, preventive practices, and prior STI/HIV screening among women tested at the WomanIST clinic.

Results: From January 2024 to February 2026, 296 women answered the questionnaire. The average age was 30 years. Regarding sexual orientation, 91% were heterosexual; 121 women (41%) were vaccinated for HPV and 19% (n. 57) declared a previous STI diagnosis (outside the WomanIST clinic). Only 43% (n. 128) were already tested for HIV before accessing our clinic (reasons are shown in Figure 1). Seventy-seven % of women did not regularly use condom during sexual intercourses. Moreover, 79 women declared more than one sexual partner per month. As far as contraception, 117 women (40%) used hormonal methods, 57 used condom as their primary contraceptive method, and 122 did not use any contraceptive method. Additionally, 41% took an emergency contraception, at least once. It should be noted that 40% of screened women tested positive for at least one STI, with 32 episodes of co-infection.

Conclusions: WomanIST data showed fragile STIs prevention practices in our female population. Missed screening opportunities frequently occur during contraception counseling, gynecological visits and routine check-ups-encounters that could be strategically used to integrate STIs and HIV testing. Overcoming these missed opportunities should not be a merely clinical objective but an ethical and public health priority. Increasing screening coverage among women enables early diagnosis, reduces long-term complications and interrupts transmission chains, improving both individual and public health outcomes.

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STI

P 199 BURDEN OF NON-16/18 HIGH-RISK HPV AND MULTIPLE-GENOTYPE INFECTIONS ACROSS ANAL CYTOLOGY GRADES IN MEN LIVING WITH HIV

L. Nekrasova^{1,4}, F. Mazza¹, E. Ottaviano^{1,4}, V. Costabile⁴, D. Tesoro², S. Ferla¹, F. Rabacchi¹, S. Ciaburri¹, P. Vella¹, D. Campisi¹, U. Gianelli^{3,4}, G. Marchetti^{2,4}, E. Borghi^{1,4}, C. Tincati^{2,4}

¹Microbiology and Virology Unit, ASST Santi Paolo e Carlo, Milan, Italy, ²Clinic of Infectious Diseases, Department of Health Science, ASST Santi Paolo e Carlo, Milan, Italy, ³Anatomical Pathology Unit, ASST Santi Paolo e Carlo, Milan, Italy, ⁴Università degli Studi di Milano, Milan, Italy

Background: Men living with HIV (MLWH) remain at increased risk of anal HPV infection and dysplasia despite widespread antiretroviral therapy and HPV vaccination strategies. The distribution of non-16/18 high-risk (HR) HPV genotypes and the role of multiple-genotype infections in lesion development remains incompletely defined. In this study we aimed to evaluate HPV genotype distribution across anal cytology grades, focusing on HR-HPV and coinfection patterns.

Materials and Methods: A retrospective longitudinal analysis of MLWH undergoing routine anal HPV screening between 2009 and 2025 at the Clinic of Infectious Diseases, Department of Health Sciences, ASST Santi Paolo e Carlo, Milan was conducted, covering two laboratory phases: testing performed at the Unit of Anatomic Pathology (2009–2022, Tretro) and, following service reorganization, at the Microbiology and Virology Unit from December 2022 onward (T0). Anal cytology was classified as negative, ASC-US, LSIL, or HSIL. HPV genotyping was performed using standardized DNA detection platforms. HR-HPV included genotypes beyond HPV-16/18 according to assay specifications. Associations between genotype distribution and cytological grade were assessed using chi-square testing and standardized residual analysis.

Results: A total of 306 MLWH (median age 48 years; 89.9% virologically suppressed; median CD4 776 cells/ μ L) contributed 871 cytology–HPV DNA paired samples. LSIL was the predominant cytological finding across screening phases ($\approx$ 58–69%), while HSIL was uncommon ($<$ 3%). In retrospective screening (Tretro; $n=396$), non-16/18 HR-HPV were detected in 32.6% of samples and multiple-genotype coinfections in 35.4%. In subsequent screening (T0; $n=426$), pooled HR-HPV were identified in 41.5% of samples, with coinfections reported in 16.7% under assay-limited definitions. Extended genotyping was performed in a subgroup of 49/177 HR-HPV–positive T0 samples, revealing multiple-genotype infections in 83.7%, with up to nine concurrent genotypes detected. Genotype distribution differed significantly across cytological categories in independent screening phases (Tretro, $p<0.001$ and T0, $p=0.007$). HSIL cases were predominantly characterized by genotype coinfections rather than isolated HPV-16 detection. Exploratory clustering across timepoints suggested lesion-specific enrichment of certain genotype combinations, including higher-than-expected frequencies of HPV-11/16, HPV-16/58, and HPV-6/58 in HSIL (trend $p=0.081$) (Figure 1).

Conclusions: Anal HPV infection in MLWH is marked by substantial non-16/18 HR-HPV burden and frequent multigenotype coinfections. Lesion severity appears more closely associated with genotype multiplicity than with single-type dominance. These findings support the need for comprehensive HPV genotyping and continued surveillance in MLWH.

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STI

P 200 CLINICAL AND VIROLOGIC FEATURES OF THE NOVEL MPOX VIRUS CLADE Ib IDENTIFIED IN MILAN, ITALY

D. Maddalena, F. Caruso, F. Petri, S. Lazzarin, C. Fusetti, V. Iannone, A. Giacomelli, M.V. Cossu, A. Antinori, A. Mancon, V. Micheli, A. Lombardi, A. Dolci, A. Gori, D. Mileto, D. Moschese

University of Milan, ASST Fatebenefratelli Sacco, Milan, Italy

Background: Recent mpox outbreaks have documented the spread of clade Ib beyond the Central Africa, where it was historically confined. However, data describing the clinical and virological features of clade Ib infections in Europe remain limited.

Materials and Methods: We conducted a descriptive analysis of patients presenting with suspected mpox to the STI outpatient clinic of Luigi Sacco Hospital (Milan, Italy) between 1 January and 1 February 2026. Infection was confirmed by real-time polymerase chain reaction (RT-PCR) on skin lesion, blood, anal, and oropharyngeal swabs. Viral clade was determined by whole-genome sequencing. Demographic, clinical, and laboratory data were collected at diagnosis and during follow-up. Cycle threshold (CT) values were used as a surrogate marker of viral load.

Results: Six male patients were diagnosed with mpox clade Ib. Median age was 38 years. One patient was living with HIV; among the five HIV-negative individuals, three reported on-demand HIV pre-exposure prophylaxis use. One patient had previously received two doses of mpox vaccine. A recent at-risk sexual exposure preceding symptom onset was reported in four cases.

Median CT values were 17.5 for skin lesions, 20 for oropharyngeal swabs, 29.5 for anal swabs, and 33 for blood samples, suggesting higher viral loads in mucocutaneous sites.

All patients presented with predominant cutaneous involvement, including pustular and ulcerative lesions. Facial lesions were observed in all cases, while truncal and/or acral involvement occurred in five. Anorectal involvement was documented in three patients and was associated with severe pain; one also reported rectal bleeding. Systemic symptoms included fever (n=4), lymphadenopathy (n=4), pharyngodynia (n=4), and myalgia (n=3). Sexually transmitted coinfections were identified in two patients (HSV-2 proctitis and anal Mycoplasma genitalium infection).

One patient required hospitalization. Tecovirimat was administered in three patients, leading to rapid improvement of painful symptoms within four days; lesions progressed to crusting over subsequent weeks. No drug-related adverse events were observed. Complications included one facial methicillin-resistant Staphylococcus aureus skin infection and one case of deep, non-epithelialized genital ulcers.

Conclusions: This cluster provides an early characterization of clade Ib mpox in Milan, and underscores the importance of clinical awareness among healthcare workers. High viral loads in skin and oropharyngeal samples, and their potential implications in transmission, underscore the importance of early recognition to facilitate timely diagnosis, appropriate clinical management, and containment as clade Ib continues to emerge in Europe.

STI

P 201 DOXYPEP EFFECTIVENESS: IDENTIFYING DOSING THRESHOLDS AND HIGH-RISK CONTEXTS

R. Rossotti^{1,2}, E. Caruso², C. Muccini^{2,3}, A. De Bona^{2,4}, D. Moschese^{2,5}, N. Frattini², D. Tesoro^{2,4}, A. Tavelli⁶, P. Vinti², G. Ancona^{2,4}, A. d'Arminio Monforte⁶, M. Cernuschi²

¹ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ²Milano Checkpoint ETS, Milan, Italy, ³San Raffaele Scientific Institute, Milan, Italy, ⁴ASST Santi Paolo e Carlo, Milan, Italy, ⁵ASST Fatebenefratelli-Sacco, Milan, Italy, ⁶ICONA Foundation, Italy

Background: DoxyPEP has proven to be highly effective against bacterial sexually transmitted infections (bSTI); however, it is unclear whether it should be used for each sexual contact or limited to specific settings. Aims of this study were (i) to describe the features of individuals who chose to use doxyPEP in our cohort of PrEP users, (ii) to assess the number of doxyPEP doses required to observe a measurable reduction in bSTI incidence, and (iii) to explore the contexts in which its use may be most appropriately targeted.

Methods: This retrospective analysis included all individuals who had at least two visits from January 2024 to September 2025 at Milano Checkpoint, a community-based service that offers free medical assistance to PrEP users in northern Italy. DoxyPEP was prescribed to all participants, but its use was recommended specifically for sexual exposures involving a high number of partners within a short time. Logistic regression was applied to identify individual and behavioral factors associated with doxyPEP uptake. We used generalized linear models with Poisson and negative binomial distributions, including person-years as offsets, robust variance estimates clustered by individual, and probability weights to assess the association between doxyPEP use and bSTI incidence.

Results: The study included 907 individuals with a cumulative number of 3,381 visits; of them, 169 used doxyPEP at least once (Table 1). The median number of doses taken between visits (i.e., 4 months interval) was 2 (IQR 1-3). Factors associated with doxyPEP use were chemsex (aOR 2.63, 95%CI 1.85-3.74) and having had a prior bSTI (aOR 1.21, 95%CI 1.2-1.44). Poisson and negative binomial models did not find that an increasing number of doxyPEP doses was significantly associated with a reduction in bSTI: the effect started to be protective >4 doses but without reaching the statistical significance (IRR 0.90, 95%CI 0.66-1.22). Regarding the context, doxyPEP use in cruising venues and group sex were at the limit of significance (IRR 0.89, 95%CI 0.78-1.00, and IRR 0.88, 95%CI 0.78-1.00, respectively), while use during sex work or chemsex sessions was not associated with a reduction in bSTI.

Discussion: In our population, doxyPEP was used very few times by individuals at major risk of exposure; the effect of the number of doses used was limited by the small utilization observed. Our data suggest a trend towards effectiveness with consistent doxyPEP use, especially when participating in group sex and cruising venues.

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STI

P 202 EFFECTIVENESS OF A STRUCTURED SCHOOL-BASED INTERVENTION ON STI KNOWLEDGE AND RISK AWARENESS AMONG ITALIAN ADOLESCENTS

M. Salvi¹, B. Fioretti¹, A. Boldini², D. Minisci¹, A. Pavesi¹, S. Rapino¹, M. Inverardi¹, C. Rossi¹, M. Calamelli¹, F. Castelli¹, E. Quiros-Roldan¹, E. Focà¹

¹Department of Clinical and Experimental Sciences, Unit of Infectious and Tropical Diseases, University of Brescia and ASST Spedali Civili General Hospital, Brescia, Italy, ²Nursing School, University of Brescia, Italy

Background: Sexually transmitted infections (STIs) are increasing among young people in Italy, with early sexual debut contributing to ongoing transmission. Understanding adolescents' knowledge and perception of risk is essential to inform effective prevention strategies. We aimed to assess baseline STI knowledge, risk perception, and the impact of a structured school-based educational intervention.

Methods: We conducted this study in two high schools in Northern Italy. All participants completed anonymous questionnaires before and after a standardized 2-hour interactive session delivered by healthcare professionals. The survey evaluated STI identification, transmission routes, prevention strategies, screening awareness, and self-perceived vulnerability.

Results: A total of 452 students (57% female; mean age 16.3±0.7 years) were included. Thirty-three percent did not consider individuals <25 years at risk for STIs. Sexual debut occurred at a mean age of 15.5±1.0 years. At baseline, 87% reported having received prior sexual health education, mainly at school (87%) and via internet (45%) and social media (49%), whereas only 22% cited healthcare services. Despite this, knowledge gaps persisted: although 98% identified HIV as an STI, only 23% recognized Hepatitis B, 46% Chlamydia, 55% Gonorrhea, and 61% HPV. Awareness of HIV testing was reported by 48%. Interestingly, 39% of sexually active students reported inconsistent condom use. Moreover, 17% believed oral contraceptives could protect against STIs.

Following the 2-hours interactive intervention, substantial improvements were observed in STI identification (hepatitis B 23%→87%; chlamydia 46%→89%; gonorrhea 55%→93%; HPV 61%→91%) and recognition of anal and oral transmission (83%→97% and 76%→96%). Awareness of HPV vaccination and preventive strategies increased, while erroneous beliefs declined. Importantly, perceived personal vulnerability improved: students acknowledging prior risk behaviors rose from 7.8% to 13%, and identification of youth <25 years as at risk increased from 67% to 83%.

Notably, 67% expressed interest in individual counselling with a specialist.

Conclusions: A short-term educational intervention was associated with substantial improvements in STI knowledge and greater alignment between theoretical awareness and perceived personal risk. These findings support the integration of structured, evidence-based sexual health education within secondary school curricula as a feasible public health strategy to strengthen STI prevention among adolescents, if conducted by trained healthcare professionals.

STI

P 203 EVALUATING THE FEASIBILITY OF INTRODUCING ROUTINE HPV SWAB SCREENING IN AN HIV OUTPATIENT CLINIC

L. Pagnucco¹, M.A. Muslimani^{1,2}, F. Siviero^{1,2}, R. Bruno^{1,2}, R. Gulminetti¹

¹Infectious Diseases Unit, Medical Department, Fondazione IRCCS Policlinico San Matteo University of Pavia, Pavia, Italy, ²Department of Medicine, Surgical, Diagnostic and Pediatric Science, University of Pavia, Pavia, Italy

Background: The incidence of human papillomavirus (HPV) infection and HPV-related malignancies is rising and represents a growing clinical concern among PWH. While women are routinely screened for HPV through cervical-vaginal cytology, the detection of HPV infections in other anatomical sites (oral and anal) is not routinely performed in either men or women.

Material and Methods: We decided to conduct a cross-sectional study on a small number of patients with HIV to determine the acceptability and attitudes towards HPV swabs and evaluate the opportunity to introduce them into routine clinical practice. PWH who were evaluated in the outpatient clinic for routine visits during the first week of February 2026 were offered oral swab (performed by the doctor) and self-sampled anal and vaginal swabs.

Results: We proposed swabs to 68 PWH, only 2 refused so we analyzed swabs collected from 65 PWH. Baseline characteristics are summarized in Table 1.

Among the anal swabs (Table 2), 45 tested positive, yielding 85 HPV detections: 58.1% were high-risk (HR), with types 53 and 16 being the most frequent, 40.7% were low-risk (LR), and 1.2% were unclassified (type 120).

For oral swabs, only 3 samples were positive, corresponding to HPV types 58 and 56 (HR) and 120 (unclassified).

Among 21 vaginal swabs (Table 3), 11 were positive, identifying 20 HPV subtypes. Half (50%) were HR, with types 16 and 13 most frequent, and the remaining 50% were LR, most commonly types 40, 44, and 54.

Unvaccinated patients were offered vaccination again.

Conclusions: HPV prevalence is high in anal swabs collected from both women and men, including MSM and non-MSM individuals. Similarly, a high prevalence has been observed in vaginal swabs, whereas comparable data for oral swabs remain limited. Although the sample size in this study is small, these findings, together with the broad acceptability of self-collected genital swabs, support the potential use of this method in routine clinical practice to facilitate early identification of high-risk HPV strains and timely referral to appropriate specialists for further evaluation.

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STI

P 204 FROM CHEMSEX TO A BROADER DRUG-SEX LANDSCAPE: COMPARING TWO MSM SURVEYS FROM A ROME STI/HIV REFERENCE CENTER

L. Gianserra, C. Stingone, M. Zaccarelli, M.G. Dona', F. Di Tullio, E. Giuliani, M. Giuliani, A. Latini

STI/HIV Unit, San Gallicano Dermatological Institute IRCCS, Rome, Italy

Background: Drug use in sexual settings among men who have sex with men (MSM) is increasing in many European settings and is a key driver of sexually transmitted infections (STIs). Importantly, chemsex is also evolving. Beyond the classic triad (GHB/GBL, mephedrone, crystal meth), new psychoactive substances (including synthetic cathinones and synthetic cannabinoids) are increasingly reported. The context of drug-related sex is also diversifying, shifting from long sessions in private homes to multiple settings such as private rooms in clubs, saunas, and night-time outdoor meeting areas, with encounters that may be brief yet supported by stimulants and disinhibition. Since our reference center regularly assesses knowledge and behavior of MSM attending the service through targeted surveys, we aimed to assess how much drug use for sex among MSM is evolving using two surveys carried out over the last 5 years.

Methods: We compared two cross-sectional surveys conducted at a Rome STI/HIV reference center among MSM: a 2018–2019 survey based on an anonymous self-compiled paper questionnaire, and a 2024–2025 survey collected through an anonymous online questionnaire. The main outcome was the self-reported use of drugs for sex in the previous year. Proportions were compared using Fisher's exact test; $p < 0.05$ was considered statistically significant.

Results: The surveys included 354 MSM in 2018–2019 and 331 MSM in 2024–2025, the proportion of PLWH was higher in the oldest survey (232/3563, 65.5% vs. 32.9% in 2024–2025 survey). In the more recent survey, the prevalence of several chemsex-related substances increased significantly: crystal meth (2.3% vs 8.2%, $p < 0.001$), mephedrone (4.0% vs 9.4%, $p = 0.005$), and GHB/GBL (3.4% vs 16.9%, $p < 0.001$). Chemsex (defined as use of at least one chemsex drug) rose from 5.1% to 15.4% ($p < 0.001$). Newer substances emerged, including synthetic cathinones (0% vs 2.7%, $p = 0.001$) and synthetic cannabinoids (0% vs 0.9%). Poppers also increased (13.0% vs 20.5%, $p = 0.008$). Any drug use for sex increased from 20.9% to 25.7%, although this difference was not statistically significant. Among people living with HIV, any drug use increased (18.5% vs 29.4%, $p = 0.035$) and chemsex showed a marked rise (5.6% vs 24.8%, $p < 0.001$). Thirty-one MSM also reported that they had not practiced it in the past year, although most continued to use drugs for sex (Table 1).

Conclusions: In our setting, drug use for sex among MSM has increased over time, with a clear expansion of chemsex and a shift toward a broader and more heterogeneous drug-sex landscape. The emergence of new substances and the diversification of contexts where drug-related sex occurs may contribute to increased STI and HIV vulnerability, challenging prevention strategies. STI/HIV services should update screening and counselling approaches, integrate harm reduction, and actively monitor evolving patterns of substance use among MSM.

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STI

P 205 HPV VACCINATION COVERAGE AND PREVALENCE OF ANAL HPV-ASSOCIATED CONDITIONS IN A COHORT OF PREP USERS

F. Ceriegi¹, S. Occhineri¹, L. del Bono¹, A. Borghetti¹, S. Ferranti¹, S. Esin², M. Pistello³, C. Menconi⁴, M. Falcone¹

¹Department of Clinical and Experimental Medicine, Infectious Disease Unit, University of Pisa, Pisa, Italy, ²Department of Translation Medicine and New Technologies in Medicine and Surgery, Microbiology Unit, University of Pisa, Pisa, Italy, ³Department of Translation Medicine and New Technologies in Medicine and Surgery, Virology Unit, University of Pisa, Pisa, Italy, ⁴Proctology and Pelvic Floor Clinical Centre, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy

Introduction: Anal HPV infection is highly prevalent in MSM, even in the absence of immune compromising conditions, but vaccine coverage in this population is still suboptimal and the prevalence of HPV-related diseases is probably under-reported. The ambulatory setting for the prescription of HIV pre-exposure prophylaxis (PrEP) could serve as a moment for improving screening and prevention of HPV-related complications.

Methods: We conducted an observational study of MSM and transgender people attending the PrEP ambulatory at Pisa University hospital from 2024 to 2025, who underwent proctological evaluation, performed either at PrEP initiation or after receiving PrEP prescription. The proctological evaluation is composed by a proctologic screening visit with anal HPV-testing and pap-test in a dedicated, multidisciplinary ambulatory service. Also, vaccination status for sexually transmitted diseases (STDs) is routinely checked and advice to vaccines against STDs is performed. The objective of the present study was to describe the percentage of HPV vaccination coverage, prevalence of anal cytological and histological abnormalities associated with HPV infection.

Result: One hundred and twenty-six individuals enrolled in the PrEP program were screened for this analysis. Median age was 35 years (inter-quartile range 21–68). PrEP modalities consisted of on-demand PrEP in 66 cases, continuous PrEP in 58, and mixed regimens in 3. A history of previous STIs was documented in 83 patients, including syphilis (56 cases), chlamydia (10), gonorrhea (13), Mycoplasma infections (2), Ureaplasma infections (13), and herpes simplex virus (4).

Among 126 PrEP users, 65 (51%) underwent proctological evaluation with anal HPV DNA testing and anal cytology. A prior history of HPV infection was documented in 29 participants. Forty-one (63%) were already vaccinated against HPV prior to assessment; of those not previously vaccinated, 16 completed HPV vaccination after the proctological visit. HPV DNA was detected in 44/65 (68%). Low-risk genotypes were identified in 40 participants and high-risk genotypes in 23 (35%). Genotypes covered by vaccination were found in 15 HPV-positive participants, specifically: HPV6 (n=8), HPV11 (n=3), HPV16 (n=2), HPV18 (n=2), HPV31 (n=2), HPV33 (n=3) and HPV45 (n=4). Anal cytology showed HPV-related abnormalities in 18/65 (28%) of the participants (13 ASC-US, 4 LSIL and 1 HSIL). Thirty-one participants underwent anoscopy, which detected 9 LSIL and 3 HSIL.

Conclusion: Anal HPV-related pre-cancerous lesions are not infrequent in this population at risk for STDs. Combining HIV prevention with broader STDs and cancer-prevention strategies may enhance overall patient outcomes and public health impact.

STI

P 206 IMPACT OF AN HPV SCREENING AND TREATMENT IN A POPULATION OF PREP USERS - DATA FROM PERUGIA HOSPITAL

M.C. Benvenuto, S. Gobbi, G. Gonnelli, C. Papalini, G. Gamboni, C. Pallotto, A. Gidari, G.V. De Socio

Infectious Diseases Clinic, Santa Maria della Misericordia Hospital, Perugia, Italy

Background: Pre-exposure prophylaxis (PrEP) is a preventive strategy that reduces the risk of acquiring HIV infection. However, PrEP does not provide protection against other sexually transmitted infections such as Human Papillomavirus (HPV); for this reason, it should be integrated into a multifactorial prevention approach. The prevalence of HPV infection and the risk of subsequent anal precancerous lesions are high among PrEP users and are estimated to be similar to those observed in people living with HIV (PLWH). The aim of the study is to evaluate the impact of an HPV screening and treatment program in a population of PrEP users.

Material and Methods: Retrospective study. All PrEP users followed at the Infectious Diseases Day Hospital of Perugia from 2020 to February 2026 were enrolled.

Results: The study population includes 197 PrEP users, of whom 179 (90.9%) are men who have sex with men (MSM), 15 male to female (MTF) (7.6%), 1 female to male (FTM) (0.5%), and 2 female users (1.0%). 127 users are on continuous PrEP (64.5%) and 68 are on an "on-demand" regimen (34.5%). Currently, 108 patients are still actively on PrEP (54.8%). The median PrEP follow-up is 16.5 months (interquartile range 6.7–29.9). The mean age is 39.4 (standard deviation 10.6). A positivity for syphilis serology was detected, before or during PrEP, in 98 users (49.7%). Moreover 32 PrEP users had a previous gonorrhea (16.2%), 16 (8.1%) had a previous Chlamydia infection and 44 (22.3%) had other previous sexually transmitted infections. A total of 80 (40.6%) PrEP users underwent anal swab. 39 users refused anal swab (19.8%). At least one HPV genotype was detected in 60 participants (75%). Among those who underwent anal swab and tested positive for HPV, at least one high-risk (HR) genotype was identified in 52 users (65%) (figure 1). Anal pap test was performed in 41 PrEP users who had positive anal swab (68.3%). Among the 60 users who tested positive for anal swab, 27 received a surgical evaluation (45%). 118 PrEP users (59.8%) underwent vaccination against HPV, 78 against monkeypox virus (MPOX) (39.6%) and 63 against hepatitis A (HAV) (32.0%).

Conclusions: The prevalence of HPV infection and the risk of subsequent anal precancerous lesions are high among PrEP users. HPV screening has demonstrated its efficacy in detecting individuals who may be at risk for neoplastic progression. The HPV screening conducted at Perugia Infectious Diseases Day Hospital has allowed us to pinpoint patients in need of surgical assessment or potential therapeutic measures. In contrast, the suggestion for HPV vaccination was well-received, while the use of anal swab and pap test for screening was not consistently embraced by patients.

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STI

P 207 INCLUSIVE SEXUAL HEALTH: MULTISECTORAL NETWORKS ADDRESSING STIS AMONG VULNERABLE GROUPS IN ITALY

A. Chinelli¹, M. Crudele¹, V. Casigliani¹, S. Moriconi¹, F. Fortunato², L. Bisceglia³, B. Suligoi⁴, A. Colucci⁵, V. Mazzotta⁶, E. Girardi⁷, D. Cereda⁸, M. Maffeo⁸, R. Ranieri⁹, B. Pellizzari¹⁰, G. Valdi¹⁰, M. Ubbiali¹¹, M. Farinella¹², M.D. Vincenti¹³, V. Vitale¹³, N. Albano¹³, L. Tivoschi¹, D. Martinelli²

¹Department of Translational Research and New Medical and Surgical Technologies, University of Pisa, Pisa, Italy, ²Department of Medical and Surgical Sciences, University of Foggia, Foggia, Italy, ³Strategic Regional Agency for Health and Social Care of Apulia (AReSS Puglia), Bari, Italy, ⁴AIDS Operations Center, Department of Infectious Diseases, Italian National Institute of Health, Rome, Italy, ⁵Operational Unit of psycho-socio-behavioural Research, Communication, Training - Department of Infectious Diseases, Italian National Institute of Health, Rome, Italy, ⁶Clinical and Research Infectious Diseases Department, National Institute for Infectious Diseases Lazzaro Spallanzani, IRCCS, Rome, Italy, ⁷Scientific Direction, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy, ⁸Department of Prevention, General Directorate of Welfare, Regione Lombardia, Milan, Italy, ⁹Infectious Diseases Service, Penitentiary Health System, Saints Paul and Charles Local Health Authority, Milan, Italy, ¹⁰Infectious Diseases Prophylaxis and Prevention Unit, Friuli Occidentale Local Health Authority (ASFO), Pordenone, Italy, ¹¹Department of Human Sciences, University of Verona, Verona, Italy, ¹²Italian National Association for the Fight Against Aids (ANLAIDS), Rome, Italy, ¹³Department of Health, Puglia Region, Bari, Italy

Background: Sexually transmitted infections (STIs) continue to present a significant public health challenge in Europe, particularly among vulnerable populations who encounter barriers in accessing healthcare. Current surveillance systems capture only partial data on the burden of STIs and under-represent vulnerable groups, such as migrants, refugees, sex workers, men who have sex with men (MSM), LGBTQIA+ individuals, drug users and homeless people. Furthermore, the determinants of access to screening, diagnosis and care services are poorly documented in Italy. Recently, the Italian Ministry of Health funded a project to assess the burden of STIs among vulnerable populations and analyse the drivers and barriers to care service provision.

Material and Methods: A multisectoral network involving academia, scientific and healthcare institutions, health services and civil society organisations (CSOs) has been established in the Italian regions. The 24-month project includes three work packages. An mapping exercise of existing organisational models for STI prevention and care will be conducted through a scoping review of available documentation and in-depth interviews with regional and local authority representatives, health professionals, and CSO representatives. A biobehavioural study is planned to measure the prevalence of STIs among vulnerable populations. This will involve integrating data from STI services with rapid STI testing activities, which are mainly performed by CSO operators. As part of the study, interviews and focus groups will be conducted to gain an understanding of the barriers and facilitators to care. Finally, a minimum dataset for standardised data collection on STIs in low-threshold and outreach services will be developed and tested.

Results: Expected outcomes include documenting multisectoral organisational model and collecting data on the prevalence of STIs among vulnerable populations and the barriers to accessing care. Standardised tools for data collection will also be developed. This evidence will inform the review and adaptation of existing models and protocols, as well as the development of new ones where necessary. The project will also establish diagnostic procedures and propose appropriate STI training in technical, scientific, and communication-related terms. The project will strengthen multisectoral networks by integrating regional health services with community-based civil society organisations (CSOs) providing low-threshold services.

Conclusions: This initiative promotes inclusive health approaches and improves STI data collection in vulnerable populations, thereby addressing health inequalities. The project will inform evidence-based policies and interventions tailored to the needs of these groups by establishing multisectoral networks and standardising data collection. The results will be shared with stakeholders to inform future national strategies for the prevention, screening and care of STIs.

STI

P 208 ITALIAN INFECTIOUS DISEASES CENTRES' PRACTICE ON MYCOPLASMA GENITALIUM MANAGEMENT: RESULTS FROM A PRIDE NETWORK SURVEY

A.R. Raccagni^{1,2}, G. Micheli³, R. Lolatto^{1,2}, E. Caruso⁵, A. Cattelan⁴, S. Cecere⁶, F.M. Fusco⁷, M. Giglia⁸, L. Del Negro⁹, M. Menozzi¹⁰, E. Milano¹¹, M. Ridolfi¹², R. Rossotti¹³, L. Taramasso¹⁴, D. Tesoro¹⁵, S. Venturelli¹⁶, A. Castagna^{1,2}, A. Antinori³, D. Moschese¹⁷, V. Mazzotta³, M. Cernuschi⁵, S. Nozza^{1,2}

¹Vita-Salute San Raffaele University, Milan, Italy, ²IRCCS San Raffaele Scientific Institute, Milan, Italy, ³National Institute for Infectious Diseases, Lazzaro Spallanzani IRCCS, Rome, Italy, ⁴University Hospital of Padova, Padua, Italy, ⁵Milano Checkpoint ETS, Milan, Italy, ⁶Bologna Checkpoint, Bologna, Italy, ⁷D. Cotugno Hospital, Naples, Italy, ⁸IRCCS Policlinico di Sant'Orsola, University of Bologna, Bologna, Italy, ⁹PLUS Roma, Rome, Italy, ¹⁰Policlinico di Modena, Modena, Italy, ¹¹University Hospital Polyclinic of Bari, Bari, Italy, ¹²Sapienza University, Rome, Italy, ¹³ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ¹⁴IRCCS Azienda Ospedaliera Metropolitana, Genova, Italy, ¹⁵ASST Santi Paolo e Carlo, Milan, Italy, ¹⁶ASST Papa Giovanni XXIII, Bergamo, Italy; ¹⁷Luigi Sacco Hospital, ASST Fatebenefratelli Sacco, Milan, Italy

Background: International guidelines recommend syndrome-based Mycoplasma genitalium (Mgen) testing, no asymptomatic and pharyngeal screening, and resistance-guided therapy. The aim is to describe current Mgen diagnostic and management practices in Italian infectious disease (ID) centres.

Material and Methods: A cross-sectional online survey was disseminated within the Italian PrIDE cohort network (NCT0718624) in December 2025. Items (n=26) covered availability and type of Mgen test (NAAT), anatomical sites tested, treatment indications, resistance testing availability, first-line therapy, test-of-cure (TOC), and partner management.

Results: Thirty-five out of 52 sites responded; community-based sites reported no access to Mgen testing. Among 32 ID centres, 27/32 (84.4%) had access to Mgen NAAT. Availability was lower in the South/Islands (3/6) than in the North (15/17) and the Centre (9/9). Multiplex NAATs with mandatory reporting were most common (20/27, 74.1%). Routine asymptomatic Mgen genital testing was frequent across groups (MSM 23/26, 88.5%; trans and gender-diverse 23/26, 88.5%; cis women 22/26, 84.6%; cis heterosexual men 22/26, 84.6%) and common in pregnancy-related settings (19/26, 73.1%) [Figure1]. Extragenital asymptomatic sampling was widely reported, particularly in MSM and trans and gender-diverse people (rectal 19/26, 73.1%; oropharyngeal 18/26, 69.2%). Regarding treatment, centres reported treating only symptomatic MSM (9/27, 33.3%), symptomatic plus selected asymptomatic (7/27, 25.9%), or all positives regardless of symptoms (11/27, 40.7%); a similar pattern was observed for trans and gender-diverse people [Figures2-3]. In cis heterosexual men and cis women, treatment of all positives irrespective of symptoms was reported by 13/27 (48.1%) for both groups, while in pregnancy, most centres treated both symptomatic and asymptomatic positives (15/27, 55.6%). Macrolide 23S rRNA resistance testing was available in 7/27 (25.9%); fluoroquinolone parC resistance testing was less common (4/27). The most frequent first-line regimen was doxycycline followed by moxifloxacin (15/27, 55.6%); doxycycline followed by azithromycin (4/27, 14.8%) and resistance-guided first-line choice (2/27, 7.4%). Routine TOC after first-line therapy was performed by 8/27 (29.6%) and in selected cases by 3/27 (11.1%). Stable asymptomatic partners were commonly managed by testing and treating if positive (15/27, 55.6%), whereas for casual partners, no routine action was reported by 14/27 (51.9%).

Conclusions: The PrIDE survey highlighted geographic heterogeneity and incomplete access to Mgen NAAT in Italian ID centres, with need to increase availability of resistance testing. Asymptomatic and oropharyngeal testing were common, likely reflecting the use of multiplex panels, and may diverge from stewardship-focused recommendations. Resistance-guided first-line therapy should be used more widely, and both treatment choices and indications need to be standardized

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STI

P 209 MINIMUM INHIBITORY CONCENTRATIONS AND ANTIMICROBIAL RESISTANCE IN NEISSERIA GONORRHOEAE BY DOXYPEP EXPOSURE AND USE FREQUENCY IN MILAN, ITALY

A.R. Raccagni^{1,2}, C. Sagramoso¹, N. Capra², R. Lolatto², D.M. Cirillo^{1,2}, S. Carletti^{1,2}, G. Loi¹, E. Bruzzesi², A. Castagna^{1,2}, S. Nozza^{1,2}

¹Vita-Salute San Raffaele University, Milan, Italy, ²IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: DoxyPEP use might influence *Neisseria gonorrhoeae* antimicrobial susceptibility. Minimum inhibitory concentration (MIC) distributions can capture early antimicrobial susceptibility changes potentially linked to doxycycline post-exposure prophylaxis (DoxyPEP) use. We investigated whether DoxyPEP exposure was associated with phenotypic resistance and MIC patterns of *Neisseria gonorrhoeae*.

Material and Methods: This is a retrospective cohort including people with culture-confirmed gonorrhoea episodes with available antimicrobial susceptibility testing at the Infectious Diseases Unit of IRCCS San Raffaele Scientific Institute in Milan, Italy. People diagnosed between January 2022 and June 2025 were included. DoxyPEP use was self-reported during routine follow-up visits; frequency was categorised as ≥ 1 (frequent) vs <1 time/month (infrequent). MICs for ceftriaxone (CRO), ciprofloxacin (CIP), tetracycline (TET), azithromycin (AZM) and benzylpenicillin (penG) were measured by gradient strips (Etest®, bioMérieux); β -lactamase activity was assessed. Susceptibility was interpreted using EUCAST v15.0; CRO decreased susceptibility (CRO-DS) was defined by ECOFF MIC >0.032 mg/L and high-level tetracycline resistance (TET-HR) by MIC >8 mg/L. Generalized estimating equation models adjusted for age, HIV status, PrEP use and number of prior STIs assessed associations with categorical resistance outcomes and compared log-transformed MICs.

Results: We analysed 376 culture-confirmed gonorrhoea episodes among 318 individuals (median age 34.8 years; 99% male; 58% on PrEP; 20% living with HIV; 68% with ≥ 1 previous STI); 77/376 (20.5%) gonorrhoea episodes occurred after DoxyPEP exposure. Adjusted geometric mean MICs did not differ between DoxyPEP-exposed and unexposed episodes (penG 0.294 vs 0.351 mg/L; CRO 0.003 vs 0.003 mg/L; CIP 0.532 vs 0.402 mg/L; AZM 0.295 vs 0.290 mg/L; TET 2.068 vs 2.576 mg/L) [Table1]. Resistance prevalence was high: CIP-R 250/376 (73.1%), TET-R 360/376 (96.0%) with TET-HR 64/376 (17.1%), AZM-R 36/376 (10.0%), penG-R 40/376 (11.8%), β -lactamase positivity 58/376 (17.3%) and CRO-DS 8/376 (2.1%); no ceftriaxone-resistant isolates were observed. In adjusted models, DoxyPEP exposure was associated with TET-HR (aOR 1.87; 95%CI 1.01–3.47; $p=0.045$) and CRO-DS (aOR 8.35; 95%CI 1.67–41.71; $p=0.010$) [Table2]. Stratifying DoxyPEP-exposed episodes by use frequency, no MICs difference was observed for ceftriaxone (0.003 [0.002–0.004] vs 0.004 [0.002–0.006] mg/L; $p=0.485$), while tetracycline MICs were lower in the ≥ 1 -month group (1.95 [1.30–2.93] vs 4.16 [2.22–7.82] mg/L; $p=0.048$) [Table3].

Conclusions: In this high-resistance setting, DoxyPEP was not associated with a measurable shift in overall *Neisseria gonorrhoeae* MICs distributions, yet it correlated with enrichment of high-level tetracycline resistance and rare ceftriaxone decreased susceptibility phenotypes. These findings support integrating AMR surveillance into DoxyPEP programmes.

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STI

P 210 NO EVIDENCE OF RISING STI PREVALENCE DURING EARLY PREP FOLLOW-UP IN THE ITALIAN PRIDE COHORT

D. Moschese¹, L. Oreni¹, G. Frate², R. Esvan³, A. De Bona⁴, A.M. Lucchini⁵, S. Lazzarin¹, A.M. Cattelan⁶, V.L. Del Negro⁷, S. Cerere⁸, M. Marra⁹, S. Venturelli¹⁰, M. Menozzi¹¹, R.J. Steiner³, M. Tutone⁵, R. Rossotti¹², S. Nozza¹³, M. Cernuschi¹⁴, V. Mazzotta³

¹Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ²Fondazione ICONA, Milan, Italy, ³National Institute for Infectious Diseases "Lazzaro Spallanzani", Rome, Italy, ⁴ASST Santi Paolo e Carlo, Milan, Italy, ⁵ASL Città di Torino, Turin, Italy, ⁶Padua University Hospital, Padua, Italy, ⁷Roma Check Point, Rome, Italy, ⁸PLUS aps (BLQ Checkpoint), Bologna, Italy, ⁹Circolo di Cultura Omosessuale Mario Mieli, Rome, Italy, ¹⁰ASST "Papa Giovanni XXIII", Bergamo, Italy, ¹¹Clinic of Infectious Diseases, University of Modena and Reggio Emilia, Modena, Italy, ¹²ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy, ¹³Infectious Diseases Unit, Vita-Salute San Raffaele University, Milan, Italy, ¹⁴ASA Milano, Milan, Italy

Background: Bacterial sexually transmitted infections (STIs), particularly Chlamydia trachomatis and Neisseria gonorrhoeae, remain highly prevalent among individuals using HIV pharmacologic prevention strategies. The PrIDE Cohort provides data to evaluate STI burden over time in a large real-world population of PrEP-users engaged in structured follow-up. We assessed prevalence and short-term trends of chlamydia and gonorrhea in this cohort.

Methods: We analyzed data from 1,959 participants enrolled in the PrIDE Cohort. Baseline demographic and behavioral characteristics were collected at enrollment (T0). Participants underwent screening for chlamydia and gonorrhea at baseline and follow-up visits at 3 (T1), 6 (T2), and 9 months (T3). Prevalence was calculated as the proportion of positive tests among those screened at each visit, with 95% confidence intervals (CI).

Results: At baseline, median age was 38 years (IQR 32–46); 98.4% were assigned male sex at birth and 97.1% identified as cisgender. A high proportion reported behavioral risk factors, including ≥6 sexual partners in the prior 3 months (60.8% among those reporting) and 10.7% reporting chemsex. Doxycycline post-exposure prophylaxis use was reported by 9.1% at T0, 6.1% at T1 and 7.9% at T2.

At T0, overall prevalence of chlamydia or gonorrhea was 15.1% (296/1,959; 95% CI 13.6–16.8). Chlamydia prevalence was 8.5% (166/1,959; 95% CI 7.3–9.8) and gonorrhea prevalence was 9.1% (179/1,959; 95% CI 7.9–10.5).

At 3 months (n=699 screened), overall STI prevalence was 13.7% (95% CI 11.3–16.5); chlamydia 7.2% (50/699; 95% CI 5.4–9.3) and gonorrhea 7.7% (54/699; 95% CI 5.9–10.0).

At 6 months (n=328 screened), overall STI prevalence was 15.2% (95% CI 11.5–19.6); chlamydia 7.3% (24/328; 95% CI 4.7–10.7) and gonorrhea 9.8% (32/328; 95% CI 6.8–13.5).

No significant differences in prevalence were observed across follow-up visits compared with baseline [Figure 1].

Conclusions: In this large prospective PrEP cohort, bacterial STI prevalence was high at initiation and remained stable over six months of follow-up, with no evidence of an increasing trend despite regular scheduled screening. These findings suggest that PrEP programs primarily engage individuals already at elevated risk, rather than driving short-term increases in STI burden. The absence of a rising trend under systematic testing does not support a detection-driven escalation of STI prevalence in the early follow-up period.

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STI

P 211 ORTHOPOXVIRUS CLADE 1B MPOX DISEASE WITH CONCURRENT HERPES ZOSTER AND EBV REACTIVATION IN AN IMMUNOCOMPETENT ADULT

B. Allegritti¹, M. Chiuchiarelli², E. Potenza¹, M.E. Varlaro¹, A. Fiore¹, L. Vahedi¹, R. Santangelo³, L. Celani¹, M.B. Lucia^{1,2}, A. Cingolani^{1,2}, G. Scoppettuolo², C. Torti^{1,2}

¹Dipartimento di Sicurezza e Bioetica - Sezione di Malattie Infettive, Università Cattolica del Sacro Cuore, Roma, Italy, ²UOC Malattie Infettive - Dipartimento Scienze Mediche e Chirurgiche, Fondazione Policlinico Universitario A. Gemelli IRCSS, Roma, Italy, ³Dipartimento di Scienze di Laboratorio ed Ematologiche, Fondazione Policlinico Universitario A. Gemelli IRRCS, Roma, Italy

Background: Mpox caused by Orthopoxvirus clade 1 b is rarely reported outside endemic regions of Central Africa. In Italy, only three cases have been documented according to WHO surveillance data as of December 2025. Coinfection with varicella-zoster virus (VZV) has been described mainly in endemic settings and predominantly in children or immunocompromised individuals. We report a rare case of systemic clade 1 mpox with concurrent VZV detection in an immunocompetent adult in Italy.

Case Presentation: A 43-year-old HIV-negative man presented with fever, asthenia, diarrhea, pharyngodynia. Cutaneous examination revealed vesicular pruritic lesions in different stages of evolution (Figure 1) and pustular "target-like" lesions involving face, scalp and palms (Figure 2-4). Clinical examination revealed labial ulcer, tonsillar exudates, bilateral inguinal micropolyadenopathy, and proctitis. Symptoms began approximately 20 days after reported sexual exposure. Molecular assays performed on vesicular fluid, pharyngeal swab, and blood confirmed Orthopoxvirus clade 1b with systemic viremia. Vesicular lesions were concurrently positive for VZV DNA, while serology indicated past immunity. EBV viremia (36 800 copies/mL, whit sierological past immunity) and HPV-16 on rectal swab were also detected. Lymphocyte subpopulation counts were normal. The patient received oral aciclovir and no mpox treatment. Fever lasted 7 days and cutaneous lesions resolved over 3 weeks, with progressive clinical improvement.

Discussion: This case is notable for the detection of Orthopoxvirus clade 1b in Italy, rarely reported outside endemic areas, and for the coinfection with VZV. Clade 1b is associated with more severe clinical manifestations, which may explain the coinfection with VZV and EBV reactivation in an otherwise immunocompetent patient.

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STI

P 212 OTHOSIPHILIS: A CASE OF MONOLATERAL HEARING LOSS WITH COMPLETE RECOVERY

R. Alpo, L. Serroni, F. Mafrica, C. Alcantarini, O. Mollaretti, G. Di Perri

Unit of Infectious Diseases, Department of Medical Sciences, University of Torino, Torino, Italy

Background: Syphilis is a common sexual transmitted infection (STI) caused by *Treponema pallidum* (TP) that provokes a multi-organ disease, most frequently in MSM and PLWHIV. Ootosyphilis is a rare and insidious presentation of that infection. Ootosyphilis often presents with progressive or fluctuating hearing loss and may be accompanied by Menière-like symptoms, including episodic vertigo, tinnitus, and vestibular dysfunction, common with other otologic diseases, making differential diagnosis difficult. According to CDC guidelines treatment reposes on 10-14 days of 18-24 million units/day of intravenous penicillin G (PCG) with or without corticosteroid treatment. At our knowledge, complete hearing recovery was described only in a few clinical cases.

Case presentation: A 23 years old male without comorbidities developed a monolateral sensorineural hearing loss and tinnitus. After an episode of pharyngitis treated with cefixime in March 2025 he developed ear pain and fever treated with cefditoren and steroid. A month later, onset of maculopapular eruption on trunk with spontaneous regression. In July recurrence of skin lesions with a hearing loss confirmed at audiological assessment (figure 1). Cerebral contrast enhancement MRI was normal. The serological testing for common STI all negative except VDRL > 1:32. The cerebrospinal fluid (CSF) analysis showed slightly increased white blood cell count, protein level and the Reiber's diagram suggestive of intrathecal IgG synthesis with oligoclonal bands at immune-isoelectric focusing. CFS VDRL and CFS TP DNA were both negative. The diagnosis of ootosyphilis was made by clinical presentation and the serological status.

Treatment and Outcome: Our patient underwent treatment with 24 million units/day of PCG administered intravenously, together with adjunctive corticosteroid therapy with prednisone 0.5mg/kg/day slowly tapered up to 4 months, in accordance with current guidelines. Moreover, although a two-week treatment course is considered the standard of regimen, we prolonged therapy for an additional week due to persistent tinnitus. After 21 days, the patient showed clinical improvement, and otoscopic examination was normal. CSF analysis at 3 months revealed persistently slightly elevated proteins level, while VDRL and TP DNA remained negative with no more signs of intrathecal synthesis. Serum VDRL was 1:1. Subsequent follow-up audiometric testing (figure 2) demonstrated complete remission, with full recovery of audiometric deficit.

Conclusion: These results seem to suggest that a longer antibiotic therapy in combination with steroid could have a key role not only in reaching microbiological clearance from both bloodstream and CSF, but also in obtaining a complete hearing recovery with a normal audiogram. Therefore, few cases are described in literature and more studies are needed.

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STI

P 213 REGIONAL SURVEILLANCE OF SEXUALLY-TRANSMITTED INFECTIONS-LAZIO, 2015–2025

M. D'Amato, A. Agresta, I. Mussetto, M.C. Fusco, V. Vantaggio, G. Pitti, R. Esvan, G. Micheli, R.J. Steiner, V. Mazzotta, A. Antinori, G. De Carli, F. Vairo

Istituto nazionale per le malattie infettive "L. Spallanzani" – IRCCS, Rome, Italy

Background: Surveillance of sexually transmitted infections (STI) in Lazio is based on official reports recorded in 2 different surveillance system databases: SIMI (Sistema Informativo delle Malattie Infettive) from 2015 to 2019, replaced by PREMAL from January 2020; both require a common core dataset for all diseases. Chlamydia was not mandatorily reported in SIMI. The Regional Service for Epidemiological Surveillance of Infectious Diseases (SERESMI) is responsible for reviewing and validating reported cases.

Material and Methods: Report in the period 2015–2025 were analyzed. Since 2020, SERESMI has conducted an intensive data verification, retrieval, and consolidation effort, involving local health authorities and major STI clinics, and integrating complementary laboratory sources.

Results: In 2015–2019, reported STIs showed a stable trend, with annual notification rates of around 4×10^5 residents. In 2020–2022, a sharp reduction was observed compared to 2019 (4.3×10^5), with annual rates of 3.3 in 2020 and 2022, and 1.9 in 2021 (fig. 1).

Starting in 2023, a significant increase in STIs reports was observed, with a notification rate steadily reaching values around 5×10^5 , higher than those observed in pre-pandemic years, except for the 2016 peak of 5.7.

The gender distribution shows a strong male predominance ($\approx 90\%$). The median age is between 37 and 40, with a higher concentration in the 20–49 age group.

Syphilis consistently represents over 85% of STIs throughout the entire observation period. However, the syphilis notification rate in the post-COVID-19 period 2023–2025 does not differ significantly from pre-COVID-19 levels and, indeed, shows a decreasing trend more pronounced in 2025. Gonorrhea shows a similarly sharp reduction in 2020 and 2021, but differs with a peak of 0.9×10^5 in 2022, well above the values observed in the pre-COVID-19 period ($0.5\text{--}0.6 \times 10^5$), with a reduction in the following two years and a new peak in 2025, 1.2×10^5 , the highest value observed since 2015. Only 25 cases of chlamydia were reported, 21 of which in 2023–2025.

Conclusions: The STI reporting system has not changed during the reporting period. Gonorrhea in Lazio has shown an increasing trend over the last four years, reaching rates well above pre-COVID-19 levels, fully consistent with the European trend in the EU/EEA. Chlamydia remains underreported in Lazio; however, it should be underlined that testing is not free in public health services. The observed decreases are likely due to the restrictions during the pandemic period and healthcare service overload. The increase in STIs since 2023 in parallel with the overcoming of the pandemic and the return to normality of health services is also related to the full reopening of PrEP centers, which diagnose the majority of cases. While reports cannot be considered representative of the actual number of infections, they can identify trends and support implementation and monitoring of preventive interventions.

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STI

P 214 SYPHILITIC UVEITIS: DESCRIPTIVE ANALYSIS OF A CASE SERIES

A. Buzzi, A. Marino, B. Bellocchi, A. Franzò, G. Carnemolla, E. Galati, E. Pistarà, S. Spampinato, B.M. Celesia, B. Cacopardo, G. Nunnari
ARNAS Garibaldi Hospital, Unit of Infectious Diseases, Catania, Italy

Background: Syphilitic uveitis is an increasingly recognized ocular manifestation of syphilis. We describe the clinical features, laboratory findings, treatment, and outcomes of a consecutive case series.

Methods: Retrospective descriptive study of 7 patients with syphilitic uveitis. Demographic, clinical, serological (VDRL, TPHA), inflammatory markers, HIV status, OCT findings, lumbar puncture results, treatment regimens, and outcomes were collected. Continuous variables are reported as mean $\pm$ SD or median (range) or n (%) as appropriate.

Results: Seven patients were included (5 males, 71.4%), with a mean age of 44.7 ± 13.9 years. The median Charlson Comorbidity Index was 1.0 (range 0–6). One patient (14.3%) was HIV-positive (Table 1). The most common comorbidities were cardiovascular, genitourinary, and gastroenterological conditions (each 28.6%) (Table 2).

OCT was performed in all patients and showed lesions in 3 cases (42.9%). Lumbar puncture was performed in 2 patients (28.6%), with negative CSF VDRL results (Table 3). Baseline VDRL titers ranged from 1:8 to 1:128. Mean TPHA was 25.51 ± 5.89 . Inflammatory markers were generally low, and hematological parameters were within normal ranges (Table 4 – Table 5).

Treatment duration ranged from 10 to 14 days; 5 patients (71.4%) received a 14-day regimen. Four patients (57.1%) were treated with intravenous Penicillin G and three (42.9%) with Ceftriaxone. After IV therapy, 3 intramuscular doses of benzylpenicillin were administered to 6 patients (85.7%) (Table 6).

Serological response was documented in 3 patients (42.8%). A favorable clinical outcome was achieved in 6 cases (85.7%), while 1 patient required second-line therapy with doxycycline for 28 days. Follow-up TPHA values (available in 4 patients) showed a decreasing trend compared with baseline (Table 7).

Conclusions: In this small case series, syphilitic uveitis predominantly affected middle-aged males with low comorbidity burden. Most patients responded favorably to standard antibiotic therapy. Larger prospective studies are needed to confirm these findings.

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STI

P 215 THOUSAND FACES DISEASE: SYPHILITIC HEPATITIS IN A PREP USER, A CASE REPORT

F. Siviero^{1,2}, L. Pagnucco^{1,2}, M.A. Muslimani^{1,2}, R. Lissandrin^{1,2}, R. Bruno^{1,2}, R. Gulminetti^{1,2}

¹Fondazione IRCCS Policlinico San Matteo, Division of Infectious Diseases, Department of Medical Science, Pavia, Italy, ²University of Pavia, Department of Clinical-Surgical, Diagnostic, and Pediatric Sciences, Pavia, Italy

Sexually transmitted infections (STIs) remain highly prevalent among men who have sex with men (MSM) receiving HIV pre-exposure prophylaxis (PrEP). Among bacterial STIs, syphilis shows the highest incidence, reaching 9.5 cases per 100 person-years. Luetic hepatitis is a rare manifestation of secondary syphilis, usually characterized by mild, reversible cholestatic liver damage, although severe cases have been reported.

A 35-year-old Italian MSM on on-demand HIV PrEP developed asymptomatic alanine aminotransferase (ALT) elevation during routine biochemical monitoring. His medical history was notable for multiple sclerosis treated with dimethyl fumarate. He denied prior STIs. Upon referral to the Emergency Department, laboratory tests showed severe hypertransaminasemia (AST 1086 U/L, ALT 696 U/L) and cholestatic enzymes elevation. The patient reported recent use of non-steroidal anti-inflammatory drugs and high-dose corticosteroids for enthesopathy. Physical examination was unremarkable except for a non-pruritic papular trunk rash sparing palms and soles. Abdominal computed tomography revealed hepatic hilar adenopathies and a nonspecific thickening of the rectal mucosa doubt for proctitis or heteroplasia. Given his history of at-risk sexual contacts, an extensive infectious work-up was performed.

Viral hepatitis serologies demonstrated protective hepatitis B surface antibodies and no evidence of infection with other major hepatotropic viruses. HIV testing, nucleic acid amplification testing on urine and rectal and pharyngeal swabs were negative as well as autoimmunity. Serology for *Treponema pallidum* was positive, with rapid plasma reagin (RPR) >1:64 and *Treponema pallidum* hemagglutination assay (TPHA) 1:1280. A documented negative syphilis serology two months earlier supported the diagnosis of early secondary syphilis with hepatic involvement. The patient denied previous or current genital lesions, and no oral ulcers were observed. Treatment with a single intramuscular injection of 2.4 million units of benzathine penicillin was administered. Serial monitoring demonstrated progressive improvement, with approximately 50% reduction in liver enzymes levels within seven days (figure 1). The patient underwent a proctological examination with the execution of anal mucosa biopsies which were found to be compatible with granulocytic aggression.

This case highlights the importance of routine biochemical monitoring and regular STI screening in MSM receiving PrEP. Early recognition of syphilis, including atypical presentations such as luetic hepatitis, is crucial to prevent disease progression and transmission. Clinicians should consider *T. pallidum* infection in patients presenting with unexplained liver enzymes abnormalities and high-risk sexual behavior. Prompt antibiotic therapy is highly effective and underscores the need for early diagnosis and management to limit complications and support control of the rising syphilis incidence.

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STI

P 216 UNSHACKLE THE PATIENT FROM IV LINES: SINGLE CENTER EXPERIENCE OF CEFTRIAXONE OUTPATIENT THERAPY FOR NEUROSYPHILIS

M. d'Amato¹, G. Viceconte¹, L. Cattaneo¹, A. Sardanelli¹, S. Mercinelli¹, A.R. Buonomo¹, V. Fotticchia¹, L. De Martino², I. Gentile¹

¹University of Naples "Federico II", Naples, Italy, ²Antonio Cardarelli Hospital, Naples, Italy

Background: Intravenous (IV) aqueous penicillin G is the guideline-recommended first-line therapy for neurosyphilis. However, ceftriaxone is increasingly used in clinical practice as an alternative option, as its once-daily administration may reduce hospital length of stay. Despite its growing use, real-world comparative data on its effectiveness remain limited. We aimed to compare clinical and serological outcomes of IV penicillin G versus ceftriaxone in patients diagnosed with neurosyphilis and related manifestations.

Methods: We conducted a retrospective observational study including all patients diagnosed with neurosyphilis, ocular syphilis and otosyphilis between 2022 and 2025. Diagnosis required at least one positive serum treponemal test (ELISA, FTA-ABS, or TPHA) in patients with either neurological symptoms, plus ≥ 1 cerebrospinal fluid (CSF) abnormality (>5 leukocytes/mm³, CSF protein ≥ 40 mg/dL, reactive CSF VDRL, or positive CSF PCR for *Treponema pallidum*), or isolated auditory symptoms or clinical signs of ocular syphilis (Fig. 1). Treatment consisted of in-hospital IV penicillin G 18–24 MU/day for 10–14 days, or ceftriaxone 2 g/day for 10–14 days as outpatient parenteral antibiotic therapy (OPAT), after a first in-hospital infusion. Clinical response and serological response (≥ 4 -fold decline in non-treponemal titer) were assessed at 6–12 months. CSF normalization was evaluated when follow-up lumbar puncture was performed.

Results: 18 patients were included: 12 received ceftriaxone and 5 penicillin (one with missing allocation in stratified analyses). Non-treponemal tests were positive in 72.2% of cases. Neurosyphilis with neurological manifestations was diagnosed in 33.3%, otosyphilis in 27.8%, and ocular syphilis in 61.1%. Among patients undergoing lumbar puncture, 60.0% had CSF abnormalities (Table 1). Clinical follow-up was available for 15 patients: 80.0% showed clinical improvement and 20.0% remained clinically stable; no worsening occurred. Among patients with serological follow-up ($n=10$), 100.0% had serological response in both treatment groups. Follow-up lumbar puncture was performed in 5 out of 9 patients with initial CSF abnormalities; CSF results were normal in 80.0% and remained abnormal in 20.0%. Retreatment with IV penicillin was required in 11.8% (2/17), both initially treated with ceftriaxone for uveitis, with serological response but persistent ocular abnormalities (Table 2).

Conclusions: In this small real-world cohort, ceftriaxone administered as OPAT showed clinical and serological outcomes broadly comparable to IV penicillin G at medium-term follow-up. Although retreatment occurred only in the ceftriaxone group, the limited sample size and retrospective design preclude definitive conclusions. Ceftriaxone may represent a reasonable alternative in selected settings, particularly when outpatient management is preferred. A larger multicentric Italian study on the topic is currently under ethic committee evaluation.

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STI

P 217 VULNERABILITY FACTORS AND INFECTIOUS DISEASE BURDEN AMONG TRANSGENDER WOMEN LIVING WITH HIV

P. Pasculli¹, M.A. Zingaropoli¹, M. Antonacci¹, F. Dominelli¹, F. Ciccone¹, M. Lichtner², M.R. Ciardi¹, C.M. Mastroianni¹

¹Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ²Department of NESMOS, Sapienza University of Rome, Rome, Italy

Background: Transgender people (those whose gender identity differs from the sex they were assigned at birth) experience poorer health outcomes than cisgender people (those whose gender identity is consistent with the sex they were assigned at birth), and are disproportionately affected by HIV.

This study aimed to describe the sociodemographic, clinical and behavioural characteristics of HIV-positive transgender women (TW) receiving medical care, compared to age/sex-matched healthy transgender woman.

Methods: A retrospective cohort study was conducted in HIV clinics at the Policlinico Umberto I, University of Rome "La Sapienza". Participants underwent blood tests, clinical interviews and infectious disease examinations. Comparative analysis between transgender women (TW) living with HIV and healthy TW was performed using Fisher test.

Results: We enrolled 36 TW living with HIV and 19 healthy TW (median age of 40 [33-46] and 45 [28-46], respectively). All participants were sex workers.

Among TW living with HIV, 50% (18/36) reported concurrent drug use, and 16.7% (6) presented with at least one comorbidity. The mean duration of HIV infection was 11 years. Two patients (5.6%) have stopped highly active antiretroviral therapy (HAART) at the time of evaluation. Regular follow-up attendance was documented in only 16 patients (44.4%).

Infectious disease screening revealed that 8.3% (3) tested positive for active hepatitis C virus (HCV) infection. Chronic hepatitis B virus (HBV) infection was documented in 5.6% (2 patients), while 19.4% (7 patients) showed serological evidence of past HBV exposure.

Regarding sexually transmitted infections (STIs), 30.6% (11 patients) tested positive for syphilis, whereas gonorrhea and Chlamydia trachomatis infection were each detected in 2.8% (1 patient).

Among healthy TW, only one participant presented with a comorbidity. Two individuals had a history of treated HCV infection, and one had chronic HBV infection. Assessment of STIs revealed a history of syphilis in 42% (8/19), chlamydia in 10.5%, and gonorrhea in 5.3%. Six TW (31.6%) started pre-exposure prophylaxis (PrEP).

No statistically significant differences were observed between groups for any of the evaluated variables (all $p > 0.05$).

Conclusions: These findings highlight a population characterized by multiple vulnerability factors, including substance use, comorbid conditions, and suboptimal adherence to both treatment and follow-up care. Although no significant differences emerged between groups, likely due to limited sample size, the findings underscore the need for integrated, multidisciplinary care and strengthened prevention strategies in this population.

STI

P 218 WHO GETS VACCINATED FOR MONKEYPOX? BEHAVIORAL PREDICTORS OF UPTAKE AMONG MSM ATTENDING AN HIV/STI REFERENCE CENTER

E. Giuliani, M. Zaccarelli, M.G. Donà, L. Gianserra, C. Stingone, F. Di Tullio, M. Giuliani, A. Latini

STI/HIV Unit, San Gallicano Dermatological Institute, Rome, Italy

Background: Following the 2022 outbreak, vaccination against monkeypox (mpox) became available in many European countries using a third-generation non-replicating smallpox vaccine (MVA-BN). It is primarily recommended for individuals at higher risk of exposure, including men who have sex with men (MSM), especially those reporting multiple partners, group sex, chemsex, or recent sexually transmitted infections (STIs).

Material and Methods: Our reference center regularly assesses knowledge and behavior of MSM attending the service through targeted surveys. A cross-sectional survey about mpox vaccination was conducted between 2024-2025. The questionnaire was self-administered online and included demographic data, sexual behaviors, STI history and drug use for sex. Univariable and multivariable logistic regression models were performed to identify factors associated with mpox vaccination.

Results: A total of 331 MSM completed the questionnaire; 85 (25.7%) reported having received mpox vaccination, 17 had already been vaccinated against smallpox. Four participants had acquired mpox infection.

In univariable analyses, mpox vaccination was associated with history of STI, higher number of sexual partners, group sex, use of dating apps, use of PrEP and multiple indicators of sexualized drug use, including chemsex.

In multivariable analysis, mpox vaccination remained independently associated with use of erectile dysfunction agents (aOR 2.27, 95% CI: 1.20-4.30, $p=0.012$), use of PrEP (3.57, 1.69-7.54, $p<0.001$) and Chemsex (aOR 3.54, 1.32-9.49, $p=0.012$), while reporting female partners in the previous year was negatively associated with vaccination (0.24, 95% CI: 0.07-0.88, $p=0.027$).

Conclusions: In this MSM sample, mpox vaccination uptake was still limited to about one quarter of attendees but was concentrated among individuals with higher-risk sexual practices, such as chemsex. PrEP engagement emerged as a key driver of mpox vaccination, reinforcing the role of integrated combination-prevention pathways in HIV/STI services.

Vaccines and Prophylaxis

P 219 ADVOCATING VACCINES AND VACCINATIONS AS AN EFFECTIVE STRATEGY IN TACKLING ANTIMICROBIAL RESISTANCE IN ITALY

F. Salvati¹, V. Baldo², P. Castiglia³, M. Falcone^{4,5}, G. Gabutti⁶, A. Lombardi⁷, G. Marchetti¹

¹Clinic of Infectious and Tropical Diseases, Department of Health Sciences, University of Milan, ASST Santi Paolo e Carlo, Milan, Italy, ²Department of Cardiac, Thoracic, Vascular Sciences, and Public Health, University of Padua, Padua, Italy, ³Department of Medicine, Surgery and Pharmacy, University of Sassari, Italian Scientific Society of Hygiene, Preventive Medicine and Public Health (SItI), Sassari, Italy, ⁴Infectious Diseases Unit, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy, ⁵Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy, ⁶Italian Scientific Society of Hygiene, Preventive Medicine and Public Health (SItI), Cogorno (Ge), Adult Immunization Board (AIB), Cogorno, Italy, ⁷Infectious Diseases Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy

Background: Antimicrobial resistance (AMR), mainly bacterial resistance to antibiotics, is defined as the new silent pandemic worldwide. One Health strategies were designed to contain AMR but effective implementation and measurable impact are hard to reach. Since years the World Health Organization (WHO) has been actively supporting vaccines and vaccinations as a tool to tackle AMR further to the established measures such as antibiotic stewardship, enhancing hand hygiene, early etiological diagnosis, improved surveillance. WHO released an Action Framework (AF) to guide vaccine stakeholders to maximize the impact of vaccines/vaccinations in preventing AMR. The AF defined 3 main goals: 1) Expand Use of Licensed Vaccines to Maximize Impact on AMR; 2) Develop New Vaccines That Contribute to Prevention and Control of AMR 3) Expand and Share Knowledge of Vaccine Impact on AMR; across these Goals, 7 Objectives were identified to drive activities. The objective of the present work was to scan how the WHO Goals and Objectives were received in the Italian context.

Materials and Methods: A literature search was conducted in the PubMed database using the following keywords: vaccinations, antimicrobial resistance, reduction in antibiotic use. The search was restricted to the period 2015-2025 to focus on the most up-to-date publications. A search for grey literature was carried out on the web.

Results: The WHO Goals and Objectives were received in Italy across different settings. In the National Plan to counteract AMR (PN-CAR), prevention of infectious diseases is part of the national strategy, and the role of vaccines is well specified in the chapter on Prevention and Control of Infections among humans (PN-CAR objective 6) where vaccinations coverage is to be supported according to the National Immunization Plan (PNPV). In the PNPV a brand new chapter on the relevance of AMR and the role of vaccinations in tackling the problem was introduced. A Position Paper on AMR management endorsed by 18 Italian Scientific Societies (including SIMIT and SItI) defined 3 strategic pillars, being the prevention of infectious diseases by means of vaccination one of those. Very few papers authored by different Italian researchers dealing with the role of vaccines in counteracting AMR could be retrieved. To inform the lay public, different institutional web pages by the Ministry of Health, the National Drug Agency (AIFA) and the National Institute of Health (ISS) on the problem of AMR including the role of vaccinations are publicly available.

Conclusions: Most of the WHO Goals and Objectives to maximize the impact of vaccines in tackling AMR were in principle received in Italy but more concrete activities are expected. Advocacy and focused communication by Institutions, Scientific Societies, researchers and healthcare providers is needed to raise awareness and drive the actions necessary to enhance prevention of infections by vaccination and reduce the threat of AMR in Italy.

Vaccines and Prophylaxis

P 220 BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE AS POST-EXPOSURE PROPHYLAXIS: ADHERENCE, EFFECTIVENESS, AND SAFETY IN A REAL-WORLD SETTING

F. Passini¹, N. Capra², R. Lolatto², A.R. Raccagni¹, T. Clemente², E. Bruzzesi², A. Danise², G. Catalano¹, D. Beretta¹, P. Rienzo³, F. Furlan³, A. Castagna^{1,2}, S. Nozza^{1,2}

¹Infectious Diseases Unit, Vita-Salute San Raffaele University, Milan, Italy, ²Infectious Diseases Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy, ³ER Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy

Background: Post-Exposure Prophylaxis (PEP) remains a cornerstone of HIV prevention strategies. Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF), administered as a once-daily single-tablet regimen, has the potential to improve tolerability and adherence compared with multi-pill approaches, yet real-world evidence is still limited. The objective of this study was to assess adherence, safety, and virological outcomes of B/F/TAF when prescribed as PEP in routine clinical practice.

Material and Methods: We conducted an observational monocentric cohort study with retrospective analysis of prospectively collected routine clinical data from individuals who initiated a 28-day course of B/F/TAF following sexual exposure at the STI Clinic, IRCCS San Raffaele, Milan, from the release of EACS guidelines 10.0 (November 2019) to January 2025. Clinical and demographic characteristics, treatment completion, follow-up at weeks 4 and 12, HIV serology, adverse events, laboratory parameters (AST, ALT and creatinine), and treatment modifications were systematically collected. Individual characteristics were described using median (interquartile range) or frequency (percentage).

Results: A total of 199 individuals were included (median age 35.4 years [IQR 30.1–41.0]; 95.9% male, 4.0% female, 0.5% transgender). Retention was high, with 80.9% attending the week-4 evaluation and reporting completion of the full 28-day course, and 62.3% maintaining follow-up at week 12. Among the 178 participants with at least one post-PEP HIV test, no seroconversions were documented, confirming the virological effectiveness of the regimen.

Adverse events were reported by 5.0% of participants, most frequently diarrhoea (2.0%), nausea (1.5%), headache (1.5%), abdominal discomfort (1.0%), and rash (0.5%). The vast majority (95.0%) experienced no side effects, and only 1.5% required a treatment switch due to intolerance. Laboratory monitoring confirmed the favorable safety profile: ALT (28 [21–36] at baseline vs. 27 [20–38] at week 4, $p=0.319$), AST (27 [22–31] vs. 25.5 [22–32], $p=0.854$), and creatinine levels (1.01 [0.93–1.12] vs. 1.05 [0.94–1.15], $p=0.126$) remained stable (Table 1).

Conclusions: In this real-world cohort, B/F/TAF demonstrated excellent adherence, an optimal safety profile, and complete virological protection, with no HIV seroconversions observed. The low incidence of adverse events, the stability of liver enzymes and renal function, and the extremely low rate of treatment discontinuation support the safety of the regimen. The simplicity of a once-daily single-tablet strategy likely contributed to the high completion rates observed and represents a significant advantage in optimizing PEP outcomes.

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Vaccines and Prophylaxis

P 221 FROM EXPOSURE TO PREVENTION: APPROPRIATENESS AND ADHERENCE TO HIV POST-EXPOSURE PROPHYLAXIS IN A REAL-WORLD SETTING

M. Inverardi¹, I. Izzo², S. Calza³, S. Bertolotti¹, I. Baggi¹, I. Polesini², D. Bonetta², F. Gaffurini², F. Castelli¹, E. Quiros Roldan¹, E. Focà¹

¹Department of Clinical and Experimental Sciences, Unit of Infectious Diseases, University of Brescia, Italy, ²ASST Spedali Civili Hospital, Brescia, Italy, ³Unit of Biostatistics and Bioinformatics, Department of Molecular and Translational Medicine, University of Brescia, Brescia, Italy

Background: Post-exposure prophylaxis (PEP) for HIV prevention has been proven to be highly effective at reducing the risk of transmission after sexual or percutaneous exposure. Nevertheless, as outlined in the 2024 WHO Guidelines for PEP, data shows that access and intake of PEP is not optimal. It is, therefore, vital to analyse risk exposure management, drug prophylaxis and protocol adherence. This study aims to assess the appropriateness of and adherence to PEP protocols in individuals who experienced occupational, accidental or sexual exposure between 2018 and 2024.

Methods: In this single-centre observational retrospective study we collected data on percutaneous or sexual exposures from the post-exposure surveillance programme of the Infectious Disease Unit between January 2018 and December 2024.

Results: The study was conducted on 1,774 subjects organized in 3 groups based on type of exposure and setting: Healthcare workers from Preventive Medicine (PM) (785, 44,25%), other Occupational/Accidental (Occ/acc) (706, 39,80%) and Sexual (283, 15,95%). The time taken to arrive at the hospital is crucial for the effectiveness of PEP. Most subjects went to the emergency room within 48 hours of exposure. However, more late presentations were recorded in the Sex group, 3,72 times higher than the reference group ($p < 0,001$). Percutaneous exposures were mostly caused by hollow needles (37,83%), sharp instruments (29,64%) and mucosal contamination (22,60%). Sexual exposures mainly involved subjects who were exposed to receptive (117, 41,34%) or insertive (113, 39,93%) intercourse. The serostatus of source subjects showed 846 (47,69%) were seronegative and 643 (36,25%) had unknown status, especially in the Sexual group, due to limited traceability. Of the positive results, HCV was most prevalent (139, 7,84%), followed by HIV (61, 3,44%). The appropriateness of PEP prescription increased over time: from 96,0% in 2022 to 99,2% in 2024 for Occ/acc and from 74,5% in 2022 to 96,8% in 2024 for PM. In the sex group, PEP prescriptions showed lower levels of appropriateness, going from 90,0% in 2022 to 87,9% in 2024. In terms of adherence to PEP and the surveillance programme, subjects in the percutaneous groups exhibited higher rates over time, reaching 100% for PM in both categories, and 92,8% in PEP completion and 90,6% in surveillance adherence for Occ/acc in 2024. In the sex group, more variability and lower values were observed, with no clear trend and a mean adherence rate of 50,2% to PEP completion and 52,2% to surveillance. None of the subjects undergoing PEP were found to have contracted HIV by the end of the surveillance period.

Conclusions: The findings of this study emphasise the need to improve the appropriateness of PEP prescriptions in cases of sexual exposure, as well as addressing issues of timely access and adherence. Therefore, effective surveillance programmes must be ensured through adequate counselling and adherence to international guidelines.

Vaccines and Prophylaxis

P 222 HPV AND YOUTH: RESULTS FROM THE VALIDATED “HPV SURVEY FOR YOUNG PEOPLE” QUESTIONNAIRE (HPVSYP)

C. Minet¹, E. Furia¹, D. Panatto¹, M. Martini¹, R. Rosselli², G. Icardi¹, A. Orsi¹

¹Department of Health Sciences, University of Genoa, Genoa, Italy, ²Liguria Health Protection Agency, ATS - ASL 3 Genoa, Genoa, Italy

Background: Human Papillomavirus (HPV) vaccination coverage rates among young people in Italy remain below the 95% target established by the PNPV 2023-25. The HPVSYP questionnaire, developed and validated by the Department of Health Sciences, was designed to investigate the specific level of HPV knowledge among youth (aged 14–29) in Genoa. The goal of this research is to identify information gaps and develop targeted strategies to encourage higher adherence to national vaccination programs.

Materials and Methods: The administration of the questionnaire was integrated into structured educational projects aimed at promoting the importance of vaccination. These activities took place within one secondary school and at the University of Genoa. University students were also invited to participate via institutional mailing lists. Data analysis was conducted using Microsoft Excel software. For the evaluation of each item, the total number of respondents (R) was recorded and analyzed to account for partial survey completion, ensuring the statistical integrity of the results.

Results: A total of 604 individuals participated in the survey; however, 29.47% of the participants did not complete the entire questionnaire. Regarding biological sex, the distribution was 28.52% male, 71.14% female, and 0.34% intersex (R: 589). The mean age of the sample was 23.02±3.33 years (R: 574).

Data analysis revealed that the primary sources of HPV information are academic institutions (53.64%), followed by relatives (52.63%) and the internet (39.27%) (R: 494). The 14.34% of respondents did not know the primary mode of infection transmission (R: 495), 11.97% were unaware of the vaccine's existence, and 2.14% explicitly believed that no such vaccine existed (R: 468). Regarding vaccination coverage, 18.84% reported not being vaccinated, while 13.28% did not recall their status (R: 467). Furthermore, 23.01% of respondents were unaware of the Pap test (R: 465), and 72.51% were not familiar with the HPV-DNA test (R: 462).

Regarding attitudes and risk perception, 59.54% of respondents did not consider themselves at risk of infection, while 31.49% were unsure of their risk level (R: 435). Despite these gaps, 89.02% believe vaccines are safe (R: 437) and 89.68% support their efficacy (R: 436). Finally, a vast majority (94.37%) emphasized the high utility of organizing formal sexual education events in schools (R: 426).

Conclusion: Despite strong confidence in vaccine safety and efficacy, important gaps persist in knowledge about HPV transmission and secondary prevention, along with a low perceived personal risk of infection. Strengthening structured, expert-led educational interventions, particularly in schools and universities, is urgently needed to improve awareness and vaccination coverage, in line with young people's expressed demand for comprehensive sexual education.

Vaccines and Prophylaxis

P 223 HPV VACCINATION AMONG MSM: COVERAGE AND DETERMINANTS OF HESITANCY IN PREP USERS VERSUS PEOPLE LIVING WITH HIV

M. Polisenò, A.I. Ritacco, E. Milano, L. De Santis, A. Cianciaruso, N. Colavito, F. Di Gennaro, A. Saracino

Clinic of Infectious Diseases, Department of Regenerative and Precision Medicine and Jonian Area (DiMePre-J), University of Bari, Bari, Italy

Background: Human papillomavirus (HPV) vaccination is strongly recommended for Men who have Sex with Men (MSM), including those living with HIV and those using HIV pre-exposure prophylaxis (PrEP). However, coverage remains suboptimal. Understanding differences in vaccination uptake and factors associated with hesitancy is crucial to inform targeted prevention strategies.

Methods: HPV vaccination status of all MSM attending our PrEP Clinic was assessed using the regional electronic health records system. Data on other recommended vaccinations (hepatitis B [HepB], recombinant zoster [RZV], meningococcal ACWY [MenACWY], pneumococcal conjugate [PCV], mpox modified vaccinia Ankara–Bavarian Nordic [MVA-BN], quadrivalent influenza [IIV4], mRNA COVID-19) were also collected. The same data were retrieved in an age- and sexual orientation-matched group of people living with HIV (PWH) (1:2 ratio). Vaccination prevalences were compared by HIV status and HPV vaccination status using the Chi-Square test. A Cox regression model was applied to identify sociodemographic factors (HIV status, older age, lower education, unemployment, distance from the Infectious Diseases [ID] Clinic, no vaccination in the last three years) associated with higher Odds Ratio (O.R.) of not being vaccinated for HPV with 95% Confidence Interval (C.I.).

Results: One-hundred and eighty-two MSM were enrolled. Their general features are reported in Table 1. The overall prevalence of HPV vaccination was 44% and was remarkably higher among PrEP users than in PWH (76% vs 30% $p < 0.001$). Vaccination, in all 81 cases performed with 9-valent recombinant HPV vaccine, had been received free of charge and in the same HIV/PrEP Clinic by the 63% of participants and had been suggested in almost all cases by the ID Specialist (74/81 subjects, 97%). While high prevalence of HepB was observed (73%), the overall rates of adherence to other non mandatory vaccinations were overall low, with lower rates reported for RZV (12%), MenACWY (10%) and COVID-19 (5%). Significantly higher prevalence of adherence to these vaccinations was reported among PrEP users compared to PWH and in subjects vaccinated vs non vaccinated against HPV, as reported respectively in Tables 2 and 3. Seventy-three subjects (43%) affirmed to have not received any vaccination in the last three years. At multivariate analysis, having received other vaccinations in the last three years resulted strongly protective against HPV vaccination hesitancy (O.R. 0.01, 95% C.I. 0.00-0.05, $p < 0.001$).

Conclusions: HPV vaccination coverage remains suboptimal among MSM, especially PWH, while PrEP users show higher uptake. Engagement with other vaccination programs strongly predicts HPV vaccination acceptance. Implementing dedicated vaccination pathways—preferably within the same clinic used for PrEP or HIV care—and optimizing counseling among PWH seem vital to improve vaccines uptake.

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Vaccines and Prophylaxis

P 224 IMMUNOGENICITY OF ANTI-RSV VACCINE 2 MONTHS AND 1 YEAR AFTER THE ADMINISTRATION IN CHRONIC KIDNEY DISEASE PATIENTS

M. Tarkowski¹, R. Gingis², S. Hussain¹, G. Lipari³, A. Gabrieli¹, V. Fatizzo³, M.A. Gallieni¹, A. Riva¹

¹Università degli Studi di Milano - Milan, Italy, ²San Carlo Hospital - Milan, Italy, ³ASST-FBF-Sacco Hospital - Milan, Italy

Background: Infection with Respiratory Syncytial Virus (RSV) constitutes significant risk of complications in fragile groups of people, including those with advanced kidney disease. Recently developed vaccines against RSV were recommended for adults over 50 years of age to prevent severe disease. Patients with kidney disease frequently exhibit impaired vaccine responses. We assessed immunogenicity of a single dose anti-RSV vaccine in nephrology patients by evaluation of anti-RSV immunoglobulin levels.

Methods: We conducted a study in 85 patients attending 2 Milan nephrology clinics. Serum was collected at baseline (T0), 2 months, and 1 year after a single Arexvy dose (T1). Anti-RSV IgG directed against the pre-fusion F antigen was quantified using indirect ELISA. Participants were categorised as non-responders, moderate responders, or high responders. Subgroup analyses compared haemodialysis (HD), peritoneal dialysis (PD), and kidney-transplant recipients (KTR).

Results: Two months after the vaccination, anti-RSV IgG titers significantly increased. The response-rates showed that 76,5% of subjects have responded with >4-fold-increase and 54,1% with >8-fold increase of anti-RSV IgG. Three patients were no-responders. Patients receiving HD on average showed most significant rise in IgG anti-RSV titers in comparison to PD patients or KTR. On average, all subgroups showed significant response to the vaccination in terms of the production of RSV specific IgG. The fold change of anti-RSV IgG titers after the vaccination most significantly increased ($p<0,001$) in patients who were free from the steroid therapy, although also those who received it augmented them significantly ($p<0,05$). One year after the vaccination mean levels of the IgG against RSV fell down to the levels before the vaccination. There were no significant associations found between demographic or clinical parameters and the changes in the levels of anti-RSV IgG titers.

Conclusions: A single Arexvy dose elicited significant increases in anti-RSV IgG titers, aligning with immunogenicity and efficacy signals from pivotal trials in older adults. These findings are notable given CKD-associated immune dysfunction and concerns for attenuated responses under immunosuppression. Our study supports RSV vaccination of eligible nephrology patients to prevent severe disease and health complications. One year post vaccination assessments however, show that the protection obtained from 1 dose at short time period might be insufficient in long term period. In future work, analyses of cell-mediated immunity will complement the current study and give better insight into the durability and the vaccine induced protection from RSV infection.

Vaccines and Prophylaxis

P 225 IMPORTED INFECTIOUS DISEASES AND LOW PRE-TRAVEL AWARENESS: OBSERVATIONAL DATA FROM A DIRECT-ACCESS POST-TRAVEL CLINIC

C. Palazzolo¹, S. Vita², A. Cavaio¹, A. D'Abramo¹, L. Scorzolini¹, A. Curtolo¹, N. Bevilacqua¹, F. Faraglia¹, E. Nicastri¹

¹National Institute for Infectious Diseases Lazzaro Spallanzani IRCSS Rome, Italy, ²Department of Neuroscience, Mental Health, and Sense Organs, NESMOS, Sapienza University of Rome, Rome, Italy

Background: Global travel and migration continue to expose individuals to tropical infectious diseases, yet pre-travel health awareness remains critically low. Despite clear guidelines and available vaccines, travelers frequently neglect preventive measures, putting themselves and public health at risk. Direct-access post-travel clinics are essential for early detection and management of imported infections.

Methods: We conducted a retrospective observational study at the direct-access outpatient clinic (ADMT) of the Istituto Nazionale per le Malattie Infettive Lazzaro Spallanzani from August 2024 to August 2025. Consecutive patients presenting with acute febrile or suspected infectious syndromes after international travel were included. Data collected included demographics, travel destination (classified by WHO region), clinical presentation, malaria chemoprophylaxis, vaccination status, and diagnostic results. Final diagnosis was defined hierarchically using microbiologically confirmed diagnoses when available; otherwise, patients were classified according to their clinical syndrome. Arboviral infections included dengue, chikungunya and Zika virus infections, and gastrointestinal infections were grouped irrespective of etiology. Descriptive statistics were used to summarize demographic, clinical and microbiological data.

Results: Baseline demographic, travel-related and preventive characteristics of the total study population (N = 189) are summarized in Tab. 1. Most returned from the WHO African Region (52.1%) or South-East Asia (25.3%). A microbiologically confirmed diagnosis was established in a subset of patients. Malaria was the most frequently identified infection (9.5%), followed by COVID-19 and influenza (9% each), and by arboviral infections (7.9%). Only 24% of patients had received a pre-travel consultation. Malaria chemoprophylaxis uptake was low overall (10.1%) and reached only 18.2% among travelers returning from the WHO African Region, despite travel to malaria-endemic areas.

The distribution of final diagnoses showed a clear geographic pattern. Arboviral infections were most frequent among travelers returning from South-East Asia and the Americas, while malaria occurred exclusively among individuals returning from the African region. Acute undifferentiated febrile illness remained the predominant clinical presentation across all regions (Tab. 2).

Conclusions: Imported infections showed clear geographic patterns aligned with travel destinations, yet preventive uptake remained very low. Arboviral infections predominated in travelers returning from tropical regions, while malaria occurred exclusively after travel to Africa, despite limited use of chemoprophylaxis. These findings highlight a major missed opportunity for prevention and support the need to strengthen pre-travel counseling and direct-access post-travel care pathways.

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Vaccines and Prophylaxis

P 226 MANAGING BIOLOGICAL RISK INCIDENTS IN FERRARA: A 6-YEAR ANALYSIS OF PEP, CLINICAL PROTOCOLS AND TRAINING NEEDS

D. Segala^{1,2}, L. Belfi¹, P. Mori², C. Sartori², R. Cultrera^{1,3}

¹University of Ferrara, Ferrara, Italy, ²Azienda Ospedaliero Universitaria di Ferrara, Ferrara, Italy, ³Azienda Unità Sanitaria Locale di Ferrara, Ferrara, Italy

Background: HIV is now a manageable condition yet remains a global emergency. With 1.3M new cases in 2024, intensifying prevention is crucial. Post-Exposure Prophylaxis (PEP) is a key tool requiring enhanced local protocols and awareness.

Methods: A retrospective, monocentric, observational study was conducted at the HIV/AIDS Section in Ferrara. The study evaluated the prevalence of biological risk incidents in Ferrara requiring clinical assessment at the Center, analyzing temporal trends and the impact of SARS-CoV-2. It further assessed protocol adherence and knowledge among subjects and students of Medical and Nursing students at the University of Ferrara to identify gaps and improve local management and training. The study included patients aged >18 presenting at the Center after biological risk incidents (Jan 2019–Dec 2024); minors and cases with incomplete data were excluded. Retrospective analysis of clinical records covered: demographics (age, sex, nationality, HBV status), exposure characteristics (type/mode), and management (T0 serology, protocol adherence, PEP, and T1/T2 follow-up). Statistical analysis was performed using IBM SPSS Statistics v.30 and G*Power v.3.1.9.4.

Results: A total of 358 subjects were enrolled. Data showed a 2019 peak, 2020–21 pandemic-related decline, and a subsequent recovery. Occupational exposures predominated (77.93%), primarily involving the 25–39 age group and nurses; accidental subcutaneous needlesticks were the main exposure mode. Non-occupational exposures, mostly unprotected sexual intercourse, were high-risk in 60.76% of cases and showed an increasing trend. No seroconversions for HIV, HBV, HCV, or syphilis occurred with HBV vaccination coverage improving. However, the PEP completion rate was low (45.76%). Protocol adherence was significantly higher in non-occupational (77.21%) vs occupational (48.39%) cases. Screening enabled early diagnosis of two syphilis and one HBV case. The survey of 230 Medical and Nursing students revealed significant knowledge gaps and confusion between PEP and PrEP, highlighting the need for enhanced academic training modules. Comparative analysis identified variables with statistically significant distribution (98% power) in both occupational and non-occupational groups: sex at birth, risk level (high vs low), exposure mode, post-exposure management (PEP not indicated/initiated/declined) and the professional figures responsible for follow-up (Tables 1-2).

Conclusions: While confirming PEP effectiveness, this study highlights critical gaps in clinical application, follow-up and incident reporting. Structured training for healthcare professionals and the public is necessary, alongside awareness campaigns to improve protocol adherence, exposure management and reduce discrimination, including in university settings. This study provides a robust foundation for local future integrated preventive strategies, enhanced counseling services and continuous monitoring of safety protocols.

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Vaccines and Prophylaxis

P 227 ON-SITE VACCINATION IN AN HIV OUTPATIENT CLINIC: UPTAKE AND OUTCOMES OF AN INTEGRATED WEEKLY SERVICE

G. Orofino¹, A. Montalbano², M. Guastavigna¹, M. Barbaro¹, G. Milone¹, A. Ndabagiriye¹, V. Ranotti³, G. Calleri¹

¹Tropical and Infectious Diseases Division A, Amedeo di Savoia Hospital, Turin, Italy, ²Medical Science Department, University of Turin, Turin, Italy, ³Hospital Pharmacy, Amedeo di Savoia Hospital, Turin, Italy

Background: People living with HIV (PLWH) face an increased risk of vaccine-preventable infections, making adherence to vaccination programmes a clinical priority. In our HIV outpatient clinic, overall vaccine coverage currently stands at 93% — a high rate, yet one that leaves a non-negligible proportion of patients unprotected, particularly given the strong guideline recommendations for vaccination and the elevated infection risk in this population. Previous work conducted at our centre identified convenience as the most actionable driver of vaccine hesitancy in this population: when access is easy and integrated into existing care routines, uptake improves. On this basis, we introduced a dedicated weekly on-site vaccination service, embedded within the routine clinical care pathway, with the aim of further reducing barriers and improving coverage.

Methods: A retrospective observational study was conducted through analysis of our vaccination registries. All patients who received at least one vaccine dose between April 2025 and February 2026 were included. Data collected for each patient comprised vaccine type and number of doses administered. Data were extracted electronically and analysed using IBM SPSS Statistics; descriptive analyses were performed reporting absolute frequencies and percentages of total administrations.

Results: Over an 11-month period, 277 patients received a total of 544 vaccine administrations. The most frequently administered vaccines were Engerix B (19.5%), Gardasil 9 (17.8%) and Shingrix (14.7%), followed by Pneumovax (9.0%), Avaxim (8.8%), Hiberix (8.1%), Nimenrix (7.2%), Bexsero (6.4%), Vaxigrip (3.9%), Prevenar 20 (3.3%) and Boostrix/Triaxis (1.3%) (Picture 1).

Conclusions: Integrating an on-site vaccination service within the HIV outpatient clinic — delivered through a dedicated weekly session — enabled a substantial number of administrations over 11 months, across a broad range of recommended vaccines. This organisational model appears to effectively improve vaccination uptake in PLWH by reducing logistical barriers and embedding preventive care within the specialist care pathway. The diversity of vaccines administered reflects the complexity of immunisation needs in this population and supports the feasibility of a comprehensive, clinic-based vaccination programme.

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Vaccines and Prophylaxis

P 228 PERSISTENT FAILURE OF HBV-SPECIFIC CELL-MEDIATED IMMUNITY AND T-CELL DIFFERENTIATION SKEWING IN YOUNG PLWH DESPITE LONG-TERM ART-INDUCED VIRAL SUPPRESSION

M. Stracuzzi¹, C. Vanetti³, F. Musto¹, F. Marinacci¹, C. Coppola¹, L. De Luca², A. Fratta⁴, M. Graziano³, D. Trabattoni³, V. Giacometti¹

¹Pediatric Infectious Diseases, Luigi Sacco Hospital, ASST FBF SACCO, Milan, Italy, ²Dipartimento di Scienze Biomediche e Cliniche "Luigi Sacco", Università degli Studi di Milano, Italy, ³Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy, ⁴Università degli Studi di Milano-Bicocca, Milan, Italy

Background: Hepatitis B virus (HBV) vaccination is a standard of care for children and adolescents living with HIV (PLWH). Despite antiretroviral therapy (ART) achieving sustained viral suppression and successful immune reconstitution, a significant proportion of this population fails to maintain protective immunity. This study aims to characterize the immune landscape of long-term non-responders to identify potential mechanisms of persistent immunological vulnerability.

Methods: We evaluated 19 young PLWH (vertically acquired, aged 15–40 years) who were classified as non-responders due to a persistently null anti-HBs antibody title (<10 mIU/mL) after the primary vaccination cycle. This cycle had been administered between 10 and 30 years prior to enrollment. All participants were on stable ART with excellent immunovirological control (HIV-RNA <20 copies/mL, preserved CD4+ T-cell counts) and no history of AIDS-defining events. Peripheral blood mononuclear cells (PBMCs) were stimulated in vitro with recombinant HBV protein. HBV-specific immune responses were characterized using multiparametric flow cytometry. Statistical correlations were assessed using Spearman's rank test.

Results: Despite more than a decade since their primary vaccination, HBV-specific T-cell memory—including effector memory (EM) and central memory (CM) CD4+ and CD8+ T-lymphocytes—was undetectable in all subjects. Furthermore, no HBV-specific CD8+ T-cell activation (assessed by Granzyme, Perforin, and CD107a expression) or expansion of switched memory B-cells/plasmablasts was observed. A significant positive correlation was identified between EM CD4+ and terminally differentiated effector memory (TEMRA) CD4+ T-cells ($r = 0.7$, $p < 0.05$).

Conclusions: The total absence of HBV-specific cellular and humoral memory decades after vaccination, even in the context of optimal HIV control, points to a profound failure in immune persistence. The correlation between EM and TEMRA CD4+ cells suggests a pathological skewing toward advanced differentiation and senescence. This process likely exhausts the pool of functional helper T-lymphocytes, preventing the maintenance of vaccine-induced protection. These findings highlight that virological success does not equate to immunological competence for neo-antigens, underscoring the need for adjuvanted vaccines or specialized booster schedules for the aging PLWH population.

Vaccines and Prophylaxis

P 229 ZERO RISK OF HIV TRANSMISSION AFTER PERCUTANEOUS EXPOSURE TO SOURCES LIVING WITH HIV WITH UNDETECTABLE VIRAL LOAD

S. Rapino, S. Arsuffi, I. Izzo, S. Bertoletti, I. Baggi, I. Polesini, F. Gaffurini, G. Tiecco, F. Castelli, E. Quiros-Roldan, E. Focà

Clinica di Malattie Infettive e Tropicali, Università degli Studi di Brescia e ASST Spedali Civili di Brescia, Italy

Background: Antiretroviral therapy in people living with HIV (PLWH) is highly effective in preventing sexual transmission of the virus (Undetectable = Untransmittable). However, evidence on risk of HIV transmission after a percutaneous exposure is limited.

This study aims to assess the risk of HIV transmission following percutaneous exposure to body fluids from PLWH with an undetectable viral load.

Methods: A retrospective single-center study was conducted and data on occupational or accidental percutaneous exposures were collected from January 1, 2018, to December 31, 2024. Only occupational or accidental exposures to body fluids from PLWH with an undetectable viral load were included in the analysis. Undetectable viremia was defined as an HIV-RNA level <200 copies/mL on a recent viral load measurement available. If no recent viral load result was available, post-exposure prophylaxis was initiated while awaiting the source's immediate viral load test. Exposed individuals were monitored with HIV serology at baseline, at 4–6 weeks, and at 12 weeks.

Results: Out of 1,491 percutaneous exposures, the source's serostatus was known in only 1,114 cases, and among these, the source was a person living with HIV (PLWH) in 91 cases.

The study population included 68 subjects: 19 (27.94%) medical doctors, 21 (30.89%) nurses, 26 (38.23%) other healthcare workers, and 2 (2.94%) were unspecified accidental exposures. Among the recorded exposures, 24 individuals (35.29%) sustained percutaneous exposure to hollow-bore needles, 15 (22.06%) to sharp instruments or suture needles, 2 (2.94%) to unspecified or discarded needles; 26 (38.24%) had mucosal exposure to biological fluids and 1 individual (1.47%) experienced an unspecified percutaneous exposure.

Regarding pharmacological management, post-exposure prophylaxis (PEP) was not prescribed in 46 cases (67.65%), while in 22 cases (32.35%) PEP was initiated due to the unavailability of a recent viral load measurement and was subsequently discontinued once the source's results confirmed an undetectable viral load. Three types of PEP regimens were prescribed: TAF/FTC/BIC in 14 cases (63.63%), TDF/FTC+RAL bid in 5 cases (22.72%) and DRV/COBI+DTG in 1 case (4.54%). In the remaining cases, the regimen adopted was unknown.

Surveillance outcomes showed no HIV seroconversion in 67 individuals (98.53%); one individual (1.47%) was lost to follow-up.

Conclusions: No HIV seroconversions were observed after occupational or accidental percutaneous exposure to body fluids from PLWH with an undetectable viral load, including high-risk exposures such as percutaneous needlestick injuries with hollow-bore needles. These findings may support the applicability of the U=U principle not only following sexual exposure, but also after percutaneous exposure.

Virology

P 230 ANTIVIRAL ACTIVITY OF MICROBIAL METABOLITES MONENSIN AND BREFELDIN A AGAINST TOSCANA VIRUS AND BOVINE VIRAL DIARRHOEA VIRUS: IN VITRO EVALUATION AND MECHANISTIC INSIGHTS

L. Di Clemente¹, M. Acunzo¹, C. Capasso¹, P. Parimal¹, A. Chianese^{1,2}, R. Giugliano^{1,3}, C. Zannella¹, A. De Filippis¹, M. Galdiero^{1,4}

¹Department of Woman, Child and General and Specialized Surgery, University of Campania Luigi Vanvitelli, Naples, Italy, ²Department of Life Sciences, Health and Health Professions, Link Campus University, 00165 Rome, Italy, ³Department of Veterinary Medicine and Animal Production, University of Naples Federico II, Naples, Italy, ⁴UOC Virology and Microbiology, University Hospital "Luigi Vanvitelli", Naples, Italy

Background: Toscana virus (TOSV) is an emerging negative-sense RNA phlebovirus transmitted by Phlebotomus sandflies and endemic in Mediterranean countries. Human infection ranges from asymptomatic or mild febrile illness to severe central nervous system (CNS) manifestations. Despite increasing incidence, no licensed vaccines or specific antiviral treatments exist, emphasizing the urgent need for novel therapeutic strategies. Bovine viral diarrhoea virus (BVDV) is a positive-sense single-stranded RNA virus belonging to the Flaviviridae family. It is an important pathogen in cattle, causing a wide range of clinical outcomes including respiratory disease, gastrointestinal symptoms, immunosuppression, and reproductive failure. Microbial secondary metabolites have garnered attention for their broad-spectrum antiviral properties. Monensin and brefeldin A have previously shown antiviral activity against diverse viruses, often by disrupting viral protein trafficking and Golgi-associated stress responses; however, their effects on TOSV and BVDV infections remain unexplored.

Material and Methods: Vero 76 cells were infected with TOSV and treated with monensin (1.5–25 μ M) or brefeldin A (10.9–175 nM) for 4, 6, 12, or 24 hours. MDBK cells were infected with BVDV and treated with monensin (0.78–12.5 μ M) or brefeldin A (5.4–87.5 nM) at the same time points. Cytotoxicity was evaluated using the MTT assay. Antiviral activity was assessed by plaque reduction assays for TOSV and tissue culture infectious dose (TCID₅₀) assay for BVDV.

Western blot analysis was performed to evaluate TFE3 expression in both Vero 76 and MDBK cells, as a marker of the Golgi stress response.

Results: Monensin exhibited rapid antiviral activity against TOSV, showing strong inhibitory effects at 4 and 6 hours post-treatment. In contrast, brefeldin A showed a delayed antiviral effect, with maximal inhibition observed after 12 hours. For BVDV, both monensin and brefeldin A displayed a delayed antiviral activity profile, with the strongest inhibition detected at later time points post-treatment. At effective concentrations, both compounds showed low cytotoxicity.

Western blot analysis revealed that monensin induced a concentration-dependent upregulation of TFE3 in both Vero 76 and MDBK cells during TOSV and BVDV infection, respectively. In contrast, brefeldin A produced only a modest increase, indicating a differential activation of the Golgi stress response.

Conclusions: These results demonstrate that monensin and brefeldin A inhibit TOSV and BVDV with virus-specific kinetics and distinct effects on host cell stress responses. Overall, the findings highlight the potential of microbial metabolites as antiviral candidates.

Virology

P 231 BROAD GENETIC DIVERSITY OF HDV AND HIGH PREVALENCE OF ACTIVE HDV INFECTION IN CAMEROON: INSIGHTS FROM MOLECULAR DIAGNOSTICS AND WHOLE-GENOME SEQUENCING

L. Piermatteo¹, E.L. Lebomo Etogo², C. Lobe³, A. Magnapera¹, L. Carioti⁴, L. Fabeni⁵, G. Torre¹, I. Grossi¹, S. D'Anna¹, G. Pascal Ngaba⁶, E. Enjema Lyonga², F. Ceccherini-Silberstein⁴, R. Salpini¹, J.N. Torimiro⁷, V. Svicher¹

¹Department of Biology, University of Rome "Tor Vergata", Rome, Italy, ²Department of Microbiology, Virology, Parasitology, Hematology and Infectious Diseases, Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Cameroon, ³Department of Biomedical Sciences, Faculty of Sciences, University of Ngaoundere, Cameroon, ⁴Department of Experimental Medicine, University of Rome "Tor Vergata", Rome, Italy, ⁵Laboratory of Virology and Laboratories of Biosafety, National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy, ⁶Department of Microbiology, Faculty of Medicine and Pharmaceutical Sciences, University of Douala, Cameroon, ⁷Department of Biochemistry, Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon

Background: In Cameroon HBV infection is endemic. However, limited data are available on epidemiology, genetic diversity and accurate diagnosis of HDV infection.

Material and Methods: We conducted a cross-sectional study on 117 HBsAg+ patients from two hospitals in Cameroon, and 42 patients with an already known anti-HDV positivity. For the 117 HBsAg+ patients, anti-HDV were detected by using an assay on the Diasorin Liaison XL analyser. For samples resulted positive to anti-HDV, HDV-RNA was tested by two different assays: RoboGene HDV-RNA quantification kit v3.0 using the Felix automated extraction instrument (LOD <6 IU/ml) and the fully automated Altostar platform for extraction and HDV RT-PCR v1.5 (LOD 1.12 IU/ml). Whole genome HDV sequencing was assessed on Illumina MiSeq. The correlation between HDV-RNA values by Robogene and Altostar assays was assessed by Spearmann test.

Results: Overall, 21/117 (18%) patients were positive to anti-HDV, highlighting a high rate of HDV seroprevalence. The percentage of anti-HDV positive patients ranged from 15.1% (11/73) in the Littoral region up to 22.7% (10/44) in the East region, highlighting local hotspot with high HDV endemicity.

HDV-RNA was tested in the 21 newly diagnosed patients and in the 42 with previously known anti-HDV positivity for a total of 63 patients. Among them, 61% had detectable HDV-RNA by Robogene assay (median [IQR]: 5.4 [3.3 - 6.0] log[IU/ml]), supporting a conspicuous circulation of active HDV infection with an intense HDV replication. Overall, HDV-RNA quantification by Robogene and Altostar showed a high degree of correlation (Rho=0.91). Such degree of correlation was reduced for HDV-RNA values >5 log(IU/ml) (Rho=0.82 for HDV-RNA >5 log[IU/ml] vs Rho=0.99 for HDV-RNA <5 log[IU/ml]).

Focusing on 38 samples with HDV-RNA >1000 IU/ml by Robogene, 26 were successfully sequenced. Phylogenetic analysis revealed the circulation of a large variety of HDV genotypes and subgenotypes with the subgenotype 1b being the most frequent (61.5%), followed by 1a (19.3%), genotype 7 (7.8%), genotype 6, 5 and 1e present in 3.8% of patients each. The correlation between HDV-RNA quantification by Robogene and Altostar was very high in all identified genotypes/subgenotypes with a slight decrease in 1b (Rho=0.96 for genotypes/sub-genotypes other than 1b and 0.82 for 1b).

Conclusions: These findings show a significant burden of active HDV infection in Cameroon, thus highlighting the urgent need of developing accessible and affordable diagnostic algorithms and surveillance tools for HDV infection in Cameroon to reduce HDV-associated morbidity.

Virology

P 232 CLINICAL AND VIROLOGICAL FEATURES OF A TREATMENT-NAÏVE HIV COHORT BETWEEN 2022 AND 2025: A SINGLE-CENTER EVALUATION

N. Randazzo¹, V. Paolozzi², G. Massobrio², L. Taramasso¹, S. Varesano¹, V. Chessa¹, M. Ogliastro¹, V. Ricucci¹, A. Di Biagio^{1,2}, A. Orsi^{1,2}, B. Bruzzone¹

¹IRCCS Azienda Ospedaliera Metropolitana San Martino Hospital, Genoa, Italy, ²University of Genoa, Genoa, Italy

Background: HIV infection continues to represent a major public health challenge despite advances in diagnosis and antiretroviral treatment. Surveillance of new diagnoses, combined with virological characterization using next-generation sequencing (NGS), allows the description of the local epidemiology of infection, the identification of circulating subtypes, and the monitoring of resistance associated mutations (RAMs) that are clinically and epidemiologically relevant. The aim of this study was to describe the clinical-demographic and virological characteristics of new HIV diagnoses made at our center during the period 2022–2025.

Materials and Methods: A descriptive observational study was conducted including all new HIV diagnoses made at our center between 2022 and 2025. For each patient, the following variables were collected at the time of diagnosis: biological sex, age, CD4 lymphocyte count, clinical status (AIDS-defining presentation vs non-AIDS), geographic area of origin (Italy, Asia, Africa, Eastern Europe, South America), and plasma viral load, (categorized as <100,000 copies/mL, 100,000–500,000 copies/mL, and >500,000 copies/mL).

All samples underwent HIV sequencing using NGS technology to determine viral subtype and identify RAMs.

Results: During the study period, 133 new HIV diagnoses were identified (95 males and 38 females).

The median age at diagnosis was 41 years (IQR 32–40.5). The median CD4 count at diagnosis was 222.5 cells/mm³ (IQR 93.25–391.75), with 24% of patients presenting with an AIDS- and 76% with non-AIDS-defining conditions.

Regarding geographic origin, 49% of patients were from Italy, 21% from South America 14% from Africa, 12% from Eastern Europe and 4% from Asia.

Viral load at diagnosis was <100,000 copies/mL in 38% of cases, between 100,000 and 500,000 copies/mL in 27%, and >500,000 copies/mL in 35%, peaking at 48% in 2025 (Table1).

NGS analysis revealed the circulation of multiple viral subtypes, with a predominance of subtype B (55%), followed by CRF02_AG (12%) and subtype C (6%) (Figure 1). RAMs were identified in 34% of new diagnoses. The most frequent RAMs involved the NNRTI class, particularly E138A (n=13) and V179D (n=7), while mutations for integrase inhibitors (INSTIs) remained rare (Figure 2).

Conclusions: This study provides an updated snapshot of new HIV diagnoses highlighting a substantial proportion of late presenters and a high degree of virological heterogeneity. The detection of RAMs in over one-third of the treatment-naïve population (primarily NNRTI-related) underscore the importance of NGS-based surveillance. The use of NGS allows for a detailed characterization of viral mutations, including those at low frequency, with potential clinical and epidemiological implications.

Therefore, integrated clinical and virological monitoring represents a key tool for guiding prevention strategies, promoting early diagnosis, and optimizing the therapeutic management of HIV infection.

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Virology

P 233 CLUSTER OF PRIMARY HIV INFECTIONS SUSTAINED BY A MULTIDRUG-RESISTANT CRF19_CPX IN MSM IN MILAN

G. Bozzi¹, V. Castelli¹, A. Pastena¹, M. Pernich^{1,2}, S. Uceda Renteria¹, A. Parisi¹, P. Bono¹, B. Mariani¹, A. Callegaro¹, A. Muscatello¹, A. Bandera^{1,2}, C. Alteri^{1,2}

¹Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano, Milan, Italy, ²UNIMI Università degli Studi di Milano, Milan, Italy

Background: Transmitted resistance to antiretrovirals (TDR), albeit limited in the current Italian panorama, remains a risk, especially in the PrEP era, and calls for active monitoring. Epidemic diversity is also sustained by HIV-1 non-B subtypes, increasingly established in Italy.

Here, we describe a cluster of primary HIV-1 infections caused by multi-drug-resistant CRF19_cpx, occurring among MSM in Milan over a six-month period.

Material and Methods: Retrospective monocentric observational analysis of HIV cases diagnosed at IRCCS Policlinico, Milan, between 06/2025 and 01/2026, and identified as part of a transmission cluster. DRMs analyzed through Stanford algorithm V 10.1 (Jan 18, 2026). Subtype and transmission cluster (TC) confirmed by IqTree through Maximum Likelihood phylogeny based on the GTR+F+GAMMA model with 1000 replicates fast bootstrapping. A transmission cluster was defined by intra-genetic distance ≤ 0.015 and bootstrap = 100.

Results: Four MSM diagnosed with HIV infection at our outpatient sexual health clinic over six months were identified as a cluster: two reported a direct epidemiologic link, while all were linked through phylogenetic analysis, which confirmed CRF19_cpx infection and identified the sequences as belonging to the same transmission cluster (TC) (bootstrap = 100; genetic distance = 0.008). Median age was 35 years, all were Italian-born, median time since last HIV negative test was 14 months. One had positive *T. pallidum* serology, and the others did not have any co-infection.

None had prior exposure to PrEP.

Two were asymptomatic, two had symptoms compatible with acute antiretroviral syndrome.

In all four cases, HIV serology was compatible with primary infection (Fiebig 2/3 in one case, Fiebig 5 in three cases). Median HIV RNA load was 265672 cp/mL. Median CD4 count was 533/mcL (35%).

At GRT, the following DRMS in the RT portions were detected: D67N (relative abundance: 98%), T215L(99%), K219E(98%), known to belong to pathway 2 of thymidine analogue mutations (TAM2), and S68G(98%), A98G(90%), V106I(93%), Y181C(99%); G190A(99%), the last three known to affect the NNRTI class. Polymorphic mutations included A71T(99%) in protease and M50I (100%) in integrase.

Conclusions: We observed a transmission cluster of CRF19_cpx, a recombinant of subtypes D, A and G associated with rapid disease progression, among MSM in Milan, with transmitted resistance to all NNRTIs and legacy NRTIs. Identification of primary infections across the cluster within six months (2025–2026) provides a snapshot of recent local transmission dynamics and suggests ongoing undetected spread. This is concerning as the resistance profile limits access to several first-line regimens, including injectable long-acting CAB+RPV. Together with missed prevention opportunities, these findings support the need for targeted public health interventions to prevent further transmission.

Virology

P 234 HIGH PREVALENCE OF NEGATIVE OUTCOMES IN HOSPITALIZED PATIENTS FOR WEST NILE VIRUS INFECTION IN A NON-ENDEMIC AREA IN SOUTHERN ITALY DURING THE OUTBREAK IN SUMMER 2025

C. Cacace¹, P. Grimaldi¹, L. Alessio¹, S. De Pascalis¹, R. Raucci³, A. Sullo⁵, F.G. Numis⁴, C. Sagnelli², M. Pisaturo¹, N. Coppola¹

¹Department of Mental Health and Public Medicine, Section of Infectious Diseases, University of Campania Luigi Vanvitelli, Naples, Italy, ²Infectious Diseases Unit, AORN Caserta, Italy, ³Pronto Soccorso, P.O. Moscati Aversa, Caserta, Italy, ⁴UOC Medicina d'Emergenza ed Urgenza, Ospedale Santa Maria delle Grazie - ASL Napoli 2 Nord, Pozzuoli, Naples, Italy, ⁵Infectious Diseases Unit, PO Nocera Inferiore, Salerno, Italy

Background: West Nile virus (WNV) infection is increasing incidence in temperate regions driven by climate change, including European areas. It is fundamental to collect data on hospitalized cases from newly affected, non-endemic areas.

Methods: We conducted a retrospective, multicentric study including adult patients hospitalized with WNV infection in five centers in the Campania region, southern Italy, between July and September 2025. We investigated factors associated with in-hospital death or a composite outcome of death or neurological sequelae at discharge.

Results: Sixty-four patients were enrolled (median age 72 years; 64.1% male), 79.7% presenting with neurological involvement, not considering headache. Fourteen patients (21.8%) died during hospitalization, and 15 (23.4%) were discharged with serious neurological sequelae. Older age and neurological symptoms at presentation were associated with negative outcomes at univariate analysis, while older age and glycorrachxa were associated with death, with no independent predictors identified at multivariate analysis.

Conclusions: In our non-endemic setting, hospitalization due to WNV infection was associated with a high rate of negative outcomes (table 1). These findings likely reflect selective hospitalization of more severe cases and highlight the need for increased awareness and preparedness in regions newly affected by WNV.

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Virology

P 235 HIGH- AND MODERATE-RISK CONDITIONS ASSOCIATED WITH COVID-19-RELATED HOSPITALIZATION ACROSS AGE GROUPS DURING THE OMICRON JN.1/KP.2 PERIOD: REAL-WORLD EVIDENCE FROM ITALIAN CLAIMS DATA

D. Malhotra¹, F.R. Ernst¹, L. Pacelli², I. Zografaki³, E. Fröling⁴, E. Otte im Kampe⁴, R. Sini de Almeida⁵, M. Lehne⁶, S. Calabria⁷, M. Leogrande⁷, L. Degli Esposti⁷, D. Curcio⁸

¹Pfizer Inc., New York, NY, USA, ²Pfizer, Verona, Italy, ³Pfizer Hellas SA, Athens, Greece, ⁴Pfizer Pharma GmbH, Berlin, Germany, ⁵Pfizer, São Paulo, Brazil, ⁶Cytel Inc., Berlin, Germany, ⁷CliCon S.r.l. Società Benefit, Bologna, Italy, ⁸Pfizer Inc., Madrid, Spain

Background: The presence of underlying conditions and multimorbidity ("risk-stacking"), defined as ≥ 2 concomitant conditions, is associated with adverse health outcomes in many diseases, including severe COVID-19. This study aims to evaluate the effects of conditions conferring high and moderate risk of severe COVID-19 and multimorbidity on the likelihood of COVID-19-related hospitalization across different age groups in Italy.

Material and Methods: This retrospective observational database study used anonymized claims data from Italian local health units (LHUs). Individuals aged ≥ 18 years were classified according to the presence of high- or moderate-risk conditions based on WHO classification (www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.2) of underlying conditions within 2 years prior to the study period (December 4, 2023 – July 1, 2024), defined by Omicron JN.1/KP.2 variant dominance (<https://covariants.org>). Underlying conditions were identified using ICD-9-CM codes, as were COVID-19-related hospitalizations (ICD-9: 043.11, 043.21, 043.31, 480.41). The proportions of individuals with high- or moderate-risk conditions associated with COVID-19-related hospitalizations were assessed across age groups during the study period.

Results: The study included 4,642,703 individuals: 18-49 years: 2,021,708; 50-64 years: 1,268,447; ≥ 65 years: 1,352,548. Overall, 51.3% of individuals were female, with mean (SD) age 53.1 (19.4) years. The most frequent comorbid conditions were hypertension (12.0%), chronic obstructive pulmonary disease (4.1%), and heart failure (3.5%). Overall, the prevalence of moderate- and high-risk conditions increased with age: 23.6%, 46.6%, and 72.7% of individuals had ≥ 1 moderate-risk condition and 0.8%, 2.2%, and 3.5% had ≥ 1 high-risk condition across age groups 18-49 years, 50-64 years, and ≥ 65 years, respectively. Overall, about 1 in 5 individuals had ≥ 2 moderate-risk conditions, ranging from 6.5% of those aged 18-49 to 46% of those aged ≥ 65 years. Among individuals with COVID-19-related hospitalizations, 51.9%, 61.7%, and 85.7% of those aged 18-49, 50-64, and ≥ 65 years, respectively, had moderate-risk conditions. Respectively, 6.5%, 21.2%, and 9.0% had high-risk conditions.

Conclusions: These preliminary results from a larger set of planned analyses suggest that the presence of moderate- and high-risk conditions and multimorbidity are still important factors for COVID-19-related hospitalizations across all age groups. Additional analyses quantifying the risk of COVID-19-related hospitalizations conferred by high- and moderate-risk conditions and multimorbidity are currently ongoing.

Virology

P 236 HUMAN ENDOGENOUS RETROVIRUS EXPRESSION IN PERIPHERAL BLOOD OF PEOPLE WITH HIV IN DIFFERENT PHASES OF THE INFECTION AND DURING ANTIRETROVIRAL TREATMENT

E. Lazzari¹, D. Pietrucci², G. Rozera¹, L. Fabeni¹, F. Smoquina¹, G. Bero¹, F. Forbici¹, V. Mazzotta¹, A. Antinori¹, G. Chillemi^{1,3}, F. Maggi¹, I. Abbate¹

¹INMI L. Spallanzani, IRCCS, Rome, Italy, ²University of Tuscia, Viterbo, Italy, ³University of Rome "Tor Vergata", Rome, Italy

Background: Human endogenous retroviruses (HERVs) are the result of an ancient retroviral integration in the human germline and currently represent around 8% of the human genome. HERV transcription may be tissue-specific and has been correlated with inflammation and tumors. Among HERVs, the HERV-K family is made up of 10 groups (HML-1 to HML-10). Various interactions have been described between HIV and HERVs, mostly mediated by HIV tat protein. Aims of the study were to explore HERV-K transcription in peripheral blood mononuclear cells (PBMC) of acute and chronic HIV infections and their modifications after antiretroviral treatment (ART).

Materials and Methods: To identify HML-2 and HML-6 transcripts, single-cell transcriptomics was carried out on PBMCs collected from 1 acute naïve to antiretrovirals HIV-infection (S1) and 1 chronic on ART HIV-infection (S2). Single-cell RNA sequencing was performed with 10x Chromium technology and Illumina NovaSeq sequencing. Bioinformatic analysis was performed using Cell Ranger together with an ad hoc established bioinformatic pipeline. Cell Typist fine annotation was used to assign cell type to the identified cell clusters. Expression levels of HML-6 env were established in plasma samples by Real-time PCR, comparing them with the beta-actin gene levels, in 7 acute/recent infections (AHI) and in 7 chronic infections (CHI), at the moment of serodiagnosis (T0) and after 1 year of ART (T1), when HIV-1 RNA levels were < 50 copies/ml in all subjects. Five plasma samples from healthy donors (HD) were used as controls. Statistical evaluation was performed using Mann-Whitney test and Benjamini-Hochberg FDR correction.

Results: LTR, gag, and env transcripts of HML-2 and HML-6 were found in PBMC from both S1 and S2 subjects. In Figure 1, cell clusters showing HML-6 transcript expression in S2 PBMC (A) and the cell-type annotation (B) are shown. From a total of 2,646 identified cells, HML-6 transcripts were significantly more expressed (% of cells of a given cell type expressing HML-6 transcripts) in non-classical monocytes (18.4%), CD4 T cm/naïve (14.1%), and CD8 Tem/Temra (11.3%). At T0, HIV-1 viremia did not differ between AHI and CHI: 6.08 (4.68-7.74) and 5.66 (4.28-6.45) Log copies/ml. HML-6 transcripts were not detected in any HD, and they were tendentially higher in CHI than in AHI, at both T0 5.29 (3.38-6.18) vs 6.69 (4.11-12.4) and T1 8.03 (6.33-8.97) vs 13.4 (13.221-14.17), median (IRQ) Δ Ct between env HML-6 and beta-actin. ART was able to significantly reduce HML-6 env expression in both AHI (p=0.031) and CHI (p=0.016).

Conclusions: HERV transcripts may be found in PWH in both acute and chronic infections, with higher expression of HML-6 compared to HML-2. Non-classical monocytes, CD4 Tcm/naïve, and CD8 Tem/Temra are the main cellular types containing HML-6 transcripts. Endogenous retrovirus expression may be successfully reduced by ART, irrespective of whether it is initiated in acute or chronic infection.

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Virology

P 237 ILHÉUS VIRUS INFECTION INDUCES A GOLGI STRESS RESPONSE IN HUMAN CELLS

L. Di Clemente¹, M. Acunzo¹, C. Capasso¹, F. Palma¹, A. Chianese^{1,2}, R. Giugliano^{1,3}, C. Zannella¹, A. De Filippis¹, M. Galdiero^{1,4}

¹Department of Woman, Child and General and Specialized Surgery, University of Campania Luigi Vanvitelli, Naples, Italy, ²Department of Life Sciences, Health and Health Professions, Link Campus University, Rome, Italy, ³Department of Veterinary Medicine and Animal Production, University of Naples Federico II, Naples, Italy, ⁴UOC Virology and Microbiology, University Hospital "Luigi Vanvitelli", Naples, Italy

Background: Ilhéus virus (ILHV) is a neurotropic mosquito-borne virus that belongs to the Flavivirus genus, family Flaviviridae. It is responsible for Ilhéus fever, an emerging zoonotic disease transmitted to humans by the bites of mosquitoes, particularly those of the Psorophora genus. Ilhéus fever is an acute febrile illness characterized by common symptoms, including fever, headache, and muscle pain. In severe cases, the infection can progress to potentially fatal encephalitis and meningoencephalitis. In the life cycle of flaviviruses, the Golgi apparatus plays a crucial role in virion maturation. During their transit through the Golgi, immature virions undergo glycan modifications in the envelope (E) protein and proteolytic cleavage of the membrane precursor protein (M) by the protease furin, becoming mature virions. In cells with increased demands on Golgi functions, the capacity of this organelle collapses. To compensate for this functional stress, a homeostatic mechanism known as "Golgi stress" is induced. This study aims to determine whether the high involvement of the Golgi apparatus during Ilhéus virus replication induces the Golgi stress response in human cells. In particular, we focus on the TFE3, CREB3, and HSP47 pathways, with TFE3 enhancing Golgi activity, CREB3 driving pro-apoptotic responses, and HSP47 mediating anti-apoptotic effects.

Material and Methods: The human lung adenocarcinoma cell line (A549) was infected with ILHV, and a time-course analysis from 6 to 72 hours post-infection was performed to assess the impact of viral replication on the Golgi apparatus. At each time point, both total RNA and proteins were extracted. Quantitative real-time PCR (qRT-PCR) was performed to analyze the expression of genes involved in the TFE3, CREB3, and HSP47 pathway: TFE3, GM130, GOLGB1, GCP60, SIAT10, WIPI49, CREB3, ARF4, and HSP47. Western blot analysis was conducted to assess the protein levels of TFE3, GM130, Giantin, SIAT10, CREB3, and HSP47. Monensin and brefeldin A were used as positive controls to induce Golgi stress.

Results: ILHV infection in A549 cells induces a marked activation of the TFE3 pathway, as demonstrated by significant regulation at both the transcriptional and protein levels of TFE3 and its associated Golgi-related effectors. In parallel, HSP47 is also significantly activated, indicating the involvement of an additional Golgi stress-related response. In contrast, the CREB3 pathway shows no significant modulation, with neither transcript levels nor protein expression showing appreciable changes compared to uninfected control cells.

Conclusions: These findings demonstrate that ILHV infection triggers both the TFE3-mediated Golgi stress response and HSP47 activation, whereas the CREB3 pathway shows minimal modulation. To the best of our knowledge, this is the first evidence demonstrating the activation of Golgi stress response pathways in the replication and pathogenesis of ILHV.

Virology

P 238 ION TORRENT GENEXUS AS A FAST AND RELIABLE SOLUTION FOR HIV 1 DRUG RESISTANCE TESTING: COMPARISON WITH THE GENESTUDIO S5 WORKFLOW

F. Smoquina¹, G. Bero¹, F. Forbici¹, A. Amendola¹, G. Sberna¹, E. Lazzari¹, I. Abbate¹, G. Rozera¹, R. Gagliardini¹, V. Mazzotta², A. Antinori², F. Maggi¹, L. Fabeni¹

¹Laboratory of Virology and Laboratories of Biosafety, National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy, ²Clinical and Research Department, National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy

Background: Next generation sequencing (NGS) has increasingly replaced Sanger for HIV-1 genotypic resistance testing (GRT) due to its superior sensitivity for minority variants. Within the Ion Torrent platform, the GeneStudio S5 (S5) provides robust performance but relies on multi step workflows. The innovative Genexus (GX) system integrates all steps, library preparation, templating, sequencing, and analysis, into a single automated workflow performed in one day, minimizing hands-on time and accelerating turnaround. This study compares the analytical performance and clinical usability of these two NGS platforms in routine HIV-1 GRT.

Materials and Methods: One hundred plasma samples from people living with HIV-1 were sequenced for the entire pol gene on both platforms using identical AmpliSeq primer pools. Each sequencing run included 12 samples. On S5 with the 520 chip, each sample yielded about 500,000 reads, while the four-lane GX5 chip produced around 1,300,000 reads per sample per lane. Mutations were analysed through Stanford HIVdb (depth ≥ 100 reads; variant threshold $\geq 10\%$). Mutations in protease (PR), reverse transcriptase (RT) and integrase (IN) were compared between platforms. Raw data were inspected manually using Geneious software.

Results: Overall concordance between the two platforms was high (95.3%), with 96.0% agreement for PR, 90.0% for RT, and 100.0% for IN. Fourteen discrepancies were observed, reflecting differing platform performance. GX demonstrated higher analytical sensitivity, identifying 8 minority variants (<20%) not detected by S5 (PR: F53L $\times$ 2, I54S, N88D; RT: L74V, L100I, K101E $\times$ 2). This asymmetric discordance reflected distinct, platform-specific performance profiles: GX demonstrated superior analytical sensitivity, detecting mutations through greater sequencing depth and optimized chemistry. In contrast, S5 showed reduced analytical specificity, detecting 6 RT variants (K65R, L74I, K101E $\times$ 2, K103N, P225H) that proved to be unsupported "ghost variants" (false positives caused by sequencing artifacts, typically arising near homopolymeric-HP-regions) after specific analysis with dedicated software, despite >500 $\times$ coverage. Detailed genomic analysis revealed that 100% of S5 ghost variants (6/6) were located in or immediately adjacent to HP regions. GX eliminated these artifacts through homopolymer-based filtering and conservative calling criteria.

Conclusion: The GX platform demonstrated high analytical concordance with the S5 system while showing superior analytical reliability. Its reduced hands-on time, fully automated workflow, and rapid one-day turnaround make it particularly suitable for routine clinical use and especially valuable in urgent cases requiring immediate resistance information. Given its higher sensitivity for low-frequency variants, its complete absence of homopolymer-related artifacts, and its operational efficiency, GX provides a more robust and clinically advantageous alternative to S5 for HIV-1 GRT.

Virology

P 239 LONG-COVID AT 5 YEARS: PERSISTENT NEUROINFLAMMATION AND PROGRESSIVE AXONAL DAMAGE IN HOSPITALIZED PATIENTS

P. Pasculli¹, M.A. Zingaropoli^{1,2}, M. Antonacci¹, F. Dominelli¹, F. Ciccone¹, M. Lichtner³, M.R. Ciardi¹, C.M. Mastroianni¹

¹Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy, ²Microbiology and Virology Unit, Policlinico Umberto I, Sapienza University of Rome, Rome, Italy, ³Department of NESMOS, Sapienza University of Rome, Rome, Italy

Background: Long-COVID sequelae remain poorly characterized, particularly regarding long-term neurological impact beyond one year. This study aimed to describe persistent symptoms in hospitalized patients, evaluate vaccination impact, and assess CNS damage via plasma biomarkers (NfL, GFAP) over a 5-year follow-up.

Materials and Methods: A longitudinal cohort study was conducted on hospitalized COVID-19 patients. Clinical assessments included symptoms, chest CT, and lung function. Plasma samples were collected for a subgroup of study population at admission (T0), 3-months (T1), and 5-years (T2) post-discharge, and compared to age/sex-matched healthy donors (HD).

Results: Overall, 144 COVID-19 patients with a median age (IQR of 58 [49–66] years) were included. During hospitalization, 51.4% (74/144) developed ARDS and 18.8% (27/144) of COVID-19 patients died. Fatigue (57%) at T1 and dyspnea (14.2%) at T2 were the most reported symptom. Compared with women, men showed a lower risk of presenting at least one long COVID symptom (OR 0.42; 95% CI, 0.23-0.73, P = .003). At T1, chest CT scans showed abnormalities in two-thirds of patients, lung function abnormalities in half of the patients. Hospitalized patients are at a higher risk of lung injury. (OR 2.17; 95% CI, 1.11-4.23, P = .023). Age increased risk of lung impairment (OR 1.03; 95% CI, 1.01-1.04, P = .001). Vaccination was associated with reduced hospitalization, respiratory support, cardiopulmonary function abnormalities, and lung parenchymal damage, but not long COVID symptom occurrence. In the biomarkers subgroup (n=77), NfL and GFAP were elevated versus HDs at all timepoints (T0: p<0.0001 and p<0.0001, respectively; T1: p<0.0001 and p=0.0220, respectively; T2: p<0.0001 and p<0.0001, respectively). Longitudinally, NfL increased significantly at T2 versus T0 (p=0.0053) with no change at T1. Conversely, GFAP decreased at T1 (p=0.0016) but showed no difference at T2 versus T0.

Conclusion: Findings confirm acute CNS involvement. Notably, longitudinal evaluation reveals a dissociation between astrocytic reactivity and axonal damage. While GFAP suggests resolution of acute inflammation followed by chronic low-grade gliosis, the significant NfL increase at 5 years indicates potential progressive axonal injury. This aligns with evidence suggesting SARS-CoV-2 may accelerate neurodegenerative processes. Persistent marker elevation underscores the need for long-term neurological monitoring.

Virology

P 240 NEAR FULL LENGTH HIV GENOME CHARACTERIZATION IN PAIRED CEREBROSPINAL FLUID (CSF) AND PLASMA SAMPLES IN PEOPLE WITH HIV (PWH) NAÏVE TO ANTIRETROVIRALS

F. Smoquina¹, Abbate¹, G. Rozera¹, G. Berno¹, F. Forbici¹, A. Amendola¹, E. Lazzari¹, V. Mazzotta², A. Antinori², C. Pinnetti², F. Maggi¹, L. Fabeni¹

¹Laboratory of Virology and Laboratories of Biosafety, National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy, ²Clinical and Research Department, National Institute for Infectious Diseases Lazzaro Spallanzani-IRCCS, Rome, Italy

Background: HIV early invades the central nervous system during primary infection, and compartmentalized viral replication in this district may lead to divergent viral evolution. HIV strains displaying a particular tropism in cerebrospinal fluid (CSF) have been highlighted in the past, mainly associated with amino acid (AA) patterns in the V3 loop of the gp120 encoded by the env gene. The aim of the study is to compare near full-length (NFL) sequences from CSF and plasma (PL) of the same subject in order to find possible new determinants of neurotropism.

Materials and Methods: Fifteen paired CSF PL samples from ART naïve chronically infected PWH were analysed. Ion Torrent NGS NFL sequencing was performed; reads were mapped to HXB2, and CSF PL consensus sequences were generated. Phylogeny was used for subtype assignment. AA alignments were obtained for gag, pol and env. CSF PL differences were categorized per position and compartments were compared using non parametric paired tests. Recurrent CSF-PL discordant sites (hotspots) were screened at position level. Positions associated with p24 region, pol transmitted drug resistance (TDR), V3-tropism, and fostemsavir (FTR) related gp120 substitutions were also analysed.

Results: Individuals were mainly male (86.6%), with a median (IQR) age of 52 (46-63), 60.0% were Italian. Median (IQR) log10 HIV 1 RNA copies/mL were 5.21 (4.63-5.89) in CSF and 4.79 (4.24-5.57) in PL. Subtype B prevalence was 66.7%. NFL was obtained in all paired samples (approximately 1- 9,719 nt), with at least 93.3% position covered, and with a mean number of mapped reads of about 1 million. AA alignments of CSF-PL NFL consensus highlighted a higher diversity in env compared with pol and gag. Recurrent CSF-PL hotspot residues in gp120 at 175/337/343 (n=7 pairs each), and at gp120 positions 335/336/363/465 and gp41 positions 580/644/835 (n=6) (p<0.05) were identified. By contrast, pol exhibited only a few discrete peaks, restricted to RT positions 306/433 (n=2 and 3) and RNaseH 590/653 (n=2 each) (p<0.05), consistent with low density hotspot profile. For gag, no position reached significance, including in p24 region. Regarding V3 region, approximately half of the pairs showed an X4 tropism, and no evidence of compartmentalization was observed: X4 was discordant in only one pair (CSF only). Similarly, FTR-related substitutions (S375N/T, M426L, M434I) were largely concordant between compartments. TDR to NRTI (T69D, L74V) was rare and showed no significant CSF-PL differences. Moreover, no significant sites showed a compartment-specific pattern.

Conclusions: Despite the presence of localized env hotspots, CSF-PL discordances were limited and did not indicate a consistent compartment-specific divergence. Across env, pol and gag, along with V3 tropism markers, FTR-related sites and pol TDR, CSF-PL sequences remained largely concordant, suggesting overall genetic continuity between compartments rather than true divergent evolution.

Figure

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Virology

P 241 TEMPORAL TRENDS OF ANTIRETROVIRAL DRUG RESISTANCE MUTATIONS IN HIV-1 SUBTYPES IN SICILY: ANALYSIS OF DATA FROM JANUARY 2021 TO DECEMBER 2025

S. Cannella¹, L. Pipitò¹, C. Mascarella², D. Graceffa², A. Cascio¹, G.M. Giammanco¹, C. Bonura¹

¹Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G. D'Alessandro," University of Palermo, Palermo, Italy, ²Unit of Microbiology and Virology, P. Giaccone University Hospital of Palermo, Italy

Background: Antiretroviral therapy has markedly reduced morbidity and mortality among people living with HIV; however, the emergence of drug resistance mutations (DRMs) continues to pose challenges in selecting the most appropriate treatment regimen. Moreover, over the past decade, epidemiological shifts have been reported, including an increasing prevalence of non-B subtypes and circulating recombinant forms (CRFs). In this dynamic landscape, the aim of this study was to examine temporal changes in HIV-1 subtype diversity and to evaluate the prevalence of DRMs in B and non-B subtypes.

Materials and Methods: Between June 2021 and December 2025, a total of 480 samples underwent genotypic resistance testing (GRT) at the University Hospital Paolo Giaccone in Palermo, Italy. Both treatment-naïve patients and treatment-experienced patients were included in the analysis. GRT requests were submitted by multiple healthcare centers across Sicily. Genotyping and drug resistance interpretation were performed using HIVdb (version 10.1), applying NGS detection thresholds of 10% and 20%.

Results: The study population included 72% males and 76% individuals of Italian origin, with a median age of 43 years (IQR 34–53). At the time of GRT, 286 individuals were ART-naïve and 140 were treatment-experienced with virological failure. The median CD4+ T-cell count and plasma HIV-1 RNA level were 202 cells/mm³ (IQR 61–434) and 4.85 log₁₀ copies/mL (IQR 3.97–5.57), respectively. Overall, 52.5% of individuals were infected with subtype B, followed by CRF02_AG (23.5%), subtype A (6.8%), F1 (5%), C (3.5%), G (1.5%), and other CRFs (6%). At the Sanger-like NGS threshold (20%), the prevalence of DRMs was 30/480 (6.2%) for NRTIs (4 ART-naïve), 37/480 (7.7%) for NNRTIs (19 ART-naïve), 10/480 (2%) for PIs (3 ART-naïve), and 17/480 (3.5%) for INIs (10 ART-naïve). At the 10% threshold, the overall pattern remained unchanged, with only three additional individuals showing INI-associated DRMs (1 ART-naïve). DRMs was higher in subtype B than in non-B subtypes, particularly for NRTIs (6% in subtype B vs 1.7% in non-B). The most frequent resistance-associated mutations were M184V for NRTIs, K103N/T for NNRTIs, L33F for PIs, and Q148K/H and S147G for INIs. Notably, among non-B subtypes, all NRTI resistance cases harbored the M184V mutation, whereas the NNRTI mutations F227I/L and G190A/E were observed exclusively in subtype B.

Conclusions: In conclusion, our findings highlight the substantial proportion of non-B variants, including among Italian-born individuals, supports the presence of sustained local transmission networks. Overall DRMs levels remained moderate and largely driven by NNRTI- and NRTI- associated mutations, with limited involvement of PIs and INIs. Although INSTI resistance was uncommon at both detection thresholds, the identification of minority variants reinforces the need for ongoing monitoring as integrase inhibitors continue to anchor first-line regimens.

Virology

P 242 TOO LATE TO FIX? LOSS OF INSTI RESISTANCE MUTATIONS FOLLOWING INSTI WITHDRAWAL IN HTE PEOPLE

L. Pagnucco¹, R. Lolatto², N. Capra², E. Foca³, S. Bonora⁴, A. Cervo⁵, M. Fabbiani⁶, G. Orofino⁷, D. Armenia⁸, F. Saladini⁹, M. Zazzi⁹, M.M. Santoro¹⁰, A. Castagna², R. Gulminetti¹, PRESTIGIO Study group

¹Medical Department, Infectious Diseases Unit, Fondazione IRCCS Policlinico San Matteo University of Pavia, Pavia, Italy, ²Unit of Infectious Diseases, IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University Milan, Italy, ³Unit of Infectious and Tropical Diseases, Department of Clinical and Experimental Sciences, University of Brescia and ASST Spedali Civili Hospital, Brescia, Italy, ⁴Dept of Medical Sciences, University of Torino Medical School, Torino, Italy, ⁵Infectious Diseases Clinic, University Hospital of Modena, Modena, Italy, ⁶Department of Medical Biotechnologies, Infectious and Tropical Diseases Unit, University Hospital of Siena, Siena, Italy, ⁷Division I of Infectious and Tropical Diseases, ASL Città di Torino, Turin, Italy, ⁸Departmental Faculty, Saint Camillus International University of Health Sciences, Rome, Italy, ⁹Department of Medical Biotechnology, University of Siena, Siena, Italy, ¹⁰Department of Experimental Medicine, University of Rome 'Tor Vergata', Rome, Italy

Background: Resistance-associated mutations (RAMs) have been observed to revert to the wild-type genotype following discontinuation of the antiretroviral class that selected for resistance. This reversion primarily reflects the partial loss of fitness in resistant viral variants and may guide strategies of drug withdrawal and recycling in fragile individuals with limited treatment options.

Methods: We retrospectively evaluated 46 heavily treatment-experienced (HTE) individuals enrolled in the PRESTIGIO Registry (NCT04098315), a large, multicenter, prospective, observational Italian cohort including people with 4-drug-class-resistant HIV (4DR-PWH; resistant to NRTIs, NNRTIs, PIs, and INSTIs), in order to investigate whether discontinuation of the selecting drug class for at least 6 months could lead to measurable changes in class-specific resistance patterns.

Results: Paired Sanger genotype analysis of on- vs off-treatment plasma samples was available for 46 viremic 4DR-PWH (median age 46.5 years, 10 females [22%]) at a median of 19.7 months after drug-class discontinuation. Class-specific RAMs became undetectable in 5/13 for NNRTI, 2/9 for NRTI, 3/9 for PI, and 10/15 for INSTI. For INSTIs, reversion was more frequent among those who also discontinued other drug classes ($p=0.044$), particularly NNRTIs (60% in the reversion group vs 0% in the non-reversion group). The distribution of specific INSTI RAMs did not differ between groups, with G140S and Q148H being prevalent in both (Table 1).

However, the number of major INSTI RAMs was higher in the non-reversion group but not significantly (3 [2;4] vs 2 [1;3], $p=0.126$). No significant differences were observed in viral load, CD4/CD8 counts, HIV infection duration, ART duration, CD4+ nadir, or number of RAMs to other drug classes. Notably, individuals who maintained INSTI RAMs had been off INSTIs longer than those who lost them (34.5 vs 18.8 months; $p=0.006$).

Conclusions: In a small population of 4-drug-class-resistant PWH, INSTI discontinuation was often associated with loss of detectable INSTI resistance, particularly in those with fewer baseline INSTI RAMs and concurrent withdrawal of other drug classes. These findings warrant further investigation using next-generation sequencing to evaluate potential selective drug washout strategies for individuals with limited treatment options.

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Virology

P 243 VIRUCIDAL BROAD-SPECTRUM ACTIVITY OF OREOCHROMICIN-1 AGAINST ENVELOPED VIRUSES FROM DISTINCT VIRAL FAMILIES

C. Capasso¹, M. Acunzo¹, L. Di Clemente¹, B.M. Nastro¹, S. Bashir¹, M. Shoaib¹, A. Chianese^{1,2}, R. Giugliano^{1,3}, C. Zannella¹, A. De Filippis¹, M. Galdiero^{1,4}

¹Department of Woman, Child and General and Specialized Surgery, University of Campania Luigi Vanvitelli, Naples, Italy, ²Department of Life Sciences, Health and Health Professions, Link Campus University, Rome, Italy, ³Department of Veterinary Medicine and Animal Production, University of Naples Federico II, Naples, Italy, ⁴UOC Virology and Microbiology, University Hospital "Luigi Vanvitelli", Naples, Italy

Background: Antimicrobial peptides (AMPs) are key components of innate immunity and represent an evolutionarily conserved first line of defense against microbial pathogens. Beyond their well-established antibacterial and antifungal properties, increasing evidence supports their antiviral activity, often mediated through interactions with viral envelopes or host cell membranes. Oreochromicins are natural AMPs derived from tilapia (*Oreochromis* spp.), yet their potential antiviral activity has not been previously investigated. In this study, we evaluated the antiviral properties of oreochromicin-1 against viruses belonging to distinct viral families.

Materials and Methods: The antiviral activity of oreochromicin-1 was evaluated against a panel of enveloped viruses, including canine distemper virus (CDV), respiratory syncytial virus (RSV), Schmallenberg virus (SBV), caprine herpesvirus 1 (CpHV-1), and bovine herpesvirus 1 (BoHV-1). Cytotoxicity was assessed by 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay to define non-toxic concentrations. Antiviral efficacy was evaluated through plaque reduction assays following direct pre-incubation of viral particles with the peptide before infection. After viral adsorption, infected cell monolayers were washed, overlaid with semi-solid medium, and incubated for 48 hours. Plaques were visualized and quantified after crystal violet staining, and the 50% inhibitory concentration (IC₅₀) values were calculated.

Results: Oreochromicin-1 showed remarkable inhibitory activity against all tested viruses in a dose-dependent manner. The peptide reached IC₅₀ values of 1.5 μ M (CDV), 4.1 μ M (RSV), 3 μ M (SBV), and 6 μ M (herpesviruses). The strongest antiviral effect was observed when viral particles were directly exposed to the peptide before infection, indicating interference with early stages of the viral replication cycle. These findings support a mechanism involving direct interaction with viral particles, consistent with a virucidal mode of action.

Conclusions: Oreochromicin-1 exhibits broad-spectrum antiviral activity against phylogenetically distinct enveloped viruses. The observed efficacy across multiple viral families suggests that the peptide may target conserved structural or biophysical features of viral envelopes involved in attachment, membrane fusion, or entry processes. These results highlight oreochromicin-1 as a promising candidate for further development as a broad-spectrum antiviral agent. Additional mechanistic investigations are warranted to elucidate its precise molecular interactions with viral membranes and fusion machinery.

Virology

P 244 WHEN TO SUSPECT A 'NON-NEUROINVASIVE' WEST NILE VIRUS INFECTION IN EUROPE: AN IDENTIKIT SUGGESTING SUBCLINICAL NEUROLOGICAL INVOLVEMENT

C. Fanelli^{1,2,3}, P. Fadda³, R. Mastinu³, D. Pasero², L. La Civita³, I. Maida²

¹Intensive Care Unit, Department of Medicine, Surgery, and Pharmacy, University of Sassari, Sassari, Italy, ²Infectious Diseases Unit, Department of Medicine, Surgery, and Pharmacy, University of Sassari, Sassari, Italy, ³San Martino Hospital, Oristano, Italy

Introduction: West Nile virus (WNV) infections have increasingly been reported in Europe and Italy. Traditionally considered a tropical disease, most European doctors fail to suspect WNV non-neuroinvasive infection when it occurs. In fact, most studies focus on epidemiology, neglecting clinical features. Based on the first WNV cluster presented in Sardinia, we aimed to provide a pragmatic description of the clinical presentation of this disease.

Methods: We retrospectively collected data on autochthonous WNV infections admitted to the Medicine Department of a secondary care hospital in Oristano, Sardinia, from January to November 2025. A descriptive analysis was performed.

Results: Within the study period, 16 patients with autochthonous non-encephalitic WNV infection were hospitalized; 14 dossiers were available. Median age was 76 years [IQR 65–91], 57.1% (8/14) male, all residents of Oristano province. Mean time from symptom onset to admission was 5 ± 12 days. All patients presented with fever (mean $39^\circ\text{C} \pm 0.6$) and confusion; somnolence occurred in 85.7% (12/14). Neurological examination and consultation excluded overt encephalitis in all cases despite psychomotor slowing in 50% (7/14), suggesting possible subclinical neurological involvement. Progressive weakness was observed in 92.9% (13/14), and arthralgia in 50% (7/14), especially in lower limbs, with postural instability. Anorexia was reported in 85.7% (12/14) and nausea in 50% (7/14), contributing to nasogastric feeding in 35.7% (5/14). Rash was observed in 21.4% (3/14), mainly transient. Hypertension (85.7%, 12/14) and hypercholesterolemia (50%, 7/14) were frequently the only comorbidities. Laboratory findings included mild neutrophilic leukocytosis, mean procalcitonin 0.22 ng/mL, and hyponatremia in 35.7% (5/14). Imaging was mostly unremarkable. WNV diagnosis was confirmed by urine PCR in 85.7% (12/14), serology in 64.3% (9/14), and blood PCR in 50% (7/14). Two patients required ICU admission (14.2%, 2/14); one other died (7.1%, 1/14). Neurologic sequelae at discharge were frequent (71.4%, 10/14), including fatigue (57.1%, 8/14), urinary catheter dependence (35.7%, 5/14), and nasogastric feeding (21.4%, 3/14).

Conclusions: According to our cohort, a non-neuroinvasive WNV patient typically presents with high fever ($>38.5^\circ\text{C}$) and somnolence, frequently misled for sepsis but without any organ recall, except for slight desaturation. Progressive weakness, anorexia, arthralgia can provide an insight into this diagnosis, when lower limbs rash is not present. Slight neutrophil leukocytosis with PCT < 1 ng/dL might be present. Brain and chest imagery are frequently normal.

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