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ABSTRACTBOOK

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SIMIT Società Italiana di Malattie Infettive e Tropicali

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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The statins breakthrough in HIV management

OC 1 ACHIEVEMENT OF LOW-DENSITY LIPOPROTEIN (LDL-C) TARGETS BASED ON INDIVIDUAL CARDIOVASCULAR RISK IN A COHORT OF PEOPLE WITH HIV (PWH): ONE-YEAR FOLLOW-UP ASSESSMENT

B. Caloni[1], G. Carrozzo[1], G. Pozza[1], L. Oreni[1], M.V. Cossu[1], D. Moschese[1], A.L. Ridolfo[1], C. Gervasoni[1], S. Antinori[1,2], A. Gori[1,2,3], A. Giacomelli[1,2]

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Introduction: People with HIV (PWH) have twice the risk of developing atherosclerotic cardiovascular disease (ASCVD) compared to the general population. The European AIDS Clinical Society (EACS) guidelines emphasize the importance of achieving low-density lipoprotein cholesterol (LDL-C) targets based on individual cardiovascular risk. The objective of our study was to assess changes in achieving these targets in two consecutive years.
Methods: We conducted a retrospective, observational, single-center study, including all PWH over 40 years old included in the cohort of the III Infectious Disease Unit of Luigi Sacco Hospital (Milan, Italy) who had at least one visit to the Infectious Diseases outpatient clinics at Sacco Hospital during two consecutive periods: March 31, 2022 – March 31, 2023 (period 1), and March 31, 2023 – March 31, 2024 (period 2). Demographic, clinical, and laboratory data were collected. Individual cardiovascular risk was assessed according to the European Society of Cardiology (ESC) and EACS guidelines using risk scores (SCORE2, SCORE2-OP, SMART, SCORE2-DM, and ASCVD) or other clinical criteria (history of cardiovascular disease, diabetes mellitus, chronic kidney disease). PWH were classified into three risk categories: very high (VHR), high (HR), and non-high (no-HR). LDL-C target achievement was evaluated through a two-step approach, as defined by the ESC. Additionally, we assessed the prescription of lipid-lowering therapy (LLT) after one year in accordance with the latest EACS guidelines.
Results: A total of 1,105 PWH were included, predominantly male (74%) and Caucasian (87%), with a median age of 58 years (IQR 51-62). Most had HIV RNA <50 cp/mL (97% in period 1 and 95% in period 2), with a median CD4 lymphocyte count of 728 cell/m3 (550-928) and 708 cell/mm3 (522-894) in period 1 and 2, respectively (Table 1). The distribution of risk categories remained stable (27% vs. 26% no-HR, 50% vs. 52% HR, 22% VHR in both period 1 and period 2). The median LDL-C decreased from 122 mg/dL (100-144) in period 1 to 115 mg/dL (91-138) in period 2, and the percentage of patients achieving at least one target phase increased from 49% to 58% (p <0.001) in period 1 and 2, respectively (Image 1). However, these percentages dropped when considering PWH on LLT who achieved phase two: 4% in HR and 4% in VHR in period 1, while 5% in HR and 9% in VHR in period 2 (Image 2). The prescription of at least one LLT increased from 38% to 48% from period 1 to period 2, with statins being the most commonly used drugs, often in combination with ezetimibe. Despite this, according to the updated EACS guidelines, only 11% in period 1 and 17% in period 2 received an appropriate LLT prescription.
Conclusions: Despite the update of the EACS guidelines, the achievement of LDL-C targets in our cohort remains suboptimal. LLT prescription also remains insufficient, with a significant gap compared to the actual universal recommendation for statin use in PWH over 40.

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The statins breakthrough in HIV management

OC 2 STATIN PRESCRIPTION, ACCEPTABILITY AND TOLERABILITY IN A COHORT OF PEOPLE LIVING WITH HIV (PLWH) AFTER UPDATED RECOMMENDATIONS ON STATIN THERAPY

A. Bailoni[1,2], M. Sambo[1,2], F. Panza[1,2], M. Crispo[1,2], E. Morelli[1,2], M. Zanchi[1], C. Puttini[2], M. Trezzi[2], S. Benedetti[2], F. Montagnani[1,2], M. Tumbarello[1,2], M. Fabbiani[1,2]

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Background: Based on the results of REPRIEVE trial, an increase in statin prescription in PLWH is expected. We aimed to assess the prevalence of potential contraindications to statin therapy, statins' proposal by physicians, patients' acceptability and tolerability in a cohort of PLWH following the update of DHHS guidelines on statin prescription.

Methods: Retrospective single centre study evaluating statin prescription in a cohort PLWH aged >40 years. A flow-chart was constructed exploring the prevalence of statin prescription at baseline (BL: first visit before February 2024, when DHHS recommendations on statins were released) and during the subsequent 1-year follow-up. Potential contraindications to statins (e.g. increased CPK or ALT, liver disease, myopathy, drug interactions) were explored. Statin proposal, acceptability, tolerability and short-term durability were also evaluated.

Results: A total of 232 PLWH (73.3% males, median age 56 years, median CD4 756 cell/mmc, 90.5% with HIV-RNA<50cp/mL) were included. At BL, 43 (18.5%) patients were already taking a statin and 10 (4.3%) reported previous intolerance to statins. Patients already on a statin were older (62 vs 54 years, p<0.001), had a longer history of HIV infection (19.7 vs 15.1 years, p=0.002), a higher prevalence of comorbidities (diabetes 30.2% vs 6.1%; hypertension 62.8% vs 27.4%; peripheral arterial disease 23.3% vs 4.5%; p<0.001 for all) and a higher SCORE2 (9.7% vs 4.8%, p<0.001) when compared to those not on a statin. Total cholesterol (159 vs 190 mg/dL, p=0.001) and LDL (93 vs 119 mg/dL, p=0.001) were lower in those treated with statins; however, LDL targets were reached by only 16.3% of patients. A relative and absolute contraindication to statins was observed in 14% and 3.9% of patients not on a statin, respectively. Statin proposal and acceptability during follow-up is detailed in the flow-chart (Fig. 1). Among those with no absolute contraindications (n=169), a statin was proposed to only 46 (27.2%) patients and 19 (41.3%) refused it. Statin proposal was lower in those with relative contraindications to statin (16.2% vs 34.7%, p=0.008), with hyperCKemia (14% vs 31.7%, p=0.024) or with HBV/HCV coinfection (12.5% vs 30.7%, p=0.046). Total cholesterol (203 vs 180 mg/dL, p<0.001) and LDL (136 vs 115 mg/dL, p<0.001) were higher in those proposed a statin. SCORE2 was not related to statin proposal by physicians but was higher in PLWH who accepted the statin (6.1% vs 3.5%, p=0.018). Over a median follow-up of 10 months (IQR 9-11), 5.7% patients discontinued statins (most for myalgias) with an incidence of 7 per 100PYFU (95%CI 1-13).

Conclusions: Low rates of statin proposal by physicians and of patients' acceptability were observed in this cohort, despite few patients had absolute contraindications to statins. High efforts should be made to increase statin prescription and acceptability in PLWH, especially in those with SCORE2 ≥5%, according to current guidelines.

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The statins breakthrough in HIV management

OC 3 IMPACT OF REPRIEVE INDICATIONS ON STATIN PRESCRIPTION IN PEOPLE WITH HIV IN A REAL-LIFE SETTING

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Background: The REPRIEVE trial has showed how people with HIV (PWH) with low-to-intermediate cardiovascular risk receiving statins have a reduced risk of cardiovascular events (MACEs), and has highlighted the critical importance of statin use as primary prevention for MACEs in PWH, leading to updates in the European AIDS Clinical Society (EACS) Guidelines.
We assessed the impact of REPRIEVE indications on incidence of statin prescription in PWH and compared statin prescription rates before and after REPRIEVE era.
Methods: We included PWH ≥40 years, without prior statin prescription and MACEs, followed at San Raffaele Scientific Institute, Milan, Italy, during two time periods: after EACS Guidelines statin inclusion (1 Nov 2015-1 Aug 2017) and following REPRIEVE trial publication (1 May 2023-1 Feb 2025).
Cardiovascular risk was estimated using the ASCVD risk score and categorized as low-to-intermediate (<20%) or high (≥20%).
A 1:1 propensity score matching, including age, ethnicity, gender, HDL, LDL and total cholesterol, systolic blood pressure, antihypertensive treatment, diabetes, smoking status, BMI and triglycerides, was conducted between individuals included in the two time periods.
Data were reported as median or frequency, and baseline characteristics were compared using Wilcoxon rank-test or chi-square/Fisher's tests.
Univariable Poisson regression model estimated incidence rates (IR) of statin prescriptions, expressed per 100 person-years of follow-up (PYFU), and 95% confidence intervals (CI).
Cumulative incidence function assessed the probability of statin prescription during each time period, accounting for death as a competing risk.
Results: A total of 1365 and 1389 PWH were included in the first and second time period, respectively. After propensity score matching, 880 PWH were identified in each time period. Baseline characteristics, according to each time period, are reported in Table1.
In the first time period, during 1445 PYFU, 65 statin prescriptions were recorded among 880 PWH (IR 4.50/100 PYFU, 95%CI=3.5-5.7). In the second time period, during 1217 PYFU, 143 statin prescriptions were recorded among 880 PWH (IR 11.75/100 PYFU, 95%CI=9.9-13.8). The incidence rate ratio between the two time periods was 2.61 (95%CI=1.9-3.5, p<0.001).
The cumulative probability of statin prescription at 20 months was significantly higher following REPRIEVE indications compared to the first time period [17.6% (95%CI=15-20.3) vs. 7.4% (95%CI=5.8-9.3), p<0.001, Figure 1, Panel A]. After stratifying individuals by cardiovascular risk, this difference remained statistically significant in those with low-to-intermediate risk, but was not significant among individuals with a high cardiovascular risk score (Figure1, Panel B).
Conclusion: Incidence of statin prescriptions for primary prevention have significantly increased following the publication of the REPRIEVE trial in PWH with a low-to-intermediate cardiovascular risk in a real-life setting.

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The statins breakthrough in HIV management

OC 4 STATINS REDUCE FRAILTY IN PEOPLE WITH HIV

J. Milic[1], A. Carobbio[1], M. Menozzi[2], G. Mancini[2], G. Cuomo[2], F. Motta[1], C. Mussi[1], C. Mussini[1,2], P. Raggi[3], G. Sebastiani[4,5], G. Guaraldi[1,2]

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Objective: Statins have pleiotropic effects beyond lowering LDL cholesterol, offering benefits in multiple cardiometabolic conditions and reducing chronic inflammation. These effects have the potential to also influence biological aging trajectories, reflected by frailty. The objective of this study was to compare frailty trajectories, in people with HIV (PWH) who used statins for primary and secondary cardiovascular prevention with those who did not. Secondary objective was to compare geriatric outcomes, such as walking speed, short physical performance battery, hand grip in statin users and non-users.

Methods: This was an observational longitudinal study including antiretroviral therapy (ART)-experienced PWH attending the Modena HIV Metabolic Clinic (Italy) who had no prior statin exposure at baseline (BL) and with at least 3 frailty assessments during follow-up. BL was defined as the first visit with available FI, and follow-up was defined as the last visit with available FI. Statin users and non-users were matched based on median time between BL and initiation of the statin therapy in the first group. Time 0 was defined as the initiation of the statin therapy. Frailty was assessed using a validated 37-item frailty index (FI), ranging from 0 to 1. Frailty trajectories were analysed using a linear mixed model (LMM) adjusted for statin use, age, sex, follow-up time, HIV variables, diabetes, hypertension, smoking (pack year), and BL LDL cholesterol. All beta-estimates were multiplied by 100 to increase readability of the results.

Results: A total of 3543 PWH were included, 1100 (31%) were women. The median age at BL was 44.7 yrs, median time since HIV diagnosis was 14 yrs, median current CD4 cell count was 558.5/microL with 88.6% having undetectable HIV viral load. At T0, PWH who started statin were older (48.4 vs 43.6 yrs), had a higher: FI (0.3 vs 0.2), LDL cholesterol (129 vs 109 mg/dL), prevalence of hypertension (31.8 vs 15.4%), diabetes (11.5 vs 4.7%), all p<0.001. In LMM, statin use over time (β= -2.33, 95% confidence interval (CI): -5.25, -0.59) was a significant predictor of FI reduction (Figure 1). Other factors associated with FI were: age (β=-0.06, 95% CI: -0.11, -0.01), female sex (β=-0.75, 95% CI: -1.55, -0.02), diabetes (β=3.94, 95% CI: 3.19, 4.69), hypertension (β=3.55, 95% CI: 3.06, 4.05), undetectable HIV RNA (β=-0.72, 95% CI: -1.09, -0.35), statins in secondary prevention (β=2.80, 95% CI: 0.52, 5.07). No differences were observed regarding secondary outcomes.

Conclusions: Statins used for primary prevention significantly reduce frailty over time, suggesting potential geroprotective effect of statins. The protective effect of statins on frailty is independent of achieving target LDL cholesterol levels or quantifying cardiovascular risk with standard algorithms. This implies the involvement of an additional mechanism, potentially HIV-related chronic inflammation, in mediating statins' protective role against frailty.

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The evolving tale of HIV: shifting patterns, emerging HIV care

OC 5 PROGRESSES IN THE CONTINUUM OF CARE OF PEOPLE LIVING WITH HIV, USING SURVEILLANCE AND COHORT DATA. ITALY, 2012-2023

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Background: In 2014, to reduce HIV transmission at the community level, UNAIDS launched the 90-90-90 target, to be achieved by 2020 (elevated to "95-95-95" for 2025), according to which 90% of people living with HIV (PLHIV) should be diagnosed, 90% of people diagnosed should be on antiretroviral therapy (ART) and 90% of people on ART should achieve viral suppression (VS). These three indicators of the continuum of care (CoC) aimed to measure progress towards the HIV infection control. Achieving all three targets provides an indication of the VS levels of the entire PLHIV with the target thresholds 73% for 2020 and 86% for 2025.
Our aim was to estimate, for each year from 2012 to 2023, the CoC for Italy overall and for the main subpopulations using standardized methodologies and routinely collected data.
Material and Methods: The size and main characteristics of PLHIV diagnosed alive and in care at the end of 2012 were obtained from the first national CARPHA survey (Camoni L, 2015). Current HIV/AIDS surveillance data were used to estimate the number of PLHIV undiagnosed (Mammone A, 2016). Data from the ICONA study cohort were used to estimate the proportion of people on ART and, among these, those who achieved VS (last year viral load ≤200 copies/mL) obtaining minimum and maximum estimates (if lost to follow-up were included or not) and their midpoint estimates (Gourlay A, 2017).
Results: From 2012 to 2023, the estimated number of PLHIV increased from 127,000 to 147,000, an increase of 16% (Figure 1.A1). Since 2012, all CoC indicators have shown an increasing trend and all have reached the 90% target by 2017. The greatest improvement was seen in the percentage of PLHIV diagnosed and on ART, from 74% to 94%. In 2023 the targets reached 95-94-93 (Figure 1.A2). Accordingly, the percentage of VS among all PLHIV increased from 56% to 83% (Figure 1 A3). The increasing trends in CoC indicators observed at global level were also confirmed after stratification by sex, origin and mode of HIV transmission (Figure 1, B, C and D, respectively). However, still in 2023 females and foreigners struggle to exceed 90% in achieving VS (91% and 90%, respectively). Furthermore, foreigners and people who inject drugs (PWID) showed the lowest percentage of VS (76% and 75%, respectively).
Conclusions: In Italy, globally, from 2012 to 2023 the three CoC indicators show a continuous increase, all above the "90-90-90" target since 2017, followed by a slow improvement towards the "95-95-95" target. Improvements appear to be mainly driven by increasingly inclusive guidelines on ART use until 2016, when treatment was indicated for all. In 2023, a non-negligible number of PLHIV are still not in VS and are sustaining the spread of infection. Furthermore, critical issues arise in the CoC for females and hard-to-reach populations, such as foreigners and PWID.
Project supported and financed by Italian Ministry of Health: CCM (4393) and General Direction for Health prevention (4023).

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The evolving tale of HIV: shifting patterns, emerging HIV care

OC 6 DISAGGREGATED DATA ON TESTING ACTIVITY FOR HIV IN THE CONTEXT OF COMMUNITY BASED VOLUNTARY COUNSELLING AND TESTING SERVICES IN THE LAST YEARS IN ITALY (2019-2023): TOWARDS A NATIONAL REGISTRY

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Background and Objectives: In recent years, the activity of testing for HIV in the context of community-based services run by Non-governmental organizations (NGOs) has rapidly increased. Our aim was to characterize the number and characteristics of people accessing these services as well the reactivity in the last years (2019-2023) in terms of tests offered for HIV and other sexual transmitted diseases (STD, namely HCV and Syphilis).
Materials and Methods: We collect disaggregated data collected from several NGOs offering HIV screening during the period of study (January 1st 2019 - December 31st 2023). 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 result. Those with no reported HIV screening test result or aged under 16 were removed from the analysis.
Results: Data from eleven single organizations from all over Italy were included in this preliminary analysis. Starting from data on 25135 tests performed and after the exclusion of 77 (0.3%) tests with inconclusive result, overall a final number of 25058 tests for HIV were performed during the investigated period, with 3456 tests performed in 2019 doubling up to 7586 tests in 2023 with a minimum of 2543 tests in 2020. The majority of persons tested were cis-males (69.2%) followed by cis-females (29.3%) and transgender persons (19.4%), with an overall median age at test of 29 years (interquartile range, IQR: 24-38). In this preliminary analysis of the ongoing project of collection, 125 (0.5%) tests 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, cis-females showed a lower prevalence (0.18%), while 0.60% in cis-males (0.65% in MSM) and higher in transgender persons (6/286, 2.10%). In a subgroup 19561 tests (78.1%) where among other information on nationality those referring a previous test (which overall represent 60.8% of all testers), prevalence was higher in foreigner vs. Italians (1.3% vs 0.4%, p<0.001), and in those referring a previous HIV-test (0.7% vs. 0.3%).
Conclusions: These preliminary data showed that over the period NGOs were able to provide an increasing number of testing opportunity. This ongoing project will give the basis to create a National Registry on tests performed in community-based setting, and the possibility to investigate characteristics of persons tested and predictors of reactivity.
Project supported and financed by Italian Ministry of Health: CCM (ref 4393) and General Direction for Health prevention (ref 4023).
Table 1

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The evolving tale of HIV: shifting patterns, emerging HIV care

OC 7 EXPANDING HIV SCREENING BEYOND HOSPITAL WALLS IN MILAN: 17 YEARS OF THE "EASYTEST" PROJECT

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Background: Early and widespread HIV testing is essential to reduce HIV transmission, enable timely diagnosis and ensure linkage to care. Despite advances in HIV screening, barriers such as lack of awareness and limited healthcare access remain. Traditional hospital-based testing services, while essential, may not effectively reach all individuals. Aim is to evaluate the effectiveness of a point-of-care (POC) project in detecting new HIV infections, ensuring linkage to care, rapid treatment initiation and overall satisfactory outcomes.

Material and methods: The EasyTest project is an ongoing, cross-sectional study coordinated by San Raffaele Hospital in collaboration with local health facilities. HIV testing was carried out using rapid POC tests [INSTI™ HIV -1/2 Antibody Test] at fixed bi-monthly appointments and public events. Individuals with a reactive HIV rapid test underwent confirmatory ELISA and Western blot testing within 24 hours and initial infectious disease consultation within 48 hours. Demographic data and participant satisfaction were systematically collected.

Results: A total of 23,553 HIV rapid tests were performed between 2008 and 2024; 118/23,553 people were diagnosed with HIV (0.5% prevalence). The annual trend remained stable, except for a temporary decrease in 2020 due to the SARS-CoV-2 pandemic with reduced access to POC testing. The median number of daily users during appointments was 83. Testing was predominantly accessed by men (72%), with 52.5% identifying as men who have sex with men (MSM). The median age was 41 years (IQR 24-52) for men and 34 years (IQR 29-41) for women. A total of 22,186 tests were performed between 2008-2022 (116 HIV reactive, 0.52% prevalence) and 1,360 in 2023 -2024 (2 HIV reactive, 0.14% prevalence). The overall cumulative HIV prevalence between 2008-2024 was 0.50% (118/23,553). Of the 118 people with a reactive rapid HIV test, 100% were diagnosed with HIV, 100% were linked to care, and 100% started ART within 48 hours. Testing at public events attracted a higher proportion of first-time testers (66%), while 34% of those attending monthly appointments were repeat users: reactive tests were 73/118 (62%) at bi-monthly appointments and 45/118 (38%) at public events. Satisfaction with the project was reported by 23,530/23,553 (99.9%) of users.

Conclusions: The EASY testing project provides a long-standing model of HIV screening outside of hospital services, demonstrating that alternative testing strategies can successfully engage individuals who might not otherwise seek testing. The programme has consistently ensured rapid access to care, with all diagnosed individuals successfully linked to care. While the overall prevalence of HIV infection remained low, this reflects the project's broad accessibility beyond key populations. The data highlight the importance of combining targeted screening of high-risk populations with broader community outreach to maximize testing coverage.

The evolving tale of HIV: shifting patterns, emerging HIV care

OC 8 DID THE COVID-19 PANDEMIC SHIFT THE LANDSCAPE OF LATE HIV DIAGNOSIS?

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Background: The COVID-19 pandemic profoundly reshaped healthcare services, affecting the management of chronic pathologies, including HIV. This study aimed to evaluate the interplay between COVID-19 pandemic and late HIV diagnosis (LD) in Italy.

Material and Methods: All people with HIV (PWH) enrolled in the Icona cohort between January2016 and December2023, diagnosed with HIV within 3 months before enrolment, were included. The incidence of LD (defined as CD4 count<350 cell/mm3 at diagnosis or AIDS-defining event [ADE] regardless of CD4 within 3 months from diagnosis) and AIDS presentation (AIDS-P, ADE within 3 months from diagnosis) were compared between pre-COVID (2016-2019) and post-COVID (2021-2023) period. The difference in prevalence of LD by period and by participants' socio-demographics was compared using Poisson regression models with an interaction term. Survival analysis was used to assess the effect of LD and AIDS-P on all-cause mortality risk and its interaction with the calendar period.

Results: Overall, 5,081 newly diagnosed PWH were enrolled in the Icona cohort over the study period, of whom 2,928 (58%) were LD and 612 (12%) were AIDS-P. The proportions of LD and AIDS-P remained stable across the pre- and post-COVID period: 1,817/3,172 (57.3%; 95%CI:55.5-59%) and 1,111/1,909 (58.2%, 95CI% :5.9-60.4%) for LD and 372/3,172 (11.7%; 95%CI:10.6-12.9%) and 240/1,909 (12.6% 95%CI:11.1–14.1%) for AIDS-P, respectively [Fig.1]. LD were more likely to be women, elderly, migrants, and heterosexuals (compared to MSM), and to have lower educational level. Risk patterns for LD remained consistent pre- and post-COVID, although there was weak evidence that the risk of LD in heterosexuals vs. MSM weakened in post-COVID (interaction p-value=0.38, Table 1). Over the follow-up, a total of 138 deaths occurred: 114 in pre-COVID and 24 in post-COVID period (41 and 73 for ADEs; 16 and 8 for not-AIDS related events). At survival analysis, LD/AIDS-P had a significantly higher probability of all-cause mortality both in the pre-COVID (3-year risk [95%CI]: non-LD (nLD) 0.94% [0.38-1.49%], LD 4.3%[3.3–5.3%], AIDS-P 9.6% [6.8–13%],p<0.001) and post-COVID (3-year risk [95%CI]: nLD 0.18%[0.02–0.52%], LD 2.7% [1.6–3.9%], AIDS-P 7.5%[3.4–11.5%], p<0.001). After controlling for confounding, LD and particularly AIDS-P were confirmed to be at higher risk of death compared to nLD, with some modest evidence that this excess in risk was exacerbated in the post-COVID period (aHR LD vs. nLD and AIDS-P vs. nLD: 13 and 49.9 in the post-COVID vs 3.56 and 7.07 in the pre-COVID [Fig. 2, interaction p>10%]).

Conclusions: Our data shows that the frequency of LD remained stable before and after COVID-19, regardless of participants' socio-demographics. LD was confirmed to be associated with an increased mortality risk, with evidence suggesting that this risk may have been more pronounced in the post-pandemic period. Longer follow-up is needed to further validate these findings.

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Long acting PrEP in clinical practice

OC 9 PRELIMINARY INSIGHTS INTO THE PHARMACOKINETICS OF LONG-ACTING CABOTEGRAVIR FOR PREP: DIFFERENTIAL BLOOD AND SEMINAL FLUID CONCENTRATIONS ANALYSIS

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Background: Long-acting injectable Pre-Exposure Prophylaxis (LAI-PrEP) with cabotegravir (CAB) has transformed the landscape of HIV prevention, offering a good alternative to oral PrEP with emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF). By addressing key challenges such as adherence, uptake, and retention, CAB LAI-PrEP provides an effective solution for individuals at substantial risk of HIV infection. This study aims to evaluate CAB, FTC, and TDF concentrations in blood and seminal fluid up to one month after CAB LAI-PrEP administration.
Materials and Methods: Longitudinal evaluation of CAB, FTC, and TDF concentrations in blood and seminal fluid was conducted via LC-MS/MS at three time points: T0 (day of CAB-LAI PrEP initiation), T1 (one week after injection), and T2 (one-month post-administration). The study included 18 men who have sex with men (MSM) enrolled at IRCCS San Raffaele Hospital between December 5, 2024, and February 28, 2025. Among them, 12 were on daily oral PrEP with FTC/TDF (continued for one-week post-CAB), 4 followed an on-demand regimen, and 2 were PrEP-naïve. Additionally, emerging HIV infections were assessed by immunological and RT-PCR testing at T0 and T2.
Results: Median blood CAB concentrations were 1997 (IQR: 920-2315) and 1043 ng/mL (IQR: 686-1235) at T1 and T2, respectively. By T2, 16 participants had plasma CAB concentrations above the 4×PAIC90 (664 ng/mL), yet all showed CAB concentrations above the PAIC90 (166 ng/mL). Median seminal CAB concentrations were significantly lower than in blood: 38 ng/mL (IQR: 20-47) at T1 and 26 ng/mL (IQR: 18-39) at T2, resulting in a mean seminal fluid-to-plasma ratio of 0.02 across time points (Figure1).
FTC and TDF concentrations in seminal fluid were notably higher than in blood, indicating substantial penetration into this HIV-relevant compartment. At T1, median FTC concentrations were 68 ng/mL (IQR: 37-78) in blood and 676 ng/mL (IQR: 596-1443) in seminal fluid (9.9-fold higher), while median TDF concentrations were 40 ng/mL (IQR: 30 -63) in blood and 196 ng/mL (IQR: 76-284) in seminal fluid (4.9-fold higher). By T2, FTC and TDF concentrations were nearly undetectable. No significant adverse effects or novel HIV infections were reported.
Conclusions: These preliminary findings support CAB-LAI as an effective alternative for HIV prevention, particularly in overcoming adherence challenges of daily oral PrEP. Future studies with larger cohorts and extended follow-ups are needed to further define the long-term pharmacokinetics and real-world effectiveness of CAB-LAI PrEP.

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Long acting PrEP in clinical practice

OC 10 PRELIMINARY RESULTS OF LONG-ACTING INJECTABLE PREP WITH CABOTEGRAVIR AT SAN RAFFAELE INSTITUTE IN MILAN

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Background: Long-acting injectable cabotegravir (CAB-LAI) has demonstrated superior efficacy over oral PrEP in preventing HIV infection. This study aims to describe the characteristics, reasons for switching to CAB-LAI, adverse events, and user satisfaction in a preliminary cohort of PrEP users receiving CAB-LAI.
Material and Methods: This is a prospective cohort enrolling people starting CAB-LAI for PrEP at the Infectious Diseases Unit of the San Raffaele Scientific Institute, Milan, Italy (NCT06418048). People who started CAB-LAI (baseline date) between November 2024 and February 2025 were included. Baseline demographics, previous oral PrEP use, sexual behaviors, STI history, and chemsex use were recorded. Post-injection assessments included perceptions of adherence, injection site reactions (ISRs), systemic adverse effects, and satisfaction at time of the second injection using a survey. Data were analyzed using descriptive statistics.
Results: A total of 79 people started PrEP with CAB-LAI, including 98.7% MSM and 1 WSM, with a median age of 41.2 years (IQR 35.0-46.4). Before CAB-LAI, 94.9% of participants used oral PrEP with FTC/TDF (68.0% daily and 32.0% event-based). Individual characteristics are shown in Table 1. Main reasons to start CAB-LAI were: sub-optimal oral PrEP adherence (46.6%), intolerance to FTC/TDF (26.7%), kidney disease (21.5%), and osteoporosis (5.0%) [Figure 1]. In total, 29 people received one CAB injection, 44 two, and 6 three, with no out-of-window administrations. Following CAB-LAI administration, ISRs disclosed at month 1 visit (n=50) were nil or very mild in 94%, moderate in 4%, and severe in 2%. No systemic adverse events were reported, but 1 case of fever. Compared to oral PrEP, 56.0% felt significantly more protected, and 98% found CAB-LAI more convenient. Improved self-perceived PrEP adherence was reported by 68%. Overall, 94% reported no difficulties in switching to CAB-LAI, and 94% were fully satisfied with injectable PrEP.
Conclusions: In this preliminary study on CAB-LAI PrEP users, this strategy was mostly used by oral PrEP-experienced MSM reporting high-risk sexual behaviors and previous STIs. Adherence issues and oral PrEP-related side effects were the most common reasons for starting CAB-LAI. PrEP with CAB-LAI was very well tolerated with limited ISRs. Participants reported improved adherence, convenience, a heightened sense of protection, and overall satisfaction with CAB-LAI.

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Long acting PrEP in clinical practice

OC 11 DETERMINANTS FOR THE START OF LONG-ACTING INJECTABLE CABOTEGRAVIR AS PRE-EXPOSURE PROPHYLAXIS: A CASE-CONTROL ANALYSIS

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Background: Long acting injectable cabotegravir (LACAB) proved to be highly effective for the prevention of HIV infection in men who have sex with men (MSM), cis- and transgender women (TGW). While no national prescribing criteria for LACAB are available yet, clinicians chose as LACAB candidates individuals who had a major need to move away from oral F/TDF. Aim of this study is to characterize PrEP users who started LACAB in this preliminary injectable PrEP era.

Methods: This retrospective, monocentric analysis evaluated PrEP users who switched to LACAB from February 2025 onwards (cases). Controls were oral PrEP users who attended the clinic on the same day. Demographic, clinical, and behavioural data were collected. Descriptive statistics, nonparametric tests and unadjusted bivariate regression analysis were used to depict study population and factors associated with the switch to LACAB.

Results: The study enrolled 100 PrEP users: 19 receiving LACAB (19.0%), the other continuing oral PrEP. They were mainly males (98, 98%) with one TGW in each group, born in Italy (85, 85.0%), with a median age of 37 (IQR 31-45) years, and a median time on PrEP of 1.75 (IQR 0.75-3.75) years. Table 1 shows detailed study population description and factors associated with the switch to LACAB. Time on PrEP (OR 1.51, 95%CI 1.13-2.02, p=0.005), complaining any grade of gastrointestinal adverse event with oral PrEP (OR 35.75, 95%CI 8.22-155.39, p<0.001), and the cumulative number of sexually transmitted infections (STIs) in their medical history (OR 1.41, 95%CI 1.10 -1.80, p=0.006) resulted associated with the switch. The number of sexual contacts in the previous 3 months — either with or without condom use — resulted associated with the switch at the limit of significance. Renal function and chemsex practices did not prove to have a role for the switch.

Conclusions: Our data suggest that in this preliminary phase clinicians chose to start LACAB in individuals who complained F/TDF-related gastrointestinal side effects and with a longer history of PrEP probably for a major pill fatigue in this population. Additionally, those who switched showed a higher number of STIs and a tendency for a higher number of recent sexual contacts suggesting the selection of individuals with behaviours at major risk for HIV acquisition. Toxicity, pill fatigue, and sexual behaviour at major risk are the foremost drivers for the switch to LACAB so far.

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Long acting PrEP in clinical practice

OC 12 REAL-WORLD IMPLEMENTATION OF LONG-ACTING PREP WITH INJECTABLE CABOTEGRAVIR: PRELIMINARY DATA FROM AN ITALIAN COHORT

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Background: Long-acting injectable (LAI) agents hold promise for addressing the challenges associated with poor adherence, tolerability, and toxicity of oral PrEP. Despite these advantages, implementation faces barriers in many countries, and the scale-up of LAI PrEP is slow to progress. The aim is to describe baseline characteristics of people who accessed a pilot implementation program of LAI PrEP with cabotegravir (CAB) in two Italian clinical centers.
Methods: Individuals either currently using oral PrEP or eligible to start PrEP at two Italian hospital centers for HIV and STIs were offered LAI CAB (600 mg, IM, every 8 weeks) from January to February 2025. The eligibility criteria for the LAI proposal were mainly, but not exclusively, related to challenges with oral PrEP or belonging to key populations. At the first assessment, CAB users underwent HIV Ag/AB and HIV-RNA testing, and same-day injection was administered following confirmation of a negative rapid HIV test. PrEP users were asked to complete a survey on the propensity to choose LAI PrEP.
Results: The study included 257 HIV-negative, PrEP-eligible individuals, the majority of whom were male (243, 95%) and Italian (232, 90%). The median age was 40 years (IQR 19-70); 72% (185) held a university degree, and 91% were employed (231). 98% (n=252) identified as cisgender, while 2% (n=5) identified as transgender. A total of 243 individuals (94.6%) were GBMSM, while heterosexuals constituted 5% (n=13) of the cohort. Most participants (n=248, 97%) were already on PrEP at enrollment (Tab1). The main reasons for starting LAI CAB included poor adherence to oral PrEP (42.0%), chemsex use (11.7%), psychiatric illness (8.4%), proactive preference with a request (8.0%), renal impairment (5.8%), osteopenia/osteoporosis (4.01%), and discontinuation or refusal of oral medications (3.28%) (Fig.1). No CAB oral lead-in was used, and no HIV infections were observed at screening.
Regarding the survey, 254 out of 257 participants responded. While 80% reported having positive experiences with injectable drug administration, their reasons for choosing LAI PrEP varied considerably. Specifically, 127 participants (50%) considered themselves at low risk for acquiring HIV/STIs, and more than half (151, or 60%) preferred receiving LAI PrEP from a medical doctor instead of other healthcare professionals.
Conclusions: Preliminary results of this LAI PrEP implementation program demonstrated user characteristics similar to those previously reported for oral PrEP, but among people for whom oral assumption was unsuitable due to adherence challenges, psychiatric morbidity, chemsex use, or intolerance to TDF/FTC. Despite TGW or CGW being prioritized for access, these subgroups remain largely underrepresented in the cohort. The diverse needs of CAB users, as self-reported in this study, could inform targeted strategies for expanding access to LAI PrEP.

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Defining immune correlates in the context of ART and vaccination

OC 13 THE IMPACT OF LONG-ACTING INJECTABLE CABOTEGRAVIR PLUS RILPIVIRINE IN PWH ON MACROPHAGE/MONOCYTE ACTIVATION AND NEURONAL INJURY

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Background: Macrophage/microglial cells are the only productively HIV-infected cells within the CNS, and an indirect neurotoxic effect has been suggested. Long-acting injectable cabotegravir plus rilpivirine (LA-CAB/RPV) has transformed the landscape of ART, but real-world data are required. In this single-center study, a longitudinal evaluation of biomarkers implicated in both chronic inflammation and pathogenesis of neuronal injury (i.e., certain phenotypes of activated monocytes/macrophages, NfL, GFAP, sCD163, sCD14, MMP-9 and TIMP-1) was conducted.

Material and Methods: On blood samples obtained from PWH before LA-CAB/RPV (T0), after 6 (T6) and 12 months (T12) the percentages of monocytes/macrophages (HLA-DR, CD14, CD16, CD11c, CD123) were analyzed by flow cytometry. Plasma biomarkers of neuronal damage (NfL), astrocyte damage (GFAP), monocyte/macrophage activation (sCD163 and sCD14) and BBB permeability (MMP-9 and TIMP-1) were investigated using a microfluidic next generation ELISA. Subsequently, each time point was compared to healthy donors (HDs).

Results: Thirty ART-experienced and aviremic PWH switching to LA-CAB/RPV and 32 HDs were enrolled. At T12, no virological failure was observed. Compared to HDs, PWH exhibited higher percentages of intermediate monocytes ($p=0.0042$), non-classical monocytes ($p<0.0001$), M-DC8 ($p=0.0014$) and higher plasma levels of sCD14 ($p<0.0001$), sCD163 ($p<0.0001$), NfL ($p<0.0001$) and GFAP ($p<0.0001$) at each time point. No difference in plasma levels of MMP -9 and TIMP-1 was observed. The stratification of PWH according to previous ART revealed no differences in the percentages of monocyte/macrophage subsets or in the plasma levels of each biomarker between dual and no dual therapy.

Overall, at both T6 and T12, a significant reduction in the percentage of non-classical monocytes ($p=0.0008$) as well as in the plasma levels of sCD14 ($p=0.0113$) compared to T0 was observed. No difference in the percentage of classical monocytes, intermediate monocytes, M-DC8, pDCs, mDCs was identified. Notably, no difference in the plasma levels of NfL, GFAP, MMP-9, TIMP-1 and sCD163 was observed too (see Table).

Conclusions: A potential involvement of chronic inflammation, cytokine release and cellular damage in the development of HAND has been previously postulated. In the present study, no imbalance between plasma levels of MMP-9 and TIMP-1 was observed, suggesting no altered profile of inflammatory cytokines/chemokines and monocyte activation. This is supported by the reduction in the percentage of non-classical monocytes and the plasma level of sCD14 observed. Moreover, the absence of fluctuations in other inflammation-linked or neuronal damage biomarkers may suggest the safety of LA-CAB/RPV on neurocognitive impairment in PWH. The value of these plasma biomarkers as prognostic pseudomarkers of the effect of LA-CAB/RPV on neurocognitive impairment in PWH should be evaluated in larger longitudinal studies including cognitive tests.

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Defining immune correlates in the context of ART and vaccination

OC 14 CHANGES IN CD8+ T-CELL ACTIVATION AFTER SWITCHING FROM SUPPRESSIVE 3-DRUG TO 2-DRUG CART IN PEOPLE WITH HIV

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Background: Two drug regimens (2DRs) are used in switching strategies in people with HIV (PWH), however, whether they affect CD8+ T-cell activation, marker of disease progression, is unclear. We explored the changes of peripheral T-cell counts and CD8+CD38+ T-cell percentages in PWH switching from 3DR to 2DR.
Materials and Methods: Retrospective study in PWH with HIV RNA levels < 50 copies/mL during 3DR cART, who switched to any combination of 2DRs. Data were retrieved from the electronic database at 1 HIV centre in northern Italy. Median values of two consecutive measurements of CD4+ and CD8+ T cells profile (6 month-1 year apart), taken before and after the switch to 2DRs (6 month-1 year apart), were compared. The determination of CD4+ and CD8+ T-lymphocyte counts as well as the percentage of activated CD8+CD38+ cells was performed by automated flow cytometry carried out on fresh peripheral blood. Data were analyzed by Wilcoxon test.
Results: A total of 266 PWH on suppressive 3DR were included: 103 switched to 3TC-DTG, 67 to DTG-RPV and 96 to RPV-DRV. Male sex was predominant, with 71 (69%), 56 (83%) and 77 (80%) men included in each 2DR treatment group, respectively. The median age of participants was 53 (IQR 48-61), 54 (IQR 47-59) and 57 (IQR 50 -63). Overall, switching to 2DR, did not change CD4 T-cell counts (801/uL, IQR 577-1024 vs 818/uL, IQR 593-1058; p=0.06) nor the CD4/CD8 ratio (0.90, IQR 0.59-1.20 vs 0.91, IQR 0.62-1.21; p=0.002), yet led to an increase in activated CD8+ cells (14.7%, IQR 8.6-23 vs 17.3%, IQR 10.7-26.1; p<0.001) (Fig 1A,B). However, differential kinetics in T-cell parameters were observed according to the dual drug regimen which was started. In people introducing 3TC-DTG, we found an improvement in CD4 counts (829/uL, IQR 566-1111 vs 924/uL, IQR 586-1178; p=0.01) vis-à-vis comparable CD8+CD38+ percentages over time (20.3%, IQR 14.1-26.7 vs 22%, IQR 15.3-31.1; p=0.05) (Fig 1 C, D). In contrast, in the DTG-RPV group, CD4 counts were unmodified (750/uL, IQR 579-1113 vs 804/uL, IQR 610 -978; p=0.58), yet CD8 activation increased (19%, IQR 10.5-32.1 vs 21.6%, IQR 16-31.5; p=0.01) (Fig 1E, F). A similar trend was also observed in individuals starting RPV-DRV, in whom CD4 counts were stable (780/uL, IQR 573 -992 vs 747/uL, IQR 560-958; p=0.8) and activated CD8+ T-cells rose (8.3%, 5.9-12.7 vs 10.8%, IQR 7.7-15; p<0.001) after cART change (Fig 1G, H).
Conclusions: Switching from 3DR to 2DR in virologically-suppressed subjects may exert a differential effect on T-cell homeostasis, according to cART composition. While 3TC-DTG may have a neutral effect on CD8+ T-cell activation, RPV- and DRV-based regimens may have an unfavourable outcome. Given the observational nature of the study, we cannot rule out confounders in the data analysis. Nonetheless, studies need to address the mechanisms by which different cART regimens may impact T-cell homeostasis, allowing for tailored approaches to contrast disease progression in PWH.

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Defining immune correlates in the context of ART and vaccination

OC 15 IMPACT OF LONG-ACTING THERAPY AND CMV-COINFECTION ON IMMUNE ACTIVATION AND SENESCENCE IN PEOPLE WITH HIV(PWH) SWITCHING TO LONG-ACTING INJECTABLE CABOTEGRAVIR PLUS RILPIVIRINE

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Background: Despite effective ART, HIV infection remains a chronic condition, characterized by a persistent inflammation and immune activation. Currently, there is limited evidence comparing the role of different therapies in this context. Long-acting (LA) formulations may better bioavailability and modulate the immunoinflammatory state associated with the disease. For this reason, we provide an analysis of the dynamic changes in the lymphoid immune activation and senescence markers in PWH switching to LA injectable ART (CAB/RPV), compared to a PWH on oral ART. Furthermore, relationship between CMV-specific immune responses and phenotypic T-cell alterations were evaluated.

Methods: An evaluation of immune activation (CD38+HLA-DR+) and T-cell senescence (CD28-CD57+) was performed before CAB/RPV (T0), at 4 (T4), 28 (T28), 48 (T48) and after 72(T72) weeks of follow-up. Each time point was compared with the control group (CG) of PWH on daily oral ART at both T0 and T48. Furthermore, specific CMV immune responses were assessed.

Results: A total of 57 PWH were recruited. The demographics are represented in Table 1. All parameters were assessed at baseline. Overall, in PWH switching to CAB/RPV LA, a non-significant increase in CD4 is observed over time with a higher percentage of CD4 than CG, while the percentage of CD8 remains stable. In PWH switching to CAB/RPV LA, the CD4 immune activation status declines, with a significant reduction at T48 and T72 compared to T0($p=0.0350$ and $p<0.0016$, respectively), while the CD8 immune activation remains stable over-time. The cross-sectional evaluation of CD4(CD38+HLA-DR+) showed a lower percentage in PWH switching to CAB/RPV LA compared to GC at T48($p=0.0079$). Concerning the immune senescent T-cell phenotype, an overall reduction over-time is observed in both CD4 and CD8 compartments, with significantly lower CD8(CD28-CD57+) in PWH switching to CAB/RPV LA compared to CG at T48 ($p=0.0044$). Regarding CMV immune response, anti-CMV antibody levels remain stable over time, while T-cell specific responses return to baseline levels at T48 after an increase at T28. Regarding CMV immune response, anti-CMV antibody levels remain stable over time, while T-cell specific responses return to baseline levels at T48 after an increase at T28.

Conclusion: CAB/RPV LA is not only effective in controlling viral load, but also in maintaining a healthy and stable immune profile. Specifically, it appears to offer several benefits in possibly reducing immune activation and slowing immune senescence. CMV-specific T-cell responses initially increased at T28 but returned to baseline at T48, suggesting long-term immune balance. However, CMV-coinfection remains a challenge for HIV treatment optimization. Further studies should explore the long-term impact of CAB/RPV LA on immune activation and senescence to enhance treatment strategies and outcomes for individuals undergoing treatment.

Figure 1

Figure 2

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Defining immune correlates in the context of ART and vaccination

OC 16 LONG-LASTING IMMUNITY: SMALLPOX-SPECIFIC T CELLS SHOW DISTINCT MEMORY TRAITS COMPARED TO SARS-COV-2 T CELLS

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Introduction: The memory of adaptive immune system cells plays a crucial role in protecting against pathogens, with vaccines relying on the induction of long-lasting memory responses. The effectiveness and duration of immunity are largely determined by the quality and quantity of these responses. Although smallpox vaccination was discontinued in the late 1970s, immunity against vaccinia virus has been shown to persist for up to 88 years. However, there is a lack of detailed data on the characteristics of these long-lived memory cells.
Objectives: This cross-sectional study aimed to identify and characterize smallpox-specific memory T cells in individuals vaccinated before the 1970s and compare their features with those of memory cells generated following SARS-CoV-2 vaccination.
Methods: We enrolled 25 individuals (boomers; mean age 68 ± 8.5 years) and 16 individuals (centenarians; mean age 97 ± 5.5 years). Using an activation-induced marker assay, we identified antigen-specific T cells following stimulation with either the Wuhan SARS-CoV-2 Spike glycoprotein or a vaccinia peptide pool. These cells were then characterized based on their phenotype and transcriptome using 21-parameter flow cytometry and single-cell total RNA sequencing (VASA-seq), respectively.
Results: The transcriptome of smallpox-specific T cells revealed a gene signature indicative of memory cells with stem-like properties (e.g., LEF1, IGFR1, TCF7, CD27, BACH2), along with a metabolic gene signature associated with oxidative phosphorylation. In contrast, SARS-CoV-2-specific T cells exhibited a gene signature of SLAMF1, LAG3, SELPG, CD74, PRF1, and IRF, primarily relying on glycolysis. Phenotypically, smallpox-specific CD4+ T cells were predominantly skewed toward a central memory Th0-2 phenotype, with fewer naïve and transitional memory Th1-17 PD1+ cells. This trend was more pronounced in centenarians. While centenarians showed a low percentage of SARS-CoV-2-specific CD8+ T cells, they retained smallpox-specific CD8+ T cells with a resting memory phenotype. TCR clonotype analysis revealed that boomers and centenarians shared only a few TCR clones for both SARS-CoV-2 and smallpox. Notably, centenarians exhibited a lower frequency of small clonotypes, particularly among smallpox-specific T cells, compared to boomers.
Conclusion: These findings provide the first evidence that the longevity of smallpox-specific T cells, even decades after vaccination, is driven by distinct transcriptional and metabolic programs.

Defining immune correlates in the context of ART and vaccination

OC 17 TWO-YEAR NEUTRALIZING AND T-CELL RESPONSE AFTER MVA-BN VACCINATION ACCORDING TO HIV INFECTION AND CD4 CELL COUNT

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Background: The current mpox resurgence raised the question of the residual immune protection conferred by the MVA-BN vaccination received during the 2022 outbreak. Available data on long-term immune response after MVA-BN are scarce, especially in PWH with low CD4 count, who are at high risk of severe and prolonged mpox and a possible impaired vaccine immune response. We described humoral, and T-cell immune responses elicited up to two years from MVA-BN vaccination, stratifying results according to HIV infection and CD4 count to provide elements to establish the need for a vaccine boost.

Methods: Blood samples from people receiving a primary two-dose course of MVA-BN were prospectively collected at the time of each dose administration (T1-T2) and then after 1 (T3), 6 (T4), 12 (T5) and 24 (T6) months. Neutralizing antibodies (nAbs) were assessed by a 50% plaque reduction neutralization test and interferon-γ producing MVA-BN specific T-cells by ELISpot assay. Data at T6 were stratified according to HIV infection and CD4 count (<350 and >350). Kruskal-Wallis with Dunn tests, Wilcoxon, and Mann-Whitney tests were used for statistics.

Results: All the 40 people enrolled were males, reported to be MSM, with a median age of 41.5 years (IQR 35-45). All participants were not primed for smallpox during childhood (vaccine-naïve). Among the 20 (50%) PWH, 9 (45%) had a CD4 count <350 mmc.

After peaking one month from vaccination, nAb titers progressively dropped in the following time points, with less than 25% of sera reactive at two years (T6).

The MVA-BN-specific T-cell response raised early after vaccination, remained stable until one year, and significantly decreased at two years (p=0.02). At two years, no evidence for a difference was detected between PWoH and PWH with CD4 count <350 or >350, both for cellular and neutralizing response (figure 1).

Conclusions: Two years after receiving MVA-BN, regardless of HIV infection and CD4 count, a poor neutralizing response was detected, while T-cell response persisted despite being substantially diminished. A booster MVA-BN dose at least two years after the primary cycle seems necessary both to reactivate the humoral response and recall the residual cellular response, accounting for most of the clinical protection observed so far.

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Defining immune correlates in the context of ART and vaccination

OC 18 ASSESSMENT OF THE SPECIFIC CELLULAR IMMUNE RESPONSE TO THE RECOMBINANT HERPES ZOSTER VACCINE IN PEOPLE LIVING WITH HIV

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GSK was provided with the opportunity to review a preliminary version of this abstract for factual accuracy, but the authors are solely responsible for the final content and interpretation.

Background: Herpes zoster (HZ) occurs more frequently in people living with HIV (PLWH) compared to the general population. An adjuvanted recombinant HZ vaccine was approved in the European Union in 2018 for patients at high risk of HZ. This study aims to evaluate the specific cell-mediated immunity (CMI) for VZV glycoprotein (g)E in PLWH.

Methods: Starting from February 2024, two-dose Shingrix regimen 2 months apart was administered to adult PLWH. Blood samples were collected at T0 (before the first dose) and T2 (one month after the second dose). CMI was assessed with an Interferon (IFN)-gamma release assay (IGRA) after overnight stimulation of heparin whole blood with gE peptide libraries (PL)-1 (provided by GSK) and -2 (purchased from JPT Peptide Technologies GmbH, Germany). IFN-gamma was measured in supernatant using ELLA. The study was approved by the local Ethics Committee (N. 115.23). Data are represented as medians (interquartile ranges). Differences between groups were assessed using the Wilcoxon or the Mann-Whitney test, as appropriate. Correlation was assessed with the Spearman correlation test or the Pearson test, as appropriate. The study is registered in a public clinical study registry (ISRCTN15045512).

Results: A total of 86 PLWH have been enrolled. An interim analysis was conducted analyzing the first 36 PLWH for whom T2 samples were available (Table 1). A statistically significant increase in IFN-γ production from T0 to T2 was observed after stimulation with gE PL-1 and 2 (Figure 1) ($p<0.001$). At both T0 and T2, IFN-γ production after stimulation with gE PL-1 and -2 were positively correlated (Figure 2) ($p=0.02$ and $p<0.0001$, respectively). At T2, lower IFN-γ production after gE PL-1 and -2 stimulation was observed in PLWH with current CD4 cell count <350 cells/µl and nadir CD4 cell counts <200 cells/µl (Figure 3). Furthermore, IFN-γ production was positively correlated with both nadir and current CD4 counts. Additionally, IFN-γ production following stimulation with gE PL-2, positively correlated with CD8 cell count (Table 2).

Conclusions: Preliminary data suggest that CMI to HZ recombinant vaccine in PLWH is influenced by patient's current and nadir CD4 count. Notably, a previous severe immune impairment, even if current CD4 cell count is recovered, seems to reduce CMI after HZ vaccination.

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Optimizing HIV infection management in Italian clinical practice

OC 19 EFFECTIVENESS OF SWITCHING TO BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE FROM NNRTI-BASED ART IN VIROLOGICALLY SUPPRESSED HIV-PATIENTS: A RETROSPECTIVE ANALYSIS (DRIVE-SWITCH STUDY)

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Background: Large real-world data in people with HIV (PWH) who switched from non-nucleoside reverse transcriptase inhibitor (NNRTI), especially from rilpivirine (RPV) to bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) is currently lacking. The aim of the study is to conduct a real-world assessment of the effectiveness of BIC/FTC/TAF in virologically suppressed PWH switched from NNRTI-based regimens.
Methods: Study design: single center retrospective study conducted at INMI L. Spallanzani IRCCS. Main inclusion criteria: PWH aged >= 18 years, virologically suppressed on stable regimen with NNRTI + 2NRTI.
Primary endpoint: proportion of PWH with HIV-RNA < 50 cp/ml at 12 months from baseline (BL, time of switch to BIC/FTC/TAF) overall and by NNRTI therapy. Secondary endpoints: change in CD4+ T cell count at 12 months, cumulative proportion of PWH with protocol defined virological failure (VF, 2 consecutive HIV-RNA ≥50 cp/mL or a single HIV-RNA >1,000 cp/mL).
Follow-up (FU) was censored at 12 months.
Results: Overall, 250 PWH were included, all with HIV-RNA < 50 cp/ml at BL: median age 59 years (interquartile range, IQR 51-65); 65 (26%) females at birth, 213 (85%) Italian natives, 18 (7.2%) HBsAg positive, 41 (16.4%) HCV-Ab positive, 40 (16%) with previous AIDS diagnosis, 18 years (IQR 13-24) since HIV diagnosis, CD4+ at BL were 675 (IQR 515-853) and CD4/CD8 1 (IQR 0.74-1.41). 141 (56%) PWH out of 250 switched from RPV/FTC/TAF, 7 (2.8%) from RPV/FTC/TDF, 96 (38.4%) from EFV/FTC/TDF, 3 (1.2%) from NVP+TDF/FTC, 2 (0.8%) from DOR/3TC/TDF, 1 (0.4%) from NVP+TAF/FTC. 187 PWH of the overall population had available data 12 months after BL.
At 12 months, 139/187 (74.3%) PWH had HIV-1 RNA < 50 cp/mL, 41/187 (21.9%) had no viral load measurement in window, 7/187 (3.7%) had HIV-1 RNA >= 50 cp/mL. Considering PWH with viral load available at 12 months, 139/146 (95.2%) had HIV-1 RNA < 50 cp/mL.
A total of 4 (1.6%) treatment discontinuations occurred: 1 for mood disorder, 1 for insomnia, 1 for pregnancy, 1 for epigastric pain; all of them had HIV-RNA<50 cp/ml at last determination pre-switch.
Only one PWH fulfilled the definition of VF while on BIC/TAF/FTC (HIV-RNA 5,700 cp/ml, due to lack of adherence) and no resistance mutations for NRTI or integrase inhibitors were detected at the historical genotype nor at genotype performed while on failure.
Considering only PWH switched from RPV/TAF/FTC, 51/79 (64.6%) PWH had HIV-1 RNA < 50 cp/mL, 25/79 (31.6%) had no viral load measurement in window, 3/79 (3.8%) had HIV-1 RNA >= 50 cp/mL at 12 months. Considering PWH switched from RPV/TAF/FTC with viral load available at 12 months, 51/54 (94.4%) had HIV-1 RNA < 50 cp/mL.
At 12 months, the mean CD4+ variation from BL was +52 cells/mmc (SE ±13) in the overall population.
Conclusions: High virological efficacy of BIC/TAF/FTC in the switch from NNRTI regimens was demonstrated. Treatment discontinuations were rare events.

Optimizing HIV infection management in Italian clinical practice

OC 20 SWITCHING TO BICTEGRAVIR IN ELDERLY PEOPLE LIVING WITH HIV-1 UNDER VIROLOGIC CONTROL: WEEK 144 RESULTS FROM THE BICTEL COHORT

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Background: The antiretroviral (ART) regimen based on bictegravir/emtricitabine/tenofovir alafenamide fumarate (BIC/FTC/TAF) is available as single tablet for both naïve and experienced people living with HIV (PWH). Data from real-life at week 144 (w144) are limited, especially among elderly PWH.

Methods: We present an interim data analysis at w144 from the BICTEL cohort, a real life observational retrospective cohort of PWH after switching to BIC/F/TAF, focusing on PWH >55years. Only ART-experienced PWH with HIV-RNA < 50 copies/mL have been included in this analysis. The primary objective was virologic efficacy, as assessed through the FDA snapshot algorithm. Secondary objectives were safety of the regimen, as well as immune and metabolic changes along time.

Data are shown as median values (interquartile range - IQR) and simple frequencies (proportions - %). Longitudinal analysis was assessed by the Friedman test, with Wilcoxon test for pair-wise comparisons between baseline (BL), week 48 (w48), week 96 (w96) and w144. p-value <0.05 was considered statistically significant, with false discovery rate (FDR) correction for multiple comparisons. All data were analyzed using RStudio (Version 1.3.1056, 2009-2020 RStudio, PBC).

Results: By March 2025, 180 PWH were enrolled into the cohort and 94 were >55years (Table 1). Overall, 118 have completed the 144 weeks follow-up, whose 53 were >55years. At the per-protocol analysis, virological control was maintained in 110 (93.2%; CI: 87.1% - 97.0%), with comparable results among 49 PLWH >55years (90.7%; CI: 79.7% - 96.9%) (Fig.1).

We witnessed an improvement of the immune profile throughout follow-up, as shown by the progressive and durable increase observed in CD4+ T lymphocytes count (BL: 690 [510-880]; w144: 790 [540-1000]; p: <0.001) and CD4 +/CD8+ ratio (BL: 0.96 [0.62-1.3]; w144: 1.0 [0.62-1.5]; p: <0.001) (Fig. 2). For what concerns metabolic values, as depicted in Fig. 3, the lipid profile improved with a decrease in triglycerides(BL: 110 [81-150]; w144: 90 [73-140]; p: <0.001), even if not accompanied by changes in cholesterol. Moreover, fluctuations of body weight and BMI observed previously between BL and other timepoints were not confirmed at w144 compared to BL. Despite the hepatic safety of the regimen, a decrease in the esteemed glomerular filtrate rate has been recorded (BL: 85 [74-100]]; w144: 80 [71-98]; p: 0.01), even if renal function remained stable after the switch without further reductions over w48 (w144 versus w48 and w96; p: 0.933). The above-mentioned results have been confirmed among PWH >55years.

Conclusions: BIC/FTC/TAF is an effective and safe single tablet regimen, also among PLWH > 55 years. The positive effect on the immune markers is promising, especially for elderly PWH among whom frailty is a concern. Further studies are needed to explore long-term exposure on renal function of PWH.

The project has been partially supported by a Gilead Sciences Medical grant.

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Optimizing HIV infection management in Italian clinical practice

OC 21 EFFECTIVENESS AND SAFETY OF SWITCHING TO BIC/FTC/TAF IN SECOND, THIRD AND LATER LINES OF THERAPY IN VIROLOGICALLY SUPPRESSED PEOPLE LIVING WITH HIV (PWH) ON ANY ARV-REGIMENS INCLUDING NNRTIS: A RETROSPECTIVE ANALYSIS (ESSENTIAL STUDY)

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Background: Switching antiretroviral treatment (ART) in the setting of HIV suppression may improve pill burden, dosing frequency, safety, tolerability, and/or food requirements. Real-life data on effectiveness and safety of bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in virologically suppressed (VS) people living with HIV (PWH) as second, third, and subsequent line of treatment in clinical practice from any regimen including non-nucleoside reverse transcriptase inhibitors (NNRTIs) are needed.
Methods: This is a single-site retrospective study in VS (HIV-RNA <50 copies/mL ≥3 months) PWH aged ≥ 18 years switched to BIC/FTC/TAF in clinical practice at ASST Fatebenefratelli Ospedale Luigi Sacco between July 2019 and February 2024 (Database freezing February 2025). Demographic, clinical and immune-virological characteristics were collected at the time of the switch and at 6 and 12 months thereafter. The primary objective of the study is to assess the effectiveness of BIC/FTC/TAF in virologically suppressed PWH at 6 and 12 months after the switch, based on an observed analysis. The secondary objectives were reasons of switch to BIC/FTC/TAF, changes in CD4 and CD8 at 6 and 12 months, and rate of virological failure (2 consecutive HIV-RNA >50 copies/mL or a single HIV-RNA >1,000 copies/mL). Virological suppression rates and 95% CI were estimated using the Wald asymptotic method.
Results: Five-hundred PWH were included in the analysis. Characteristics of the study population at the time of the switch to BIC/FTC/TAF are reported in Table 1. PWH were frequently male (332, 66.4%), Italian born (399, 80.3%), with a median age of 54 years [IQR 47, 59], and most had ≥1 comorbidity (419, 83.8%). The median CD4 cell count at the time of the switch was 705 cell/mm3 [IQR 503, 903]. Reason of switch to BIC/FTC/TAF are depicted in Figure 1 and regimens before the switch (including out-dated regimens) in Figure 2. The virological suppression rate at 6 and 12 months was 97.9% (95% CI 96.6%-99.2%) (observed 459/469) and 98.2% (95% CI 97.0%-99.4%) (observed 443/451), respectively. The virological failure rate was 1.2% (95% CI 0.3%-2.2%) at 6 months and 0.6% (95% CI 0.0%-1.4%) at 12 months. The discontinuation rate for any reason at 6 months was 6.2% (95% CI 4.1% - 8.3%) (observed 31/500) and between 6 and 12 months was 3.8% (95% CI 2.1% - 5.6%) (observed 18/469). Reasons of discontinuations are reported in Figure 3. Median CD4 cell count at 6 and 12 months were 713 cell/mm3 [IQR 517 -893] and 727 cell/mm3 [543-931], respectively. Seven (1.4%) and 2 (0.4%) individuals experienced adverse events at 6 and 12 months, respectively.
Conclusions: In a VS population of PWH with a high burden of comorbidities, BIC/FTC/TAF demonstrated excellent virological suppression rates (98% at 12 months) following the switch, with few drug-related discontinuations.
Disclaimer: ESSENTIAL Study (GS-IT-380-7059) is sponsored by Gilead Sciences.

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From virus variability to disease and treatment

OC 22 EVALUATION OF GENETIC VARIABILITY AND RESISTANCE PROFILE IN HIGHLY TREATMENT-EXPERIENCED PEOPLE WITH HIV-1 WITH MULTI-DRUG RESISTANCE ENROLLED IN THE PRESTIGIO REGISTRY TREATED WITH LENACAPAVIR

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Background: Lenacapavir (LEN), the first-in-class HIV-1 capsid (CA) inhibitor, was recently approved for highly treatment-experienced (HTE) people with HIV and multidrug resistance (MDR). Resistance-associated mutations in HIV-1 have been reported for LEN. We evaluated the resistance profile and the genetic evolution of the CA region in HTE individuals with MDR treated with LEN in the Italian PRESTIGIO Registry.

Materials and Methods: Plasma and PBMC samples from nine HTE with MDR were collected before LEN switch (T0, when available) and during LEN treatment (T1) from the PRESTIGIO biobank. Next-generation sequencing (NGS) of CA, PR/RT and IN regions was performed using MiSeq Illumina platform. Resistance to LEN, PIs, RTIs, and INSTIs was evaluated using the HIVDB Program v.9.8. Intra-patient p-distance, estimated by MEGA11, was used to assess the HIV-1 DNA genetic variability over time and the genetic differences between HIV-1 DNA and RNA.

Results: Participants were treated with LEN for a median of 20 months [IQR 19-24] (Table 1). At T0, no major LEN resistance mutations were detected in plasma or PBMCs. One participant harboured the CA accessory mutation T107A as a minority variant (5.9%) in PBMCs, with a minimal genetic variability compared to plasma compartment in the CA region (p-distance= 0.005 [SE:0.002]). In two participants who started treatment with plasma HIV-1 RNA <50 cps/mL and maintained virological control, no intra-patient evolution in PBMCs over time (after about 20 months) was found (p-distance=0.000). Seven participants started LEN during virological failure (median HIV-1 RNA 2,010 [IQR 763-24,400] cps/mL). Among them, five achieved virological suppression with a genetic variability over time in PR/RT regions (mean p-distance=0.053 [SE:0.006]) but not in CA and IN (p-distance=0.000). A participant achieved virological suppression showing a viral blip (52 cps/mL), with the presence of Q67K mutation (5.7%) at T1 in plasma only (Table 2), and a genetic variability between plasma and PBMCs at T1 in CA (p-distance of 0.040 [SE:0.008]) and PR/RT (0.050 [SE:0.006]). The only participant with persistent viremia (HIV-1 RNA 39,400 cps/mL) at 28 months under LEN harboured the primary mutations K70H (97.8% in plasma, 75.6% in PBMCs) and Q67K (98.5% in plasma, 75.7% in PBMCs) (Table 2); however, no evolutionary divergence was found in the CA region (p-distance=0.000 between plasma and PBMCs) at T1, while a genetic variability was found in PR/RT (p-distance=0.057 [SE:0.007]).

Conclusions: In this small cohort of HTE people with MDR, LEN was associated with maintenance or achievement of virological suppression, with one participant remaining viraemic and harbouring LEN-resistant variants, however without evolutionary diversity in the CA region between plasma and PBMCs. A genetic stability of CA and IN regions was found over time. By contrast, PR/RT regions showed a continuous ongoing evolutionary pressure over time and between plasma and PBMCs.

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From virus variability to disease and treatment

OC 23 EVALUATION OF THE VIRAL RESERVOIR IN VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV TREATED WITH LA CABOTEGRAVIR + RILPIVIRINE REGIMEN

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Background: Despite the availability of data from clinical trials that led to the approval of Long-Acting Cabotegravir and Rilpivirine (LA CAB+RPV), the effectiveness of this regimen on HIV burden needs to be determined in real-life settings. We aimed to assess the archived resistance profile before LA CAB+RPV switch and the impact of this regimen on the total HIV-1 DNA levels after 13 months of treatment.

Material and Methods: This study included 36 virologically suppressed people with HIV who switched to LA CAB +RPV at the Infectious Diseases Unit of the University of Foggia. Whole blood samples were collected before switch (baseline, BL) and after 13 months of treatment (M13). Archived resistance was evaluated through Next-Generation Sequencing (NGS) on the Illumina® MiSeq platform. NGS data were analysed using the HIVdb algorithm (v. 9.8), with NGS cut-off set at 10% and 20%. Total HIV-1 DNA levels were quantified using Real-time PCR on the ELITe InGenius instrument. Differences in HIV-1 DNA levels between BL and M13 were assessed using the Wilcoxon signed-rank test.

Results: At BL, participants had been on virological suppression for a median of 8.5 years (IQR: 5.8-12.3) (Table 1). HIV-1 DNA NGS data were successfully obtained for NNRTI and INSTI in 35 and 33 individuals, respectively. By setting HIV-1 DNA NGS cut-offs at 10% and 20%, archived NNRTI major mutations were detected in 12/35 (34.3%) and 7/35 (20%) people, respectively (Fig.1), and major RPV-related mutations were found in 10/35 (28.6%) and 5/35 (14.3%), respectively. Of note, using the 2 cut-offs, 9 (25.7%) and 4 (11.4%) participants harboured RPV APOBEC-context mutations E138K and/or M230I. Archived major INSTI mutations were detected in 4/33 (12.1%) and 2/33 (6.1%) individuals at NGS set at 10% and 20%, respectively. Mutations found were G140R, E138K and G140S, all CAB-related and APOBEC-context mutations. The overall BL median (IQR) genotypic susceptibility score was 1(1-1), indicating full susceptibility to LA CAB+RPV. Two participants failed treatment during the period of observation; any of them harboured archived RPV or CAB mutations, tough NNRTI mutations were detected in the historical GRT (L100I, K103N, P225H) of one participant, and in the BL HIV-1 DNA NGS of the other one (K103T and V106I, as majority variants). Regarding the evaluation of the HIV-1 reservoir, the median (IQR) total HIV-1 DNA levels were 3.5 (2.7-3.9) and 3.7 (2.8-3.9) log10/106 CD4 cells at BL and M13, respectively. No significant difference was found in HIV-1 DNA levels between BL and M13 (median [IQR]: 0.03 (-0.1; 0.2) log10 copies/106 CD4 cells, p=0.324) (Fig.2).

Conclusions: In our study, a considerable proportion of individuals who started LA CAB+RPV harboured archived mutations for RPV and/or CAB (both as majority and minority mutations); however, most were APOBEC-context mutations with negligible clinical impact. After 13 months of treatment, LA CAB+RPV did not impact the total HIV-1 DNA levels.

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From virus variability to disease and treatment

OC 24 AN INCREASED GENETIC VARIABILITY CHARACTERISES HDV SUB-GENOTYPES 1 AND CAN DRIVE THE SELECTION OF DIVERGENT GENETIC PATHWAYS MODULATING HDV REPLICATIVE POTENTIAL AND CYTOLYTIC ACTIVITY

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Background: Limited information is available on the extent of HDV genetic diversification in ribozyme (critical for HDV replication) and HDAg domains (crucial for viral morphogenesis and containing cytotoxic T lymphocytes epitopes [CTLE]) and their correlation with virological and biochemical parameters.

Methods: 103 individuals with chronic HDV infection were included. Full-length HDV genome sequences were obtained by Illumina (median [IQR] reads/seq: 62045[30460-91899]). Sub-genotypes 1 were defined by phylogenetic analysis. Amino acid (aa) residues were defined conserved if not mutated in 99% of sequences. HDAg domains and CTLE (N=18) were defined according to Pascarella 2010 and Kohsar 2021.

Results: Individuals were mostly males with a median age of 54 (44-60) years, mainly from Eastern Europe (EE,51%) and Italy (IT,44.8%). Serum HDV-RNA and ALT were 5.6 (4.9-6.2)logIU/ml and 94 (65-152)U/L. Sub-genotypes 1c and 1e were the most prevalent (47.1% and 45.2%): 1c predominated in individuals from EE(77.6% vs 22.4%,P<0.001) while 1e in IT(77.5% vs 22.5%,P<0.001).

HDV ribozyme was characterised by a high degree of genetic conservation. An opposite scenario was observed for HDAg in which the number of conserved aa in HDAg dropped to 36.7% (79/214), with 18.2% in coiled coil sequence (CCS), 27.3% RNA binding domain (RDB)2, 30.8% in RBD1, 33.3% in nuclear localization sequence (NLS), 40% in virus assembly signal (VAS) and 63.3% in RBD3. The degree of genetic conservation of CTLEs ranges from 11.1% in CTLEs 46-54 and 43-51 to 60.0% in 140-149.

Notably, CTLE 170-179 from individuals with HDV-RNA >5logIU/ml (70% of conserved aa with vs 20% without HDV-RNA <5 logIU/ml, P=0.025) showed lower genetic conservation, suggesting that an enrichment of mutations in this CTLE can enhance viral replication.

Finally, despite a comparable degree of genetic conservation between sub-genotypes 1e and 1c, they were characterized by divergent genetic pathways. In particular, sub-genotype 1c was significantly associated with the selection of 7 specific mutations (I16T/V, N22S, D47E, R112K, T180A, A202S, prevalence ranging from 26.5% to 44.9% vs 0% in 1e, P<0.001). Conversely, sub-genotype 1e was significantly associated with the selection of 6 specific mutations (D29E, D46E, K113R, R131K, M171L, I188V prevalence ranging from 23.9% to 43.5% vs 0% in 1c, P<0.009). Notably, in sub-genotype 1c, the co-presence of I16V/T+D47E+A202S correlated with ALT>3ULN (100% vs 27.5%, P=0.001)

Conclusion: Sub-genotypes 1 are characterized by a conspicuous degree of genetic diversification in HDAg that has contributed to the selection of divergent genetic signatures. The enrichment of mutations in specific CTL epitopes could potentially hamper HDV recognition by immune response and in turn enhancing viral replication.

Overall, the role of the high degree of genetic variability in affecting the proper HDV detection by the currently available diagnostic assays deserves further investigation.

From virus variability to disease and treatment

OC 25 EVALUATION OF THE SARS-COV-2 VIRUS GENETIC BARRIER TO REMDESIVIR AND NIRMATRELVIR IN VITRO AND IN VIVO

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Introduction: Remdesivir (RDV) and Nirmatrelvir (NRM) are direct-acting antivirals (DAAs) for early SARS-CoV-2 treatment. Both show high resistance barriers, with few in vitro mutations and rare in vivo cases. This study assesses in vivo resistance emergence post-DAA treatment and the in vitro genetic barrier of B.1 and KP.3 Omicron variants to RDV and/or NRM.

Materials and Methods: Seventy-one paired swabs were collected (Mar-2022–Sept-2024) from 66 and 5 subjects treated with RDV and NRM, respectively, at baseline (T0) and post-treatment (T1, 5 [4-6] days). Cases with Ct ≤29 at both time points underwent full-length NGS (Illumina COVID-Seq, 5% threshold). Emerging mutations (>5% to >20%) were identified via Stanford CoV-DB. In vitro antiviral activity (IC50) was tested in VERO-E6 using a live virus assay. Resistance selection (IVRS) experiments were performed with KP.3 and B.1 under increasing drug concentrations (2-fold IC50) until no viral breakthrough was observed for 3 weeks.

Results: The median age of the participants was 79 years [68-85], 48% were female and 88% had a median of 3 [2 -4] comorbidities. Sixty-eight subjects were hospitalized and 79% needed oxygen support; 2 patients died. The longitudinal analysis included 20 subjects with Ct ≤ 29 (20±4 and 26±3 Ct at T0 and T1 respectively), most harboring XBB and BA.2.86 variants. No amino acid variations were observed in the spike region and in 3CL-Protease. Two distinct mutations emerged in 2 subjects treated with RDV reaching >20% of prevalence (V792VI: V/I = 50/49% and M794MI: M/I =60/40%; sample 31 and 6 respectively). While the role of M794I was not previously characterized, V792I is reported as a resistance mutation in vitro and anecdotally in vivo. In vitro, B.1 and KP.3 showed a mean µM IC50 of 0.04±0.01 (RDV), 0.07±0.02 (NRM) and 0.07±0.01 (RDV), 0.15±0.05 (NRM), respectively. B.1 replication was observed up to 128-fold IC50 with each individual drug (20±4 days post infection [DPI]). KP.3 replication was observed up to 73-fold (21 DPI and still ongoing) in one RDV IVRS but was arrested at 9-fold IC50 in the second one (11 DPI) and at 11±5 fold IC50 in both NRM IVRS (11±1 DPI). Both KP3 and B.1 IVRS were arrested at 11±6-fold IC50 with combined RDV+NRM (9±3 days DPI). SARS-CoV-2 sequencing is ongoing to evaluate possible emergent resistance in all IVRS experiments.

Conclusions: In vitro, KP.3 seems less prone to viral breakthroughs under DAA pressure compared with B.1. However, the combination of RDV+NRM strongly inhibits viral replication with both viruses. In vivo study, emergent genotypic resistance to DAAs appears to be a rare event, with only one case detected in 18 subjects treated with RDV. Inclusion of further subjects in the study population, particularly immunosuppressed individuals with prolonged infection may help to better define the impact of resistance mutations against DAAs.

From virus variability to disease and treatment

OC 26 WHOLE GENOME SEQUENCING OF ADENOVIRUS GENOTYPES AND CLINICAL IMPLICATIONS IN PEDIATRIC PATIENTS

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Background: Human adenoviruses (HAdV) are classified into 116 genotypes grouped into seven species (A-G) with remarkable difference in term of tropism and species-specific immune-response. HAdVs cause a wide variety of clinical manifestations that can be severe in immunocompromised patients (pts).
The aim of our study was to characterize HAdV-species involved in pediatric infection, in order to understand their potential impact on disease progression and to guide towards the selection of therapies based on AdV-specific T-cell response.
Materials: From January-October 2024, 595 new HAdV diagnoses were performed in pediatric pts at the Bambino Gesù Children Hospital (Rome). Among them, 60 positive specimens (53 stool; 7 nasopharyngeal-swabs) were randomly selected for HAdV Whole-genome-sequencing (WGS) using Illumina-MiSeq.
Results: Among the 60 selected pts, 45 (75%) were immunocompetent with a median age of 1.4 years (IQR:0.74–2.61) and 15 (25%) were immunocompromised with a median age of 12.5 years (IQR:4.99–15.85). Most of them (55/60,91.5%) were hospitalized.
At HAdV diagnosis, gastrointestinal and respiratory symptoms were more prevalent in immunocompetent than immunocompromised pts (91.1% vs 72.7% and 53.3% vs 27.3%, respectively). However, the immunocompromised have shown a longer length of hospitalization and viral-infection ($p<0.001$).
Overall, the majority of HAdV (63.3%) belonged to species-F (specifically F41), followed by species-C (25%), -A (8.3%) and –B (3.3%). Moreover, a higher prevalence of genotype-F41 was observed in immunocompetent pts (75.6% vs 26.7%; $p=0.001$). Differently, immunocompromised pts had higher rates of species-A (26.7% vs 2.2%; $p=0.012$) and species-C (40% vs 20%; $p=0.169$), the latter already known to cause severe infections in children and immunocompromised pts.
Co-infections with other viruses and/or bacteria were detected in 63.3% (38/60) of pts. No significant difference between immunocompetent and immunocompromised pts (62.2% vs 66.6%, $p=1.000$) were observed. Species-C was predominantly detected in co-infections (73.3% vs 26.7% of mono-infections, $p= 0.027$). In contrast, the distribution of species-F was comparable between mono- and co-infections (55.2% vs 44.8%, $p = 0.492$).
Conclusions: Our results showed a different distribution of HAdV-strain between immunocompromised and immunocompetent patients. In particular, species-F was most prevalent in immunocompetent patients with gastrointestinal and respiratory symptoms. Otherwise HAdV species-C and species-A characterized immunocompromised patients.
A closer screening and the use of WGS will be essential in immunocompromised setting to anticipate the time of HAdV diagnosis and to improve HAdV surveillance. This study is a starting point, to identify which HAdV-genotypes are likely to be more severe, to identify specific genes that make a strain more harmful and to guide selection of an appropriate cell therapy.

Beyond viral suppression: rethinking quality of life in HIV care

OC 27 STIGMA EXPERIENCED BY PERSON WITH HIV/AIDS IN THE HEALTHCARE SETTINGS

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Background: Stigma and discrimination have a negative impact on people with HIV/AIDS (PWH), leading to anxiety, depression, social isolation, substance use and decreased adherence to treatment, ultimately reducing quality of life. Specifically, HIV-related stigma may occur in various social contexts, including healthcare settings. The aim of the study was to explore the prevalence and characteristics of HIV-related stigma among PWH across the Infectious Diseases Unit and other hospital settings.

Material and Methods: A cross-sectional, single-center survey was conducted among PWH between December 2024 and February 2025. Participants were invited to complete a self-administered, 10-item questionnaire adapted from two validated questionnaires comprising different aspects of perceived stigma, including access to care, quality of care, and inclusion in the healthcare environment (1-3). Descriptive statistics and multivariate logistic regression models have been used in order to assess factors associated with HIV-stigma

Results: 634 PWH participated in the study. 466 (73.5%) were male,156 (24.6%) females, 12 (1.9%) male to female; 570 (89.9%) Caucasian and 233 (36.8%) heterosexual; median age was 56 years (IQR 45-62). Demographic and clinical characteristics of participants are described in Table 1. Out of 634 individuals, 253 (39.9%) reported experiencing stigma in healthcare settings at least once. The perception of stigma was significantly lower in the Infectious Diseases Unit compared to other wards, with 59 cases versus 194 (P<0.001) (Table 2). Multivariate analysis revealed that being an intravenous drug user (IVDU) was associated with an increased risk of stigma perception within the Infectious Diseases Unit (p<0.037). Outside of this Unit, the perception of stigma in healthcare settings was significantly linked to the duration of HIV infection, indicating that a duration of less than 5 years resulted as a protective factor (p<0.001) (Table 3).

Conclusion: This survey indicates that HIV-related stigma in healthcare settings is still very present, especially outside of Infectious Diseases Unit. Of note, time since diagnosis has demonstrated to be an important determinant of stigma; it is likely that perceptions of infection have evolved in recent years. However, these findings underscores the urgent need of a multifaceted approach that combines education, training and supportive polices to fight HIV-related stigma within our hospital.

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Beyond viral suppression: rethinking quality of life in HIV care

OC 28 CHALLENGES IN MEASURING HEALTH-RELATED QUALITY OF LIFE AMONG ANTIRETROVIRAL THERAPY EXPERIENCED PEOPLE WITH HIV

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Background: Health-related quality of life (HR-QoL) should be routinely assessed in all people with HIV (PWH) as part of comprehensive HIV care, trying to achieve the fourth 90-goal. However, multiple barriers limit its collection in clinical settings. This study aimed to identify PWH whose HR-QoL status was unknown and to analyze the socio-demographic and clinical factors that may act as barriers to HR-QoL evaluation.
Methods: Cross-sectional study of antiretroviral therapy (ART)-experienced PWH receiving care at the Modena HIV Metabolic Clinic (MHMC) between November 2014 and February 2025. Participants were invited via email to complete an online HR-QoL questionnaire. Demographic, anthropometric, HIV-related, and other clinical characteristics were collected. Impaired neurocognitive function was defined as a Cogstate Global Deficit Score (GDS)≥0.5. Logistic regression models were created to identify factors associated with a higher likelihood of responding to the questionnaire.
Results: Among 3016 PWH, 2198 (72.9%) were male, with a median age of 56 years (IQR 50–61) and a median HIV duration of 24 years (IQR 15–31). Median nadir and current CD4 counts were 202 (IQR 85–322) and 722 (IQR 543–948) cells/μL, respectively. Overall, 2689 (89.2%) completed the questionnaire.
Table 1 summarizes the characteristics of respondents and non-respondents.
PWH who were older (56 vs. 54 years, p<0.01), male (73.5% vs. 67.9%, p<0.01), and had a longer duration of HIV infection (24 vs. 22 years, p<0.01) were more likely to complete the questionnaire.
In contrast, lower education levels (8 vs. 9 years, p=0.01), unhealthy lifestyles (current smoking 45% vs. 33%, p<0.01; lower physical activity 50% vs. 56%, p=0.05), higher visceral adipose tissue (VAT) (147 vs. 133 cm², p=0.042), higher ART pill burden (1.85 vs. 1.65, p<0.01), higher CD8 count (834 vs. 758, p<0.01), lower CD4/CD8 ratio (0.91 vs. 0.96, p<0.01), and impaired neurocognitive function (23.9% vs. 21.5%, p<0.01) were associated with non-response.
Multivariate logistic regression analysis (Table 2) showed that impaired neurocognitive function (OR 0.60, 95% CI 0.40–0.91, p=0.017), higher BMI (OR 0.93, 95% CI 0.89–0.97, p=0.001), active smoking (OR 0.50, 95% CI 0.33–0.76, p=0.001) and sarcopenia (OR 0.40, 95% CI 0.25–0.63, p=0.001) were independently associated with lower response rates. The model was adjusted for age, sex, HIV duration, physical performance, and ART pill burden.
Conclusions: Despite the importance of HR-QoL assessment in PWH, several barriers limit participation in HR-QoL evaluation. Impaired neurocognitive function, higher BMI, active smoking, and sarcopenia were significantly associated with non-completion of HR-QoL questionnaires. These factors highlight the urgent need for targeted tools and strategies to improve HR-QoL data collection, ensuring that the most vulnerable populations are not excluded from patient-reported outcome assessments, in order to achieve the fourth 90 goal.

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Beyond viral suppression: rethinking quality of life in HIV care

OC 29 POOR TREATMENT SATISFACTION AND LOW QUALITY OF LIFE IN HIGHLY-TREATMENT EXPERIENCED PEOPLE WITH HIV PWH: INSIGHTS FROM PRESTIGIO REGISTRY

M. Mazzitelli[1], S. Calza[2], R. Lolatto[3], T. Golnaz[4], B. Menzaghi[5], A. Cervo[6], A. di Biagio[7], R. Papaioannu Borjesson[3], F.R. Colombo[2], D. Minisci[8], S. Piconi[9], M.M. Santoro[10], A. Cattelan[1], A. Castagna[3,4], E. Focà[8]

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Introduction: Since achievement of a good quality of life (QoL) was granted as the 4th goal by UNAIDS, recent guidelines endorsed assessment of patient's reported outcomes (PROs) in people with HIV (PWH) in routine clinical practice. Therefore, we decided to assess QoL by using PROs in PWH harboring 4-drug resistance (4DR) participating in the Italian PRESTIGIO registry, and assess factors associated with worst QoL outcomes in this cohort.

Methods: A cross-sectional study was performed by administering to all people who accepted to participate a set of questionnaires assessing PROs (including QoL, sleep disorders, mood disorders, treatment satisfaction, and resilience) was conducted within the Italian multicenter PRESTIGIO registry, including people able to fill-in the questionnaires. Questionnaires were administered to people who accepted to participate. Participant relevant information (ARV treatment, comorbidities, polypharmacy, HIV-history related characteristics) was retrieved by the PRESTIGIO Registry platform. Logistic regression analyses were performed to identify associations between clinical/demographic features and lower QoL defined as EQ5D3L VAS < 90.

Results: From October 2024 to January 2025, 137 people responded to questionnaires, mainly males (69.3%), and with a mean age of 59 (SD:10), 90.5% (N=124) people had an undetectable HIV viral load. In our cohort, VAS was available for 132/137 persons, with 65% people disclosing a VAS < 90.

Features of the study population overall and by QOL (<90 and ≥ 90), with survey results are reported into Table 1. People with longer history of 4DR were more likely to have a VAS < 90 (p=0.022). People with a worst QoL reported significantly worst outcomes in every PROs (sleep, resilience, mood disorders, and treatment satisfaction). When multivariable analysis was performed the only significant association with a worst QoL were years spent on ART (OR: 1.22, CI 1.05-1.44, p=0.014).

Discussion: This is the first real word evidence exploring PROs in a 4DR PWH. Despite prolonged exposure to antiretrovirals and multiple failures, viral suppression was achieved in 90% participants. However, QoL in every of the explored aspect and treatment satisfaction were quite poor in this cohort. This is an urgent need to routinely assess PROs in this setting in order to address modifiable factors affecting QoL, including treatment options, and to achieve UNAIDS targets in also this special population.

Beyond viral suppression: rethinking quality of life in HIV care

OC 30 NEUROCOGNITIVE IMPAIRMENT, SLEEP QUALITY, DEPRESSION AND ANXIETY IN PEOPLE LIVING WITH HIV: A CROSS-SECTIONAL STUDY

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Background: HIV-associated neurocognitive disorders (HAND) remain one of the major challenges faced by people living with HIV (PLWH), potentially impacting their quality of life and daily functioning. Early detection and evaluation are essential to provide adequate management and interventions. In the last years neurocognitive impairment (NCI) was also associated with poor sleep quality, depression and anxiety.

Methods: We conducted a cross-sectional study randomly screening 45 PLWH for NCI using the Montreal Cognitive Assessment (MACE) and grooved Pegboard. Participants with significant impairment were referred for second-level neurocognitive evaluation (cognitive areas investigated: attention, memory, language, frontal functions and instrumental activities of daily living). Additional assessments included sleep quality (Pittsburgh Sleep Quality Index, PSQI), depression (Beck Depression Inventory, BDI), anxiety (Hamilton Anxiety Rating Scale, HARS) and quality of life (EQ-5D-5L).

Results: 45 people were tested, median age was 56 years (IQR 50-63), median HIV time was 172 months (IQR 81 – 228), 12 (26%) had a previous AIDS-defining condition, everyone was receiving HAART and only 1/45 (2%) had HIV-RNA >50 cp/ml (HIV-RNA 123 cp/ml) (table 1). Sixty-four percent of patients reported at least 1 comorbidity, arterial hypertension and Type 2 diabetes being the most represented. Ten people (22%) met the definition of polypharmacy, being administered with more than 5 concomitant drugs. Among the participants 13 (28.9%) exhibited significant neurocognitive impairment and required further evaluation. Poor sleep quality (PSQI >5) was observed in 20 individuals (44.4%), while 10 (22.2%) had depressive symptoms (BDI >10) and 7 (15.6%) had moderate to severe anxiety (HARS >17). Quality of life was considered to be good in 40 people (89%) with an EQ-D5-L5 score over 50/100.

Conclusion: Our study highlights a high prevalence of neurocognitive impairment among PLWH, with nearly one-third of participants requiring further evaluation. Additionally, poor sleep quality, depressive symptoms, and anxiety were frequently observed, emphasizing the complex interplay between neurocognition and mental health in this population. Despite these challenges, most participants reported a good quality of life, suggesting that factors beyond neurocognitive status may influence overall well-being. Given the high burden of comorbidities and polypharmacy, a multidisciplinary approach integrating cognitive screening, mental health support, and comprehensive clinical management is crucial to optimizing care for PLWH.

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Beyond viral suppression: rethinking quality of life in HIV care

OC 31 ADHERENCE TO ELECTRONIC MONITORING OF PROS ACCORDING WITH MULTIDIMENSIONAL BIOPHENOTYPES (MBP)

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Background: The electronic monitoring of PROMs (ePROMs) has been suggested as a gold standard for QoL assessment in PWH.
Adherence to ePROMs is a challenging aspect, frequently limiting the wide use of ePROMs in clinical practice. To implement these outcomes we applied a multidimensional profiling of PWH to identify clusters with different adherence to ePROMs.
Materials and Methods: A cohort of adult PWH on cART—diagnosed with HIV for more than 3 months, having provided informed consent, and capable of using smart devices—was enrolled in the Multiface study across three Italian centers.
Comprehensive remote assessments were conducted using the Healthentia SaMD (Software-as-Medical-Device), which enabled the submission of a battery of questionnaires (HIVSRQ, ADH5Q, GAD-7, PHQ-9, HSS) through a mobile App. An algorithm-based pathway, initiated by the screening questionnaire (EQ5D3L), tailored the assessment battery to individual needs and generated real-time alerts for altered responses.
Self-reported data (demographics, questionnaire answers, tags and alerts) was extracted from the Healthentia database. Weekly EQ5D3L answers were used to calculate response rates, further analyzed to harmonize follow-up time to a maximum of 1 year for all patients across all three pilot sites.
Correlation analysis was performed using the Pearson correlation coefficient to identify the most important variables and their potential associations among demographics, symptoms, quality of life aspects and app usage metrics. K-means algorithm was fitted on selected variables and optimized in terms of cluster number to classify patients in different groups (MBP) with certain adherence and symptomatology.
Results: 228 PWH responded at least once (female 18.4%, mean age 50.0 [SD +11.1]). The mean EQ5D3L response rate was 29.8 (SD+15.9). The cluster analysis yielded five MBP based on the means in demographics, health status, mental health and symptoms (figure 1, A): MBP 1 (N=91; 40%) (woman, good general health status, without identified specific needs); MBP2 (N=7, 3%) (older, relatively low general health status, high burden of mental health needs); MBP3 (N=5; 2%) (low general health status, high burden of MH needs); MBP4 (N=28; 12%) (quite old, relatively low general health status, without identified specific needs); MBP5 (N=47; 21%) (young, good health, without specific needs).
The mean response rate to EQ5D, identified as proxy of app response, according with different phenotypes was shown in figure 1, B, with highest response in MBP1 (46.1, SD+10.6) and lowest in MBP5 (17.9, +7.3).
Conclusions: Adherence to ePROMs was found to be relatively low. Cluster analysis identified MBP of PWHs with different adherence to ePROMs: low adherence was found in MBP with more complex MH and symptoms needs (MBP3 and MBP4).
A further in-depth multidimensional approach could better identify PWH profiles for tailored systems to enhance ePROM use and engage less responsive PWH.

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Durability of long-acting ART

OC 32 EFFECTIVENESS AND SAFETY OF LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN OLDER PEOPLE WITH HIV: INSIGHTS FROM THE GEPPO COHORT

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Background: Long-acting intramuscular cabotegravir and rilpivirine (LA CAB+RPV) has been proven effective and safe for the maintenance treatment of people with HIV (PWH). However, data on its use in older PWH (OPWH) aged ≥65 years remain scarce. This study aimed to evaluate the efficacy and safety of LA CAB+RPV in OPWH within the Italian GEPPO cohort.

Material and Methods: PWH in the Italian GEPPO cohort (age >65 years) who started LA CAB+RPV were included. Duration of LA CAB+RPV administration, reasons for drug preference and discontinuation, and HIV-RNA/CD4+ T-cell count at the last available observation were recorded together with geriatric variables, including multimorbidity (defined as the presence of ≥3 comorbidities) and polypharmacy (defined as the use of ≥5 medications other than antiretroviral therapy). Baseline (BL) was defined as the time when participants started LA CAB+RPV.

Results: 136 PWH aged >65 years old were included. At baseline they hey were mostly male (86%) and had a long time since HIV diagnosis [21 (IQR 13) years] and of ART [20 (IQR 12) years] as well as moderately low median nadir CD4+ T cells [250 (IQR 272) cell/mm3]. Only three participants had an HIV RNA >50 copies/mL (55, 234, and 945 copies/mL) at the time of the switch. The pre-switch regimen was mainly based on a three-drug combination in 50% of study participants (mostly bictegravir or rilpivirine-based) or two-drug combinations by 43.3% (mostly dolutegravir/rilpivirine and dolutegravir/lamivudine). Multimorbidity (31%) and polypharmacy (65%) were prevalent. A history of NNRTI resistance-associated mutations, an A1/A6 genotype, and a body mass index >30 Kg/m2 were observed in 5 (3.8%), 7 (6%), and 7 (7.2%) participants, respectively.

After a median follow-up of 17.6 (CI 95% 17.2-18.3) months, 120 participants (89%) were still receiving LA CAB +RPV. No virological failure was observed, and HIV RNA remained <50 copies/mL in all PWH; CD4+ T-cell count at the last available observation was 666 (IQR 352) cells/mm3. The reasons for 21 discontinuation were toxicity/intolerance events (7), patient's choice (6), death (1), HBV flare in occult B hepatitis (1), physician's choice (1), other/unknown (5).

Discussion: This is the largest longitudinal study evaluating LA CAB+RPV in OPWH. The findings confirm that LA CAB+RPV remains highly effective and well-tolerated in OPWH, even in those with long-standing ART exposure, multimorbidity, and polypharmacy. Importantly, the low discontinuation rate and absence of virological failure suggest that age should not be a barrier to LA ART regimens. As the HIV population ages, it is critical to avoid ageism in ART decisions and ensure that treatment choices align with both clinical needs and patient preferences. Future research should explore the long-term impact of LA ART on geriatric syndromes, functional status, and quality of life in OPWH.

Durability of long-acting ART

OC 33 INCREASING CD4/CD8 RATIO CONFIRMED AFTER TWO YEARS OF LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN THE SCOHOLART STUDY

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Background: The long-term impact of long-acting HIV therapy remains an area of ongoing research, given its recent approval. The aim of this study was to evaluate changes in immunologic, metabolic and renal parameters, including the CD4/CD8 ratio, a marker for predicting the risk of non-AIDS-defining events and death, in people with HIV (PWH) switching to long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV).
Methods: SCohoLART (NCT05663580) is a single-center, prospective cohort study that includes PWH with virological suppression who transitioned to a two-monthly LA CAB/RPV regimen. Participant characteristics were summarized using medians (interquartile range, IQR) or percentages. Linear mixed models were used to estimate crude annual mean changes (slopes) along with their 95% confidence intervals (95% CI). Participants who initiated or discontinued statin therapy during follow-up were not included in the analysis.
Results: We included 549 participants: 91.3% were male, median age was 48.9 years (39.7-56.3), median exposure to ART 11.3 years (7.9-17.3), and median follow-up of participants receiving CAB/RPV 24.0 months (17.0-26.8). At the start of LA therapy, PWH had a median CD4/CD8 ratio of 0.98 (0.70-1.28), with a median CD4 count of 795 cells/μL (604-994) and a median CD8 count of 850 cells/μL (642-1113). From the total 549 participants, we also focused on those who had completed around two years of follow-up (allowing a range of up to three months before the two-year mark) to assess how many reached a CD4/CD8 ratio >1. Among the 202 subjects included, 17.39% (20/115) with a baseline ratio ≤1 showed improvement to >1, while 9.19% (8/87) with a baseline ratio >1 declined to ≤1. Median total cholesterol was 179 (158-201) mg/dL and median low-density lipoprotein (LDL) cholesterol 112 (95 -135) mg/dL; moreover, median creatinine was 1.1 (0.9-1.20) mg/dL and median estimated glomerular filtrate rate (eGFR) 80 (70-90) mL/min/1.73 m2. During the follow-up, we observed a yearly mean increase in the CD4/CD8 ratio of 0.05 (0.04-0.06; p<0.001), led by a significant decrease in CD8 count (-27.90 cells/μL/year; p<0.001). Regarding metabolic and renal profiles, we observed a significant decrease in total and LDL cholesterol (-1.72 mg/dL/year and -4.40 mg/dL/year with a p=0.016 and <0.001 respectively), as well as an increase in eGFR (+1.16 mL/min/1.73 m2/year; p<0.001) and a reduction in serum creatinine concentration (-0.04mg/dL/year; p<0.001). No significant differences were seen in weight and body mass index throughout the study. Changes in immunologic, renal, and metabolic parameters are reported in Table 1.
Conclusions: Together with improved metabolic and renal parameters, the CD4/CD8 ratio continued to increase in PWH who switched to CAB/RPV over 24 months, mainly due to a reduction in CD8 count.

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Durability of long-acting ART

OC 34 DURABILITY OF LONG ACTING CABOTEGRAVIR AND RILPIVIRINE IN A MULTICENTER REAL-LIFE COHORT OF PEOPLE WITH HIV

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Background: We herein present a prospective multicenter experience on injectable cabotegravir and rilpivirine from 11 different HIV clinics in Northern Italy (Padova, Bologna, Belluno, Modena, Verona, Trento, Bolzano, Santorso, Rovigo, Treviso, Vicenza), focusing on the regimen durability, safety and tolerability in a real-life setting.
Materials and Methods: From August 2022, we included all individuals who received at least one dose of injectable cabotegravir and rilpivirine across the 11 participating centers. We recorded demographic data and laboratory results, and assessed factors associated with treatment discontinuation (TD) for any cause and virological failure (VF), defined as two confirmed consecutive values of HIV RNA > 50 copies/ml or one single measurement of HIV RNA > 200 copies/ml. Kaplan-Meier curves were used to assess TD probability and logistic regression to identify significant predictors of TD and VF.
Results: 483 PWH were included, mostly males (81.6%) and Caucasian (91.1%), with a median age of 49 (40-58) years, living with HIV for a median time of 12 (IQR:7-21) years, and a median CD4+ T cell count of 708 cell/mm3 (529-929). 45.5% and 7.5% had multimorbidity and polypharmacy, respectively. For 224 (43.6%) people HIV subtype was not available, 215 (44.5%) and 6 (1.2%) had a B and A subtype, respectively. 45.8% and 12.8% of participants had no genotype resistance test for INI and NNRTI at baseline, respectively, while participants before switching received a median number of 3 (IQR: 2-4) cART lines. 74.1% started LA according to their wish, and 51.8% coming from a dual oral cART (either dolutegravir/lamivudine or dolutegravir/rilpivirine).
During a median time of 22 (IQR: 13-26) months of follow-up, 54 (11.1%) people had TD (incidence of TD was 6.24 person-months of follow-up). Figure 1 shows KM curve for TD. Most people discontinued to side effects (31, 6.4%), while 7 (1.4%) due to virological failure. Among these 71.4% reported major resistance mutations both to INI and NNRTI and were switched darunavir/cobicistat/tenofovir alafenamide/emtricitabine. The remaining 28.6% came back to the previous oral regimen. When multivariable analysis was performed, age, years living with HIV, CD4/CD8 ratio, and BMI were significantly associated with TD. Also, we detected that numbers of previous antiretroviral regimens and black-African ethnicity were significantly associated with VF.
Conclusion: While the regimen demonstrated overall effectiveness, TD was observed in a specific subset of individuals, primarily due to side effects, with a smaller proportion experiencing VF. Factors we detected as associated with both TD and VF underscore the importance of personalized people selection and close monitoring to optimize long-acting ART outcomes. Further studies are warranted to refine strategies for mitigating treatment failure and improving regimen persistence.

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Durability of long-acting ART

OC 35 TWO-YEARS EFFICACY AND SAFETY OF LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN THE SCOHOLART STUDY

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Background: The long-acting strategy has only recently been introduced into the treatment of HIV, so there are no medium- or long-term data in real-world settings. Aim of the study was to evaluate the cumulative probability of treatment discontinuation (TD) and the proportion of people with HIV (PWH) with HIV RNA <50 copies/mL at month 24 in participants switching to long-acting cabotegravir (CAB) and rilpivirine (RPV).

Methods: SCohoLART (NCT05663580) is a single-center, prospective, cohort study enrolling PWH on virological suppression who switched to bimonthly long-acting CAB/RPV.

After initiation of CAB/RPV, HIV RNA testing was monitored at month 1, 3 and 6 and then every 6 months.

TD occurred at switch to another regimen for any reason including virological failure (VF); VF was defined as HIV RNA ≥50 copies/mL at two consecutive measurements or a single HIV RNA ≥1000 copies/mL. Viral blip was identified as an isolated HIV RNA value ≥50 and <1000 copies/mL with adjacent values <50 copies/mL. Participants' characteristics were reported as median (interquartile range, IQR) or frequency (%). Cumulative probabilities of TD were estimated by Kaplan-Meier curve.

Results: We evaluated 549 participants: 501 (91.3%) were male and median age was 49 (40-56). At the time of switching, median years from HIV diagnosis and of ART were 13.8 (8.7-20.4) and 11.3 (7.9-17.3), respectively; median CD4 count was 795 (604-994) cells/mcL and median CD4/CD8 0.98 (0.70-1.28), while median nadir CD4 was 335 (221-513) cells/mcL. Other participants' characteristics are reported in Table 1.

During the SCohoLART study, 5925 injections were administered. Excluding 549 first injections, 5376 injections were performed through the follow-up, and 5276 (98.1 %) of the scheduled injections were administered within the dosing window of ±7 days; in addition, 94 (1.8 %) were received more than 7 days before the scheduled injection date and 6 (0.1 %) more than 7 days after the scheduled injection date.

During a median study follow-up of 24.0 (17.0-26.8) months, 86 PWH experienced TDs (15.6%), including 6 (1.0%) for VF; detailed characteristics of participants with VF are summarized in Table 2. The cumulative probabilities of TD were 10.5% (95%CI: 7.9%-13.1%) at month 12 and 16.4% (95%CI: 13.0%-19.5%) at month 24 (Figure 1). The main cause of TD was injection site reaction (ISR) in 37 participants (43.0%) and median time to TD was 8.3 (4.5-15.3) months; other reasons to discontinuation are described in Table 3.

The proportions of participants with HIV RNA <50 copies/mL at month 12 and 24 were 99.0% (95%CI: 98.2%-99.9%) and 98.6% (95%CI: 97.5%-99.6%), respectively; moreover, PWH with viral blips throughout the study were 41 (7.7%).

Conclusions: Our two-year long-acting experience in PWH confirmed excellent rate of virological success and a small number of VFs; over the study, the main reason for CAB/RPV discontinuation was ISR.

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Building connections across care, prevention and education

OC 36 ANLAIDS SCHOOL - THROUGH A POSITIVE AND INCLUSIVE VIEW OF SEXUALITY, OUR STI PREVENTION TRAINING

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Background: Since 1993, Anlaids has been committed to creating an open and direct dialogue with male and female students with the aim of providing them with useful tools to learn about and prevent HIV and other STIs (Sexually Transmitted Infections). The project is operational thanks to the actions that each Anlaids office carries out in its region.
The educational proposal evolved over time and, consistent with the new national guidelines, reworked in the 2023 -2024 school year, has HIV/AIDS/STIs as its focus, but builds and promotes scientifically accurate, age- and developmentally-appropriate, gender-diverse, culturally relevant and transformative knowledge about the physical, cognitive, emotional, and social aspects of sexuality, useful for developing attitudes and behaviors for STI prevention and taking care of one's sexual health.
Material and Methods: The project is aimed at Grade I and II Secondary Schools, and since the current school year it has been experimenting, in several Italian institutions, with the treatment of prevention issues according to the EduForIST model, based on the extensive sex education (CSE) approach. Characteristic of the model is the active involvement of young people through techniques and activations capable of stimulating attention and the cognitive and emotional sphere, thanks to the support of appropriately trained educators with expertise in the field of prevention and sex education.
A questionnaire is administered before and after the interventions. The sum of true answers to questions on HIV/AIDS knowledge and prevention methods total a maximum score of 14 points.
Results: From October 2024 to February 2025, 3,402 post-intervention questionnaires were filled out by about 7,000 students from 77 institutions met by practitioners from 7 ANLAIDS Regional Offices. 76% were trained in the CSE approach. 52.4% are female; median age is 16 (range 13-21). 63.9% come from high schools. 74.7% attend 3rd-4th -5th grade classes.
Those who received the intervention using the CSE approach totaled a higher mean score on the overall scale of true responses than those who received the intervention without a CSE approach (M = 10.8 vs 9.5; t = 12.067 p < .001). With respect to perceived usefulness of the intervention (M = 3.52 vs 3.46; t = 1.172 p = .241) or thinking that one's prevention behavior might change (M = 2.78 vs 2.71; t = 1.156 p = .248) there were no significant differences between the two groups. While the CSE group reports that they are more satisfied with the operators' activities (M = 3.64 vs 3.46; t = 3.143 p = .002).
Conclusions: It is shown that activities based on the 'CSE approach are more effective because they stimulate the emotional dimension that facilitates learning. From the positive impact of sex and affective education programs on the health of young people and the desire to fill an educational gap resulting from the absence of regulation, the Anlaids project moves.

Building connections across care, prevention and education

OC 37 PROACTIVE TESTING FOR SEXUALLY TRANSMITTED AND ENDEMIC DISEASES AT AN OPEN ACCESS CLINIC FOR MIGRANTS: A ONE YEAR UPDATE

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Background: Compared to the native population, migrants typically have worse health outcomes and are more susceptible to infectious diseases (IDs). As a result, the ECDC advises screening new arrivals from high-prevalence countries for schistosomiasis, HIV, HBV, HCV, active and latent TB, and strongyloidiasis.
Materials and Methods: The research builds upon the data that was first gathered between September 2023 and March 2024, expanding them up to March 2025. Adult migrants seeking medical care at a weekly free-access outpatient clinic were evaluated for latent tuberculosis (IGRA), HIV (HIV Ab), HBV (HBsAg, HBcAb, HBsAb), HCV (HCV Ab), and T. pallidum (TPHA, VDRL). Symptomatic patients were also offered serological and urine cytology testing for N. gonorrhoeae, C. trachomatis (NAT), and S. haematobium. Additionally, all screenings were accompanied by medical counseling.
Discussion: We enrolled 113 migrants, consisting of 71 males (62.8%) and 42 females (38.2%). The median age was 40 years (IQR 17-74). Of the participants, 52 (46.02%) were from Africa, 39 (34.51%) from South America, 15 (13.27%) from Asia, and 7 (6.2%) from Eastern Europe. A total of 91 individuals (80.53%) completed the screening, while 22 (19.47%) did not attend their scheduled testing. Before enrollment, even with an average of over 5 years since entering the country, only 13 migrants had ever been tested for STDs.
Five individuals (5.49%) tested positive for HIV, five (5.49%) for syphilis, and 18 (19.78%) for latent tuberculosis infection (LTBI). Two patients (2.2%) were newly diagnosed with HBV (HBsAg+), while 12 (13.18%) had a history of HBV infection (HBc Ab+ and HBsAb+), 10 (10.98%) were vaccinated (HBsAb+ and HBcAb-), and 65 (71.42%) had negative HBV serology (HBc Ab- and HBsAb-) (Figures 1-6). No patients tested positive for HCV. Among the four individuals reporting urinary symptoms, none tested positive for N. gonorrhoeae or C. trachomatis (NAT), but three (3.29%) tested positive for schistosomiasis (IgG). All patients who were newly diagnosed were successfully retained in care and received the necessary and appropriate treatment for their condition. A predictive model was developed to identify factors associated with missed screening tests. The analysis revealed that older age, shorter duration of residence in the country and a complete language barrier were significant predictors of test non-completion (Figure 7).
Conclusion: Proactively screening migrants for latent infections proves to be both feasible and effective. However, despite being in the country for several years, most migrants still do not receive essential infection testing or routine vaccinations. These findings underscore the importance of improving access to healthcare services for migrants in order to bridge the gap between their arrival and the timely medical care they need.

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Building connections across care, prevention and education

OC 38 NGO ROLE IN CONTINUUM OF CARE (COC): AN OPPORTUNITY NOT TO BE MISSED

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Background: As part of the project funded by the Ministry of Health, an online survey was implemented, targeting Non-Governmental Organizations (NGOs) working in the HIV field. The objective was to assess the feasibility of producing estimates of the Continuum of Care (CoC) for key populations that are "invisible" in information systems/cohorts: Sex Workers (SW), Transgender (GD) individuals, and People Who Inject Drugs (PWID). In addition to producing estimates, this survey had the objective to investigate the role of NGOs and their contribution to CoC for these populations.

Materials and Methods: An online survey was conducted in October 2024. It was delivered by email to umbrella organizations participating in the project and operating at the national level. The collected self-reported data, referred to the period 1/1/2024-30/6/2024, include information about the reached target populations (as number of clients and their main characteristics, including reported HIV status), as well as NGO workers' qualitative insights regarding the strengths and weaknesses of NGOs' contribution to the CoC of these vulnerable groups.

Results: A total of 11 umbrella organizations responded to the survey, representing 53 NGOs implementing activities in support of the CoC. Of these, 58% are based in Northern Italy. As of 12,867 clients reached by the respondents, 49% are PWID, 25% are SW, 4% are GD individuals, and the remaining are clients with intersecting vulnerabilities. Outreach units are the primary mean of contact with these populations. From January to June 2024, the NGOs conducted 3,207 HIV tests and facilitated 236 referrals to clinical centers (CC) for testing and treatment. A total of 441 PLWH were followed by NGOs, with PWID showing the lowest adherence to therapy, while GD individuals had the highest detectable viral load. The identified strength key points include outreach activities, which enable direct contact in the places where these populations live and work, the development of meaningful NGO worker-client relationship, and the non-judgmental approach. The main highlighted weakness points concern the sustainability of outreach interventions. Retention in care of vulnerable populations highly depends on their registration in the National Health System (through ID or documents enabling access to NHS if migrant not registered) and is significantly impacted by stigma and discrimination, as well as by the lack of cultural mediation services in clinical centers.

Conclusion: NGOs can play a crucial role in the CoC of individuals belonging to the so-called invisible populations, thanks to their procedural flexibility and the tailored approaches of outreach activities. However, greater coordination with clinical centers and increased sustainability, including financial support, for these low threshold services would be beneficial.

Building connections across care, prevention and education

OC 39 CHEMSEX AND MDPV: THE EXPERIENCE OF A COMMUNITY-BASED CHEMSEX SERVICE WITH INCREASINGLY SEVERE AND COMPLEX CLIENTS

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Background: Since 2017 ASA offers group and individual therapy sessions to address problematic chemsex. In 2023, the rapid spread of MDPV use sharply increased the frequency of requests for help we received, which required scale-up in service delivery and the establishment of a network with local addiction services. To address a knowledge gaps about chemsex within addiction services, we provided training and supervision to multiple centres.
Methods: Characteristics of clients and their requests received between March 2024 and February 2025 were analysed to inform further prevention and care interventions for problematic chemsex. For each client sociodemographic characteristics were collected, and these themes were investigated during interviews: behavioural and socio-psychological aspects of drug use, motivations for requesting help, history of drug use, history of pharmacological or psychological treatment, HIV status, frequency of condom use. Descriptive statistics and thematic analysis were used.
Results: 49 requests were received, and detailed characteristics are presented in Table 1. Clients were mostly male (98%), gay (90%), university graduates or higher (53%), aged 31-40 (45%), employees (68%), born in Northern Italy (44%), living in Milano (55%). Clients predominantly reached out because they felt they had lost control (59%) or a specific episode severely scared them (34%), and asking for help to quit drugs (83%).
Characteristics of clients' drug use are presented in Table 2. 92% used stimulant drugs, most frequently MDPV (70%). Most clients used drugs on a weekly (41%) or monthly basis (31%), and with occasional partners (41%). 14% did chemsex alone. 42% first started chemsex due to traumatic events or loneliness and 52% to emulate their partners. 58% had been doing chemsex for more than one year. 36% never used drugs before doing chemsex. 56% were not currently able to have sober sex.
Clients' history of treatment is presented in Table 3. 40% had been hospitalized or accessed the ER at least once to treat chemsex-related issues. 51% had previously accessed another health service for problematic chemsex, 60% of them felt their issue was not understood, 7% felt judged, and 35% were still in follow up there. 52% did psychotherapy in the past but 8% said it was not helpful. 90% reported never using condoms, and 23% were neither on ART or PrEP.
Conclusions: Clients who reach our service present with increasingly complex and severe issues, as evidenced by the length of chems use and frequency of inpatient and outpatient treatment. Providing training and supervision to addiction centres in Milano encouraged mutual trust and started a fruitful cooperation, which is crucial for complex cases. Significant gaps remain for addiction centres outside of Milano to effectively address chemsex, and specific trainings for all centres are urgently needed. Raising awareness on the risks of MDPV use is needed to reduce its use by emulation.

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Clinical HIV insights

OC 40 INCIDENCE OF NON-AIDS-RELATED CANCERS IN PEOPLE WITH HIV IN THE PERIOD 2000-2023: A SINGLE CENTER RETROSPECTIVE STUDY

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Introduction: Uncontrolled HIV infection has been linked to a higher risk of AIDS-defining cancer (ADC). With the introduction of antiretroviral therapy an increasing occurrence of non-AIDS-defining cancers (NADCs) has been observed in people with HIV (PWH). We aimed to assess the incidence of NADCs in PWH.
Methods: We performed a single center observational retrospective study from January 2000 to December 2023 including PWH included in the cohort of the III Infectious Disease Unit of Luigi Sacco Hospital, Milan, Italy. Three 8-year calendar periods were chosen to assess changes in cancer incidence (2000-2007, 2008-2015, 2016-2023). NADCs were further stratified in virus-related and smoking-related. If more than one NADC occurred only the first was considered in the analysis. Cancer incidence was estimated with Poisson regression models and expressed as rate per 100,000 person years of follow-up (PYs). The relative risk of cancer incidence per calendar period was estimated with multivariable Poisson regression model adjusting for age, mode of HIV acquisition and previous AIDS.
Results: Overall, 580 cases of malignancy were observed among 4,642 PWH contributing for 50.052 PYs. Characteristics of the study population are reported in Table 1. Most of the malignancies were NADC (371/580, 63.9%) and the remaining were ADC (209/580, 36.1%). NADCs incidence significantly increase from 580.5/100.000PYs in first period to 974.4/100.000PYs in third period (RR 1.42, 95%CI 1.07-1.88). The same was observed for virus-related cancers (236.7/100.000PYs in first period to 333.4/100.000PYs in third period, [RR 1.67, 95%CI 1.03-2.72]), and smoking-related cancers (450.9/100.000PYs in first period to 859/100.000PYs in third period [RR 1.64, 95%CI 1.2-2.24]). Regarding NADCs, increasing age (RR 1.25, 95%CI 1.14-1.38) was significantly associated with an increased incidence such as a previous AIDS (RR 1.33, 95%CI 1.06-1.68) and mode of HIV acquisition (PWID vs HE; RR 1.70, 95%CI 1.32-2.18). In the analysis restricted to lung cancer only aged appeared to be significantly associated (RR 1.50, 95%CI 1.19-1.88). Regarding, virus-related cancers mode of HIV acquisition (people who inject drugs (PWID) and men who have sex with men (MSM) vs heterosexual (HE); RR 2.83, 95%CI 1.8 -4.43 and RR 1.95, 95%CI 1.26-3.01 respectively) and previous AIDS (RR 1.73, 95%CI 1.2-2.5) resulted associated to a higher incidence. Regarding anal cancer, mode of HIV acquisition (MSM vs HE; RR 3.28, 95%CI 1.75-6.16) and prior AIDS (RR 3.18, 95%CI 1.87-5.41) were associated with a higher risk. Regarding smoking related cancers, increasing age (RR 1.25, 95%CI 1.13-1.39), mode of HIV acquisition (PWID vs HE; RR 1.79, 95%CI 1.37-2.36) and previous AIDS (RR 1.51, 95%CI 1.18-1.93) emerged to be associated to a higher incidence (Table 2).
Conclusions: We observed that the incidence of NADCs has increased over time with people with previous AIDS and PWID showing a disproportionately higher risk of NADCs.

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Clinical HIV insights

OC 41 TREATMENT INTERRUPTIONS AMONG PWH ON INSTI: VIROLOGIC FAILURE AND OTHER REASONS FOR SWITCHING THERAPY IN A REAL-LIFE COHORT

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Background: Reasons for interrupting antiretroviral therapy (ART) have deeply changed in the last decades. Our aim was to investigate the rate of virologic failure (VF) and other causes of treatment switching, in a real-life cohort including people with HIV (PWH) treated with integrase inhibitors (INI).

Methods: All consecutive PWH enrolled in the SCOLTA project in the INI cohorts (raltegravir, RAL, dolutegravir, DTG, and bictegravir, BIC), with at least one HIV-VL per year for three consecutive years, or treatment discontinuation within three years since treatment initiation. A Cox regression model was used to evaluate risk factors for treatment discontinuation. To evaluate VF, we adopted a competing model approach.

Results: 1746 PWH were selected. 365 (20%) were ART-naïve (N), 1381 (79.1%) were ART-experienced (EXP). At baseline, 1037 EXP (75.1%) had HIV-VL<50 copies/ml, 105 (7.6%) had HIV-VL between 50 and 200 copies/ml and 239 (17.3%) had HIV-VL>200 copies/ml.

PWH demographics are depicted in table 1.

Over a median observation time of 38 months (interquartile range 25-56), 709 (40.6%) treatment interruptions were registered: 44 (6.2%) were for VF and 665 (93.8%) for other reasons.

Evaluating PWH with baseline HIV-VL< 50 copies/ml, 36 (3.5%) PWH experienced a HIV-VL>50 copies during the first year of observation: this was more frequent in PWH on RAL (9.2%) vs DTG (2.8%) and BIC (2.8%) (p=0.006). In the same group, at least one HIV-VL>50 copies/ml was observed in 39/948 (13.1% vs 3.4% vs 1.5%, respectively; p<0.0001) during the second year, and 31/858 (10.2% vs 2.8% vs 2.5%, respectively; p=0.0005) during the third.

In a competitive model including baseline age, years of ART, N or EXP status and HIV-VL level, enrolment cohort and HIV-VL>50 in the first year, we found that HIV-VL>50 during the first year (Hazard ratio [HR] 3.72 [95% confidence interval (CI)] 1.81-7.63) and being on RAL-containing regimen (HR 3.23 [95% CI 1.34-7.80]) represented risk factors for VF.

The survival curve comparing time on treatment among INI cohorts is depicted in Figure 1.

The most frequent (>5%) reasons for interruptions other than VF were: Adverse Events (164 [23.1%]), Being lost to follow-up (138 [19.5%]), Simplification (135 [19%]), Switch to Long-Acting (63 [8.9%]), death (38 [5.4%]) and patient's willing (40 [5.6%]).

As regards discontinuation due to any reasons, in a non-competitive model including baseline age, years of ART, N or EXP status and HIV-VL level, enrolment cohort and HIV-VL>50 in the first year, age was associated with a lower risk (by 5 years, HR 0.96 [95% CI 0.93-0.99]) and being ART-naïve with an increased risk (HR 1.56 [95% CI 1.25 -1.95]).

Conclusions: In our INI cohorts, virological failure represents only 6.2% of the reason for interruption and was associated with the detection of at least one HIV-VL >50 copies/ml in the first year of treatment.

Younger age and ART-naïve status are risk factors for any treatment interruptions.

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Clinical HIV insights

OC 42 KEY PREDICTORS OF OPTIMAL VIRO-IMMUNOLOGICAL RESPONSE IN PRIMARY HIV INFECTION

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Introduction: Although the benefits of initiating antiretroviral therapy (ART) during primary HIV infection (PHI) are well documented, the proportion and clinical profiles of people with HIV (PWH) achieving optimal virologic control and immune recovery in this setting remain poorly characterised.

Material and Methods: Prospective, monocentric, observational study including all PWH diagnosed with PHI and starting ART between July 2013 and December 2024 at a clinical center in Rome. Kaplan-Meier curves were used to estimate the probability of achieving (1)low-level HIV-DNA (LL-HIVDNA: ≤200 cp/10^6 PBMC), (2)optimal immunological recovery (OIR: CD4 count >500 cells/mm³ + CD4/CD8 >1), and (3)optimal viro-immunological response (OVIR: undetectable HIV-RNA [<40 cp/mL] + LL-HIVDNA + OIR). Predictors of OIR and OVIR were assessed by Cox regression analysis. Participants were followed from ART initiation until the achievement of viro-immunological outcomes or a maximum of 12 months.

Results: Overall 286 PWH with PHI were included, contributing to a median of 182 PYFU. Participants (Ps) were mainly male (96%), Italian (90%) with a median age of 35 (IQR 28-44) years, 83% acquired HIV through homosexual intercourse. At baseline, the median HIV-RNA and HIV-DNA levels were 5.6 $\log_{10}$ cp/mL (IQR 4.8–6.6) and 4.11 $\log_{10}$ cp/10^6 PBMC (IQR 3.65–4.6), respectively. The median CD4 count was 512 cells/mm³ (IQR 364–686), with 21% ps exhibiting a CD4/CD8 ratio>1. At diagnosis, 20% Ps had a concomitant sexually transmitted infections, mostly (62%) syphilis, and 57% were CMV IgG positive. ART was initiated a median of 5 (IQR 2–10) days post-HIV diagnosis, mainly with a 4-drug regimen (48%: 2 NRTIs + DRV/b + INSTI) or a 3-drug INSTI-based regimen (50%).

The estimated 1-year probability of achieving LL-HIVDNA, OIR and OVIR were 31.4% (95CI% 21.9-43.8), 60.5% (95CI% 52.7-68.5) and 14.2% (95%CI 9.6-20.9), respectively (figure 1). By multivariable analysis (table 1), immunological competence at baseline was the strongest predictor of achieving OIR (aHR: 8.48 [95% CI: 4.85–14.86] for each point CD4/CD8 increase,p<0.001 and aHR 1.14 [95% CI:1.06–1.21] per 100-cell increase of CD4 count,p<0.001). Similarly, a higher baseline CD4/CD8 ratio was associated with a greater probability of achieving OVIR (aHR 2.58 [95% CI: 1.09–6.11] for each point CD4/CD8 increase, p=0.031), while higher pre-ART HIV-DNA was strongly related to a lower likelihood of reaching OVIR (aHR 0.28 [95% CI: 0.14–0.56] per 1 $\log_{10}$ increase, p<0.001). Notably, neither the time from diagnosis to ART initiation nor the type of ART regimen influenced these outcomes.

Conclusions: Our data showed that in PHI, the size of the viral reservoir and the level of immune competence, particularly CD4/CD8 ratio, at ART initiation are key predictors of optimal viro-immunological response. These factors may serve as prognostic markers for treatment outcomes and help identify PWH most likely to benefit from future eradication strategies.

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Clinical HIV insights

OC 43 BODY COMPOSITION AND PHARMACOKINETICS OF LONG-ACTING ANTIRETROVIRAL THERAPIES IN A COHORT OF PEOPLE LIVING WITH HIV

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Cabotegravir/rilpivirine long-acting injectable therapy (LAI-CAB/RPV) represents a paradigm shift in pharmacokinetics, with studies revealing significant interindividual variability in plasma concentrations. A careful consideration is needed accounting for comorbidities, body composition, sex, and age. This study aims to explore the pharmacokinetics of CAB/RPV-LAI in a cohort of PLWH in a real-life setting.

This observational study was conducted at the Infectious Diseases Unit at Spedali Civili Hospital of Brescia. We enrolled all the patients who switched to CAB/RPV-LAI from February 2023 to March 2024. We measured plasma concentrations at 1, 5, and 11 months post-initiation of CAB/RPV-LAI, with analysis performed at the Laboratory of Clinical Pharmacology and Pharmacogenetics of Turin. Moreover, we assessed weight, BMI, lean mass percentage and grip strength. We applied linear regression models and a correlation matrix.

We enrolled 37 patients, 30 (81.6%) males, with a mean age of 44.9 years (SD 10.99), 73.7% of subjects had at least one comorbidity and 65.8% at least one concomitant drug. Oral lead-in was prescribed in 30 (79%) subjects, excluding the subjects with ongoing RPV/DTG oral regimen. The mean BMI was 23,8 (SD 2,9) kg and HIV subtype was B in 20 (83,3%) of the available cases. RPV concentrations were <50 ng/mL in 23 observations (25.8%) but increased over time, from mean value of 57,98 (SD 24,88) ng/mL at T1 to 75,68 (SD 27,70) ng/mL at T5 and to 109,09 (SD 34,03) ng/mL at T11 (Fig. 1a). CAB was <664 ng/mL in 5 observations (5.4%) and had a trend similar to RPV, rising from a mean value of 1351,49 (SD 622,69) ng/mL at T1 to 1640 (SD 606,22) ng/mL at T5 and to 1888,17 (SD 685,03) ng/mL at T11(Fig. 1b). No significant correlations were found between plasma levels and age, sex, weight, BMI, and grip strength. A strong correlation was observed between body fat percentage and CAB and RPV concentrations at T11 applying a correlation matrix (Fig. 1c). Still, this result was not confirmed with the regression models, beta 101 (CI95%-2.9, 205 and p-value=0.054) and beta 3.8 (CI95%-3.0, 11 and p-value=0.2) respectively. Oral lead-in did not correlate with CAB or RPV concentrations (p-value=0.28 and 0.14, respectively). We observed only one virological failure (HIV RNA 613 cp/ml at T1, 27 cp/ml at T5 e 42 cp/ml at T11), without selection of RAMs; RPV had low concentration (25 ng/mL) at the time of the failure (T1) and had an increase at T5 (RPV di 54 ng/mL).

The study highlights the accumulation of CAB and RPV over time, consistent with some literature, though interindividual variability remains a challenge. Body composition doesn't seem to influence drug absorption, but findings were inconclusive. These results underscore the need for further real-life studies to optimize LAI-CAB/RPV use. This research contributes to understanding the pharmacokinetic profile of LAI therapies and their implications for clinical practice.

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The long-acting ART landscape in Italy

OC 44 VIROLOGIC OUTCOMES OF LONG ACTING CABOTEGRAVIR AND RILPIVIRINE IN VIRAEMIC AND POORLY ADHERENT PLWH

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Background: Long-acting injectable (LA) cabotegravir and rilpivirine may provide an effective alternative for people living with HIV (PLWH) struggling with adherence to daily oral regimen. This study aims to assess virologic success and failure rates and identify associated factors in PLWH who initiate LA therapy with detectable viral load (VL).
Materials and Methods: We conducted a retrospective analysis of all PLWH who started LA treatment with detectable VL due to poor adherence. Virologic success was defined as two consecutive undetectable VL measurements, while virologic failure was defined as a single VL >1000 cp/mL or two consecutive values >500 cp/mL during follow-up. Descriptive and nonparametric tests characterized the study population, incidence per 100 patients/year follow up (PYFU) and standard survival analyses were used to assess the risks of virologic success and failure.
Results: A total of 45 PLWH were evaluated over a median follow up time of 76 weeks. Most were male at birth (84.4%), with a median age of 53 yeas (IQR 44-58), a median infection duration of 12.5 years (IQR 6.6-19.9), and a nadir CD4 count of 334 cells/mm3 (IQR 127-406). At baseline, the median VL was 39 cp/mL (IQR 31-80) and the median CD4 count 677 cells/mm3 (IQR 475-1088). The Kaplan-Meier curve showed a virological success rate exceeding 75% (Fig. 1A). In unadjusted Cox regression analysis, baseline VL of 20–50 cp/mL (HR: 0.24; 95% CI: 0.09–0.63; p=0.004), 51–200 cp/mL (HR: 0.16; 95% CI: 0.04–0.65; p=0.011), and 201–500 cp/mL (HR: 0.19; 95% CI: 0.04–1.00; p=0.049) were associated with lower virological success rates. Higher BMI was positively associated with virological success (HR: 1.10; 95% CI: 1.01–1.20; p=0.037). In adjusted models, only baseline VL of 20–50 cp/mL (HR: 0.30; 95% CI: 0.11–0.85; p=0.024) and 51–100 cp/mL (HR: 0.21; 95% CI: 0.04–0.89; p=0.034) maintained significance. Virologic failure occurred in two individuals (4.4%), with an incidence of 3.3 per 100 PYFU (95% CI: 0.6–11.0) over a cumulative follow-up of 60.63 years (Fig. 1B). One case failed at week 4 due to pre-existing rilpivirine-associated resistance mutations that were accidentally overlooked. The other failed at week 44 after maintaining undetectable VL from week 4 onward; this individual had a baseline BMI of 36, and genotypic resistance testing is ongoing. None of the individuals who did not achieve viral success presented subsequent virologic failure. Cox regression analysis showed that none of the traditional risk factors for LA failure were significantly associated with this outcome.
Conclusion: LA treatment achieved virologic suppression in over 75% of PLWH who initiated therapy with detectable VL, suggesting that LA could be safely used in PLWH struggling with adherence and with maintaining durable virological suppression.

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The long-acting ART landscape in Italy

OC 45 SWITCHING TO LONG-ACTING CAB/RPV: A REAL-WORLD ANALYSIS IN PEOPLE LIVING WITH HIV

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Background: Long-acting antiretroviral therapy (LA ART) is an important advancement in HIV treatment, offering an alternative to daily oral regimens and addressing challenges such as adherence, stigma, and pill fatigue.This study evaluates the impact of switching to CAB/RPV LA in a cohort of virologically suppressed people living with HIV (PLWH) in terms of metabolic parameters, immune senescence and immune activation.
Methods: An observational study was conducted on 82 virologically suppressed PLWH who switched to CAB/RPV LA regardless of their previous ART regimen. An overview of the cohort's epidemiological characteristics is reported in Table 1. Clinical and laboratory parameters, with a focus on renal function, lipid profile, liver enzymes, and immune virological markers were assessed at baseline, week 24 and week 48. Virological data at weeks 24 and 48 are reported in Table 2 and virological efficacy was evaluated using statistical approaches, whose methodologies are described in Figure 1. The Friedman test was used to compare values over time, and results are illustrated in Figure 2. CD38 and HLA-DR expression on CD4+ and CD8+ T cell subsets [naive, central memory (CM) and effector memory (EM)], as well as CD57 and PD1 expression on NK cells and CD4+ and CD8+ T cells were evaluated by multiparameter flow cytometry in eight patients at baseline and week 48.
Results: Virological suppression was maintained in most PLWH at week 48. However, two PLWH experienced virological failure and were switched back to a triple ART regimen. In the per-protocol analysis (PP), PLWH who adhered to the regimen maintained HIV RNA <50 copies/mL, confirming the effectiveness of CAB/RPV LA. In the intention-to-treat analysis (ITT), virological suppression was also maintained, reinforcing the robustness of these findings. A statistically significant improvement in renal function was observed, with increased eGFR and reduced creatinine levels at weeks 24 and 48 ($p < 0.05$), suggesting a potential nephroprotective effect of this regimen. No significant changes were detected in lipid profile, liver enzymes, or other immune parameters, indicating that CAB/RPV LA had no negative impact on metabolic or hepatic function. Frequencies of EM CD4+ CD38+ and EM CD4+ HLA-DR+ T cells ($p = 0,0391$), CD8+ CD57+ T cells ($p = 0,0234$) and CD57+ NK cells $p = 0,0391$) were reduced at 48 week compared to baseline [Figure 3].
Conclusions: In this real-world cohort, CAB/RPV LA maintained virological suppression over 48 weeks, with no major changes in metabolic parameters. A significant improvement in renal function was observed, but its clinical relevance remains to be determined. Moreover, the reduced frequencies of EM CD4+ Tcells expressing immune activation markers (CD38 and HLA-DR) and of CD8+ T cells and NK cells expressing senescence marker CD57 could indicate a positive impact of this therapy on immune status. Further studies are needed to better understand these findings.

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The long-acting ART landscape in Italy

OC 46 EFFECTIVENESS AND PATIENT REPORTED OUTCOMES (PROS) OF LONG-ACTING ART WITH CABOTEGRAVIR/RILPIVIRINE: THE LONG-ICONA STUDY

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Background: Cabotegravir (CAB) + Rilpivirine (RPV) Long Acting (LA) have been effective and tolerable in phase 3 studies. However, real-life data on the effectiveness of CAB+RPV LA and the correlation with patient reported outcomes (PROs) are scarce.

Material and Methods: People with HIV (PWH) enrolled in the ICONA cohort who agreed to participate in the prospective observational Long-Icona study initiating LA with CAB/RPV while on a stable antiretroviral therapy (ART) and virologically suppressed were included. Time to treatment discontinuation (TD), to TD for toxicity/intolerance/PWH's choice and to virological failure (VF, 2 viral loads [VLs]>50 cp/ml or 1 VL>1,000 cp/mL followed by ART-change) were estimated using the Kaplan-Meier curves. The following PROs were evaluated: HIVTSQs and HIVTSQc, HIV HIVDQoL, HIV-Stigma scale, PHQ-9 and PIN (PROs description, interpretation and timepoints in Table 1). Linear mixed models with random intercept and slope per subject were used to evaluate the mean score in the different questionnaires/domains at each timepoint. The association between the domain "Acceptance of Injecting Site Reactions" (ISR) of PIN (injection 1) and the mean HIVTSQc score (injection 2) with TD due to intolerance/toxicity/PWH choice was evaluated using Cox regression models adjusted for age, sex and mode of HIV transmission.

Results: Overall, 226 PWH switching to CAB/RPV LA with >=1 follow-up were included: 11.9% were female, median age 45 years (interquartile range, IQR, 37-55), 88.5% Italian natives, median CD4 at BL 743 cells/mmc (IQR 603 -925). An oral lead-in was used in 24.8% of cases.

The 1-year estimated cumulative probability of TD for any cause was 11.6% (95% confidence interval, CI, 7.8 -17.0%). Reasons for TD were toxicity/intolerance (7.1%, injection site reactions 3.1%), PWH's choice (1.3%), VF (1.3%) and pregnancy (0.4%). The 1-year cumulative probability of TD for toxicity/intolerance/PWH's choice was 9.7% (95%CI 6.2-15.0) while for VF was 1.6% (95% CI 0.5-4.9%).

At 1 year, improvements in 3/4 domains of HIV-Stigma scale, in HIVTSQs and in generic quality of life item of HIVDQoL were observed.

Instead, no significant changes were detected in PHQ9. Acceptance of ISR domain in the PIN questionnaire significantly improved after 1 year (Figure).

Moreover, lower acceptance of ISR using the domain of PIN questionnaire at injection1 (per 1 point higher: adjusted hazard rate, aHR 1.76, 95% CI 1.29-2.41, p<0.001) and lower treatment satisfaction at injection2 (per 1 point mean HIVTSQc score lower: aHR 3.18, 95% CI 1.73-5.85. p<0.001) significantly correlated with treatment discontinuation due to toxicity/intolerance/PWH's choice.

Conclusions: This analysis shows good short-term effectiveness of CAB-RPV, with a low rate of virological failure but a 11.6% probability of TD at 1 year, mainly due to toxicity/intolerance. Small improvements were observed in stigma-related PROs, treatment satisfaction and overall quality of life.

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The long-acting ART landscape in Italy

OC 47 PATIENT-REPORTED OUTCOMES (PROS) AS A MEASURE OF SATISFACTION WITH LONG-ACTING THERAPY IN PWH

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Background: The introduction of Long-Acting therapy (LAt) into the clinical management of patients living with HIV (PWH) is a contribution to improving quality of life, perception and relationship with their health. The main objective of this study is to assess the degree of satisfaction with LAt and its impact on health, daily life, and long-term outcome in PWH by using patient-reported outcomes (PROs).

Material and Methods: We included participants (pts) of PRO-ACT study (EC approval:35/2023) who met clinical criteria to switch from the oral antiretroviral regimen (OAr) to LAt. All pts signed informed consent and were asked to complete the following PROs, in a self-report modality: AIM-IAM-FIM, a questionnaire measuring acceptability (AIM), appropriateness (IAM) and feasibility of intervention (FIM), administered at baseline (BL), HIV Treatment Satisfaction Questionnaire (HIVTSQs), a questionnaire measuring satisfaction with treatment and Perception of Injection (PIN), a questionnaire investigating effects in the 7 days following injection, both administered at BL and 12 months after the start of LAt (T2). Descriptive summary was presented using frequencies, proportions, and cross-tabulations. McNemar's test was used for paired categorical data analysis.

Results: 277 pts underwent PROs with a median age of 48 years (28-81), 82.3% male, 32.1% with previous comorbidities. In AIM-IAM-FIM, pts expressed a higher percentage of "totally agree" responses (vs "totally opposed/opposed/don't know/agree"; Table 1). Moreover, the percentage of "very satisfied" responses (vs "very unsatisfied "and "satisfied") in HIVTSQs increased from 79.7% to 98.4% ($p<0.0001$), from 76.6% to 99.2% ($p<0.0001$), from 71.5% to 97.6% ($p<0.0001$) and from 72.2% to 98.4% ($p<0.0001$) in terms of satisfaction as current therapy, lifestyle-matching, in continuing over time and degree of flexibility of LAt from BL to T2 (Figure 1). Finally, PIN assessment showed a decrease in perceived pain and difficulty in movement due to the injection from BL to T2 (77.6% vs 93.9% $p=0.021$, 80% vs 94% $p=0.016$ of "not at all/slightly/quite a bit" vs "very much/mostly" responses, respectively; Figure 2).

Conclusion: Our data suggest that switching from OAr to LAt, treatment satisfaction and efficacy improve over time, increasing therapeutic adherence. Therefore, injection takes on the characteristics of existing therapies, particularly through the degree of flexibility and lifestyle adaptation. In addition, PROs have been confirmed to be extremely useful tools in the clinical management of HIV infection. These data can help solidify the important goal of improving quality of life in PWH.

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Advances in viral pathogenesis

OC 48 HBV INTEGRATION CAN SUSTAIN INTRAHEPATIC HDV ACTIVITY AND CAN MODULATE HBV PATHOGENETIC POTENTIAL

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Background: HDV depends on HBsAg for its infectivity. HBsAg can derive from cccDNA and also from the integration of the so-called linear HBV-DNA in the genome of infected hepatocytes. Here, we elucidate the contribution of HBsAg production from linear HBV-DNA integration in sustaining HDV activity and its pathogenetic potential.

Material and Methods: 70 liver biopsies from eAg-negative individuals (74% NUC-treated) were included: 35 with CHB and 35 with CHD. Droplet-digital PCR was used to quantify intrahepatic levels of cccDNA, pgRNA, HDV-RNA and HBs transcripts from cccDNA and from integrated HBV-DNA (Grudda, 2022). Next-generation sequencing by Illumina was applied to assess the integration of linear HBV-DNA in hepatocytes' genome (in 22 CHB and 32 CHD).

Results: Individuals with CHD and CHB had comparable age and NUC-treatment duration. CHD was characterized by lower cccDNA and pgRNA than CHB (median [IQR]: 1 [0.02-12] vs 24 [8-93] copies (cps)/1000 cells and 8 [1-147] vs 518 [57-3,894] cps/1000cells, P<0.0001 for both). In CHD, no correlation was observed between cccDNA and intrahepatic HDV-RNA, supporting that HDV replicative activity is not strictly related to the extent of HBV reservoir.

At least 1 event of linear HBV-DNA integration was observed in 100% and 78.1% (25/32) of individuals with CHB and CHD (total number of unique HBV-integration events: 847 in CHB and 427 in CHD). Furthermore, in both CHB and CHD, a comparable production of HBs transcripts was observed, with >99% of them from integrated HBV-DNA (median [IQR] cps/1000cells: 12,776 [4,570-55,977] in CHB and 6,041 [323-29,446] in CHD).

Among the 427 HBV-integration events observed in CHD, 180 involved coding regions of the hepatocytes' genome, corresponding to a median (IQR) number of 5 (2-10) unique events per patient. Notably, the number of HBV-integration events in coding regions showed a positive correlation with the amount of integration-derived HBsAg transcripts and with serum HBsAg (Rho=0.54 and 0.64, P<0.01 for both). Even more, HBV-integration events were significantly more frequent in individuals with CHD characterized by higher serum HBsAg levels (median [IQR] number of unique HBV-integration events: 10 [7-16] in people with vs 2 [1-7] in people without serum HBsAg >4 logIU/ml; P=0.01).

In 19/25 individuals with CHD characterized by >1 HBV-integration event, HBV-DNA integrants localised in human genes regulating cell proliferation. Among the 60 genes identified, 40 genes are already known to be specifically involved in hepatocarcinogenesis.

Conclusions: HDV persistence is independent from the intrahepatic HBV reservoir and is sustained by HBsAg production from integrated HBV-DNA. Higher HBsAg levels (>4logIU/ml) can reflect an enrichment of HBV-DNA integration events in coding regions of hepatocytes' genome.

Localization of HBV integrants suggests that these events may potentially induce hepatocytes proliferation, paving the way for carcinogenesis.

Advances in viral pathogenesis

OC 49 PLASMA JCV-DNA CHANGES AS PROGNOSTIC MARKER IN PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

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Background: Progressive Multifocal Leukoencephalopathy (PML) is a severe demyelinating disease caused by JC Virus (JCV). Currently, there is no consensus on how to predict patients' outcome. Better prognosis has been related to lower CSF and plasma JCV-DNA levels at diagnosis, and to either clearance of viral load in the CSF or its reduction of ≥0.25 Log copies/mL by day 60 of follow-up. Since no data on JCV-DNA longitudinal changes in plasma are available, the aim of our study was to assess its role to predict PML prognosis.
Materials and Methods: This study included 36 patients who developed PML between 1996 and 2024, followed at or referred to the Infectious Diseases Unit of San Raffaele Hospital, Italy. The inclusion criterion was the availability of at least two plasma samples, drawn between 30 and 120 days apart, with the first sample drawn after a median of 14 days (25th-75thIQR 0-49) from diagnosis. Plasma JCV-DNA level was measured by real-time polymerase chain reaction assay. To optimize assessment of plasma JCV-DNA changes over time, we measured plasma JCV-DNA slopes, defined as the ratio between the difference of plasma JCV-DNA level from second (P2) to first (P1) sample and the number of days between P2 and P1. We assessed the best slope cutpoint to predict one-year survival with the maximized metric method by Youden Index, and presented its sensitivity and specificity by ROC curve. Mann-Whitney test was used to evaluate differences among groups, while univariate logistic regression to assess the association between plasma JCV-DNA levels and one-year survival.
Results: PML patients were 19 females and 17 males (Table 1), with a median age of 46 years (IQR 37-56) and included 18 people with HIV, 9 with hematological malignancies, 6 with primary immunodeficiencies, 2 with multiple sclerosis treated with natalizumab, and 1 who received bilateral lung transplant for idiopathic pulmonary fibrosis. One-year survivors were 23 (63.9%), mostly females (p=0.047) (Table 1). Median JCV-DNA level at P1 was 2.0 Log copies/mL (IQR 2.0-2.99), and 2.64 Log c/mL (IQR 2.0-3.33) at P2. The optimal JCV-DNA plasma slope cutpoint separating survivors from non-survivors at one year was 0.0118, with a sensitivity of 92% and a specificity of 100% to predict one-year survival. With this model we identified only a single false negative (Figure 1, Figure 2). Compared to JCV-DNA level at P1 or at P2, or to viral load change from P1 to P2, JCV-DNA plasma slope was the best at separating survivors from non-survivors, with the least overlap between the two groups (Figure 3).
Conclusions: This is the first study showing how JCV-DNA monitoring in plasma in the first weeks from PML diagnosis may help predict clinical outcome, by providing a plasma JCV-DNA cutpoint with high sensitivity and specificity. Consistently, longitudinal measurements of plasma JCV-DNA level may provide a new non-invasive biomarker to be investigated for monitoring the course of PML in real-time.

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Advances in viral pathogenesis

OC 50 BASELINE VIRAL LOAD IMPACTS THE AGING PROCESS IN INFANTS WITH PERINATALLY ACQUIRED HIV ENROLLED IN THE EARTH COHORT

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Backgrounds: The aim of this study is to define the impact of baseline viral load on the premature aging process in infants with perinatally acquired HIV (PHIV), from the Early Anti-Retroviral Treatment in HIV children (EARTH) cohort.
Methods: Thirty-six PHIV infants, ART-naïve at enrolment, with a median age of 1.6 (1.3-2.5) years, were studied for their immune aging profile (activated, senescent and exhausted T cells) by flow cytometry. Relative telomere length, T-cell receptor excision circle (TREC), and HIV-DNA in peripheral blood mononuclear cells (PBMC) were measured by multiplex real-time PCR, real-time PCR and ddPCR, respectively. Statistical analyses were performed using SigmaPlot software.
Results: Plasmaviremia significantly correlated with HIV-DNA in PBMC (r=0.525, p=0.003). According to plasmaviremia at enrolment, PHIV infants were divided in group 1 (VL <25 percentile of Log2 HIV-RNA) and group 2 (>75 percentile of Log2 HIV- RNA). Baseline levels of HIV-DNA in PBMC were significantly higher in group 2 than in group 1 (1159 [617-4426] vs 89 [9-1607] copies/106 PBMC, p=0.011). Similarly, group 2 had higher percentages of activated, senescent and exhausted CD4 and CD8 T cells than group 1 (table). Relative telomere lengths were significantly shorter in group 2 than in group 1 (1.82 [1.68-1.90] vs 1.93 [1.78-2.26], p=0.020). TREC levels were lower in Group 2 than in Group 1 (518 [426-666] vs 647 [538-865], p=0.061).
Conclusions: Higher levels of viral load strongly correlates with HIV-DNA in PBMC and lead to higher immune activation, senescence and exhaustion, thus suggesting that baseline levels of plasmaviremia may accelerate the aging process.

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Advances in viral pathogenesis

OC 51 EXPRESSION OF HCMV-ENCODED MIRNAS IN CO-INFECTED PLWH AND RELATIONSHIPS WITH INFLAMMA-TION/IMMUNE ACTIVATION

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Background and Aim: HCMV-encoded miRNAs play a role in the regulation of both viral and host transcription. HCMV co-infection determines a more rapid progression of HIV disease, mainly due to increased inflammation/immune activation. The aim was to analyze HCMV-encoded miRNA expression in acute HIV subjects (AHI), in comparison with HCMV mono-infected individuals. Correlations between HCMV miRNA expression, viral replication, and inflammation markers at baseline and after one year of early antiretroviral treatment (ART) were also evaluated.

Methods: Fourteen HCMV miRNAs were analyzed in 16 HIV/HCMV subjects and 10 HCMV mono-infected individuals by Real-time-PCR. HCMV DNA detection in whole blood discriminated lytic vs. latent HCMV infection. HIV -1 RNA, VEGF, and CXCL-10 levels were quantified before (T0) and after (T1) 6 and (T2) 12 months of therapy, together with HCMV DNA. Fisher's exact test, Mann Whitney and Spearman correlation tests were used as appropriate.

Results: At baseline, HCMV DNA was detected in two AHI with two transient low-level HCMV reactivations during the follow-up. Among the HCMV mono-infected group, 4 were viremic: median (IQR) 3.77 (3.39-5.16) Log HCMV DNA IU/ml. HCMV miRNAs showed a distinctive pattern in lytic vs. latent HCMV infection. Except for hcmv-miR-70 -3p detected in all subjects, hcmv-miRUL112-3p, hcmv-miR-US25-1-5p, hcmv-miR-US25-2-3p, hcmv-miR-US4-5p, hcmv-miR-US5-1, hcmv-miR-US5-2-3p, hcmv-miR-UL36-3p, and hcmv-miR-UL36-5p were more frequently detected in lytic infection, without statistical differences between mono- and co-infected subjects. When restricting the analysis to the latent HCMV phase of the infection, hcmv-miR-UL22A-5p and hcmv-miR-UL148D were more frequently observed in HIV/HCMV subjects than in HCMV mono-infected individuals at baseline, and during the follow-up, when also hcmv-miR-US33-5p displayed a higher frequency of detection (Table 1). In HCMV co-infected PLWH, expression levels of hcmv-miR-22A-5p and hcmv-miR-US33-5p showed a significant positive correlation with HIV-1 RNA (r=0.555, p=0.0002 and r=0.513, p=0.0008, respectively). Other significant positive correlations were found between hcmv-miR-UL22A-5p and IP-10 (r=0.435, p=0.006) and between hcmv-miR-UL148D and VEGF (r=0.324, p=0.044).

Conclusions: HCMV-encoded miRNAs are differently modulated in HCMV lytic and latent infections. In HCMV co-infected AHI, in the absence of HCMV replication, hcmv-miR-UL22A-5p, hcmv-miR-UL148D and hcmv-miR-US33-5p were more frequently expressed than in HCMV mono-infected sub-jects. While hcmv-miR-UL22A-5p and hcmv-miR-US33-5p were directly correlated with HIV-1 RNA and their expression may be controlled by ART, hcmv-miR-UL148D continued to be over-expressed also during effective therapy, in correlation with plasma levels of the inflammatory marker VEGF. A deeper knowledge of HCMV-encoded miRNA biology may open the way for developing new therapeutic strategies in HCMV/HIV coinfection.

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Long-term effectiveness of oral ART

OC 52 LONG-TERM EFFECTIVENESS OF BICTEGRAVIR-EMTRICITABINE-TENOFOVIR ALAFENAMIDE (B/F/TAF) AS FIRST-LINE THERAPY AND AS SWITCH STRATEGY IN VIROLOGICALLY SUPPRESSED PERSONS WITH HIV UP TO 192-WEEKS: DATA FROM THE ICONA-BIC STUDY

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Background: We aim to confirm in a real-life setting the clinical trial data of the long-term effectiveness of B/F/TAF, both as first-line therapy and as a switch strategy, in virologically suppressed persons with HIV (PWH) up to 192-weeks.

Materials and Methods: Observational cohort study of PWH enrolled in ICONA who started B/F/TAF as initial therapy or as switching regimen while virologically suppressed from June 2016 to August 2023.

The primary endpoint was time to treatment failure (TF): discontinuation for toxicity/intolerance or virological failure (VF, 2 HIV-RNA>200 copies/ml or 1 >1000 copies/ml followed by ART change, >6 months from starting for naive). Secondary endpoints: i) VF as previously defined and ii) discontinuation for toxicity/intolerance (TDT). Cumulative probabilities of the three endpoints were calculated by Kaplan-Meier curves at 144 weeks (and 192 weeks for ART experienced).

Results: 929 ART-naive and 1653 ART-experienced PWH initiated B/F/TAF. Baseline characteristics are shown in Table 1.

ART-naïve group: over a median follow-up of 141 weeks (IQR 94-189), 54 (5.8%) ART-naïve PWH experienced TF, 17 VF and 37 discontinuations for toxicity/intolerance. The cumulative probability of TF at 144 weeks was 6.7% (95% CI 5.0-8.8) [Figure 1A]. The 144-week probability of VF was 2.7% (1.6-4.4): in detail, 9 of 17 VF did not reach VS after 6 months, while 8/17 had a viral rebound after the first suppression. The median HIV-RNA at VF were 2,287 and 958 copies/ml. Only 4 changed B/F/TAF after VF, 6 out of the 9 PWH with virological follow-up after VF reached HIV-RNA<50 while remaining on B/F/TAF. The 144-week probability of TDT was instead 4.3% (3-6.2). The reasons for TDT are shown in Table 2A.

ART-experienced virologically suppressed group: Over a median follow-up of 216 weeks (IQR 156, 244), 76 (4.6%) out of 1653 switching PWH experienced TF (11 VF and 65 TDT); The cumulative probability of TF at 144- and 192-weeks were 4.0% (4.2-6.7) and 5.3% (4.2-6.7), respectively [Figure 1B]. The probabilities of VF were 0.7% (0.4-1.4) at 144- and 1.0% (0.5-1.8) at 192 weeks. Median HIV-RNA values at VF were 3400 and 1539 copies/ml, respectively. Only 4 PWH changed B/F/TAF after VF, 6/6 PWH with virological follow-up after VF while remaining on B/F/TAF reached HIV-RNA<50 copies/ml. Finally, the 144-week and 192-week probability of TDT were 3.4% (2.6 -4.4) and 4.4% (3.4%-5.7%), respectively. The reasons for TDT are shown in Table 2B.

Conclusion: Overall, we in the clinical real-life setting B/F/TAF is well tolerated and virologically effective in ART-naïve and experienced PWH in the long term up to 192-weeks. Discontinuation for toxicity remains a rare event both in naïve (4.3% at 144 weeks) and experienced (3.4% and 4.4% at 144 and 192 weeks). VF was low both in naïve and experienced PWH, given the subsequent VS without ART change, we can hypothesize that in those PWH, poor adherence was the cause of VF.

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Long-term effectiveness of oral ART

OC 53 OBSERVATIONAL EFFECTIVENESS AND SAFETY OF BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (B/F/TAF) IN TREATMENT-EXPERIENCED PEOPLE WITH HIV ACROSS AGE GROUPS: 24-MONTH RESULTS FROM THE ITALIAN BICSTAR COHORT

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Background: The aim of the multi-country BICSTaR cohort study (start of enrolment 2018) is to provide observational data on the effectiveness, tolerability and safety of B/F/TAF in people with HIV (PWH). Focusing on age groups, we present the final month 24 (M24) outcomes for treatment-experienced (TE) PWH from the prospective Italian cohort.

Material and Methods: Outcomes of interest were viral suppression (HIV-1 RNA <50 c/mL; missing/discontinuation=excluded [M=E] and discontinuation=failure [D=F] analyses), treatment retention, drug-related non-serious/serious adverse events (DRAEs/DRSAEs), and weight change – all stratified by age (<50, 50–64 and ≥65 years).

Results: Of 176 TE participants with follow-up data, 54% (n=95) were aged <50 years, 40% (n=70) 50–64 years and 6% (n=11) ≥65 years. Baseline characteristics are depicted in Table 1.

At M24, in the M=E analysis, HIV-1 RNA was <50 c/mL in 97% (144/148) of participants (<50 years: 97% [76/78], 50–64 years: 97% [58/60], ≥65 years: 100% [10/10]). In the D=F analysis, HIV-1 RNA was <50 c/mL in 92% (144/156) of participants (<50 years: 90% [76/84], 50–64 years: 95% [58/61], ≥65 years: 91% [10/11]). Resistance testing during follow-up was documented in two cases, with no emergent B/F/TAF-specific resistance-associated mutations (RAMs).

At M24, overall retention in treatment was 93%; 7.4% (13/176) discontinued for reasons other than virologic failure (<50 years: 9.5% [n=9], 50–64 years: 5.7% [n=4], ≥65 years: 0% [n=0]) including 2.3% [n=4] discontinuing B/F/TAF due to DRAEs (involving 11 MedDRA preferred terms: anxiety [n=2; all other n=1], affect lability, depression, loss of libido, abdominal distension, fatigue, weight increase, amnesia, headache, and alopecia).

In total, 20 DRAEs (no DRSAEs) were reported in 11 (6.3%) participants (most common events were psychiatric [n=6], nervous system [n=5], and gastrointestinal [n=5]). The proportions of PWH experiencing DRAEs in each age group were 7.4% (7/95; <50 years), 5.7% (4/70; 50–64 years), and 0% (0/11; ≥65 years).

In participants with BL and M24 data (n=110), median BL weight (Q1, Q3) was 76 kg (66, 82). Median weight in each age group was 76 kg (64, 85; <50 years [n=63]), 75 kg (68, 82; 50–64 years [n=42]), and 80 kg (74, 84; ≥65 years [n=5]).

Overall, the median relative weight change (Q1, Q3) at M24 was +0.4% (-3.5, +4.2); and by age groups 0% (-3.5, 5.3; <50 years [n=63]), +1.5% (-2.7, 3.4; 50–64 years [n=42]) and -4.8% (-6.3, 1.4; ≥65 years [n=5]).

Conclusion: During the 2-year observation period of the Italian BICSTaR cohort, effectiveness and safety outcomes were consistent across age groups of treatment-experienced PWH. B/F/TAF was well-tolerated with high virologic suppression rates and high treatment persistence. There were no emergent B/F/TAF-specific resistance-associated mutations (RAMs) and no discontinuations due to virologic failure in either age group; overall, only 2% discontinued due to DRAEs.

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Long-term effectiveness of oral ART

OC 54 TEN YEARS RESULTS ON THE EFFECTIVENESS AND SAFETY OF DTG+3TC AS A SWITCH REGIMEN IN THE ODOACRE COHORT

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Background: We aim to assess the effectiveness, safety and tolerability of DTG+3TC as a switch regimen after 10 years from its introduction in clinical practice.
Material and Methods: This was an observational study enrolling virologically suppressed people with HIV (PWH) switching to DTG+3TC in the Odoacre multicenter cohort; we collected their clinical history as well as virological, immunological and metabolic parameters. We performed Kaplan-Meyer survival analysis to evaluate time to virological failure (VF, defined as two consecutive HIV-RNA>50cps/mL or one single >1000cps/mL) and treatment discontinuation (TD), Cox-regression to find predictors of VF or TD and linear mixed model for repeated measures to measure changes in immunological and metabolic parameters.
Results: We analyzed data from 2,530 PWH: 1,650 (65.2%) were males, with a median age of 55 years (IQR 46-62). Characteristics of the study population are shown in Table1.
During 9617.8 PYFU, we observed 88 VF (0.9 per 100 PYFU); no emergent resistance mutations were registered among failing PWH. Estimated probabilities of maintaining virological suppression at 240 and 480 weeks were 96.2% and 90.5%, respectively. At a multivariate analysis, we found that a history of at least one previous VF before switch (aHR 2.03, p=0.003) was significantly associated with a higher risk of failing (DTG/3TC), while a peak HIV-RNA over 500'000 cps/mL was associated with VF risk even though it did not reach statistical significance (aHR 1.67, p=0.06); meanwhile, a longer time of virological suppression (per 1 year more, aHR 0.90, p<0.001) resulted inversely correlated with VF risk. We found no correlation between the presence of the M184V mutation and the risk of VF, even after adjusting for time of virological suppression.
During 9712.3 PYFU, we observed 362 TD (3.7 per 100 PYFU). Estimated probabilities of maintaining DTG/3TC were 83.5% at 240 weeks and 78.7% at 480 weeks. Discontinuations for toxicity were 88 (24.3% of all TD), with CNS toxicity accounting for 27 (7.5%) cases. Other frequent reasons for TD were: switch to CAB+RPV (67, 18.5%) and treatment intensification (37, 10.2%).
After 240 weeks, we registered a significant improvement in both CD4+ count (median +52 cell/mm3, p<0.001) and CD4/CD8 ratio (+0.1, p<0.001). CD4+ improvement was more pronounced in younger PWH (p<0.001) and PWH with a lower CD4+ count at baseline (p<0.001). We also registered an improvement in CD4+ at 480 weeks (+135 cell/mm3, p<0.001).
As to metabolic parameters, we observed significant improvement in total cholesterol, triglycerides and HDL cholesterol and we also registered a significant decrease in median METS-IR score at week 120 (p=0.035. Median SCORE2 in our cohort increased modestly in an age-related manner. Finally, we did not observe changes in BMI.
Conclusions: We assessed the efficacy and safety of DTG+3TC in the long term in a multicenter cohort.

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Long-term effectiveness of oral ART

OC 55 LONG-TERM DURABILITY OF DOLUTEGRAVIR/LAMIVUDINE DUAL REGIMEN IN A REAL-WORLD SETTING (DOLU3TC STUDY)

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Background: Dolutegravir/lamivudine (DTG/3TC) is a recommended option according to treatment guidelines for naïve and experienced people living with HIV (PLWH). However, data are limited on its long-term efficacy. We report on the durability of this dual regimen assessed by treatment discontinuation (TD) over time.
Material and Methods: Retrospective, observational, single-centre study in PLWH consecutively enrolled in DTG/3TC. The primary composite endpoint was TD defined as any reason of discontinuation, including virological failure (VF) (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. Multiple Cox proportional hazards model was used to estimate the probability of TF following the initiation of DTG/3TC.
Results: A total of 556 individuals were included (73% males, 48% heterosexual and 31% MSM), Median age (IQR) was 55 (46-62) years. 525 (94.4%) switched for simplification and 31 (5.5%) were naïve to therapy. None had HBV coinfection. Number of comorbidities were 0, 1-2 and 3-5 in 29 (5%), 234 (%) and 28 (%) subjects, respectively. Median nadir (IQR) CD4 count was 276 (106-433) cells/ml and 15% had AIDS. Median duration (IQR) of HAART was 10 years (IQR 4.3-17) and 47% had received 2 or less treatment lines. Their last regimens were PI-, NNRTI- or INSTI-based in 46 (8%), 179 (33%) or 228 (41%). 45 subjects had ≥ 1 resistance mutations (none INSTI-associated, 8 with M184V/I). At study entry, median CD4 count (IQR) was 794 (569-1061) cells/ml. Median follow-up was 21.7 (IQR 11- 38.6) months since DTG/3TC initiation. 48 (8.6%) subjects discontinued the regimen. Main reasons for stopping were intolerance in 14 (2.5%), toxicity in 14 (2.5%), death in 8 (1.4%). VF was detected in 6 (1%) subjects, 3/6 had 184V (as in historical genotypes), 1 developed INSTI mutations. The probability of TD was 5%, 8%, 9%, 13%, 15%, 18%, and 20% after 1, 2, 3, 4, 5, 6 and 7 years of treatment, respectively (figure1). At Cox regression analysis, AIDS, CD4 nadir, duration of ARV and type of last regimen were not associated with a reduced probability of TD over time.
Conclusions: DTG/3TC is an effective and durable dual regimen as switch strategy in real life. TD is infrequent with reasons mainly due to intolerance/toxicity.

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Access to prevention in different settings

OC 56 RISING CHEMSEX TRENDS AMONG PREP USERS IN MILAN: A 2024-2025 STUDY

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Background: Chemsex is defined as the use of psychostimulants (GHB/GBL, synthetic cathinones and crystal methamphetamine) during sexual intercourse, particularly among MSM. These drugs are often used in combination with other substances varying by geographical contexts.
A previous 2024 survey conducted in two STI services in Milan reported a high prevalence of drug use (33%) among PrEP users, with 16% engaging in chemsex.
The aim of our study is to assess changes in substance use over the past year and, secondly, evaluating the proportion of problematic use.
Methods: From January to March 2025, we conducted an anonymous online survey among PrEP users attending two STI services in Milan: one hospital-based and one community-based. Data collected included drug use, frequency and type, chemsex practices, use of PDE5 inhibitors and physical enhancers, perceptions of problematic use, and requests for psychological support.
For descriptive statistics, continuous variables are expressed as median and IQR, and categorical variables as absolute numbers and percentages. Changes in chemsex and drug use prevalence between 2024 and 2025 were analyzed using two-proportion z-tests.
Results: 376 PrEP users completed the questionnaire. The median age was 38 years (IQR 33 – 45), 98% (370/376) were assigned male at birth, and 365/376 (97%) identified as GBMSM.
In the past year, 119/376 (32%) reported drug use (110/376, 29% in the past 6 months) and 22% (81/376) reported chemsex practice (74/376, 20% in the past 6 months).
5% (6/119) reported using substances >1/week, 16% (19/119) weekly, 31% (37/119) >1/month, 11% (13/119) monthly and finally 37% (44/119) <1/month.
Among chemsex-specific substances, mephedrone was the most commonly used (38%, 45/119), followed by GHB/GBL (22%, 26/119), MDPV (13%, 16/119) and crystal meth (8%, 9/119). Among other substances, cocaine was the most frequently reported (23%, 27/119; crack 8%, 10/119), secondly MDMA (21%, 25/119) and ketamine (14%, 17/119). Table1 and Figure1 show the proportion of specific substances use.
20/376 (5%) of respondents reported using physical enhancers (testosterone, SARMs), of whom 55% (11/20) co-used chems.
54% (44/81) of those who engaged in chemsex also used PDE5 inhibitors.
Problematic use was reported by 30% (24/81) of chemsex practicing, with 29% (7/24) seeking psychological support.
Compared to 2024, overall substance use remained stable (32% in 2025 vs. 33% in 2024, p = 0.6). However, the prevalence of chemsex increased significantly from 14% (52/365) in 2024 to 22% (81/376) in 2025 (p =0.01).
Conclusions: Our survey found a high prevalence of chemsex among PrEP users, with an increasing trend since last year. It also revealed problematic drug use among a significant proportion of chemsex users (30%).
These findings highlight the urgent need to raise awareness among healthcare professionals, enabling them to screen for problematic drug use and facilitate referrals to specialized support services.

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Access to prevention in different settings

OC 57 TELEPREP: NEW DATA ON A BEST PRACTICE IN HIV PREVENTION

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Background: TelePrEP is an exclusively online PrEP service, implemented through the collaboration of a team of community health workers and infectious disease specialists. Since its launch in Feb.2023, 389 people have contacted the service for preliminary information and 168 have been enrolled: 165 cis men and 3 cis women [Demographic data Fig1-5]. 89 individuals unaware of nearby PrEP programs were referred to such services to benefit from drug reimbursement options; 132 people did not proceed after 1st consultation. Main reasons for service discontinuation are success in accessing local PrEP programs, changes in couple relationships.
This analysis focuses on data collected from clients during follow-up (F/U) consultations conducted to date.
Material and Methods: TelePrEP services (consultations, prescriptions, test result exchanges) are facilitated online through an ePlatform, enabling the establishment of effective relationships and providing counseling on psychological and medical aspects. Clients' demographic/behavioral data are collected in a dedicated database for M&E purposes and for scheduling F/U call reminders. After the first F/U call, occurring one month post PrEP initiation when necessary, subsequent calls are generally scheduled quarterly; flexibility is adopted to adjust to individual situations (delays in PrEP initiation, abstinence from sex for different reasons…)
Results: As of March 10, 2025, 99 F/U consultations were performed: 15 after one month, 39 after 3 months; 21 after 6; 10 after 9; 9 after 12; 3 after 15; 2 after 18 [Figure 6]. With respect to the choice of schedule, 44.5% of clients report taking PrEP daily (with/without initial booster); 51.5% taking it on-demand; 4% switching from one schedule to the other. 20.2% of clients report having had one or more transient side effects, such as nausea/gastrointestinal problems (41.7%), headache (12.5%), chills (4.2%). One HCV infection was detected during F/U after 3 months; 1 syphilis and 1 gonorrhea infections at 9-mos F/Us; 1 syphilis and 1 chlamydia infections at 12-mos F/Us. No HIV infections were detected.
66.7% of clients do not have a steady partner; 30.3% are in a stable, non-monogamous relationship; 3% are in a monogamous one. They search for sexual partners on dating apps occasionally (25.3%); always/often (53.6%); rarely/never (21.2%).
Since PrEP initiation, number of sexual partners increased (39.4%), greatly increased (7.1%) [Figure 7]; condoms are used always (10.1%), often (25.3%) [Figure 8].
Only 13 clients (13.1%) report Chemsex use [Figure 9].
Most clients (92.9%) strongly agree/agree with the statement “Since starting PrEP I live my sexuality with greater peace of mind” [Figure 10].
Conclusions: TelePrEP services succeed in retaining clients in F/U and detecting new STIs, providing advice on linkage to care. Clients are highly satisfied and want to continue benefiting of online support due to lack of widespread PrEP programs in the Italian territory.

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Access to prevention in different settings

OC 58 IS PREP KNOWLEDGE A PRIVILEGE? THE UNEQUAL ACCESS TO PREP INFORMATION FOR CIS AND TRANS WOMEN AND GENDER NON-CONFORMING INDIVIDUALS AT HIV TESTING SITES

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Background: In Italy, the majority of PrEP users are gay, bisexual and other men who have sex with men (GBMSM), while other populations - cisgender women, transgender women, transgender men and non-binary individuals with a cervix - face considerable barriers in accessing PrEP information and services. This study explores potential barriers to PrEP awareness and HIV testing for these populations. The initial hypothesis was that these groups are not being adequately informed about PrEP when tested for HIV.

Materials and Methods: To validate this hypothesis, Brescia Checkpoint and Anlaids Torino conducted a survey targeting cisgender women, transgender women, transgender men and non-binary individuals with a cervix. It was distributed across multiple regions and informal networks, including social media and community-based platforms. The responses were collected through Google Forms. Data were analyzed using descriptive statistics. The survey complied with GDPR regulation.

Results: A total of 765 respondents participated in the survey (Table 1), with 56.3% not having been tested for HIV in the past two years, mainly due to lack of knowledge on where or how to get tested (37.1%), absence of recent sexual activity (23%), fear or shame (21.1%), the misconception that monogamy is a protection (18.1%), and lack of time (16.5%) as described in Figure 1.

Among those tested, 72.2% were not informed about PrEP by testing providers (Table 2). Only 20% of those tested in STI/infectious disease departments had access to information. In contrast, checkpoints were more effective, with 55% receiving PrEP-related guidance. However, HIV associations provided information to only 29% of those tested.

Indeed, insufficient information (32.9%) is one of the key factors preventing these populations from initiating PrEP, along with no perceived risk (34.8%) and socioeconomic barriers (33.5%) as displayed in Figure 2.

Twelve people of all respondents reported using PrEP.

Conclusion: This study confirms our initial hypothesis that these populations are not being adequately informed about PrEP, particularly in institutional healthcare settings. Checkpoints' work to inform cisgender women, transgender women, transgender men and non-binary individuals with a cervix about PrEP remains insufficient.

It is crucial that STI/infectious disease departments, together with the Italian HIV community, join forces to expand HIV testing awareness and provide comprehensive PrEP education and combination prevention counseling to ensure equitable HIV prevention access for all.

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Access to prevention in different settings

OC 59 FACILITATORS AND BARRIERS HIV/STI INFORMATION AND SERVICES AMONG LGBTQI+ IMMIGRANTS IN ITALY

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Introduction: Italy receives thousands of immigrants every year, some of whom seek asylum to escape the hostility and violence related to homophobia in their home countries. Lesbian, gay, bisexual, transgender, intersex, queer/questioning (LGBTQI+) immigrants in Italy are disproportionately affected by HIV. In Italy, “people born abroad” are a high-risk population who are least likely to be aware of their HIV status. This demonstrates an acute lack of access to timely HIV testing. This study, thus, aimed to understand the facilitators and barriers to health services among this population in Italy.

Method: We conducted 33 semi-structured interviews and two focus group discussions (n=14) in Italian, English and Spanish languages. We recruited participants through community-based organizations in North, Central and Southern Italy. Eligibility included: migrated to Italy ≤10 years ago, identified as LGBTQI+, ≥18 years old. Participants were from South America, Asia and Africa. Audio files were transcribed and translated into English. Phronetic iterative process was used to analyze data. Ethical review was approved by the University of Missouri(IRB# 2104686).

Results: The mean age was 30.5 years (SD=8.5). Average years in Italy was 4.8 years (SD=6.61). Sixteen (50%) were cismen, 4(23.5%) were ciswomen, 5 (15.6%) transwomen, 2 (6.3%) transmen and 5 (15.6%) identified as non-binary. These themes emerged: stigma and discrimination due to intersecting minority identities, language difference and lack of support. Regarding LGBTQI+ identity, race and immigrant experience, a participant said, “In Italy-I always say homophobia stripped me of respect, racism stole my dignity.” Another participant recounted their experience of filling out forms at a health center, “They bring you to a point of anger and you enter the stereotype of a racialized person, of someone who is always angry. A person who insults you, who throws documents in your face, for them you must stay calm,” highlighting institutional discrimination. Participants also spoke about the rising cost,“I used to pay 150€ for Tessera Sanitaria. But they increased it to 700-800€. It's incredible, wild.” Among facilitators, participants mentioned having the support of community health organizations gave them confidence to seek and understand HIV/STI prevention information and connect with services. One participant said, “This place helps you remove that shame, bring out that boldness in you to meet up with someone and get some information.”(Table 1)

Conclusion: LGBTQI+ immigrants in Italy experience individual and structural barriers to access HIV/STI prevention and treatment services, including stigma, discrimination and lack of communication services. This group seem to navigate the health system with the help of community health organizations. Communication technologies could potentially bridge the gap of information to reach a wider population of immigrants in need physical and psychological healthcare.

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HIV and comorbidities

OC 60 LONG-TERM SUCCESS OF COMBINED KIDNEY-LIVER TRANSPLANTATION IN PEOPLE WITH HIV: EVIDENCE FROM A REAL-WORLD COHORT

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Background: This study aimed to compare outcomes in combined kidney-liver transplantation (CKLT) based on HIV serostatus.
Methods: We included people with HIV (PWH) who underwent CKLT at the University Hospital of Modena between 2007 and 2024. Transplant-related and HIV-specific characteristics were collected. Recipients with HIV were compared with those without HIV transplanted in the same period, using Fisher exact test and Mann-Whitney U test, as appropriate.
Results: Six individuals with HIV received CKLT: all males, median age of 49 years (IQR 37-60), HIV duration of 25 years (IQR 23-38); at transplant, CD4 cell count of 211 cell/mm3 (IQR 10-348) and all with undetectable HIV RNA. Detailed characteristics shown in Table1.
All PWH had HCV co-infection, with 50% showing active replication at transplant. Before 2015, antiretroviral therapy (ART) was primarily based on raltegravir combined with protease inhibitors (with or without a booster) and/or lamivudine. At the last follow-up, all recipients were on INSTI-based regimens, and no cases of virological failure were observed.
During the same period, 15 HIV-negative individuals underwent CKLT. Viral co-infection and chronic glomerulonephritis (including HIV-associated nephropathy) were significantly more frequent among PWH than among HIV-negative recipients (83.3% vs 20%, p<0.05; 83.4% vs 6.7%, p<0.05, respectively) (Figure 1). All recipients received organs from deceased donors. As detailed in Table 2, PWH had higher MELD at transplant (25 [IQR 21-32] vs 11 [IQR 11-21], p=0.002) and pre-emptive strategy for kidney transplant was adopted less frequently than in non-HIV recipients (6.6% vs 73.3%, p=0.029). No one had liver primary non function, but 2 recipients per group had delayed kidney graft function. Kidney rejection incidence rate (IR) was 0.1 [95%CI 0.02-1.0] vs 0.3 [95%CI 0.01-1.1] per 100PYFU in recipient with and without HIV, respectively. No liver rejection nor failure was observed in PWH, while one liver rejection occurred in the HIV-negative group. Kidney graft failure occurred in one recipient per group: in HIV recipient, failure was followed by death, while in recipient without HIV, it resulted in a return to haemodialysis 5 years after transplant. Overall recipient survival was 83% in PWH vs 86.7% in HIV-negative recipients, with a death IR of 1.73 [95%CI 0.24-12.31] vs 2.62 [95%CI 0.65-10.45] per 100PYFU, respectively (p=0.845).
Conclusion: This study demonstrates that CKLT in PWH can achieve excellent outcomes, with patients and graft survival rates comparable to those observed in non-HIV transplant recipients. Despite higher MELD scores at transplant and greater prevalence of viral co-infections, rejection and graft failure rates were low, and no virological failure was reported post-transplant. These findings provide further evidence that CKLT is a viable and effective option for PWH, supporting broader clinical consideration and tailored management strategies for this population.

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HIV and comorbidities

OC 61 HIV-TO-HIV ORGAN TRANSPLANTATION: A COMPARATIVE ANALYSIS OF LIVER AND KIDNEY TRANSPLANT OUTCOMES IN PEOPLE WITH HIV RECEIVING ORGANS FROM DONORS WITHOUT HIV INFECTION

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Background: This study aims to compare outcomes in people living with HIV (PWH) who received a liver transplant (LT) or kidney transplant (KT) from donors with HIV infection (D+/R+) versus those who underwent transplantation with organ from donors without HIV(D-/R+).
Methods: Retrospective study of PWH who underwent LT or KT at University Hospital in Modena from 2003 to 2024. Data collected included demographics, HIV-related characteristics, clinical and graft-related outcomes. Recipients were compared according to donor HIV serostatus, using Fisher exact test and Wilcoxon Mann Whitney test as appropriate. Kaplan-Meier curves were used to explore graft-related outcomes.
Results: Among 118 transplants in PWH, 8 were in the D+/R+ group(5 liver, 3 kidney; among those,1 received a liver form a living donor) while 110 were in the D-/R+ group (77 liver, 27 kidney, 6 combined liver-kidney; among those, 2 received liver from living donors). All donors with HIV were on ART, all except two had undetectable viral load; most of them had past HBV or HCV co-infection. After transplant, one LT recipient experienced low-level viremia and one KT recipient had a viral blip (HIV RNA 247cps/ml) after receiving graft from viraemic donor without emerging resistance mutations. Recipient characteristics stratified by donor HIV serostatus are reported in Table 1. Compared to the D-/R+ group, D+/R+ group had longer HIV duration (33 [IQR17-37] vs 23 [IQR 6-38] years, p=0.014), none had active HCV co-infection (0% vs 29%, p=0.067). D+/R+ kidney recipients had a shorter dialysis duration (0.8 [IQR 0.8-1.2] vs 3.2 [IQR 0.61-11.9] years, p=0.016). D+/R+ liver recipients had a lower MELD-Na score at transplant (10 [IQR 9-15] vs 17 [IQR 7-35], p=0.05). At transplant, all recipients had HIV RNA<50 cps/mL, with no significant difference in median CD4 cell count (p=0.610). Recipient survival in D+ and D- was 75% and 66%, respectively, with a median follow-up of 2.5 and 3.7 years. The mortality incidence rate was 9.7 (95% CI 2.4-39.2) per 100 PYFU in D+/R+ vs 6.3 (95% CI 4.6-8.7) per 100 PYFU in D-/R+ (p=0.783). Graft survival was 100% in D+ and 67% in D- recipients, evaluated at last available follow up (logrank= 0.176) (Figure1). Graft rejection occurred only in D-/R+ group (23%), with more frequency in kidney recipients as shown in Figure 2 (logrank=0.172).
Conclusions: This study demonstrates that solid organ transplantation from donors with HIV is a feasible option for PWH, with comparable recipient and graft clinical outcomes to transplants from donors without HIV. Notably, D+/R+ recipients had no graft rejection events, shorter dialysis duration before KT, and lower MELD-Na scores at LT, suggesting they may have received transplants at an earlier disease stage. While overall survival and mortality rates were similar between groups, the 100% graft survival rate in the D+/R+ group, despite limited sample size, is a promising finding that warrants further investigation.

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HIV and comorbidities

OC 62 TOBACCO AND ALTERNATIVE NICOTINE PRODUCT USE AMONG PEOPLE WITH HIV: SHOULD WE BE CONCERNED?

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Background: People with HIV (PWH) have a significantly higher prevalence of smoking habits compared to the general population, contributing to an elevated risk of non-AIDS-related complications, including lung cancer and cardiovascular disease. The increasing use of heated tobacco products (HTPs) and electronic cigarettes (e-cigarettes) adds complexity to tobacco consumption behaviors.
Methods: We conducted a cross-sectional, multicenter survey among PWH aged ≥18 years across five Italian university hospitals. An anonymous online questionnaire was distributed via QR codes displayed in outpatient clinics from November 2024 to February 2025. Participants provided information on their smoking status, use of HTPs and e-cigarettes, motivations for product use, and engagement with smoking cessation services and lung health screenings. Differences in categorical and continuous variables were analyzed using Chi-square, Fisher's exact test, one-way ANOVA, or Kruskal-Wallis tests as appropriate.
Results: 1,081 PWH were included, 41.9% were current smokers, 31.5% were former smokers, and 26.6% had never smoked. In current smokers, the median consumption was 15 (IQR: 10–20) cigarette/day, with a smoking habit duration of 30 (IQR: 20–40) years (Table 1). HTP use was reported by 10.6% of participants, predominantly among current (13.3%) and former smokers (14.4%), while e-cigarette use was reported by 15.9% people, mainly among younger individuals. Combined use of cigarettes and e-cigarettes was present in 21.0% of current smokers (Table 2). The primary motivations for e-cigarette use were smoking reduction (75%), and perceived lower harm (53.5%).
Despite high smoking rates, only 5% of participants had accessed smoking cessation services, and 60.5% of current smokers had attempted to quit. However, physician recommendations for cessation support were quite infrequent (21.0%). Lung health screening was underutilized, with only 17.0% undergoing a CT scan and 12.7% receiving pulmonary consultations. Screening rates were significantly higher among those with ≥20 pack-years of smoking, but engagement remained suboptimal even among high-risk individuals (Figure 1).
Conclusion: This study provides a comprehensive analysis of smoking behaviors among PWH in Italy, revealing a significantly higher smoking prevalence than in the general population (41.9% vs. 19.5%). The high rates of tobacco use, coupled with the increasing adoption of e-cigarettes and HTPs, underscore the evolving landscape of nicotine consumption. Furthermore, our findings highlight a significant gap in lung health screening and preventive care, despite the elevated smoking-related risks in PWH. Targeted interventions within HIV care settings, including improved smoking cessation programs and greater access to lung health screening, are crucial to reducing the long-term health impact of tobacco use in this vulnerable population.

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HIV and comorbidities

OC 63 HYPERTRIGLYCERIDEMIA AND GENDER DIFFERENCES IN THE RISK OF MAJOR ADVERSE CARDIOVASCULAR EVENTS IN PEOPLE WITH HIV: A SINGLE CENTER RETROSPECTIVE LONGITUDINAL STUDY

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Background: In PWH hypertriglyceridemia is associated with increased risk of major adverse cardiovascular events (MACE), however the association is often attributed to concomitant metabolic abnormalities and fewer data is available on isolated hypertriglyceridemia as a risk factor for MACE. Aim is to assess whether hypertriglyceridemia represents an independent risk factor for MACE, beyond factors included in the atherosclerotic cardiovascular disease (ASCVD) risk score. Additionally, we investigated whether the impact of hypertriglyceridemia and traditional risk factors (included in ASCVD score) on MACE is modified by gender.

Methods: Retrospective study on PWH followed at Infectious Diseases Unit, San Raffaele Scientific Institute, between January 2013 and January 2025. Baseline (BL) as the first evaluation from 2013 onwards. BL differences by sex were analyzed using Wilcoxon, Chi-square or Fisher's exact test, as appropriate. A multivariate Cox regression model was used to assess the effect of hypertriglyceridemia (defined as two determinations of triglycerides >150 mg/dL or intake of Fibrates or Omega3) on the occurrence of MACE, adjusting for age, sex, smoking status at baseline, total cholesterol, HDL cholesterol, statin use, diabetes, hypertension, CD4 count, nadir CD4 count and viremia. The interaction term was tested to evaluate whether sex modified the effect of variables statistically associated with MACE.

Results: Overall, 5278 PWH were included, of which 993 were women. Overall, 2586 (49.0%) had hypertriglyceridemia, with similar proportions in men and women [48.5% vs 51.2%]. Characteristics at BL according are displayed in Table 1. During a median follow-up of 11.40 [6.83;12.02] years, 187 MACE occurred. In the multivariate analysis, hypertriglyceridemia (p=0.042), older age (p<0.0001), smoking (p=0.003), higher total cholesterol (p=0.003), lower HDL cholesterol (p=0.004), hypertension (p=0.008), statin use (p=0.003), diabetes (p=0.002) and unsuppressed viremia (p=0.002) were significantly associated with MACE (Table 2). Analyzing the interaction with gender, none of the variables associated with MACE were significantly modified by sex except for diabetes, which showed a marginally significant interaction (p=0.059).

Conclusions: In this study, hypertriglyceridemia resulted as independent risk factor for MACE, in addition to traditional factors included in ASCVD risk score. Therefore, normalization of triglycerides should be advised to further reduce the risk of MACE. The impact of these parameters was not modified by gender, however women with diabetes may present with a slightly increased cardiovascular risk.

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Diagnosis, prevalence and prevention of STIs

OC 64 CLINICAL EVALUATION OF GONOCOCCAL-SPECIFIC CULTURE TEST FOR RECTAL GONORRHEA DIAGNOSIS

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Background: Neisseria gonorrhoeae infections is a common sexually transmitted infection in men who have sex with men (MSM). Nucleic acid amplification tests (NAATs) are the recommended testing method for gonorrhea screening. However, recently the need to test asymptomatic MSM for gonorrhea has been debated, due to over-detection by means of NAATs. The aim of this study is to assess factors associated with positive gonococcal culture-based tests in NAAT-confirmed rectal Neisseria gonorrhoeae (NG) infections.

Material and Methods: This is a retrospective study on MSM receiving HIV care, pre-exposure prophylaxis (PrEP) prescription or sexually transmitted infection (STI) screening at the Infectious Diseases Unit of San Raffaele Hospital, Milan, Italy, who were diagnosed with NAAT-confirmed rectal Neisseria gonorrhoeae between January 2021 and January 2025 (freeze date). First episodes of gonorrhea were considered. Demographic data, presenting symptoms, and sexual behaviors were collected during medical visits. Only individuals who underwent both rectal NAAT (NG/Chlamydia trachomatis Cobas, Roche) and gonococcal-specific culture test and with positive NAAT results were included. Continuous variables were presented as median and interquartile range [IQR], while categorical variables were reported as number (%). Chi-square test or Fisher's exact test were used to compare positive and negative cultural test results for categorical variables. Demographic continuous variables were analyzed by Mann-Whitney test.

Results: Overall, 552 MSM (164 PWH and 306 PrEP users) and 4 women who have sex with men (WSM) were diagnosed with rectal Neisseria gonorrhoeae; among them 200/556 (35.3%) had a positive gonococcal culture rectal swab. Median age was 35.7 years [IQR=30.7;41.9]. People with culture-negative rectal gonorrhea were older [36.4 years (IQR=31.4;42.2) vs 34.9 (IQR=29.8;40.1), p=0.013] compared to those with culture-positive results. Individuals with a positive culture test were more frequently symptomatic 56.5% (113/200) vs 16.6% (59/365), p<0.001 compared to those negative (Figure 1). In details, burning [31% (62) vs 6.74% (24), p<0.001], gastrointestinal alterations [13.5% (27) vs 3.09% (11), p<0.001], tenesmus [19% (38) vs 3.93% (14), p<0.001], and anal discharge [29.5% (59) vs 8.99% (32), p<0.001] were more common among those with positive cultural exams. No other clinical or demographic differences were observed.

Conclusions: Gonococcal culture was positive in less than half cases of rectal gonorrhea. Individuals with asymptomatic rectal gonorrhea had less frequently positive culture testing, suggesting lower infection pathogenicity. The need to test asymptomatic MSM for rectal gonorrhea requires careful consideration.

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Diagnosis, prevalence and prevention of STIs

OC 65 PROGRESSIVE INCREASE OF NEW SYPHILIS DIAGNOSES AMONG MSM WITH HIV INFECTION: A 30-YEAR REPORT FROM ROME STI REFERENCE CENTER

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Objective: To describe the trends and characteristics of new syphilis diagnoses over the last 30 years (1991/2022) collected by the reference center for Sexually Transmitted Infections (STI) in Rome, with a specific focus on the trends of new infections among people with HIV infection.

Methods: The center offers screening tests for syphilis and other STIs to all symptomatic individuals or those requesting tests for other STIs, including walk-in access. Additionally, immediate therapy is provided to patients with positive tests. For each screened person, data about sexual orientation, history of STI and HIV serological status are collected. HIV-negative patients who have not been tested for at least three months also undergo, after informed consent, HIV-Ab test together with syphilis and other STI screening.

Results: From January 1991 to December 2022, 3,093 new syphilis cases were diagnosed in our center, the majority of which were found among MSM: 1,992 (64.4%). The prevalence of new syphilis diagnoses among MSM progressively increased from 1991-2000 (95/332, 28.6%) to 2001-2010 (827/1390, 59.5%) and further to 2011-2022 (1070/1371, 78.0%). The prevalence of new syphilis diagnoses was mainly detected among people with known HIV infection, among whom they progressively increased (from 5.7% to 11.9% up to 27.1% by ten years periods). In contrast, the detection of new HIV infections at the time of syphilis diagnosis progressively decreased (from 4.2% to 4.1% up to 1.9% in the last decade, (Table 1). The table also reports that the overall increase in new syphilis diagnoses among known HIV people has been particularly observed from 2011, with higher percentages among MSM (from 14.7% in 1991-2000 years to 31.7% in the last decade). Furthermore, in recent years, the prevalence of MSM with known HIV infection acquiring syphilis continued to rise reaching 33.0% from 2016 (year in which the acronym U=U from WHO/CDC was assessed) to 38.3% during the COVID-19 pandemic years, when over 120 syphilis diagnoses per year were still observed. Conversely, the number of new HIV diagnoses concomitant with syphilis diagnosis has progressively decreased, with only 2 new infections observed since 2016 among HIV positive MSM and no new HIV infections during the pandemic period.

Conclusions: Using new syphilis diagnoses as an indicator of increased sexual activity or risk of STI acquisition, the data collected at our center suggest that new HIV infections have dramatically decreased in recent years, despite a high number of syphilis diagnosed. Indeed, the high number of new syphilis diagnoses still observed may indicate a more open sexual lifestyle among MSM, with the understanding that current antiretroviral therapy with guarantee of steady virological HIV suppression, along with the initial availability of PrEP, can protect against HIV infection.

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Diagnosis, prevalence and prevention of STIs

OC 66 HIGH-RISK HPV OTHE THAN HPV16 ARE COMMON IN ADVANCED ANAL PRECANCEROUS LESIONS IN MSM LIVING WITH HIV

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Background: Squamous cell carcinoma of the anus (SCCA) and its precursors (high grade squamous intraepithelial lesions, HSIL) are caused by high-risk human papillomavirus genotypes (HR-HPV) persistent infection of the anal mucosa. While HPV16 is considered the most persistent and oncogenic genotype in the anus, men who have sex with men (MSM) living with HIV (LWH) show an increased proportion of SCCA cases associated with HR-HPV other than HPV16 (non16HR-HPV).

Advanced HSIL (anal intraepithelial neoplasia grade 3, AIN3) are considered to be the direct precursors of SCCA. Understanding the epidemiology of non16HR-HPV in advanced anal precancers could help refine SCCA screening strategies.

Material and Methods: To evaluate the role of non16HR-HPV in advanced HSIL we retrospectively analyzed data from 81 MSM LWH and 32 MSM not living with HIV (NLH) that received histologic diagnosis of high grade dysplasia during screening for SCCA between June 2023 and June 2024.

All participants underwent anal HPV DNA test with partial genotyping (HPV16/other HR-HPV), anal cytology, and high resolution anoscopy (HRA).

Participants showing concomitant infection due to HPV16 and non16HR-HPV were categorized as having HPV16 anal infection.

Results: Median age of participants was 43 for participants LWH and 41 for individuals NLH (p=0.10). 51.8% of participants LWH and 56.2% of those NLH received HPV catch-up vaccination (p=0.72). Smoking habit was slightly more frequent among individuals LWH (42% vs. 34%; p=0.06).

All participants LWH were on antiretroviral therapy with undetectable plasma HIV RNA since at least 2 years, median time from HIV diagnosis was 11 years, median current CD4 count was 790 cells/mL.

Prevalence of anal HR-HPV was 100% in both groups.

Infection due to non16HR-HPV was more frequently observed in MSM LWH than MSM NLH (54% vs. 31%; p=0.02), while anal HPV16 infection was more prevalent among MSM NLH (46% vs 69%; p=0.03).

AIN3 was observed in 26% of participants LWH and 40% of those NLH (p=0.06). AIN3 was associated with non16HR-HPV in 41% of cases and with HPV16 in 59% of cases (p=0.14) among participants LWH. In individuals NLH, AIN3 was associated with non16HR-HPV in 23% of cases and with HPV16 in 77% of cases (p=0.33). The proportion of AIN3 associated with non16HR-HPV was similar between the two groups (p=0.28).

Conclusions: Despite literature reports an increased frequency of SCCA cases associated with non16HR-HPV among MSM LWH in respect to MSM NLH, we observed a similar prevalence of AIN3 lesions associated with non16HR-HPV between the two groups, suggesting that these lesions might be more prone to neoplastic progression in MSM LWH. A thorough screening and aggressive treatment of advanced HSIL is warranted in MSM LWH in the presence of non16HR-HPV (as well as HPV16, indeed).

Diagnosis, prevalence and prevention of STIs

OC 67 THE ACTUAL NEED OF DOXYPEP MIGHT NOT BE AS LARGE AS EXPECTED

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Background: DoxyPEP proved to be effective in preventing bacterial sexually transmitted infections (STIs) and the Centers for Diseases Control and Prevention (CDC) recommended it in men who have sex with men (MSM) and transgender women (TGW) who have had at least one infection in the previous 12 months. However, the risk of antibiotic overuse and the potential spread of antimicrobial resistance led many scientific societies to issue more cautious and restrictive position statements. Aim of this study is to evaluate if CDC recommendations would be appropriate in a cohort of PrEP users assessing factors that describe individuals who might benefit the most from doxyPEP.

Methods: Milano Checkpoint is a community-based, peer-led service that provides medical assistance to one of the largest PrEP cohorts in Italy. Individuals who had at least one STI from July 2022 to June 2023 were selected. Demographic and behavioral features were collected. The diagnoses of syphilis, Chlamydia, and gonorrhea in the following 12 months were evaluated: potential antibiotic overuse was defined if no STIs were recorded during the follow up. Descriptive statistics were used to depict study population. Incidence rates (IR) per 100 persons/year follow up (PYFU) were calculated. Bivariate regression was used to describe variables associated to appropriate doxyPEP prescribing conditions (i.e., no antibiotic overuse).

Results: The analysis included 360 individuals with a cumulative number of 488 STIs (230 Chlamydia, 185 gonorrhea, 73 syphilis, 106 had two or more infections). IR was high: 182 x100PYFU (95%CI 167-199). During follow up, 312 PrEP users acquired 210 STIs (95 Chlamydia, 83 gonorrhea, 33 syphilis); 49 individuals (23.3%) had two or more infections. IR decreased significantly to 82 x100PYFU (95%CI 71-93) even without doxyPEP (IRR 0.34, p<0.001). If doxyPEP had been taken, 174 (95%CI 155-184) STIs would have been avoided. Nevertheless, 169 individuals (54.2%) had no further infections and would have had antibiotic with doxyPEP. Bivariate regression found that having at least 5 sexual contacts per week (aOR 2.45, 95%CI 1.27-4.70, p=0.007) and having had more than 2 STIs in the previous year (aOR 8.57, 95%CI 1.88-39.06, p=0.005) were associated with adequate doxyPEP prescription.

Conclusions: Our data suggest that CDC recommendations for doxyPEP prescription leading to a considerable antibiotic overuse. The evaluation of further behavioral variables could refine the selection of individuals who might benefit the most from doxyPEP.

ARV drugs from prevention to treatment

OC 68 THE ROLE OF DORAVIRINE IN THE TREATMENT OF MULTIDRUG-RESISTANT HIV: DATA FROM THE PRESTIGIO REGISTRY

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Background: Despite NNRTI cross-resistance, doravirine (DOR) maintains in vitro activity to some multidrug-resistant HIV strains. Our aim was to explore virological outcomes of DOR-containing regimens in people with 4-class drug-resistant HIV (4DR-PWH).

Methods: Retrospective, cohort study on antiretroviral treatment (ART)-experienced PWH with resistance to NRTIs, NNRTIs, PIs, and INSTIs from the PRESTIGIO Registry, who started a DOR-containing regimen. Baseline (BL) was defined as the date of initiation of DOR.

The primary outcomes were virological suppression [(VS) defined as ≥1 viral load (VL) <50 copies/mL] in 4DR-PWH with BL viremia ≥50 copies/mL and virological failure [(VF) defined as ≥2 consecutive VLs ≥50 copies/mL or ≥1 VL ≥1000 copies/mL] in individuals with BL viremia <50 copies/mL.

The cumulative incidence function was used to estimate cumulative probabilities of VS in 4DR-PWH with BL viremia ≥50 copies/mL and of VF in 4DR-PWH with BL viremia <50 copies/mL, considering as competing risks those who discontinued DOR; for these analyses, follow-up accrued from BL to the VS or VF event, the last available VL, or the date of DOR discontinuation, whichever occurred first. Other changes in regimen without DOR discontinuation were allowed.

Descriptions by median (interquartile range) or frequency (percentage).

Results: Overall, 52 4DR-PWH initiated a DOR-containing regimen: 29 viremic and 23 nonviremic (Table 1).

After a median follow-up of 1.0 (0.3-1.7) years, 17/29 (58.6%) 4DR-PWH with BL VL ≥50 copies/mL achieved VS; genotypic susceptibility score (GSS) of BL regimen [VS: 2 (2-3); non-VS: 3 (2-3.3); p=0.324] and susceptibility to DOR [VS: 10/17 (58.8%); non-VS: 3/12 (25%); p=0.237] were not associated with VS. Cumulative probabilities of VS reported in Figure 1A. Interestingly, 3/17 (17.6%) had a new VF after undetectability, and 2 of them (66.7%) regained VS on DOR (1 with and 1 without changes in accompanying drugs).

After a median follow-up of 1.8 (0.6-3.3) years, 4/23 (17.4%) 4DR-PWH with BL VL <50 copies/mL experienced VF; susceptibility to DOR [VF: 0/4 (0%); non-VF: 14/19 (73.7%); p=0.009], but not GSS of BL regimen [VF: 1.5 (1.3-2); non-VF: 2 (2-3); p=0.136] was associated with VF. Cumulative probabilities of VF reported in Figure 1B. Of the 4 individuals with VF, 3 (75%) regained undetectability on DOR (1 with and 2 without changes in accompanying drugs).

Reasons for DOR discontinuation reported in Table 2.

Three individuals viremic at BL selected new resistance-associated mutations: all to DOR, 2 also to background therapy.

Conclusions: In our cohort of 4DR-PWH, DOR-containing regimens showed good virological effectiveness, in both achieving and maintaining undetectability. The use of DOR should be considered in designing new regimens for heavily treatment-experienced individuals with multidrug resistance.

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ARV drugs from prevention to treatment

OC 69 RISK OF DEVELOPING LOW-LEVEL VIRAL REBOUND (LLVR) AMONG PEOPLE WITH HIV (PWH) WITH CURRENT HIV-RNA≤50 COPIES/ML RECEIVING 2DR VS 3DR: A CASE CONTROL STUDY

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Background: Low-level viremia may indicate residual replication and is potentially linked to an increased risk of virologic failure, serious non-AIDS events and all-cause mortality. It can be persistent or occurs after sustained viral suppression (low-level viral rebound, LLVR). The risk of developing LLVR after achieving viral load suppression under dual-drug regimens (2DR) compared to triple regimens (3DR) is yet to be fully understood.
Methods: PWH enrolled in the Icona Foundation Study cohort with virological suppression (≥2 consecutive HIV-RNA≤50copies/ml over 6 months) after NOV/2014 (baseline, BL) were included. Follow-up of PWH in the cohort accrued from BL and was censored at time of viral rebound (HIV-RNA>200 copies/ml) or last available HIV-RNA. It is a 1:3 case-control study nested within the cohort and matched on previous gaps in care (>12 months between visits) and number of regimens failed. Cases were PWH experiencing LLVR (2 consecutive HIV-RNA 51-199 copies/ml or 1 HIV-RNA 51-199 copies/ml followed by ART change within 30 days) after BL. Controls were PWH who, after the same time from baseline to the date of LLVR of the matched case (index date), still had HIV-RNA≤50 copies/ml. The main exposure of interest was the type of regimen received prior to index date [2DR (DTG/3TC, DTG/RPV, DTG/DOR, CAB/RPV) vs. 3DR (DTG/BIC or RPV/DOR or boosted DRV or ATV + TXF/XTC)]. The association between regimen received (2DR vs. 3DR) and risk of LLVR was evaluated using a conditional logistic regression. Confounding factors were identified a priori (see Figure for full description of the confounder sets) and sensitivity analyses were conducted using alternative definitions for the cases and for the exposure of interest.
Results: 1,023 PWH included: 254 with LLVR and 769 matched controls. N=72 (28%) cases were currently receiving 2DR compared to N=229 (29%) controls. Overall, 19% were females, 78% were born in Italy, median age was 43 (Interquartile range, IQR 34-51), CD4 count 586/mm3(380, 819) and calendar year of baseline was 2015 (2015 -2020). Younger participants, MSM and those with higher education were more likely to currently use 2DR vs. 3DR regimens; PWH starting 3DR were older and with a lower nadir than 2DR, which were also more common in more recent years compared to 3DR (Table 1). Among those receiving a 2DR, 82% were on DTG/3TC, and 12% were on a RPV-based regimen. Among those using 3DR, 33% were on RPV+TXF/XTC followed by 20% BIC+TXF/XTC and 18% DRV/cobi+TXF/XTC. After adjusting for confounding, evidence was inconclusive, although our data could rule out a >80% higher risk of LLVR with 2DR vs. 3DR [OR = 1.21 95% CI (0.82, 1.79)]; results were similar in sensitivity analyses (Figure 1).
Conclusion: Our analysis appeared to be underpowered for the comparison at stake. However, importantly, we can exclude with 95% confidence that in PWH who achieved HIV-RNA≤50copies/ml the use of 2DR can increase the risk of LLVR by >90% when compared to 3DR.

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ARV drugs from prevention to treatment

OC 70 ADVANCING HIV CARE IN PREGNANCY: TRENDS IN VIROLOGICAL SUPPRESSION, MOTHER-TO-CHILD TRANSMISSION AND POSTPARTUM RETENTION OVER TWO DECADES

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Background: This study aimed to describe the characteristics of pregnant women living with HIV (pWLWH) followed at the HIV Clinic in Modena and assess epidemiological trends in virological suppression (VS) and mother-to-child HIV transmission (MTCT). Additionally, we evaluated postpartum retention in care among pWLWH.
Methods: This retrospective study included all pregnancies followed at the Modena HIV Clinic from 2002 to 2024, categorized into three calendar periods (CY1:2002–2008; CY2:2009–2015; CY3:2016–2024). Data on viro-immunological status, ART use, and pregnancy outcomes were collected. Pregnancies in treatment-naïve (TN) and ART-experienced (Exp) WLWH were compared using appropriate statistical tests. MTCT was defined as a positive HIV status in the newborn, while high-risk (HR) MTCT was identified when HIV RNA>50 copies/mL in the third trimester or at delivery. Adequate HIV follow-up was defined as a viral load test within 3 months postpartum, and retention in care as at least one Infectious Diseases visit within 12 months postpartum.
Results: Of 272 pregnancies, 207 had complete outcome data: 13 (6.3%) voluntary interrupted, 24 (11.6%) miscarriages and 170 (82.1%) pregnancies carried to term in 110 women. pWLWH were 23.6% Italian and 70% of African origin (mainly Western countries). VS at conception was observed in 74.8% of pregnancies in Exp-pWLWH, showing an increasing trend (58% in CY1, 67% in CY2, and 84% in CY3) (Figure 1). Characteristics of the 170 live births are described in Table 1. Among 55 TN-pWLWH, HIV diagnosis occurred before pregnancy in 20%, during the 1st and 2nd trimesters in 29% and 42%, respectively, and in the 3rd trimester in 9% (restricted to CY1 and CY2). ART regimens in Exp-pWLWH were continued in 48.5% and modified in 51.5% of pregnancies (Table 2). The use of AZT-based regimens was phased out after 2016, with 97% transitioning to tenofovir-based regimens. Protease inhibitor (PI) use declined from 87% in CY1 to 26% in CY3, replaced by INSTIs (42%) and NNRTIs (32%) in CY3. VS by the 3rd trimester improved over time (77.4% in CY1, 82.2% in CY2, and 93.9% in CY3, $p<0.05$). MTCT was reported in 3 cases, accounting for 12.5% of HR pregnancies and 1.8% of all pregnancies. Postpartum HIV follow-up was adequate in 77%, while retention in care was observed in 92.4%, with no significant differences across time periods.
Conclusion: This study demonstrates significant advancements in HIV care for pregnant women over the past two decades, with increasing VS rates at conception and delivery contributing to a substantial reduction in high-risk MTCT cases, particularly after 2016. Moreover, the high postpartum retention in care highlights the success of long-term HIV management strategies. However, MTCT still occurred in a small subset of HR pregnancies, emphasizing the need for continued vigilance, tailored interventions, and enhanced perinatal monitoring to further minimize vertical transmission and optimize maternal outcomes.

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ARV drugs from prevention to treatment

OC 71 PREDICTORS OF LINKAGE TO PREVENTION SERVICES AFTER HIV POST-EXPOSURE PROPHYLAXIS (PEP): A RETROSPECTIVE ANALYSIS FROM 2019 TO 2024

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Background: HIV post-exposure prophylaxis (PEP), a 28-day course of antiretroviral therapy given within 48-72 hours of a potential HIV exposure, is part of a comprehensive package of HIV prevention strategies that also include condom use, frequent testing, pre-exposure prophylaxis (PrEP), rapid ART initiation in people newly diagnosed with HIV and Treatment as Prevention (TasP). The aim of this study is to describe the characteristics of PEP recipients and explore predictors of linkage to prevention services.

Methods: We performed a case-note review of PEP recipients following sexual exposure from 1st January 2019 to 31st December 2024 at an HIV clinical and prevention center in Rome. We collected demographic and behavioral data, type of exposure, previous PEP or PrEP use, and follow-up consultations until 28 February 2025. A logistic regression analysis was fitted to identify predictors of linkage to prevention services at our center within the following 3 months.

Results: During the study period, 1,376 persons received PEP; 1,126 (81.8%) were male, and 1,104 (80.2%) were Italian-born. The most common risk exposure was receptive anal sex (481, 36.2%), followed by insertive anal sex (362, 27.2%), insertive vaginal sex (153, 11.5%), and sexual assaults (123, 9.3%). 229 (17.4%) had previously received PEP, 65 (4.9%) had prior PrEP exposure and 102 (7.7%) reported chemsex during exposure. The number of PEP prescriptions increased after 2023 (Fig.1). Follow-up consultation for HIV/STI screening was suggested for every PEP recipient, and PrEP initiation was recommended to 629 persons (47.8%), with 231 (17.3%) starting PrEP. 632 (46.1%) reattended the service for HIV/STI screening and/or other prevention services (i.e.,STI vaccinations). Multivariable logistic regression analysis on 876 users with complete data showed that Italian origin, older age, previous PEP use and active PrEP initiation recommendations were predictors for re-attending the service (Table2). According to WHO guidelines, since October 2024, we have offered an immediate transition to PrEP following the completion of PEP; since then, 25 started PrEP immediately after PEP without a gap. Overall, 9/1,376 (0.7%) were tested HIV positive. Of those, 2 tested positive at baseline and continued antiretroviral drugs as treatment, 6 seroconverted after a negative HIV test performed at least 6 weeks after the end of PEP. One did not return for post-PEP HIV testing, and seroconversion was documented 13 months after PEP.

Conclusions: Our data suggest that in recent years, PEP has continued to be prescribed for high-risk HIV exposure despite the scale-up of PrEP. PEP remains an effective tool for HIV prevention, serving as a bridge to or from other prevention strategies. Older age, Italian origin, and PrEP referral were identified as the main predictors of linkage to service. Additional efforts are needed to connect PEP recipients at ongoing risk for HIV with other prevention tools, such as PrEP.

Table 1
Table 2
Figure 1

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PrEP issues: adherence and STI

OC 72 COMPARISON OF USERS ACCESSING PREP IN HOSPITAL-BASED OR COMMUNITY-BASED SETTINGS: FIRST PICTURE FROM THE PRIDE COHORT

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Background: Although PrEP scale-up in Italy has been encouraged since its reimbursement in May 2023, barriers still hinder the expansion of access to PrEP. "Let community lead" is part of UNAIDS strategies for enhancing PrEP engagement. In Italy, checkpoints have been actively involved in PrEP delivery and are part of the newly formed multicentric cohort PrIDE (Prevention ICONA Dedicated Ensemble). The aim is to compare PrEP users who access hospital-based (HB) and community-based (CB) centers as part of PrIDE.

Methods: All PrEP users (PrUs) enrolled in the PrIDE cohort from Sep24 to Mar25 were included. PrUs at HB were compared to those at CB regarding demographic features and sexual behaviors. At each visit, PrUs were asked to complete questionnaires about risk, stigma and adherence: responses were compared between the HB and CB groups. The stigma and risk perception questionnaire responses were also analyzed based on self-reported adherence. A chi-square test for categorical variables and a non-parametric Mann–Whitney test for continuous variables were used to compare the HB and CB groups and PrUs reporting self-perceived good versus poor adherence.

Results: Among the 1,400 PrUs included, 1,109 (79.2%) were enrolled at HB (mainly in central Italy, 51.4%) and 291 (20.8%) at CB (mainly in northern Italy, 94.2%, p<0.001). Of note, CB PrUs were enrolled after January 2025. The overall median age was 38 years (32-47). More than 98% were male, and 96.5% self-identified as cisgender. Non-binary people were most common in the CB, while transgender in HB (2.4% vs 0.7% and 0.7% vs 2.9%, respectively, p=0.005). Graduates and employed were more frequent among CB (77% and 96.6%, respectively) (Tab1). 365 PrUs completed all the questionnaires during at least one visit, 116 (39%) in CB and 249 (22.2%) in HB (p=<0.001). Among the 234 (69.8%) on daily PrEP, HB reported slightly better adherence than CB PrUs (68% vs 56%, p= 0.034); the same was not observed for 131 (36.7%) taking on-demand PrEP, but those in HB reported more frequent start of 2-1-1 schedule (>12 times in three months: HB 35% vs CB 14%, p= 0.024). No differences in reported adverse effects after PrEP assumption were found. No differences in answers to the questionnaire on risk and stigma perception were identified between the HB and CB groups. PrUs self-perceiving good adherence reported more frequent use of condoms in sexual intercourse than those non-adherent (32.5% vs 21.2%, p=0.042).

Conclusions: The first picture of the new PrIDE cohort illustrates the rapid growth of PrUs enrolled at community-based centers. Despite some differences observed among PrUs at HB and CB, efforts are needed to include special populations (e.g., TGW, people with low educational levels, and young) in both settings. Although each setting emphasizes different aspects related to PrEP use, friendly and comprehensive counseling still serves as a strategic tool for prevention, enhancing both adherence and risk perception.

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PrEP issues: adherence and STI

OC 73 COMPARING SELF-REPORTED AND PHARMACY-BASED MONITORING ADHERENCE RATES IN INDIVIDUAL ACCESSING HIV PRE-EXPOSURE PROPHYLAXIS (PREP): AN 18-MONTH RETROSPECTIVE ANALYSIS

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Background: HIV Pre-Exposure Prophylaxis (PrEP) is a well-established preventive therapy, made reimbursable in Italy since August 2023. Under the national healthcare system, PrEP can only be prescribed by an infectious diseases specialist, who is required to complete a specific AIFA-issued prescription form. Traditionally, this process has relied on paper-based documentation, adding administrative burden for clinicians. To streamline prescribing procedures, enhance adherence monitoring, and ensure appropriate use, we implemented a digital version of the prescription form. This tool streamlines the prescribing process, improves Individual monitoring, and enables the collection of self-reported data on adherence rates and adverse events (AEs) in individuals at risk of HIV. This study aimed to describe the demographic of the cohort receiving PrEP at Padova University Hospital over the past 18 months. Moreover, it assessed adherence by comparing self-reported data with pharmacy records on dispensed drug rates.

Material and Methods: Data extracted from digital form and pharmaceutical flows were crossed to create a dataset of individuals with at least one PrEP refill between August 2023 and March 2025. Only Individuals receiving Continuous Dosing Therapy (CDT) were included in the adherence analysis, and those who chose On-Demand therapeutic regimen (ODT), interrupted or switched it, were excluded. Adherence was assessed by calculating the proportion of days covered (PDC), with a threshold of ≥80% considered adherent. PDC data was compared with self-reported adherence from Individuals during therapeutic planning.

Results: (Table1) A total of 611 users were collected, consisting of 603 males (98.7%), 5 females, and 3 with unspecified gender, with a median age of 38 years (IQR 31–54). Of these, 241 (39.4%) opted for CDT regimen, while 370 (60.6%) chose ODT regimen. The final analyzed cohort for adherence purposes comprised 200 users (32.7%) who maintained the CDT, with 100% self-reported adherence. However, our analysis revealed that 29 users had a PDC ≤80%, indicating suboptimal adherence, 158 users had a PDC ≥80%, reflecting adequate adherence. Additionally, 13 users had a PDC ≥120%. From a safety perspective, only 2 not serious AEs (diarrhea) were recorded.

Conclusions: Our findings provide valuable insights into PrEP adherence and prescribing patterns. In fact, 14.5% of those reporting treatment adherence had rates below 80%, underscoring the importance of implementing counseling on adherence to prevention. Additionally, some Individuals, reporting 120% adherence, may be sharing their medication, highlighting a self-management issue that must be addressed. Therefore, in this setting the implementation of a digital prescription form has proven to be an effective tool for streamlining workflows, reducing administrative burden, and improving adherence monitoring.

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PrEP issues: adherence and STI

OC 74 STI OCCURRENCE AMONG PREP USERS: A SIX-YEAR FOLLOW-UP STUDY FROM THE BERGAMO CENTRE

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Background: Pre-Exposure Prophylaxis (PrEP) is an evidence-based strategy of HIV prevention in high risk individuals. Some studies showed an increase in condomless sex and sexually transmitted infections (STIs) in PrEP users while others showed stable STIs incidence rate. We investigated STI occurrence in our cohort and risk factors association.

Methods: This retrospective study included all individuals who initiated PrEP from 1st June 2018 to 31st December 2024 at the Bergamo PrEP clinic in northern Italy. We collected data on demographics, PrEP-regimen first choice, previous Post-Exposure Prophylaxis (PEP) use, previous and incident STIs. Follow-up (FU) visits at our centre were planned every three and four months for daily and on-demand users, respectively. Using a Kaplan-Meier estimator and multiple Cox regression model, we evaluated the association between the occurrence of incident STIs and age, level of education, previous STIs and PrEP regimen.

Results: A total of 459 persons commenced PrEP, with annual enrolments from 6 in 2018 to 21, 23, 44, 76,141 and 148 persons in 2019, 2020, 2021, 2022, 2023 and 2024, respectively. 99% were male (96% MSM). Median age was 36 (IQR 30-44). A total of 53 users (12%) reported previous PEP use and 317 users (69%) reported past STIs with 160 with more than one. Out of 413 users with available data on education level, 11% had middle school diploma, 43% high school diploma and 46% University degree. A total of 292 persons (64%) opted for the “on-demand” regimen at first PrEP prescription. The cohort users were followed up for a median of 14 months (IQR 6-25). 41 users (9%) discontinued PrEP and 53 (11%) were lost at FU. Among the 404 users who had at least 1 FU visit, 200 (49%) were diagnosed with at least one STI. A total of 531 STIs were diagnosed (216 gonorrhoea, 209 chlamydia, 71 syphilis, 15 Mycoplasma genitalium, 9 first-episode warts, 7 Mpox, 3 first-episode genital herpes, 1 viral hepatitis). 76 (19%) users had three or more incident STIs accounting for 380 (72%) of all STIs. According to Kaplan-Meier estimator, the risk of STI at 1, 2 and 3 years after PrEP initiation was 15%, 45% and 66%, respectively, showing higher risk in the second year (Figure 1). According to Cox model, the daily PrEP-regimen-choice was associated with higher STI occurrence (p value 0.03) while younger age, lower level of education and previous STI at baseline visit were not associated.

Conclusions: Our results showed that daily PrEP users have a higher risk of STI acquisition, that the second year after PrEP start is the higher risk period and that a small subgroup shows a high rate of STI reinfection. Considering increasing annual enrolments and the potential future need to optimise FU visits and STI screening frequency, our data show the opportunity to tailor high frequent STI screening according to risk profile in PrEP users. We believe a better characterization of the subgroup at high risk of STI reinfection is needed.

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PrEP issues: adherence and STI

OC 75 PREP AND STIS SCREENING POLICIES: ONE SIZE FITS ALL?

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Background: The frequency of NG/CT screening in PrEP protocols is under debate, as the current quarterly frequency lacks a strong scientific basis. This study aims to assess the acceptability of potential modifications among PrEP users and, more broadly, their perception of STIs.

Material and Methods: We conducted a survey among PrEP users of our Checkpoints, assessing their willingness for biannual and symptom-only screening, key factors influencing their preferences, and sexual behaviors. We examined correlations between preferences, behaviors, and self-perceived risk.

Results: The sample consisted of 192 PrEP users. Over the past 3 months, 52% reported having more than 10 partners, with low condom use (62% "Never or almost never"). Also, 62% engaged in group sex and 25% in chemsex (Fig. 1).

Most participants opposed both policy changes, with 77% responding "Not at all" or "Slightly" in favor of biannual testing and 85% for symptom-only testing (Fig. 2).

The main reason for opposing biannual screening was the concern of transmitting an STI (65% "Very important", 33% "Quite important"), followed by the self-perceived risk level (53% and 45%) (Fig. 3). The main reason for opposing symptom-only testing was the risk of missing an asymptomatic STI (66% "Very important", 26% "Quite important"), followed by the perceived risk level (53% and 39%) (Fig. 4).

We assigned an STI risk index based on the number of sexual partners, condom use, and participation in group sex, dividing users into 4 risk groups: low (16), medium-low (46), medium-high (41), and high (89).

Comparing our classification with users' self-perceived STI risk, higher-risk users showed more accurate self-assessment (Fig. 5). Among high and medium-high risk users, nearly 50% matched our classification, while the rest positioned themselves in an adjacent group. In contrast, 81% of low-risk users rated themselves as medium-high risk, and 30% of medium-low risk users rated themselves as high risk.

Opposition to the proposed screening models followed two opposing risk-related trends (Fig. 6): for biannual screening, opposition increased with risk level (from 56% in low-risk users to 82% in high-risk users), while for symptom-only testing, it decreased (from 94% in low-risk users to 80% in high-risk users).

Conclusions: Our users are largely opposed to the considered policy changes, due to concerns about compromising their social networks and health. Higher-risk users, who demonstrate better self-assessment, show similar opposition levels to both policy changes. In contrast, lower-risk users show very different opposition levels, being the most resistant to symptom-only testing. Their lower risk self-assessment, often overestimated, could affect their psychological well-being and explain the strong opposition to a testing policy without a guaranteed frequency. Given the diversity of users, we question the effectiveness of uniform testing policies in favor of more tailored approaches.

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HIV 2025: disparities and trajectories

SC 1 INTEGRATING HPV VACCINATION PROMOTION INTO COMMUNITY-BASED SEXUAL HEALTH SERVICES: AN EMPOWERMENT APPROACH

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Background: In September 2024, Lombardy expanded eligibility for HPV vaccination. Now it is available for free to all individuals up to 26 years of age and to all individuals engaging in risky sexual behaviors, although HPV is transmissible beyond traditional risk categories: via skin-to-skin contact, even with condom use.
Prevention efforts often remain limited to specific populations, such as gay, bisexual and other men who have sex with men and young adolescents. Lombardy's policy marks a crucial step in increasing vaccine accessibility for all, especially for sexually active adults of all genders and sexualities.
Brescia Checkpoint was established in 2024 and is the first local community-based organization providing comprehensive sexual health services, including HPV vaccination promotion.
Material and Methods: Between November 2024 and February 2025, Brescia Checkpoint offered free and confidential rapid HIV and syphilis testing once a month. During pre-test counselling, all clients completed an anonymous questionnaire and discussed with peer providers about HPV and vaccination benefits.
The unvaccinated were informed by peers that the physician conducting the tests could sign a document recommending their eligibility for free HPV vaccination under the new regional guidelines. This initiative leveraged the physician's authority to facilitate free vaccination at public centers and to empower individuals to get vaccinated. To reinforce support, clients were encouraged to report any barriers encountered.
Results: 61 clients received HIV and syphilis testing, and 36.1% of them were already vaccinated for HPV. Among those vaccinated, 8 (36.4%) had purchased the vaccine out-of-pocket. The majority of clients were not vaccinated for HPV (63.9%), all of them were willing to get vaccinated and received the recommendation from the physician. Demographic data revealed that HPV vaccination rates were higher among gay and bisexual men (45.5%). Significant gaps in vaccination coverage can be seen in all populations, particularly among young people under 26 years of age and those over 30 years, despite the extended eligibility criteria (Table 1). No client reported experiencing barriers at vaccination centers.
Conclusions: This initiative highlights the crucial role of community-based organizations in bridging gaps in HPV vaccine access through peer-mentorship and collaboration with physicians. We firmly believe that this approach strengthens public health efforts beyond traditional clinical settings. Providing individuals with strong peer and physician support could enable them to effectively prioritize their health.
We plan to investigate further the effectiveness of vaccination recommendations issued within our program in increasing vaccination uptake. This experience could serve as a replicable model in other settings and contribute to a more comprehensive HPV prevention strategy.

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HIV 2025: disparities and trajectories

SC 2 FAST TRACK HEALTH PATH: SCREENING, INFORMATION AND CARE OF FRAGILE PEOPLE IN ROME

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Background: Today ART therapies allow people living with HIV to reach an undetectable load, not to transmit the virus, and to have a good quality of life. But the international goal of viral suppression is still far away. The main obstacles are specific characteristics of the virus, stigma, poor information and difficulty in accessing services, which hinder early access to care.

Methods: The Villa Maraini Foundation (VMF), Red Cross' national addiction agency, deals with the treatment and rehabilitation of pathological addictions and has an infectious disease unit within it that
offers a counseling service, rapid testing for HIV and HCV and support for treatment of people with a positive test, aimed primarily at vulnerable people such as substance users and sex workers. For this purpose, the Infectious Disease Unit makes use of the collaboration of the Street Unit of the VMF to reach and test all the people who do not spontaneously go to get tested but who adopt high-risk behaviors.

Results: In 2024 over 2000 people were contacted and received specific counseling on HIV and HCV, both on site and by phone, and at the Street Unit. 491 people (56% people who use drugs; 26% born in Italy; 82% had not been tested for HIV/HCV for more than a year; average age 33) underwent rapid HIV and HCV testing, of which 41% were tested at the Foundation's clinic and 52% at the Street Unit. Only people who were not already aware of their serological status were tested. All were given a short anonymous questionnaire to investigate risky behaviors related to substance use and sexual intercourse. 11 people (2.2%) tested positive preliminarily to the rapid HIV test and 28 (5.7%) tested positive to the rapid HCV test; all were sent and in some cases also accompanied to the clinical center to take the confirmatory sample and undertake specific therapies. Of the 11 people who tested positive for HIV, 9 declared that they used substances, of these 5 had exchanged material for the preparation and intake of substances by inhalation and intravenous; 5 declared that they had had unprotected sexual intercourse with occasional partners, of these last only two declared that they knew what Prep is. Six of the 11 people who tested positive for HIV in the rapid test were reached in places of prostitution and substance use.

Conclusions: The teamwork carried out by doctors, social operator former drug addicts and psychologists of the VMF, who daily reach out to the most vulnerable, breaking down the barriers of prejudice, and the collaboration with the clinical centers for the creation of a fast truck route for the care of people who tested positive to the screening, has made it possible to reach, test and start treatment people who adopt high-risk behaviors (PWID and Sex WORKER) and people who probably would not have taken the test otherwise. The high number of people contacted, tested and sensitized among those who live in marginal conditions, prove the importance of the work of VMF.

HIV 2025: disparities and trajectories

SC 3 WHEN HEALTH SERVICES ARE HARD TO REACH: INSIGHTS FROM A MOBILE HIV/STI PROGRAMME FOR MIGRANT SEX WORKERS

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Background: In October 2023, ASA has introduced a mobile HIV/STI testing programme for sex workers, in partnership with Naga, a community-based organization that offers health services to migrants. The programme serves migrant outdoor sex workers, mainly trans women, a population that is particularly vulnerable to HIV and STIs, due to increased risk of exposure at work, racism, stigma, language and bureaucratic barriers in accessing healthcare services. Migrant sex workers are often undocumented, which can involve additional layers of stigma and bureaucratic barriers. Therefore, facility-based sexual health services are hard to reach for this population, often resulting in limited uptake of HIV/STI testing, and low rates of linkage to care and retention in care. This programme aims to provide voluntary and confidential HIV/STI testing in an environment that is safe, gender-affirming and free of stigma, and to facilitate linkage to care as needed.
Methods: Rapid testing for HIV/syphilis and HCV was offered twice a month with a mobile unit. The mobile unit visited alternatively one of the two most popular streets for sex work. Mobile teams always included at least one infectious diseases specialist and one counsellor. Testing was performed after receiving informed consent. A brief questionnaire was used to collect demographics and sexual health history. In case of reactive test results, an appointment would be booked at the infectious diseases clinic of Niguarda Hospital for confirmatory tests. In case the HIV test was non-reactive an appointment to start PrEP was offered. Counsellors were available to attend the appointments with them. Undocumented sex workers were offered support for registration with the national health system (STP). A phone contact was provided.
Results: Between October 2023 and January 2025, the mobile unit was out 16 times, always late at night. 122 sex workers were reached, testing was provided to 30 of them, with 38 HIV/syphilis tests and 28 HCV tests performed overall. 8 sex workers tested 2 times. 1 test was reactive for HIV and was lab-confirmed. 7 tests were reactive for syphilis, 3 of them possibly due to a previous infection. No HCV tests were reactive. Counsellors attended appointments with 5 sex workers: 2 for syphilis confirmation and treatment, 2 for additional STI testing, 2 for STP, 1 for HIV confirmation, 1 for collecting lab results. 1 appointment for PrEP initiation was cancelled and not rescheduled.
Conclusions: Mobile teams progressively built a relationship of trust with sex workers in the two streets visited, with some coming back for testing or counselling, and many getting tested after being reached multiple times. Still, a considerable number were unwilling to get tested. The programme has supported linkage to care for HIV and STIs and increased access to healthcare. Retention in care proved to be difficult to support in a population that is affected by multiple layers of stigma and vulnerability.

HIV 2025: disparities and trajectories

SC 4 POOR RETENTION IN CARE AMONG TRANSGENDER WOMEN LIVING WITH HIV(TWLWH): A CALL FOR TARGETED INTERVENTIONS

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Background: Transgender persons living with HIV face unique challenges in accessing and maintaining healthcare. Barriers such as social stigma, economic hardship, and discrimination within healthcare settings contribute to suboptimal retention in care and poorer health outcomes.
The aim of this study was to describe the population of transgender women living with HIV (TWLWH) followed by our clinic to understand their specific needs and vulnerabilities, with a particular focus on retention in care, to improve HIV care and support services.
Methods: We conducted a retrospective analysis of TWLWH followed at the Infectious Diseases Clinic of Fondazione Policlinico Universitario Agostino Gemelli IRCCS. Demographic, clinical, and behavioral characteristics were assessed, focusing on key factors affecting healthcare access, including past medical history, substance use, and sex work involvement.
Retention in care was evaluated by assessing the continuity of clinical follow-ups through the frequency of the laboratory testing and clinical evaluation over time. Loss to follow-up (LTFU) was defined as the absence of blood tests and/or clinical evaluations for more than 12 months. The probability of TWLWH experiencing LTFU was estimated by Kaplan-Meier.
Results: A total of 78 transgender TWLWH were included in the study. The median age at HIV diagnosis was 30 years (IQR 24.8 – 35.0), with a median duration of HIV infection of 22.5 years (IQR 15.8 – 27.3). The median nadir CD4 count was 238 cells/mm³. The majority (76, 97.4%) were born in South America. Only 8 (10.3%) had undergone gender-affirming surgery. A certain proportion (15, 19.2%) engaged in sex work, and 21 (26.9%) had been diagnosed with HIV before arriving in Italy. High rates of past syphilis infection (60, 76.9%) and alcohol use (76, 97.4%) were observed, while a smaller percentage reported a history of chemsex (3, 3.8%) or injecting drug use (1, 1.3%). Additionally, 14 (17.9%) had a history of tuberculosis.
A total of 43 TWLWH (55.1%) showed poor retention in care, experiencing one episode of LTFU after their first visit to our center. The median time from initial engagement in care to the LTFU episode was 181 days (IQR 181–365).
Moreover, 24/43 participants (55.8%) had a detectable viral load (≥50 copies/mL) at their last clinical evaluation before LTFU, indicating gaps in effective HIV treatment adherence and monitoring.
Conclusions: Our findings suggest the significant unmet needs of transgender persons living with HIV, particularly regarding healthcare accessibility and retention in care. The high prevalence of past infections and substance use underscores the need for targeted interventions to improve comprehensive HIV care. The high proportion of patients with poor retention in care and unsuppressed viral load suggests that barriers to sustained care must be urgently addressed through gender-affirming services, peer navigation programs, and tailored retention initiatives.

HIV 2025: disparities and trajectories

SC 5 STIS TESTING AMONG YOUNG PEOPLE: STRATEGIES, RESULTS, AND EDUCATIONAL IMPLICATIONS

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Background: Young people aged 15 to 24 represent about 12% of the population in Bergamo and its province cohort, and they are a key target for the Bergamo Fast-track City network. The strategy involves awareness-raising, information and training courses in high schools with the #cHIVuoleconoscere project, the universities in collaboration with the Rectorate and Student Council, and events among the territory with significant youth participation. Making young people proactive is the core of the system.
Specific actions concerned contexts frequented by young migrants, as CPIA (Provincial Centers for Adult Education).
Materials and Methods: Data were collected with the anonymous and optional Cobatest questionnaire.
From November 2021 onward, 2,877 individuals under 24 were tested for HIV, HCV, and Syphilis, representing 38% of all the tests did by the Bergamo FTCI. (FIGURE 1)
29% did the test at the checkpoint, the others on events among the territory. (FIGURE 2)
Results: The median age at testing was 20.69 years: 2.3% were under 18, 50.4% identified as male, 48.7% as female, 0.5% as transgender, and 0.4% as non-binary.
17.4 per cent were foreigners, most of them reached in CPIAs (Provincial Adult Education Centres) or in outreach services.
92% of participants were first-time testers.
20% declared they did the test because of a risk, 83% for control (multiple answers allowed). About the use of a condom in the last intercourse, 53% say they used it and 47% said they didn't use it. Among those who didn't use a condom, only 24% stated that they did the test because they were aware of having taken a risk.
75% of the young people who did not use a condom during their last sex stated that they had never had a test before and only 21% reported that they had taken a risk. (FIGURE 3)
These data do not differ in the adult population.
The ongoing collaboration with high schools and universities has enabled a considerable increase in participation by young people in testing initiatives (in 2022 28% of the total were <24 years old, in 2023 40%, constant data to date).
Relating the number of tests carried out by young people to the total population of young people in Bergamo gives an impact index of 2.4%; compared to the over 24s, where the index is 0.5%.
Conclusions: Youth demonstrated higher testing participation, reflecting potential greater sensitivity, but also the impact of educational efforts.
While their reactive case rate is lower, risky behaviours are under-recognized.
Testing initiatives enhance awareness, encourage safer behaviours and promote health-consciousness in early sexual experiences, fundamental to reduce future infections.
In Italy, sex education should be supported financially and made curricular in schools, and the potential in terms of the propensity to be tested especially in the school environment should be exploited.

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HIV 2025: disparities and trajectories

SC 6 PROMOTING HEPATITIS AND HIV SCREENING IN HIGH PREVALENCE POPULATIONS: THE 'TEST IN THE CITY' PROJECT

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Background: Test in the City project involves 14 Italian Fast-Track Cities and targets high-prevalence populations, such as migrants and IDU. The goal is to implement a screening campaign for hepatitis (HBV, HCV, HDV) and HIV, supporting the healthcare system to identify and manage undiagnosed patients. In Bergamo, syphilis test is also offered. The project, funded by Gilead Sciences, runs from January to June 2025 and involves third-sector organizations, healthcare facilities, and FTC network institutions (FIGURE 1).
Materials and Methods: During the first phase, coordination was established among participants to share strategies and best practices. A dedicated website, multilingual communication tools, and a data collection method, including a simplified version of the COBATEST questionnaire, were developed. Each city defined procedures for referring people with reactive tests to healthcare facilities for confirmation testing and linkage to care. At this stage, cities are identifying the best contexts and opportunities. Milano, Ancona, and Bergamo have already launched their initiatives involving migrant groups.
Results: In February, 413 tests were conducted, all targeting migrants: 112 at the Pakistani Embassy in Milano, 90 with a mobile unit in Ancona, and 215 at the CPIA (Provincial Centers for Adult Education) in Bergamo. Activities for substance users have not yet started.
The average age of those tested is 31.24 years and 65% were male (FIGURE 2, FIGURE 3).
Participants come from 45 different countries, predominantly Pakistan (28.57%), followed by Bangladesh (6.05%). Others mainly originate from sub-Saharan Africa (12.11% Senegal) and, to a lesser extent, North Africa (7.27% Morocco).
In Bergamo, 40% reported having previously taken an HIV test in earlier screenings events by the Bergamo FTC network, while the rest hadn't or didn't remember.
The overall reactivity rates were: HBV 2.64%, HCV 1.20%, and syphilis 0.93% (TABLE 1).
5 HCV reactivities involved Pakistani individuals, 11 reactivities for HBV were among people from sub-Saharan Africa (e.g., Senegal, Cameroon) and North Africa (Tunisia), 2 syphilis cases involved two women, one from the Central African Republic and one from Burkina Faso. Confirmation testing and linkage to care were activated for all the reactivity.
Conclusions: The data presented are preliminary but underscore the importance of promoting screening among migrant populations. Significant incidences related to geographic origin are evident, aligned with expected trends. Administrative requirements for the confirmation tests have caused delays in linking people to care. No HIV cases have been found until now, even though past projects showed significant incidences.
Participants responded positively to the proposal, highlighting the lack of structured and standardized screening for hepatitis, HIV, and STIs in migrant reception centers, which represents a critical gap in both personal and public health.

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ART and comorbidities

SC 7 MANAGEMENT OF POLYPHARMACY AND POTENTIAL DRUG-DRUG INTERACTIONS IN PEOPLE WITH HIV AND CANCER: INSIGHTS FROM A 4-YEAR MULTIDISCIPLINARY CLINIC EXPERIENCE

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Background: People with HIV and cancer (PWHC) are often treated with different combinations of antiretroviral and oncology drugs, frequently associated with other co-medications; this significantly increases the risk of potential drug-drug interactions (DDIs).
Methods: A prospective observational study has been carried out from May 2020 to May 2024 to describe the management of therapies in PWHC in an outpatient clinic.
Results: 140 PWHC treated with 42 different antiretroviral and 59 oncology regimens were enrolled, resulting in the identification of 410 DDIs. Of these, 8% were scored as red-flag DDIs). Among antiretroviral medications, 77% of red-flag DDIs involved ritonavir or cobicistat. Paclitaxel was the oncology drug most frequently associated with red-flag-DDIs (77%). Proton pump inhibitors (PPIs) were involved in 19% of red-flag and 32 of orange-flag DDIs. The most frequent recommendations included performing an electrocardiogram (38%), conducting therapeutic drug monitoring (31%), discontinuing PPIs (29%) and/or adjusting the timing of drug intake (28%).
Conclusions: A high prevalence of polypharmacy and clinically relevant DDIs was observed in our cohort of PWHC. A multidisciplinary team could play a pivotal role in optimizing pharmacological therapies in this clinical setting, for example, by reducing the use of PPIs and booster-based antiretroviral regimens.

ART and comorbidities

SC 8 NEUROCOGNITIVE IMPAIRMENT OVER TIME IN PEOPLE WITH HIV (PWH) WITH AND WITHOUT CEREBROSPINAL VIRAL ESCAPE (CHVE)

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Background: Despite the success of combined antiretroviral therapy (ART), HIV-associated neurocognitive disorders (HANDs) remain common in people with HIV (PWH). Concerns persist regarding the role of cerebrospinal fluid HIV escape (CHVE) and its association with HANDs. The objectives were: a) to explore the association between CHVE and neurocognitive impairment (NCI); b) to longitudinally investigate the clinical evolution of previously diagnosed CHVE cases and their potential link to long-term NCI.
Methods: Retrospective, multicenter, cross-sectional analysis of PWH with and without CHVE at lumbar puncture (LP) who received a neuropsychological assessment (NPA) within six months before or after LP, and longitudinal analysis of NPA assessments at least six months apart. NPA was performed using a standardized battery of 12 tests across five domains. HANDs were classified according to Frascati's criteria. CHVE was defined as CSF HIV RNA > plasma HIV RNA in treated PWH, and discordant CHVE (dCHVE) in naïve PWH. Univariate comparisons were made between groups and explanatory variables (Pearson χ^2 and/or Fisher's exact, two-sample Student's T or paired T-test, or Analysis of Variance for multiple groups or Kruskal–Wallis test). Statistical significance was set at ≤0.05, unless adjustment for multiple comparisons was needed.
Results: 188 PWH included: 84.6% male, mean age 45.2±12.9 years, 34.5% heterosexual, 55.5% MSM, 8.4% IVDU; 22.5% CDC C. At T0, 28.7% had neurological signs/symptoms. 50 PWH (27.3%) were on stable ART. Average current and nadir CD4 counts were 432±320 and 297±245 cells/mm³, respectively; median log10 HIV-RNA in plasma was 9.8 (IQR 6.2-11.9) and in CSF 7.4 (IQR 4.3-9.3). CSF HIV-RNA was <50 cp/mL in 18% of plasma and CSF samples. According to Frascati's criteria, 94 PWH (53.7%) were unimpaired, 74 had NCI (66 ANI 37.7%; 8 MND 4.6%), and 7 (4%) had major confounders. Of 180 evaluable CSF/plasma pairs, 15 had CHVE (12%) and 17 dCHVE (10.5%). Compared to non-CHVE and dCHVE, CHVE PWH had more frequent AIDS diagnoses, longer illness duration, lower CD4 nadir, and worse performance in working memory and fine motor skills at T0, as well as more frequent HAND diagnoses. No significant differences were found between T0 and T1 in most domains, except for memory (-0.4±1.3 at T0 and -0.2±1.4 at T1, p=0.002) and fine motor skills (-1.4±4.3 at T0 and -1.7±4.9, p=0.014). Of the 32 ANI cases at T0, 28 remained ANI at T1, and 3 were reclassified as unimpaired. Of 5 MND cases at T0, 2 remained MND at T1, 2 were reclassified as ANI, and 1 as unimpaired.
Conclusions: In this large study of PWH with CHVE and NPA, a higher incidence of HANDs was observed in those with CHVE, leading to worse neurocognitive performance, particularly in memory and fine motor skills. Over time, while overall NPA remained stable, there was an improvement in memory but a slight decline in fine motor skills.
Table 1

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ART and comorbidities

SC 9 COMPARISON BETWEEN THE FRASCATI CRITERIA AND EQUIVALENT SCORES FOR THE NEUROCOGNITIVE ASSESSMENT (NCA) OF PEOPLE LIVING WITH HIV (PWH)

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Background: The risk of overestimation of the diagnoses of Asymptomatic Neurocognitive Impairment (ANI) through the Frascati criteria is still debated.Possible causes include the use of zeta scores (zs) that are not adjusted for variables which may impact the neurocognitive performance (NP) such as gender,education and age.In the present study,we aim to evaluate neurocognitive deficits in a sample of PWH diagnosed with ANI,using equivalent scores (es) as an alternative assessment method.

Material and Methods: We included PWH enrolled in the “Pre-IMP Study” (EC approval:4/2018).After signing the informed consent,all the study participants (pts) underwent a NCA of 11 tests across 5 cognitive domains (memory, attention,language,executive functions,speed of psycho-motor processing).All the raw scores were standardized;zs indicates how many standard deviations below or above the reference mean the NP is placed.In addition,all the raw scores were corrected for age,gender and level of education and then converted into es,on an ordinal scale ranging from 0 to 4: 0 below normal NP, 1 borderline NP,2-3 normal NP,4 above normal NP.The presence of neurocognitive impairment was defined by scores below the normative reference value(<cutoff-es=0).In order to assess agreement among the two methodologies,we used Kendall t,both marginal and after adjusting for possible confounders (partial Kendallt).Statistical significance was assessed by means of permutation tests.

Results: Out of 510 pts who performed NCA, 502 had diagnoses of ANI:88 (17.2%) females,median age of 50.77 (IQR17-46),median of 5 years(IQR13)of HIV infection and 13 years(IQR 4.75)of instruction,464 (91%) on antiretroviral treatment (ART),411 (80.6%) with suppressed HIV viral load, median CD4 cell count of 555 (445.75%). Comparison of zs and es with adjustments(sex,age,schooling,nadir and current CD4 cell count,being on ART and years of HIV infection)showed moderate discordance for all the tests except trial making test A (TMTA,t=0.579),trial making test B (TMTB,t=0.424) and phonological verbal fluency (FAS,t=0.679) for which discordance was marked (Table1). Moreover,higher proportions of above-normal NPs were found with es values (es=4: TMTA 0.66%,TMTB 0.78%,FAS 0.55%) compared with normal/below-normal NPs observed using zs of the Frascati criteria (Table2).

Conclusion: Our study shows that the NPs of PWH diagnosed with ANI according to the Frascati criteria,could be classified in the normal range using es rather than zs,especially for the domains of information processing speed, cognitive flexibility and verbal initiative.This different assessment method could lead to decreased diagnoses of ANI. However,the lack of universally accepted diagnostic criteria with high sensitivity and specificity for the diagnosis of neurocognitive impairment in PWH,does not allow us to better clarify the difference found between ze and es. Longitudinal studies aimed to evaluate the NP trajectories over time,are needed.

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ART and comorbidities

SC 10 ATHEROGENIC INDEX OF PLASMA AS A PREDICTOR OF CARDIOVASCULAR EVENTS IN PEOPLE LIVING WITH HIV: EVIDENCE FROM THE ICONA COHORT

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Background: The Atherogenic Index of Plasma (AIP) is a recognized predictor of coronary artery disease (CAD) in both the general population and people living with HIV (PWH) in Africa. This study aimed to investigate the association between AIP and cardiovascular (CV) events in the ICONA cohort.

Methods: AIP was calculated as log10((triglycerides /88.57)/(HDL/38.67) for mg/dl. Five consecutive nested case-control studies have been adopted. Each Case-control includes all patients in ICONA with CV (CASES) who reported AIP value 1 to 5 year before the CV event and 5 concurrent control without CV individually matched for age,-sex and time (i.e. in FUP in the same year of the case). Association between CV events (binary) and AIP, HDL and triglycerides (all as continuous variables) by conditional logistic regression model. In order to evaluate the role of AIP, and HDL and triglycerides alone to predict CV events over time mixed effect regression model with random intercept on case-clusters were used. All models were adjusted for the same set of potential selected confounders.

Results: Overall 168 cases (CA) and 840 controls (CO) have been included: 154 CA and 770 CO , 138 CA and 690 CO, 126 CA and 630 CO and 105 CA and 525 CO were enrolled for Year 1, Year 2, Year 3, Year 4 and Year 5 before CVE, respectively (see Table 1 for Cohort's characteristics).

Mean AIP score remains higher for cases throughout the 5 five years, with higher values in the later years from the CV event (Figure 1).

AIP was strongly associated with Cardiovascular event occurrence for each calendar year of observation with the following Odds Ratio (OR) at unadjusted analysis: 2,94 (Confidence interval [CI] 95% 1.7-5.0), 2.28 (CI 95% 1.3-4.0), 2.83 (CI 95% 1.6-5.0), 2.83 (CI 95% 1.6-5.0), 4.47 (CI 95% 2.4-8.5) and 2.28 (CI 95% 1.2-4.5) or Year 1, 2, 3,4 and 5, respectively.

Adjusting analysis for current Cd4, current Cd4/Cd8 ratio, nadir Cd4, years since HIV diagnosis, years on Antiretroviral Therapy (ART), Months on PI, Months on InSTI, Months on NNRTI, Months on Abacavir and current smoking status AIP remained strongly associated with CVE for Year 1, 2, 3 and 4 but not for Year 5 : OR 3.05 (CI 95% 1.6-5.8), 2.04 (CI 95% 1.0-4.0), 2.65 (CI 95% 1.3-5.3), 4.5 (CI 95% 2.1-9.9) and 1.77 (CI 95% 0.8-3.9), respectively.

Comparing the association with HDL alone , HDL showed an association for Year 2, 3 and 4 (OR 0.79 [CI 95% 0.7 -0.9]; OR 0.75 [CI 95% 0.6-0.9] and OR 0.72 [CI 95% 0.6-0.9]) but not with Year 1 and 5 (OR 0.88 [CI 95% 0.8-1.0] and OR 0.75 [CI 95% 0.7-1.0].

Triglycerides did not show any association with CV events.

Conclusions: Our findings provide strong evidence that AIP is a significant predictor of CV events in PWH in Italy, with its predictive strength increasing as the event approaches. The superior performance of AIP compared to HDL and triglycerides alone suggests that it may serve as a better risk stratification tool for cardiovascular prevention in this population.

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ART and comorbidities

SC 11 CRITICAL ILLNESS IN PEOPLE WITH HIV (PWH). TEMPORAL TRENDS, REASONS FOR ADMISSION, AND MORTALITY OF PWH ADMITTED TO ICU FROM 2010 TO 2024. THE EXPERIENCE OF TWO ITALIAN REFERRAL CENTRES

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Background: Universal access to antiretroviral therapy (ART) has significantly improved the prognosis of PWH. However, these individuals still face a higher incidence of comorbidities and complications, often requiring admission to intensive care units (ICUs). Recent studies indicate a shift in ICU admissions among PWH over the last 20 years, with an increasing proportion attributed to non-AIDS-related disorders, such as cancers and cardiovascular diseases. To date, no European studies have explored the causes of ICU admissions in PWH. Therefore, this study aims to examine the reasons for ICU admission in a cohort of PWH treated at two Italian referral centres.
Methods: We conducted a retrospective, bicentric, observational cohort study including PWH aged ≥18 years admitted to ICUs between 01.01.2010 and 31.12.2024. Elective ICU admissions were excluded. Demographic and clinical data were collected for each patient. The Cochran-Armitage test was used to estimate trends in ICU admission causes and mortality over three time periods: 2010–2014, 2015–2019, and 2020–2024.
Results: As shown in Table 1, a total of 331 PWH were included. Median age was 50 years (IQR: 43–57); 123 were men (37.2%) and 207 were women (62.5%); 245 were Italian (74%). At ICU admission, the median SOFA score was 8 (IQR: 5–10); 111 patients (37.9%) were antiretroviral-naïve, and 111 (37.9%) were off-therapy. Advanced HIV disease was present in 224 patients (67.7%). Regarding CD4 counts at ICU admission, 195 patients (73.6%) had <200 cells/μL, and 41 (15.5%) had 200–349 cells/μL. ICU admissions for AIDS-defining events accounted for 111 cases (40.5%) in 2010–2014, 114 (48.2%) in 2015–2019, and 105 (33.3%) in 2020–2024 (p = 0.3). ICU mortality rates were 34.3% (102/331) in 2010–2014, 28.6% (112/331) in 2015–2019, and 38.2% (102/331) in 2020–2024 (p = 0.56).
Conclusions: Our findings suggest that in the last five years, most ICU admissions among PWH were due to non-AIDS-related causes. However, no statistically significant trend was observed over the study period. This shift may be attributed to the reduced incidence of AIDS-related events due to cART, the impact of the COVID-19 pandemic, and the rising burden of cardiovascular and oncological comorbidities in PWH. Larger, multicentre studies are needed to better recognize the characteristics and outcomes of PWH admitted to ICUs.
Table 1
Table 2
Figure

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ART and comorbidities

SC 12 CORRELATION AMONG LIPID PROFILE, SUBCLINICAL ATHEROSCLEROSIS AND HEPATIC STEATOSIS IN PLWH: THE ROLE OF INFLAMMATION

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Introduction: Cardiovascular Diseases have emerged as a leading cause of morbidity and mortality in patients with HIV (PLWH). Several studies on the general population, have reported a relationship between higher carotid Intima Media Thickness (c-IMT), a measure of subclinical atherosclerosis (SAT), and hepatic steatosis (HS). However, few data are available on the relationship between SAT and HS in HIV subjects and it is unclear how the role of chronic inflammation markers, such as the CD4/CD8 ratio and nadir CD4 count, could be drivers in atherogenesis process. Therefore, objective of our study is to evaluate this relationships in a cohort of PLWH not coinfected for viral hepatitis.
Patients and Methods: In this observational, retrospective, cross-sectional study we enrolled 184 patients, 52 females and 132 males. We divided the patients in 2 groups based on cIMT: A) (#118) with normal cIMT(<1.3 mm) and B)(#66) with pathologic cIMT (>1.3 mm). Patients were submitted to measurement of carotid intima-media thickness (cIMT) with high resolution B mode Doppler USG and evaluation of HF using a process based on vibration-controlled transient elastography (Fibroscan) and HS by an ultrasonic controlled attenuation parameter (CAP). The cut-off value for defining the presence of c-IMT is 1,3 mm, for significant HS is CAP > 260 dBm and for liver fibrosis is > 7 kPa. For each group we also considered the body mass index (overweight >25kg/m2), alcohol abuse (>2 alcohol units in a day for men and > 1 alcohol unit for women), current CD4 value, CD4 nadir, CD4/CD8 ratio, years on HAART, type of ART, total, HDL and LDL cholesterol and triglycerides levels. For statistical analysis we used t-student and X-square tests.
Results: Results are shown in table 1. We observed a significant difference in the two groups in alcohol intake, indeed, patients in group B have current and history of alcohol abuse. No significant differences emerged between the two groups regarding current CD4, LDL, triglycerides and HDL values. A significant difference emerged for nadir CD4, CD4/CD8 ratio, and total cholesterol. Patients with c-IMT>1,3 have been associated with higher steatosis levels (p<0,004).
Conclusions: Our data confirm a strong correlation between liver steatosis and subclinical atherosclerosis in PLWH. Moreover, modifiable risk factors (total cholesterol and triglycerides), markers of chronic inflammation (CD4+ nadir and CD4/CD8 ratio<1), and alcohol abuse play a role in the development of intima-media changes. Furthermore, it seems that some antiretroviral regimes, could be more “protective” than others in plaque development. Finally, these data suggest the importance and need for broader diagnostic evaluation in PLWHs.

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Open issues in virology and pharmacology

SC 13 PLASMA SARS-COV-2 RNA ASSOCIATES WITH DISEASE SEVERITY DURING ACUTE INFECTION BUT NOT WITH PERSISTENT SYMPTOMS

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Background: The clinical significance of SARS-CoV-2 RNA detection in blood (SARS-CoV-2 RNAemia) is unclear. While several studies associate it with acute disease severity, follow-up results are conflicting due to differences in cohorts and technical approaches. We quantified SARS-CoV-2 RNAemia in a large cohort of COVID-19 individuals, during acute infection and 3 months post healing, assessing its link to both disease severity and enduring symptoms compatible with post-COVID condition (PCC).
Materials and Methods: We consecutively enrolled COVID-19 subjects during acute infection (T0); an unselected subgroup was followed-up 3 months post-symptoms onset (T1). Disease severity was defined according to WHO severity scale, persistent symptoms as persistence of at least one non-pre-existing symptom at T1. SARS-CoV-2 RNAemia (log10(N-copies/mL)RT-PCR) was quantified at T0 and T1. Logistic regression assessed its association with severity or PCC by categorizing as second and third tertile versus first; above or below the median with zero as reference; detectable versus undetectable. SARS-CoV-2 RNAemia kinetics was defined as follows: detectable (D) at T0-undetectable (UD) at T1; UD-T0-D-T1; D-T0-D-T1, using individuals with consistent undetectability as reference.
Results: 442 patients were enrolled during acute infection (Tab.1), 184 of whom were followed-up at T1. Median age was 62 (IQR 49-73), 59.3% were male, 66% presented at least one comorbidity, 64.5% were hospitalized, 70.4% presented a radiologically documented pneumonia. Of 184 individuals followed-up, 78.3% presented PCC. Adjusting for age, sex, comorbidities, patients with SARS-CoV-2 RNAemia levels in the second or third tertile had a higher probability of presenting a more severe disease compared to those in the first tertile (II: 2.44 OR, 1.17-5.05 95%CI; III: 2.50 OR, 1.21-5.19 95%CI) (Fig.1). Individuals with SARS-CoV-2 RNAemia below or above the median had a higher probability of presenting a more severe diseases than those without detectable RNAemia (below: 2.34 OR, 1.13-4.83 95%CI; above: 2.66 OR, 1.28-5.55 95%CI). Likewise, individuals with any level of SARS-CoV-2 RNAemia showed a higher probability of presenting a more severe disease compared to individuals with undetectable RNAemia (2.49 OR, 1.29-4.81 95%CI). The associations lost significance when analyzing less severe forms of disease. No associations were found between SARS-CoV-2 RNAemia (baseline, follow-up, kinetics) and PCC.
Conclusions: SARS-CoV-2 RNAemia measured during acute COVID-19 is associated with a more severe disease course. Although in our cohort RNAemia persists for several months after acute disease in many individuals, it is not associated with PCC. By showing the connection between RNAemia and COVID-19 disease severity, our data support its potential as a prognostic marker of the clinical course of disease, also offering insight into possible underlying pathogenetic mechanisms, warranting further investigation.

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Open issues in virology and pharmacology

SC 14 THE POTENTIAL IMPACT OF PHARMACOGENETICS ON BULEVIRTIDE PLASMA EXPOSURE IN THE CLINICAL SETTING

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Background: Bulevirtide is a first-in-class entry inhibitor for chronic hepatitis delta virus (HDV) infection, acting as a potent NTCP (sodium taurocholate co-transporting polypeptide) inhibitor. Despite its promising efficacy, inter-individual variability in drug exposure and response remains a critical concern. Currently, no data are available in the literature concerning the variability in bulevirtide plasma exposures and the potential role of genetic variants in affecting this drug levels. Consequently, the aim of this study was to evaluate bulevirtide plasma concentrations at different timings, investigating the potential impact of NTCP gene polymorphisms on drug levels.
Materials and Methods: A cohort of patients with chronic HDV infection receiving bulevirtide therapy was enrolled. Plasma bulevirtide levels were quantified at 4 (W4), 12 (W12), 24 (W24), 36 (W36), and 48 (W48) weeks using liquid chromatography-mass spectrometry. Pharmacogenetic analysis focused on the analysis of key NTCP single nucleotide polymorphisms (rs8011311 and rs2296651) through PCR-based genotyping.
Results: 66.7% of enrolled patients were men, the median age was 45 (interquartile range, IQR, 37; 56) years, the median BMI was 24.5 (21.6; 25.9) Kg/m2 and 40% had cirrhosis. Median baseline AST were 57 (32; 91) U/L, whereas ALT were 75 (47; 112) U/L.
Median bulevirtide concentrations (figure 1) were 0.38 (IQR 0.29; 2.05) ng/mL at W4, 0.86 (IQR 0.43; 2.66) at W12, 1.07 (IQR 0.56; 2.39) ng/mL at W24, 1.18 (IQR 0.86; 4.46) ng/mL at W36, and 1.06 (IQR 0.80; 3.46) ng/mL at W48.
NTCP rs8011311 G>C genetic variant influenced bulevirtide plasma exposure at 24 weeks of treatment: particularly, GC genotype patients had reduced bulevirtide concentrations compared to GG genotype patients (CC genotype patients were not present in our cohort of patients).
Conclusions: This study reported for the first time bulevirtide concentrations for 48 months and the potential impact of genetic determinants on this drug plasma exposure. Further studies in larger cohorts of patients are required for leading personalized dosing strategies enhancing treatment efficacy and safety in HDV-infected patients.

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Open issues in virology and pharmacology

SC 15 CLINICAL AND LABORATORY PARAMETERS CORRELATED TO HDV UNDETECTABILITY AFTER 48 WEEKS OF BULEVIRTIDE

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Hepatitis Delta Virus (HDV) is a small RNA virus that can cause a severe chronic hepatitis in patients already infected with Hepatitis B virus (HBV). HDV co-infection is a risk factor for cirrhosis and hepatocellular carcinoma (HCC) development. For a long time, there was no effective treatment for HDV hepatitis. On January 2023 bulevirtide (BLV) was approved in Italy as the first therapeutic option for HDV infection. The undetectability of HDV-RNA is an end-point of the treatment. Despite the observation of a good clinical and laboratory response, the identification of parameters to predict a more rapid and durable response to therapy remains uncertain.
The aim of this study is to analyze which parameters can be predictive of undetectable HDV-RNA during BLV treatment.

We analyzed intrahepatic and peripheral virological parameters, ALT, information on cirrhosis status, combined response at 12 and 24 weeks from seven patients of our cohort of HDV patients from Policlinico Tor Vergata of Rome, who received BLV at least for 48 weeks by March 2025. Droplet digital PCR was used to quantify intrahepatic HBV and HDV markers. Combined response was defined as the achievement of >2 log HDV-RNA or undetectable HDV-RNA along with ALT normalization. HDV-RNA <22 copies/ml was the lower limit of quantification (LLoQ). HDV-RNA was defined undetectable when it was below the LLoQ (22IU/ml).

Seven patients, all virologically suppressed under nucleos(t)ide analogues (NUC), received BLV for 48 weeks. Median [IQR] age was 47 (44-55) years. 1 patient was Italian, 5 from Eastern-Europe, 1 from Togo.
At baseline, median (IQR) serum HDV-RNA and HBsAg were 5.9 (4.8-7.1) and 4.1 (3.8-4.4) log IU/ml, respectively. Median (IQR) ALT was 91 (47-118) U/l while Ishak score was 5 for five patients, 4 and 3 for the remaining two. Intrahepatic median (IQR) HDV-RNA was 3563 (1777-9045) copies/1000cells (Table1). Three patients received Peg-Interferon-alfa but discontinued after 2, 4 and 8 weeks respectively for adverse effects.
Combined response was achieved at week 12 by 4 patients and at week 24 of BLV by all patients. Serum HDV-RNA<LLoQ was achieved by 4 patients, but undetectability only by 2.
Notably, a lower baseline intrahepatic HDV-RNA tended to correlate with the achievement of undetectable serum HDV-RNA at week 12 of BLV (median [IQR] intrahepatic HDV-RNA: 2262[1777-2913] copies/1000cells in patients achieving vs 8759[4656-9046]copies/1000cells in patients not achieving undetectable HDV-RNA at week 12).
Conversely, the intrahepatic HBV markers were comparable between the two groups of patients.
A limited intrahepatic HDV reservoir at baseline tends to correlate with a stronger reduction of HDV replication after 24 weeks of BLV. The virological and clinical monitoring in longer follow-up and larger sample size is ongoing in order to corroborate this result. This can also have implication for therapeutic strategies aimed at setting up a finite course of BLV treatment.

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Open issues in virology and pharmacology

SC 16 ANALYSIS OF HIV PROVIRAL INTEGRATION SITES IN THE HOST GENOME OF PWH WITH A VIRUS DISPLAYING AMINO ACID POLYMORPHISM IN THE INTEGRASE C-TERMINAL REGION

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Background and Aim: Proviral integration sites in the host genome may influence HIV reservoir expression, including the production of HIV transcripts capable of disturbing the immune-inflammation status of the host in the presence of effective antiretroviral therapy. Amino acid substitution K258R in HIV integrase may redirect provirus integration into a transcriptionally silent zone, in which the provirus remains hidden and inactive. Aim of the study was to establish the pattern of HIV provirus integration in the host genome in people with HIV (PWH) subjects harboring integrase polymorphisms in the C-terminal domain, i.e., the minimal nonspecific DNA binding region (MDBD).
Materials and methods: DNA samples from 14 PLWH, either naïve or on antiretroviral therapy, were selected on the basis of harboring an amino acid polymorphism in the MDBD. Proviral integration site detection was performed with a shotgun next-generation sequencing (NGS) approach; bioinformatic analysis was carried out considering a threshold of a minimum of 8 reads and a frequency of more than 0.1% of the subject's reads. HIV-1 DNA quantification, either of the intact or defective provirus, was performed by multiplex probe digital PCR with primers and probes designed on both packaging signal and env regions, together with a third additional unconjugated probe targeting hypermutated env region.
Results: Of the 14 PLH, 2 were naïve to treatment, and 12 had been on antiretroviral treatment for a median (IQR) of 9 (5.75-20.25) years. The median (IQR) total HIV-1 DNA was 733 (295–2,767) cp/million PBMC, with a mean percentage of intact proviral DNA of 7.9%. Twelve PWH harbored subtype B, one CRF02_AG, and one subtype C. None of them showed known integrase resistance mutations, and all displayed at least an amino acid polymorphism in the MDBD (see Table 1). NGS provided a median (IQR) of 323 (132-1,964) reads per sample and a median (IQR) of 16.5 (11.5-25.25) different integration sites per sample, located at 67.1% in genic and at 32.9% in intergenic sites. Interestingly, provirus integration in the intergenic site position 102,815,760 in chromosome 8 was detected in 13 out of 14 subjects, followed in large numbers by the insertion in the genic position in the ESRRG gene in chromosome 1 and by the insertion in the SLIT3 gene in chromosome 5. A list of the most representative HIV proviral insertion sites is reported in Table 2, in which the 2 naïve vs. on-therapy subjects are highlighted.
Conclusions: The analysis of proviral integration sites of HIV displaying integrase polymorphisms in MDBD has revealed some preferential sites of insertion in the host genome, without appreciable differences between naïve and chronically suppressed subjects. Further analysis on a larger number of subjects is needed to confirm these preliminary data and to better evaluate differences between recent and older infections together with the possible influence of long-term antiretroviral therapy.

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Open issues in virology and pharmacology

SC 17 PERFORMANCE OF A NEXT-GENERATION SEQUENCING TEST FOR HIV DRUG RESISTANCE ANALYSIS IN PROVIRAL HIV-DNA

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Introduction: The new long-acting injectable dual therapy (cabotegravir + rilpivirine) improves quality of life and adherence in virologically controlled patients on ART. However, risk factors for virological failure include HIV subtype and resistance mutations in HIV RNA or DNA. When subtype and genotypic history are incomplete, HIV DNA sequencing should be performed. This sequencing is now routine for HIV-infected individuals on ART. Successful amplification and sequencing of the HIV pol gene with NGS technology has not yet correlated with HIV DNA levels. Since plasma HIV RNA predicts sequencing success, HIV DNA load in blood cells is likely associated with sequencing success.

Objective: To evaluate the performance of a home-brew genotype drug resistance (GRT) test based on next-generation sequencing for analyzing HIV drug resistance mutations in the protease (PR), reverse transcriptase (RT), and integrase (INT) gene regions in proviral HIV-DNA (GRT-DNA).

Materials and Methods: We analyzed 52 PBMC samples from 52 HIV-1 patients using the GRT-DNA test, a home-made assay based on NGS technology. PR, RT, and INT genes of total proviral HIV-DNA were amplified using nested PCR and sequenced using DNA Library Prep on the iSeq100 instrument (Illumina). Drug resistance mutations (DRMs) and genotypic susceptibility were evaluated through Stanford HIVdb (ver.9.8) with mutation detection thresholds set at 10% and 20%. In 24 samples, total HIV-DNA was quantified with the HIV-1 DNA Test PRO (Diatheva) processed with the Elite InGenius platform (Elitech).

Results: More than half of the participants (51.9%) had HIV-1 B strains, 38.5% were non-B subtypes, and 9.6% were untypable. Success rates of the GRT-DNA sequencing test in the 52 PBMCs were 84%, 84%, and 75% for PR, RT, and INT amplicons, respectively. Five samples were not successfully sequenced. Mean levels of HIV-DNA were 665 and 50.6 copies/10^6 cells for successfully sequenced and failed samples, respectively. A statistically significant difference was observed (Wilcoxon test, p=0.002). A threshold for sequence success was estimated at 55 copies/10^6 cells (ROC curve). Overall, 12/52 (23%) major DRMs were detected with the GRT-DNA test: 19% (10/52) at frequencies above 20%, and 4% (2/52) at frequencies below 20%.

Conclusions: The GRT-DNA assay provided valid results for most samples and correlated with total HIV-DNA quantity. A threshold for sequence success was identified at 55 copies/10^6 PBMC. This test resulted accurate for detecting major DRMs, even at lower levels compared with the Sanger sequencing method.

Open issues in virology and pharmacology

SC 18 LONG ACTING CABOTEGRAVIR AND RILPIVIRINE PLASMA AND INTRACELLULAR PHARMACOKINETICS IN THE CLINICAL SETTING AFTER 2-YEAR FOLLOW-UP

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Background: Scarce data on plasma exposure and no data on intracellular (IC, intra-PBMC) accumulation of long-acting cabotegravir and rilpivirine (CAB/RPV LA) as intramuscular (IM) administration, are reported in literature. Therefore, our aim was to evaluate CAB and RPV plasma and IC pharmacokinetics (PK), exploring the potential role of PK parameters on virological efficacy in almost 2-year follow-up (FU)

Methods: Participants administered with CAB/RPV every 2-month were included, after informed consent given. Plasma and IC CAB and RPV concentrations as Ctrough were measured by means of UHPLC-MSMS validated method at the end of dosing interval (24+/-4 hours after intake) every 2 months concomitantly with the IM ARVs administration during 21 month of follow-up (FU), month 1 to month 21 (M1-M21). A plasma exposure cut-off of 50 mg/mL and 664 ng/mL were reported for RPV and CAB respectively as 4xprotein-adjusted inhibitory concentration 90% (4xPA-IC90). Virological assessment was collected at every timepoint. Non-compartmental PK parameters were expressed as geometric mean (CI95%). Participants' characteristics were compared by Mann-Whitney and Spearman's test, as appropriate.

Results: 177 participants were included in the study. 85,3% of them were male, age and BMI were 51 years (43–59) an 24.5 Kg/m2 (23.9–25.0), 93,1% was virologically suppressed at baseline (BL, viral load, VL <20 cp/mL), other clinical characteristics of study population are reported in Tab.1. CAB and RPV plasma and IC Ctrough and the significative modification of exposure during the time of FU are reported in Fig 1. Linear and significative correlations were reported between CAB and RPV plasma, IC Ctrough and IC/plasma ratio as well as CAB plasma and IC Ctrough, and RPV plasma and IC Ctrough at every timepoint. CAB plasma and IC Ctrough was found to be higher in the female participants from M3 to M15. No correlation with BMI was reported with PK parameters. No impact on virosuppression was found at any time-point based on 4xPAIC90 for both drugs. 96% of participants presented virological suppression at the end of FU (p=0.317). Inter-individual and intra-individual variability for plasma RPV and CAB was found to be respectively 58%, 69% and 52%, 48%.

Conclusions: Our study Is the first to explore IC penetration of LA RPV and CAB, showing an opposite trend: CAB IC accumulation in proportion of 12-15% than plasma and a higher RPV accumulation 6-8 times more than plasma. Both RPV and CAB plasma concentration and the concomitant IC penetration were observed to increase during follow-up with plasma Ctrough values above 4xPAIC90 after the first year. In our population we confirmed the higher CAB plasma and IC exposure in female participants during follow-up ranging respectively from 28% to 88% and from 51% to 139%. No association between lower exposures and virological failure was found.

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Data that matter: epidemiological realities of HIV in the modern era

SC 19 INCIDENCE OF NEW HIV DIAGNOSES IN ITALY: A COMPARISON WITH MAJOR WESTERN EUROPEAN COUNTRIES

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Introduction: In Western European countries, a gradual and slow decline in new HIV diagnoses was observed from 2014 through 2019, followed by a more marked decrease in 2020 due to the COVID-19 pandemic with an inversion in the trend of last three years. ECDC (European Centre of Diseases Control) data report an increase in HIV incidence between 2021 and 2023 from 4.6 to 6.2 cases per 100,000 residents, in Italy the incidence increased from 3.2 to 4.0. The aim of the work is to analyze the epidemic dynamics of HIV infection in major Western European countries.

Materials and Methods: Countries with a population over 40 million in 2023 were selected in this study, including Italy, Germany, the United Kingdom (UK), France and Spain. HIV data from 2014 to 2023 were extracted from the National HIV Surveillance system and the European HIV Surveillance system published in the last ECDC report (1,2).

Results: The five studied countries accounted for 75% of new HIV diagnoses of all Western Europe, and in 2023 they reported 27,043 new diagnoses, of which 6,402, 4,981, 3,321, 3,196 and 2,349 respectively in the UK, France, Germany, Spain and Italy. The Figure shows the incidence trend of new HIV diagnoses over the past 10 years: the United Kingdom, France and Spain, have incidences above average of the Western European, while Italy and Germany have incidences of new HIV diagnoses below the average. Since 2021, the trend has an inversion and increase with a more pronounced growth in the UK and France, where the HIV diagnoses include also those related to people who had already been diagnosed abroad (50% in the UK and 20% in France). In 2023, HIV incidence across Western Europe exceeds that observed in 2019, and the most significant increase occurring in the UK, in Germany incidence slightly exceeds the pre-COVID-19 value, in France and in Italy incidence reaches almost pre-COVID-19 value, while Spain does not show any increase. In 2023 the most frequent mode of transmission is: in Spain MSM (55%); in Germany heterosexual (31%) and MSM (31%); in the UK, Italy and France heterosexual respectively 59%, 48%, and 37%. Late presenters (CD4 <350 cells/μL) account 60% in Italy, followed by France (57%), Germany (50%), Spain (49%) and the UK (30%). The proportion of foreigners is the lowest in Italy (37%) and the highest in the United Kingdom (83%).

Conclusions: The increase in incidence of new HIV diagnoses post-COVID-19 in Italy appears to be in line with that observed in major Western European countries, among them the largest increase is observed in the UK and France. The increase in HIV diagnoses in 2023 may be attributed to a resumption of HIV testing after the COVID-19 pandemic, or to new screening promotion campaigns that have allowed the emergence of new HIV cases. However, a resumption in the spread of HIV infection in Western European countries cannot be excluded.

References:

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Data that matter: epidemiological realities of HIV in the modern era

SC 20 COMPARISON OF NEW HIV DIAGNOSIS INCIDENCE BETWEEN ITALIANS AND FOREIGNERS PRESENT IN ITALY FROM 2012 TO 2023: ANALYSIS OF THE INCREASE POST- COVID19 PANDEMIC

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Background: In 2023, foreigners in Italy account for 9.5% of the total population, increasing from 7.3% in 2012 to 9.0% in 2016, and stabilizing in recent years. Among new HIV diagnoses, foreigners represented around 30% until 2022, rising to 36.9% in 2023. This study aims to estimate HIV incidence among foreigners in Italy from 2012 to 2023, comparing trends with Italians and different macro-areas of origin.

Material and Methods: Data on HIV infection among foreigners were obtained from the National HIV Surveillance System, while population data were sourced from ISTAT and ISMU. ISTAT provides figures for legally residing foreigners by nationality and macro-area, while ISMU estimates irregular foreigners without regional breakdowns. To estimate the number of irregular foreigners by macro-area, we applied ORIM data from Lombardy. HIV incidence was calculated as the number of new HIV diagnoses among foreigners divided by the total number of foreigners (regular and irregular) per 100,000 inhabitants, both overall and by macro-area of origin.

Results: Between 2012 and 2023, 36,289 new HIV diagnoses were recorded, of which 11,197 (30.9%) involved foreigners. The highest percentage of foreign cases came from Sub-Saharan Africa (40.1%), followed by Latin America and the Caribbean (23.8%), Central Europe (12.8%), and Eastern Europe (8.1%). HIV incidence among foreigners was consistently higher than among Italians (17.4 vs. 3.8 per 100,000, $p<0.05$). Both groups experienced a significant decline from 2012 to 2020, followed by an increase in the last three years. In 2012, incidence among foreigners was 26.7, decreasing to 15.7 in 2023, while for Italians, it dropped from 5.4 to 2.8. Comparing 2019 and 2023, incidence among Italians fell by 17% (from 3.3 to 2.8 per 100,000), whereas among foreigners, it rose by 25% (from 12.6 to 15.7) (Figure 1). The highest incidences were observed in individuals from Sub-Saharan Africa (77.8), Latin America and the Caribbean (52.8), Eastern Europe (14.5), and Central Europe (6.3). Over time, incidence among those from Sub-Saharan Africa was initially the highest but has since aligned with or fallen below that of Latin America and the Caribbean. Eastern Europe maintained a higher incidence than Central Europe, reaching five times the rate in 2023. The most significant contributors to the recent increase in HIV incidence among foreigners were those from Sub-Saharan Africa and Eastern Europe, with increases also observed in other macro-areas (Figure 2).

Conclusions: HIV incidence among foreigners in Italy remains about four times higher than among Italians. Following an initial decline, incidence among foreigners has risen since 2021, particularly in 2023. Sub-Saharan Africa and Eastern Europe have been the primary contributors to this trend reversal. These findings highlight the need for targeted HIV prevention initiatives, especially aimed at improving access to testing for foreigners from high-incidence regions.

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Data that matter: epidemiological realities of HIV in the modern era

SC 21 A SURVEY ON THE CONTINUUM OF CARE FOR HIV IN SEX-WORKERS IN ITALY: THE CONTRIBUTION OF NGOS

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Background: In Italy, there are scarce data on the Continuum of care (CoC) for HIV in Key-Populations (KPs) such as sex-workers (SWs) which often are "invisible" in surveillance systems. We aimed to investigate the CoC for HIV in SW in collaboration with Italian Non-Governmental Organizations (NGOs) devoted to the fight against HIV/AIDS.
Materials and Methods: We conducted an on-site survey aimed at SWs during outreach unit/drop-in/help desk activities with the collaboration of NGOs by interviewing SWs, asking about HIV testing, result of last HIV test and eventual ARV therapy with detectable/undetectable viremia. The survey was conducted for a period of 14 consecutive days between Nov-24/Jan-25. Descriptive statistics were performed as well as univariate and multivariate logistic regression to identify factors associated with reported HIV seropositivity.
Results: 31 Italian NGOs from all over the country participated in the survey. 578 SWs were contacted (45.0% F, 49.3% trans; 86.9% not born in Italy; 26.3%≥ 45 years) (Figure 1). People were mainly contacted through outreach unit (82.7%). Regarding housing conditions, 8.7% declared inadequate housing, 5.5% homeless, and 2.2% living in community/institutions. About HIV testing history, 391 (67.6%) performed an HIV test at least once in their life, 62 (10.7%) reported never been tested for HIV, and 125 (21.6%) preferred not to answer. As of 391 subjects tested for HIV, 295 (75.4%) declared to be HIV-negative, of whom 256 (86.8%) last tested in 2023/24 while 10 tested (3.4%) before 2020. Overall, 96 people (24.6%) declared to be HIV-positive, 87 (90.6%) were on ART while 6 (6.3%) were not on therapy (Figure 2). Considering the 87 people on treatment, 41 (47.1%) reported an undetectable viremia and 13 (14.9%) a detectable viremia. In the multivariable logistic analysis, factors significantly associated with a reported HIV-positive result were to be aged 30 to 44 years (aOR: 2.37; p = 0.018), a transgender person (aOR: 10.20; p = 0.015) and PWID (aOR: 4.78; p = 0.019) (Table 1).
Conclusions: Reported data emphasize the necessity to reach out to sex workers to test for HIV (at least 22% have never been tested for HIV) and to promote access to ART (91%, reporting to be in ART) but, above all, in maintaining treatment considering that about 15% reported a detectable viremia and 38% were not aware of their viremia. To achieve the CoC objectives, it is essential to implement interventions that promote SWs empowerment and their active involvement, involving NGOs that are capable to promote access to health services and whose interventions are generally more easily accepted by marginalized people. As consequences, delivering CoC estimates will be more feasible, and periodically replicable and extended within the SW community.
Project implemented with the technical and financial support of the Ministry of Health - General Directorate of Health Prevention. (ref 4023).

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Data that matter: epidemiological realities of HIV in the modern era

SC 22 HBV AND HCV TESTING IN ITALY'S MARGINALIZED GROUPS: ADVANCING WHO'S 2030 ELIMINATION GOAL

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Introduction: The health of the marginalized communities is crucial for public health and inequalities. The WHO Global Hepatitis Report 2024 stated that over 304 million people were living with HBV/HCV infection in 2022.
Aim: We performed HBV/HCV screenings among marginalized people to reveal hidden infections and link-to-care positive individuals.
Materials and Methods: From January 2019 to February 2025, finger-prick tests were used to conduct on-site screenings at non-profit organizations (meal centers, shelters for migrants, and help centers for other vulnerable people) in the metropolitan areas of Florence, Prato, and Pistoia, three cities in Tuscany, Italy.
Positive participants were referred to the closest outpatient clinic to be linked to care.
Results: Eighty-three/2108 (3.9%) participants were HBsAg+, mostly men (p<0·001) and non-Italian natives compared to those HBsAg- (p<0·001). Fifty-two/2108 (2·5%) were anti-HCV+ with a higher proportion of Italians (p<0·001). Intravenous drug use was an independent factor for being anti-HCV+ (p<0·0001). Among the HBsAg+ individuals, 67.5% (56/83) were linked and 91% (51/56) retained in care (treated/monitored). Of the anti-HCV participants requiring clinical evaluation, 37·8% (14/37) were linked to care, and all the 11/14 (88·6%) viremic patients were successfully treated.
Conclusions: We found higher HBV/HCV positivity compared to national prevalences. Participation and linkage to care were successful. The young mean age (39 yrs) of HBsAg+ individuals, primarily from regions with low vaccinal adherence, indicated geographical origin as a key risk factor. The profile of the HCV+ individual was that of a person experiencing extreme marginalization, who engages in risky behaviors, and whose priorities do not include their health. The results stress the need to implement the marginalized groups screening to target hidden HBV/HCV infections, reducing disparities in healthcare and advancing towards the WHO plan to end viral hepatitis as a public health threat by 2030.

Data that matter: epidemiological realities of HIV in the modern era

SC 23 CHARACTERISTICS OF PEOPLE LIVING WITH HIV WHO WERE LOST TO FOLLOW-UP

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Background: Despite the high efficacy and tolerability of modern HIV regimens, people living with HIV (PWH) continue to face various problems related to adherence and retention in care. Discontinuity in care can reduce the overall health and fuel the HIV transmission. The COVID-19 pandemic favoured the disruption to HIV-related services for multiple reasons.

Materials and Methods: This is a retrospective study in an HIV Clinic in northern Italy, investigating the rate and characteristics of PWH who were lost to follow-up (LTFU) during the period immediately following the SARS-CoV-2 pandemic. From January 01, 2022 to December 31, 2024 all patients who did not attend the planned follow-up visits were evaluated. Refill pharmacy reports were checked for consistency. LTFU was defined as those who had not attended any visit for at least two years. Comparison were assessed by Chi-square test.

Results: A total of 2,789 PWH were included in the analysis. Median age was 56 years (IQR 49-61), with 720 (26%) female and 453 (16%) not born in Italy. By the end of 2024, 106 (3.8%) individuals were LTFU. They were classified as follows: Group 1 (deceived): 35 (33%) subjects were identified as dead according to civil registration systems (median age was 61 years, IQR 54-69); Group 2 (movers): 7 (6%) subjects had moved to other HIV centers; Group 3 (persistent collectors): 25 (23%) subjects continued to collect antiretroviral therapy at the hospital's pharmacy, without attending the follow-up visits, and Group 4 (real LFTU): 41 (38%) individuals were untraceable. As far as the Group 4: median age (IQR) was 47 (35-57) years, 12 (29%) were women and 19 (46%) were born outside Italy. The median duration of HIV infection was 15 (IQR 6.75-21) years. Among those born in Italy, 9 (40%) subjects were past/current intravenous drug users (IVDUs). All participants were on ARV during their last visit, 85% had undetectable plasma HIV RNA and median CD4 count were 649 cells/mL. Median (IQR) nadir CD4+ count and treatment duration was 225 (36.5-369.5) cells/mL and 10 (IQR 5.5-18) years, respectively. A total of 16 (40%) subjects had comorbidities, of whom 68% had past/current HCV coinfection. Individuals in Group 4 were more likely to be younger, predominantly of foreign origin and men (70%), but the only factor significantly associated with being LTFU was “born outside Italy” ($p<0.001$).

Conclusions: Our findings confirm a good overall retention in care. The real LTFU persons were more likely to be men, IVDUs, younger and born outside Italy suggesting that targeted projects for people living in marginal situations may help improving retention in care.

Data that matter: epidemiological realities of HIV in the modern era

SC 24 ALL-CAUSE MORTALITY IN PEOPLE WITH FOUR-CLASS DRUG-RESISTANT HIV: A MATCHED COHORT ANALYSIS WITH DATA FROM THE PRESTIGIO REGISTRY

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Background: It is unclear if heavily treatment-experienced people with HIV (PWH) have a higher risk of mortality compared to PWH without multidrug-resistant viruses. We aimed to assess whether individuals with four-class drug resistance (4DR-PWH) have an increased risk of death compared to those without 4DR (non-4DR-PWH).
Methods: This retrospective, propensity score-matched cohort study compared 4DR-PWH (exposed) with non-4DR-PWH (unexposed), all receiving antiretroviral therapy (ART). 4DR-PWH were identified from the multicenter PRESTIGIO Registry, while non-4DR-PWH were selected from the CSL cohort (IRCCS San Raffaele Hospital). Matching was performed at a 4:1 ratio based on age (±3 years), sex assigned at birth, and ART duration (±3 years). The index date (baseline) was defined as the time of 4DR development for the exposed group, while for the unexposed group, it corresponded to the time point used for matching on age and ART duration, employing a nearest-neighbor method with a caliper distance of ±3 years for both variables. Incidence rates (IRs) and incidence rate ratios (IRRs) for death were estimated using Poisson regression, while cumulative mortality probabilities were assessed by Kaplan–Meier curves. Cox proportional hazards models were used to examine the total effect of 4DR status on mortality, adjusting for pre-existing comorbidities at the index date (major cardiovascular events, chronic kidney disease, diabetes, hypertension, HCV, and cancer) and in alternative model also for previous AIDS.
Results: A total of 228 4DR-PWH and 869 non-4DR-PWH were included, contributing 2,003 and 7,260 person-years (PY) of follow-up, respectively, with a median follow-up of 8.7 years (IQR 5.6–11.3). Participant characteristics are detailed in Table 1, and causes of death in Table 2. The median age was 51 years (IQR 46–55) and the majority were male (809/1,097, 73.7%). During follow-up, 28/228 (12.3%) 4DR-PWH and 67/869 (7.7%) non-4DR-PWH died, corresponding to IRs of 1.4/100 PY (95% CI 0.93–2.02) and 0.92/100 PY (95% CI 0.72–1.17), respectively, yielding an IRR of 1.51 (95% CI 0.97–2.35, p=0.063). Kaplan–Meier analysis showed a non-significant increase in the 10-year probability of death for 4DR-PWH compared to non-4DR-PWH [12.37% (95% CI 7.28–17.58) vs. 8.76% (95% CI 6.42–11.05); p=0.068] (Figure 1). In univariable analysis, 4DR-PWH had a non-significant increased risk of death compared to non-4DR-PWH [hazard ratio (HR) 1.50, 95% CI 0.97–2.34, p=0.07]. In multivariable analysis adjusted for comorbidities, 4DR-PWH had a significantly higher risk of death [adjusted HR 1.70, 95% CI 1.08–2.66, p=0.021] compared to non-4DR-PWH which was attenuated after adjusting also for previous AIDS [adjusted HR 1.57, 95% CI 1.00–2.48, p=0.052] (Table 3).
Conclusions: 4DR-PWH have a significantly increased risk of death compared to non-4DR-PWH, highlighting the need for enhanced clinical and preventive strategies tailored to this vulnerable population.

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Deep insights in two-drug antiretroviral regimen

SC 25 COMPARABLE DYNAMICS OF CELL-ASSOCIATED HIV-RNA, TOTAL AND INTACT PROVIRAL HIV-1 DNA IN VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV SWITCHING TO 2DR OR CONTINUING 3DR OVER A 18-MONTH FOLLOW-UP

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Background: Two-drug antiretroviral therapy (2DR-ART) regimens are increasingly being used with comparable efficacy and reduced drug toxicity compared to 3DR-ART. The aim of this work was to assess, in an observational, prospective pilot study, whether switching virologically suppressed people with HIV (PWH) from 3DR-ART to 2DR-ART has an impact on their HIV reservoir.

Materials and Methods: PWH who continued a 3DR-ART (n=18) and PWH that switched to 2DR-ART (n=16) were investigated at enrolment (T0) and 18 months later (T1) for cell-associated HIV-RNA (CAR), HIV-DNA (CAD) and HIV intact proviruses (IP) in CD4+ T-cells. CAR was quantified using a digital PCR (dPCR) assay targeting LTR. CAD and IP were quantified by a triplex dPCR targeting LTR for CAD and psi and ENV regions for IP. All the assays were performed on a QIAcuity platform. Multivariate linear regression analysis was performed to identify predictors of CAR, CAD and IP changes over time (T1-T0).

Results: At T0, the median (IQR) age was 46.5 (14), 94% of participants were male, nadir and baseline CD4+ count was 388 (231) and 792 (430) cells/μL, respectively, with a zenith HIV-1 RNA of 4.9 (1.1) log copies/mL and therapy duration of 60.5 (76.5) months. The only difference between the treatment groups was a longer ART duration in the 3DR group (median [IQR]: 56 [86] vs. 63 [58] months for 2DR and 3DR, respectively) ($p<0.001$). In the whole dataset, CAD(T0) was 2.8 (1.0) log copies/million CD4+ cells, CAR(T0) was 4.2 (1.3) log copies/million CD4+ cells, and IP (T0) was 3.2% (17.8%), with 4/34 samples excluded from IP analyses because failed to amplify psi and/or ENV. At baseline, there were no significant differences between 2DR and 3DR groups for CAD, CAR and IP. Among the three HIV-1 molecular parameters, there was a significant correlation between CAD(T0) and CAR(T0) (Rho=0.645, $p<0.001$). No significant changes over time (T1-T0) were observed for any of the three reservoir indicators, both in the overall population (median CAD +0.19 [+0.69] log, median CAR -0.05 [+1.8] log, median IP -1.25% [+18.4%]) and within or between the 2DR and 3DR groups.

In a regression model including treatment group, age, nadir and baseline CD4+ cell counts, zenith viral load, ART duration, and baseline CAD, CAR and IP values we found that higher baseline CD4+ counts was positively associated with changes of CAD ($p=0.043$), while zenith viral load and CAD(T0) were negatively associated with changes of IP ($p=0.017$ and $p<0.001$, respectively).

Conclusions: CAD and CAR were correlated with each other but not with IP at T0. CAD, IP and CAR values were stable over 18 months irrespective of treatment, reassuring that switching to 2DR does not affect the size of the viral reservoir in the medium term. Higher CAD values seem to predict larger decreases in the IP proportion. Prolonged follow-up is needed to establish the clinical utility of testing for molecular markers of the HIV reservoir before treatment simplification.

Deep insights in two-drug antiretroviral regimen

SC 26 EFFECTIVENESS OF FIRST-LINE LAMIVUDINE-DOLUTEGRAVIR ANTIRETROVIRAL THERAPY IN PERSONS WITH HIV: REAL-LIFE DATA FROM THE ICONA FOUNDATION COHORT

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Background: Dolutegravir plus lamivudine (DTG/3TC) is as effective as standard triple therapy for first-line antiretroviral therapy (ART) in persons with HIV (PWH), but its long-term effectiveness, the impact of pre-ART CD4 count, viral load, and in vulnerable populations need further exploration.
This analysis aimed to evaluate the rate of failure of 3TC/DTG in a real-world data population of PWH starting the combination when ART-naïve.
Methods: The study included PWH from the ICONA Foundation cohort who started first-line 3TC/DTG between 2016 and 2024. The primary objective was to assess time to treatment failure (TF), defined by treatment discontinuation for toxicity/non-adherence, virological failure (2 viral load >50 copies/mL after six months) or death. Secondary objectives included time to treatment discontinuation for any reasons (TD) and virological failure (VF). Main exposures of interest were CD4 count, age, sex, HIV-RNA, and geographic location. Survival analysis was conducted using Kaplan-Meier curves and Cox regression.
Results: This analysis included 446 PWH, all HBsAg-negative: 20% started 3TC/DTG with HIV-RNA >100,000 copies/mL. The median age was 37 years, 15% were female, and 57% MSM, the median CD4 count was 478 cells/mm³, with 6% with CD4 ≤200 cells/mm³ and <1% with an AIDS diagnosis. After a median follow-up of 22 months, 19 PWH (4.3%) experienced TF. The cumulative probability of TF for all exposure of interests are shown in Figure 1. Baseline CD4 count was associated to a 3-fold higher risk of TF, which decreased after adjustments (aHR=2.67; 95%CI 0.75-9.49); higher viral loads (>100,000 copies/mL) and foreign-born status were associated with an increased risk of treatment failure, older participants also had a higher risk (Table 1). Overall, a total of 42 participants (9.4%) discontinued 3TC/DTG over follow-up, mainly for simplification to the long-acting injecting regimen (47.6%), detailed reasons for discontinuation are showed in Table2. The cumulative probability of experiencing 3TC/DTG discontinuation regardless of the reason was 4.6% (95% CI: 2.5-6.8) at 1 year, 10.1% (95% CI: 6.6-13.6) at 2 years and 13.4% (95% CI: 9.1-17.6) at 3 years; n=5 (1.1%) participants experienced pure virological failure, by 3 years the risk of pure VF by Kaplan-Meier was 2.3% (95%CI 0.2-4.4).
Conclusions: In our real-world setting, the TF rate for first-line 3TC/DTG was below 20% at 3 years, lower than in randomized trials. Our data suggest that PWH starting 3TC/DTG with CD4 ≤200 cells/mm³, HIV RNA >100,000 cps/mL, older age and foreign-born status may be at higher risk of TF, though larger studies are needed to confirm these findings.

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Deep insights in two-drug antiretroviral regimen

SC 27 REAL-WORLD EXPERIENCE WITH DORAVIRINE IN ITALY: COMPARING THREE-DRUG AND TWO-DRUG REGIMENS

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Background: This study aimed to evaluate the effectiveness, durability, and metabolic effects of a two-drug regimen (2DR) based on doravirine (DOR) plus lamivudine (3TC) compared to a three-drug regimen (3DR) containing DOR/3TC/TDF.

Methods: This was a retrospective multicentric study including treatment-experienced people with HIV (PWH) who started regimen with DOR/3TC/TDF (single tablet regimen) or DOR+3TC. The regimens were compared according to demographic, HIV-related and metabolic characteristics. Reasons for treatment discontinuation (TD), including virological failure (VF)(defined as HIV-RNA>200cps/ml for two consecutive measurements or HIV-RNA>1000cpsml), were analysed.

Results: Two-hundred-eighteen individuals were included: 171 (78.8%) in 3DR with DOR/3TC/TDF and 47 (21.6%) in 2DR with DOR+3TC. Individuals receiving DOR+3TC were older, had a longer history of HIV infection, and greater prior ART exposure (p=0.01)(Table 1). The primary reasons for switching to 2DR were metabolic concerns and psychiatric symptoms, followed by toxicity or intolerance to previous regimens (Figure 1). Lipids profile at baseline was similar in the two groups, as well as the frequency of statin use; however, hypertension, diabetes, osteopenia/osteoporosis and chronic kidney disease were more prevalent in the DOR+3TC group (Figure 2). TD were 59 (35%) in the DOR/3TC/TDF group and 12 (25.5%) in the DOR+3TC group, with an incidence rate of 1.3 (95%CI 0.8-2.3) and 1.5 (95% CI 1.2-1.9) per 100 PYFU, respectively (logrank =0.843, Kaplan-Meier curve not shown). The primary reasons for discontinuation were toxicity/intolerance [24/59 (40.6%) in 3DR vs. 5/12 (41.6%) in 2DR], reduction in pill/drug burden [18/59 (30.5%) vs. 2/12 (16.6%)] and VF or need for increased genetic barrier [9/59 (15.3%) vs. 5/12 (41.6%)]. In the 3DR group, during a 25 months (IQR 2.8-44.3) follow-up period, 5 VF (2.9%) occurred, leading to discontinuation in 4 individuals and emergence of resistance mutations in 2. In the DOR+3TC group, during a follow-up of 23.8 months (IQR 2.8-37.7), 1 VF (2.1%) was reported with emergence of N348I mutation (with no impact on DOR susceptibility but archived Y188L mutation) and 2 viral blips (VF>50 cps/ml) occurred, leading to treatment intensification. A cumulative genotypic susceptibility score <2 was reported in 7 (17.9%) PWH on DOR/3TC primarily due to archived M184V mutations and, in 3 individuals, to DOR mutations: of those, 4 maintained virological suppression until last available follow-up (median 19.2 months).

Conclusions: Both DOR/3TC/TDF and DOR+3TC demonstrated comparable efficacy and durability. DOR+3TC regimen may be a suitable option for individuals with complex metabolic profiles and prior ART intolerance, provided that full susceptibility to the regimen is confirmed and adherence is reinforced. The presence of archived mutations in 17.9% of DOR+3TC recipients underscores the importance of prior resistance testing before prescribing this regimen.

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Deep insights in two-drug antiretroviral regimen

SC 28 ADVERSE EVENT DEVELOPMENT IN PEOPLE WITH HIV ON LONG-ACTING CABOTEGRAVIR + RILPIVIRINE: TIMING AND CLINICAL INSIGHTS

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Background: Long-acting (LA) injectable cabotegravir (CAB) and rilpivirine (RPV) is a well-established and tolerated option for antiretroviral treatment (ART) in eligible people with HIV (PWH). This study aims to describe adverse events (AEs) reported in a multicentric, prospective cohort, assessing their severity and the timing of occurrence. Additionally, it explores the characteristics of PWH who experienced these reactions.

Materials and Methods: This observational, prospective multicentric study included PWH who started LA CAB/RPV regimen and developed an AE between July 2022 and February 2025. AEs were defined, according to the study protocol, as any harmful and unintended effect, graded using the DAIDS Adverse Event Grading, resulting from the use of the LA regimen. Data were described using mean ± standard deviation (SD) for normally distributed continuous variables, median and interquartile range (IQR) for not normally distributed continuous variables and percentage for categorical and ordinal variables.

Results: A total of 667 PWH who initiated the LA treatment were included, 512 were male (76.8%) and had a median age of 49 (IQR 40-58). Most were in CDC stage A (379/667, 56.8%) and had a mean prior ART duration of 12.0 years (SD 7.6). At baseline, 654/667 (98.0%) had undetectable viral load, with a median CD4+ T count of 780 cells/mm³ (IQR 568–1015). Additionally, 352/667 (52.8%) were on at least one concurrent treatment.

In our cohort, 42 (6.3%) PWH developed ≥1 AE. In 7/42 (16.7%), AEs were difficult to correlate with the LA treatment or were not assessable.

PWH with AEs had a median age of 54 years (IQR 47-61) and were mostly males (32/42, 76.2%); 26/42 (61.9%) were concurrently receiving at least one other pharmacological treatment. Most PWH staged CDC class A (21/42, 50.0%), with mean prior ART duration of 14.0 years (SD 9.1) and a baseline CD4+ T count of 750 cells/mm³ (IQR 497-1074). Baseline CD4+ T count was not significantly different between PWH with and without AEs (p=0.57).

Prior to the initiation of LA regimen, 31/42 PWH (73.8%) received an oral ART with INSTIs, and 18/42 (42.9%) with NNRTIs. The median follow-up period for PWH with AE was 3 months (IQR 2-6); AEs mainly occurred within the first 66 days (IQR 28-176) after the first injection. Thirty-seven/42 (88%) PWH discontinued due to AEs. The most prevalent AEs were injection site reaction (13/42, 30.9%) and lower limb pain (7/42, 16.7%), followed by fever (6/42, 14.3%) and neurological symptoms (4, 9.5%). Nine PWH (21.4%) developed more than one AE.

In regard to severity, only two AEs related to the LA regimen (34/42) were grade 4 and ten grade 3; 5/42 had no grading, while 18/34 were graded 1 and 2.

Conclusions: Real-life data confirm that LA CAB/RPV is well-tolerated, with most AEs occurring within the first months of treatment (Figure 1). AE rates were lower than in registration trials, especially for injection site reaction, though more PWH discontinued LA due to AEs.

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Deep insights in two-drug antiretroviral regimen

SC 29 REASONS FOR DECLINING LONG-ACTING-INJECTABLE THERAPY IN ELIGIBLE PLWH: INSIGHTS FROM THE WHY-NOT STUDY

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Background: Long-acting injectable (LAI) therapy with cabotegravir and rilpivirine (CAB/RPV) represents a significant and innovative advancement in switch strategies for the treatment of HIV. Such an option, characterized by bimonthly intramuscular administrations received in hospital setting, may offer several advantages over conventional regimens based on daily oral drugs, mainly associated to enhanced adherence and de-stigmatization.
However, a subset of people living with HIV (PLWH), who qualify for LAI and after direct proposal, decline this option. We aimed to investigate the reasons for refusal despite qualification.
Material and Methods: Retrospective, multicenter, observational cohort study aimed at investigating the reasons why persons eligible for LAI treatment decline this option.
From 1 January 2025 to 7 March 2025, all consecutive PLWH attending two HIV centers in northern Italy, were offered LAI therapy (if they qualified for) during routine follow-up visits and the reasons for refusal were collected by proponent physicians.
Eligibility criteria were: HBsAg negativity, virological suppression for at least six months, no history of virological failures and adherence to scheduled visits (not necessarily to ART).
Clinical, sociodemographic data and comedications were retrieved from medical records.
Results: A total of 432 subjects were enrolled. Reasons for LAI declination (Table 1) were:
logistical challenges in 272 subjects (63%). Among these reasons (multiple choices were admitted), the distance from the HIV center (34%), the number (62%) and frequency (bimonthly) (4%) of required visits by current LAI were the most frequent complaints.
Other reasons were: reluctance to change current and well tolerated therapy (95 pts, 22%) and fear of needles (43 pts, 10%), the impossibility of self-administration for 13 patients (3%), the absence of benefit (as they were already taking oral comedications) for 9 subjects (2%) 2(Figure 1).
Only 99 subjects (23%) were aware of this LA option before the doctor's interview.
Conclusions: Logistical challenges represent the main reasons for declining LAI therapy in eligible and successfully treated PLWH. In this perspective, the possibility of administering LAI therapy at longer intervals and the availability of facilities closer to home might facilitate the acceptance rate.

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Deep insights in two-drug antiretroviral regimen

SC 30 REAL-WORLD DISCONTINUATION AND VIROLOGICAL OUTCOMES OF LONG-ACTING CABOTEGRAVIR + RILPIVIRINE IN VIROLOGICALLY SUPPRESSED ADULTS LIVING WITH HIV: A MULTICENTER OBSERVATIONAL STUDY IN TUSCANY (LAHIV)

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Background: Cabotegravir (CAB) + rilpivirine (RPV), available in Italy from June 2022, dosed intramuscularly every 2 months, is the first long-acting (LA) regimen used to maintain HIV-1 virological suppression. We evaluated the durability of this regimen.

Materials & Methods: This multicenter observational study enrolled virologically suppressed adults living with HIV (HIV-RNA <50 cp/mL) from 11 Tuscan centers who initiated CAB+RPV. Participants were monitored from their first injection until regimen discontinuation, death, or last visit. Discontinuation criteria included regimen switch or two consecutive missed injections. Virological failure (VF) was defined as two consecutive HIV-RNA >50 copies/mL detections or a single detection >1000 copies/mL. Statistical analyses included chi-square, non-parametric tests for categorical and continuous variables, and Kaplan-Meier survival analysis for discontinuation probability estimation.

Results: The cohort included 185 PLWH and a combined at-risk period of 170.25 years, with a median follow-up of 1 year [IQR 0.4-1.4]. Most participants (n=151; 81.6%) were male, with a median age of 51 years (IQR 43-58), and a median ART duration of 13 years (IQR 8-20). Seventeen participants (10.8%) discontinued CAB+RPV: 7 (3.7%) due to adverse events, 5 (2.7%) due to VF, 4 (2.1%) by patient choice, and 1 (0.5%) due to loss to follow-up [Table 1]. All VFs occurred within 28 weeks, except for one at week 72, the only case that developed INSTI and NNRTI resistance (N155H, Q146L, and M230L, respectively) despite having no known risk factors for VF. Additionally, one VF had a pre-existing RPV resistance mutation. The VFs presented different clinical profiles, summarized in Table 1. The discontinuation rate was 9.9 per 100 person-years (95% CI 6.2-16.1), and the virological failure rate was 2.9 per 100 person-years (1.2-7.06). Only one participant missed one administration by more than seven days. All recorded VFs happened with CAB+RPV administrations within the scheduled timeframe.

Conclusions: Early findings indicate that discontinuations for CAB + RPV are higher than in clinical trials but align with other real-life studies (approximately 9-10% at 44 weeks). However, our study showed a higher virological failure rate (2% vs. 1%) compared to other real-life studies.

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Deep insights in two-drug antiretroviral regimen

SC 31 DURABILITY, ADHERENCE, AND DISCONTINUATION OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE: A 96-WEEK REAL-WORLD STUDY

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Background: Cabotegravir/Rilpivirine (CAB/RPV) is the first long-acting injectable (LAI) antiretroviral therapy (ART) approved for virologically suppressed adults with HIV-1. While clinical trials have demonstrated its safety and efficacy, real-world data are limited. Concerns about the sustainability of the frequency of injections are still a matter of discussion. This study evaluates the long-term persistence, durability and discontinuation patterns of CAB/RPV LAI administered every 8 weeks (Q8W) over a period of 96-weeks.

Methods: A retrospective observational study analyzed PWH who switched to commercially available CAB/RPV LAI Q8W within the first 96 weeks of its use. Adherence to the injection schedule and reasons for discontinuation were assessed.

Results: A total of 322 patients were included (median age of 51 years [IQR: 42-61], 23 % female), with a median follow-up time of 70 weeks (IQR: 24-96). Most had prior exposure to INSTIs (64.9%), followed by NNRTIs and PIs. The most common previous regimen included an INSTI-based combination (78.1%).

By 96 weeks, 8,3% of patients (27/322) had discontinued treatment, with a median time to discontinuation of 19 weeks (IQR: 12-35) and a median of four injections before stopping. Adherence to the prescribed schedule was high (92.8% at 48 weeks, 92.5% at 96 weeks). (FIGURE 1)

The main reasons for discontinuation included pregnancy planning (n=2), chemotherapy initiation (n=1), transfer to another healthcare center (n=6) leading to therapy interruption, injection fatigue (n=4), and adverse effects (n=9). In five patients, treatment was changed following a reassessment of medical history. (FIGURE 2)

No cases of virological failure were observed. Viral suppression was maintained in 95.6% at 48 weeks and 94.8% at 96 weeks, with only occasional virological blips.

Conclusions: This 96-week real-world study confirms that CAB/RPV LAI Q8W is a durable and well-tolerated option, with high adherence and minimal discontinuation rates. The primary reasons for stopping treatment were unrelated to efficacy, and fatigue-related symptoms had a negligible impact. These findings support the long-term viability of CAB/RPV LAI in clinical practice, though further research studies are warrented to refine patient selection and optimize treatment strategies.

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From epidemiology to innovation: vaccine coverage and viral pathogenesis

SC 32 IMPLEMENTATION OF A MONITORING SYSTEM FOR IMMUNIZATION COVERAGE IN PEOPLE LIVING WITH HIV IN THE LOMBARDY REGION

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Background: Vaccination coverage (VC) among people living with HIV (PLWHIV) is not routinely assessed. This work aims to develop a monitoring system for VC in PLWHIV in the Lombardy region, providing public health officials and infectious disease clinics (IDCs) with relevant data on VC among individuals under their care.

Materials and Methods: Administrative data were used to identify PLWHIV, defined as individuals with at least one prescription for HIV treatment or an HIV viral load in 2024. Each person was assigned to an IDC based on their most recent prescription. People who could not be assigned to any IDC were categorized as "Other".

VC was stratified by IDC, age group (0–49, 50–64, and ≥65 years), and sex. The analysis focused on vaccines recommended for PLWHIV according to regional guidelines. Vaccination records were extracted from the regional vaccination registry as of March 6, 2025, including vaccinations performed in other regions but registered in Lombardy. Vaccinations administered in all settings (e.g., vaccination centers, general practitioners) were included.

Results: A total of 28,575 PLWHIV were identified and assigned to an IDC. The average regional VC for each vaccine is reported in Table 1.

Regarding variability across IDCs, coverage for the first dose of the pneumococcal vaccine ranged from 14.8% to 66.9%, while for the Herpes Zoster vaccine ranged from 6.8% to 58.3%. We observed higher coverage against hepatitis A virus (HAV) among men (30.2%) than among women (12.9%) in the 0–49 age group. Among older adults, coverage for the 2024–2025 influenza season was 52.8%.

Conclusions: Establishing a monitoring system for VC in PLWHIV is essential for assessing immunization levels, raising awareness among IDCs, encouraging vaccination efforts, and evaluating the impact of interventions. A wide heterogeneity in coverage across IDCs was observed for nearly every vaccine.

Coverage also varied by sex and age, reflecting specific vaccination recommendations and comorbidities. For example, the high HAV VC observed among young men is likely driven by recommendations made for men who have sex with men. Similarly, VC against influenza for the 2024–2025 season among PLWHIV aged ≥65 years was 52.8%, compared to 52.6% in the general population of the same age, suggesting that PLWHIV may not perceive themselves as being at greater risk for severe influenza compared to individuals not living with HIV.

It is important to emphasize that this assessment does not evaluate individual IDCs' performance, as vaccination efforts are shared across the healthcare system, including general practitioners, vaccination centers, and pharmacies. Nevertheless, IDCs play a key role in promoting, administering, and facilitating access to vaccines, especially among PLWHIV. With this monitoring system now in place, VC data will be regularly tracked, enabling the evaluation of interventions aimed at improving immunization coverage across the Lombardy region.

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SC 33 IMPLEMENTING THE NATIONAL VACCINATION PLAN IN PEOPLE WITH HIV (PWH): A NATIONAL SURVEY AMONG ICONA CENTERS

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Background: We aimed to assess adherence to the Italian National Vaccination Plan (NVP) and differences in vaccination practices among people with HIV (PWH) in centers participating in the ICONA cohort.
Methods: A cross-sectional survey was conducted online in Jan-Feb 2025 to all ICONA cohort centers requesting information about center features (geographic localization, number of PWH in care, type of center), type, number, and modality of vaccine offering, and investigating possible barriers to NVP implementation. Vaccinations were grouped into sexually transmitted infections (STI-V) (HAV, HBV, HPV, Mpox); seasonal (S-V) (SARS-CoV-2); age and immunodepression related (A-V) (dTP, anti-Zoster, and others).
Results: 59 out of 61 ICONA centers completed the survey: 47.5% in Northern Italy, 18.6% in Central Italy, and 33.9% in Southern Italy, with 50.8% being academic centers. The distribution of PWH in care (<500, 500–1000, >1000) varied significantly by region (p=0.009), with most centers (60.7%) following >1000 PWH being in Northern Italy. Regarding the vaccination offer, 37.3% of centers could provide on-site vaccinations at Infectious Diseases Units, 27.1% had a hospital-based service, and 35.6% referred PWH to an out-of-hospital local vaccination service (Table 1). Either PWH or doctors could make vaccination booking in 65.4% of centers in Northern Italy and in 9.1% of centers in Central Italy (p=0.024). Vaccinations were offered at the time of engagement in care in 47.5% centers, while in 45.8%, vaccinations were started within a year. The lack of registry access was more frequent in Southern Italy and Central Italy compared to Northern Italy (Table 1). Most centers (96.6% to 91.5%) offer STI-V, apart from Mpox, which is offered only in 42.4%. S-V. In particular, SARS-CoV-2 was provided in 47.5% of centers, and A-V from 96.6% to 54.2%. PWH's hesitancy (55.9%) was the primary barrier reported, followed by a lack of dedicated staff (32.2%) and organizational constraints (25.4%). Considering STI-V, there wasn't a substantial difference between geographic areas, except for Mpox, whose offer varied widely, with a higher rate in Central Italy, 72.7%, and less than 40% in South and Northern Italy. Mid-sized centers expressed more concerns about a lack of staff. Centers reported low PWH's hesitancy (11.9%) for non-Italian born. Notably, 86.2% provided free vaccinations for those with a code for temporary health service (STP), while 64.9% did so for European Non-Italian (ENI)-coded individuals. However, 12.3% did not cover people with ENI-code, and 22.8% stated that their region did not accept ENI-coded individuals. Finally, 49.2% of centers had trained staff in the NVP, with rates ranging from 64.3% in North to 18.2% in Central Italy (Table 1).
Discussion: This study showed marked disparities in vaccination offers, pathways, and registry accessibility across Italian HIV centers. Addressing these issues will foster and optimize broader adherence to vaccinations for PWH.
Table 2

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SC 34 GENERATION OF A NOVEL AND SAFE VIRAL-BASED NEUTRALIZATION ASSAY FOR MONITORING FLAVIVIRUS EMERGING AND RE-EMERGING ZOONOSES

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Background: The spread of Flavivirus including Dengue Virus (DENV), Zika Virus (ZIKV), West Nile Virus (WNV) and Tick-borne Encephalitis Virus (TBEV) in previously non-endemic temperate areas represents a significant threat for both human and animal health. Flaviviruses infect both humans and animals, exhibit similar routes of transmission and symptomatology, share circulation areas and show extensive cross-reactivity, making difficult the diagnosis. To control outbreaks and prevent virus dissemination, accurate tracing activities of the areas of viral circulation and a rapid diagnosis are essential. Molecular techniques are the main methods used to diagnose an ongoing Flavivirus infection and the plaque reduction neutralization test (PRNT) is employed as confirmatory assay to evaluate the presence of neutralizing antibodies (nAbs) in both human and animal sera. Although PRNT is considered the gold standard assay for Flavivirus diagnosis, it presents several issues in terms of safety and complexity, as it is performed using live infectious viruses and requires high biosafety level laboratories. Here, we describe the development of an innovative neutralization assay based on pseudoviruses to safely evaluate nAbs in human and animal samples without using live infectious viruses. The platform employs non-replicating single-round infectious particles expressing luciferase (SRIP-Luc) derived from Yellow Fever Virus (YFV) and pseudotyped with heterologous prME glycoproteins (SRIP-Luc/prME) from representative Flaviviruses, including ZIKV, DENV, WNV and TBEV.
Materials and Methods: To produce SRIP-Luc/prME, 293T Lenti-X cells were transiently co-transfected with a YFV-based plasmid expressing the luciferase reporter protein, a plasmid codifying the YFV-capsid protein and each of the prME-expressing plasmid from selected Flaviviruses. Titres of produced SRIP-Luc/prME were evaluated on VERO cells. In the neutralization assay, positive and negative sera were serially diluted and incubated with SRIP-Luc/prME and added to VERO cells. Luciferase activity was evaluated after 72 h. NAbs titres were expressed as the serum dilution reducing by 50% (ID50) the luciferase output compared to cells treated only with SRIP.
Results: SRIP-Luc/prME from each Flavivirus were produced and titrated on VERO cells, showing high infection titres. A panel of PRNT-positive sera and sera from TBEV experimentally infected goats provided by National Reference Laboratory for Arboviruses and Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna, respectively, were assayed by the SRIP-based NT. Results showed that SRIP-based NT was able to determine and quantify the presence of anti-Flavivirus neutralization activity in both human and animal sera.
Conclusions: This novel and versatile platform will allow for rapid, safe and accurate nAbs quantification, representing a promising tool for emerging and re-emerging viruses surveillance and research purposes.

From epidemiology to innovation: vaccine coverage and viral pathogenesis

SC 35 INCIDENCE AND RISK FACTORS OF HPV-16 CLEARANCE AT THE ANAL SITE IN MSM WITH HIV

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Background: 9-valent HPV vaccine is effective as a prevention tool, rather than therapeutic at cervical site. Insights on viral clearance at anal site is still unknown, especially in the high-risk population of MSM with HIV (MwH). Aim of the study is to determine incidence and factors associated with the clearance of HPV-16 at anal site in MwH.
Methods: Retrospective cohort analysis in MwH in care for HIV at the Infectious Diseases Unit of San Raffaele Hospital, Milan, Italy, with ≥1 HPV tests positive for HPV-16, performed from 2010 and January 2025 (data lock). Follow-up was defined as the period from the first positive HPV-16 test to the first subsequent negative test for those who cleared it and to the last for those who did not.
HPV-16 genotype was detected by multiplex real-time PCR (CFX96™, Seegene).
Incidence rates (IR) of clearance were calculated by univariable Poisson regression model and expressed per 100 person-years of follow-up (PYFU) and cumulative probabilities of clearance by Simon-Makuch method. Incidence rate ratio (IRR) was estimated to compare HPV-16 clearance between vaccinated and unvaccinated. Multivariable Cox regression model was employed to estimate risk factors associated with clearance of HPV-16 genotype.
Results: Among 278 MwH with a positivity for HPV-16 at anal site, 114 (41%) cleared the infection at a subsequent HPV test. Those who cleared HPV-16 were significantly younger with a median (IQR) age of 39.6 (32.7-48.4), as compared to those who cleared [42.2 (36.1; 49.5) years], with shorter duration of HIV infection.
Immuno-virological characteristics were similar between the two groups: overall median CD4 nadir was 328 (214 -478) cells/uL, CD4+ count 676 (528-823) cells/uL, CD4/CD8 ratio 0.70 (0.49-0.96); 31 (11.2%) had history of AIDS (Table 1).
Median follow-up duration was 4.29 years [2.77; 6.09]. Overall, IR of HPV-16 clearance was 8.71 x 100 PYFU (7.19-10.46). Only 2 were immunized at first HPV test; among the 52 immunized with HPV vaccine during the follow-up period, 19 cleared HPV-16 after immunization, after a median of 2.22 years [0.84-3.51]. Cumulative 6-year probability of clearance after immunization (65.2% [45.4%-84.1%]) was higher than that observed in the non-immunized individuals (36.5% [29.3%-44.8%]), with an IRR of 2.31 [1.42-3.74, ($p < 0.001$)], (Figure 1).
At multivariable regression, hazard of clearance decreases with age and increases with higher CD4/CD8 ratio, independent of vaccine. Specifically, for every 5-year increase in age, the clearance rate decreases by 26.5%, while for each 0.2 increase in the CD4/CD8 ratio, the clearance rate rises by 14.6% (Table 2).
Conclusions: Clearance of HPV-16 at the anal site was more frequent in individuals who were immunized. Factors such as younger age and a more rubust immune status were associated with higher clearance, indicating that host-related factors play a significant role in the pathogenesis of HPV-16 clearance.

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From epidemiology to innovation: vaccine coverage and viral pathogenesis

SC 36 G-QUADRUPLEXES ARE MOLECULAR SWITCHES IN HIV-1 LATENCY REGULATION

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Background: Despite four decades of intensive research, HIV-1 remains a major global health challenge. While current antiretroviral therapy (ART) effectively suppresses viral replication, it falls short of targeting the integrated provirus responsible for latency onset, making latent reservoirs impossible to eradicate. Understanding the fundamental mechanisms underlying HIV latency and identifying new therapeutic strategies are thus crucial in the ongoing effort to combat HIV.
In this study, we have investigated a molecular mechanism that provides new insights into HIV-1 latency and may contribute to the development of novel treatment approaches. We demonstrate that G-quadruplexes (G4s) within the viral promoter play a pivotal role in establishing and maintaining HIV-1 transcriptional latency.
G4s are alternative nucleic acids secondary structures that form within guanine-rich strands. In virology, G4s have been characterized as key players in viral processes, like viral transcription and replication, and as innovative antiviral targets. Building on our previous discovery of four overlapping G4s in the HIV-1 long terminal repeat (LTR) promoter, and their ability to recruit cellular proteins, we've now delved deeper into their role in latency establishment and maintenance.
Material and Methods: We used different latency cell models and peripheral blood mononuclear cells deriving from patients living with HIV-1 to directly assess the folding status of LTR G4s. We sorted transcriptionally active and inactive cell population by fluorescence-activated cell sorting, isolated the chromatin and performed immunoprecipitation with antibodies specific for G4s and associated proteins, such as nucleolin and SP1. We also employed immunofluorescence to monitor the effect of nucleolin depletion on transcription.
Results: Using cutting-edge techniques, we provide the first evidence that G4s are folded in the HIV-1 promoter of transcriptionally silent proviruses embedded in chromatin. Conversely, reactivation from latency is associated with G4 unfolding, making G4s molecular on-off switches for HIV-1 transcription. We also show that the protein nucleolin binds and stabilizes these G4 structures in the latent state, while the transcription factor SP1 preferentially binds the unfolded G-rich promoter in the transcriptionally active state. Intriguingly, depleting nucleolin partially reactivates the virus, suggesting its crucial role in maintaining latency.
The clinical relevance of our findings is underscored by our observation in peripheral blood mononuclear cells deriving from patients living with HIV-1, where G4 folding also correlates with low viral transcription.
Conclusions: These findings uncover G4s as molecular switches that control HIV-1 latency and identify nucleolin as a key regulator of this process, highlighting G4-targeting approaches as potential strategies for latency reversal or deepening the latent reservoir.

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SC 37 LOW-LEVEL VIREMIA DURING ANTIRETROVIRAL TREATMENT IS NOT ASSOCIATED WITH IMPAIRED IMMUNOLOGICAL RECOVERY IN THE SECOND-GENERATION INSTI ERA

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Background: The clinical correlates of low-level viremia (LLV) during antiretroviral treatment (ART) remain controversial. Few data are available on the relationship of this condition with immune recovery, especially in the second-generation integrase inhibitor (INSTI) era. Our aim was to explore the effect of LLV on CD4+ and CD4+/CD8 + trends in the current period.

Methods: Retrospective, cohort study on people with HIV (PWH), who: i) initiated ART from 01st Jan 2014 to 18th Feb 2024 [date of ART initiation defined as baseline (BL)]; ii) had available BL CD4+ and CD8+ counts; iii) had ≥1 CD4+ and CD8+ determinations during follow-up; iv) had ≥2 viral loads (VLs) at ≥1 year from BL.

PWH were categorized in 3 groups: i) virological suppression (VS) if they had all VLs at ≥1 year from BL <50 copies/mL; ii) LLV if they had ≥1 VL at ≥1 year from BL between 50 and 999 copies/mL and none ≥1000 copies/mL; iii) virological failure (VF) if they had ≥1 VL at ≥1 year from BL ≥1000 copies/mL. Follow-up accrued from BL to the date of the last available CD4+ and CD8+ determination (freezing date: 18th Feb 2025).

Primary outcomes were CD4+ and CD4+/CD8+ trends. A linear mixed model with random intercept and random slope was applied to compute crude mean changes for CD4+ and CD4+/CD8+, using the time*group interaction term. Adjusted mean changes (aMCs) were estimated employing a multivariable linear mixed model, including also sex assigned at birth, age (time-dependent), BL viremia (log-transformed), BL value of the respective immunological parameter, BL HCV serostatus, BL HBV coinfection, and number of sexually transmitted infections during follow-up (≥3 vs. <3).

A sensitivity analysis was performed excluding individuals in LLV group for only unconfirmed VLs between 50 and 999 copies/mL (viral blips).

Results: Overall, 1025 PWH who initiated ART in the second-generation INSTI era were included in the analysis: characteristics reported in Table 1.

Considering VLs at ≥1 year from ART initiation, 696 (67.9%) remained always on VS, 252 (24.6%) had ≥1 LLV episode [168/252 (66.7%) viral blips only], and 77 (7.5%) had ≥1 VF. BL CD4+ count and CD4+/CD8+ ratio were significantly lower in both LLV and VF groups compared to VS (Table 1).

During a median follow-up of 7.5 (5.3-9.2) years, an increase in CD4+ count and CD4+/CD8+ was observed in all groups (Figure 1). CD4+ trends were not worsened in case of VF or LLV (Figure 1A), whereas CD4+/CD8+ increase was reduced in case of VF, but not LLV (Figure 1C).

These results were confirmed after excluding individuals with only viral blips [for LLV group: CD4+ aMC=+45.8 (95% confidence interval (95%CI)=+37.6/+54.0) cells/mm3 per year, p=0.002; CD4+/CD8+ aMC=+0.059 (95%CI=+0.047/ +0.072) per year, p=0.615].

Discussion: In our cohort of PWH initiating ART in the second-generation INSTI era, LLV was not associated with worse immune recovery compared to continuous undetectability. The clinical significance of LLV remains uncertain.

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Challenges in prevention

SC 38 PREDICTORS OF STI REINFECTION IN A MONOCENTRIC COHORT OF HIGH-RISK MEN WHO HAVE SEX WITH MEN

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Background: Men who have sex with men (MSM) experience a higher incidence of sexually transmitted infections (STIs), including syphilis, chlamydia and gonorrhea. Understanding STI reinfection patterns is essential for optimizing prevention and screening strategies in key populations.
This study aimed to assess the determinants of STI reinfection in a cohort of MSM living with HIV (MSMWH) and MSM using pre-exposure prophylaxis (MSM-PrEP), to improve tailored interventions and public health responses.
Methods: We conducted a retrospective monocentric cohort study including MSMWH and MSM-PrEP followed at our center between 2020 and 2023. Participants were enrolled if they had at least one episode of STI requiring specific treatment during the study period. Reinfection was defined as a new episode of syphilis, chlamydia or gonorrhea that required specific treatment during the follow-up period. We compared reinfection rates between MSMWH and MSM-PrEP and assessed potential risk factors. Kaplan-Meier survival analysis was performed to evaluate the probability of reinfection, and multivariable Cox regression was used to identify independent predictors of reinfection.
Results: A total of 574 participants were included, comprising 436 MSMWH and 138 MSM-PrEP, with a total of 1,111 observed STI events (841 in MSMWH and 270 in MSM-PrEP). Characteristics of the study population are summarized in Table 1.
MSM-PrEP were more likely to have multiple STI diagnoses per person during follow-up compared to MSMWH ($p < 0.001$).
Among the STIs observed, syphilis was the most frequent (986 cases: 819 in MSMWH and 167 in MSM-PrEP). Gonorrhea was diagnosed in 75 cases (12 in MSMWH and 63 in MSM-PrEP), while chlamydia was found in 50 cases (10 in MSMWH and 40 in MSM-PrEP). Frequencies of different STIs are summarized in Table 2.
Reinfection occurred in 349 participants (60.8%), with a higher rate observed in MSM-PrEP compared to MSMWH (127/138, 92.0% vs 222/436, 50.9%, $p<0.001$). At Kaplan-Meier survival analysis, the probability of reinfection was significantly higher among MSM-PrEP, compared to MSMWH (log-rank $p < 0.001$), with a 1-year reinfection probability of 48% for MSM-PrEP and 33% for MSMWH.
In the multivariable Cox regression model, MSM-PrEP (vs MSM-HIV, aHR = 2.21, 95% CI 1.32 – 3.70, $p < 0.001$) and HCV coinfection (aHR = 1.51, 95% CI 1.15 – 1.95, $p = 0.003$) were independently associated with an increased risk of reinfection.
Conclusions: Our findings highlight a high burden of STI reinfections among MSM, particularly in MSM-PrEP and people with HCV coinfection. The highest probability of reinfection in this group suggests the need for enhanced screening strategies and targeted prevention measures, such as more frequent STI testing and tailored risk-reduction counseling.

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Challenges in prevention

SC 39 MPOX VACCINATION AND NATURAL IMMUNITY: A COMPARATIVE SEROLOGICAL STUDY

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Background: Human mpox, formerly known as monkeypox, is a zoonotic disease caused by the monkeypox virus (MPXV). Until the early 2000s, outbreaks were confined to Africa, with sporadic imported cases in Europe and minimal human-to-human transmission. However, a major outbreak began in May 2022, prompting the WHO to declare a Public Health Emergency of International Concern (PHEIC) from July 2022 to May 2023. Due to a resurgence in cases, the WHO re-declared a PHEIC on August 14, 2024.
This study aims to compare anti-mpox antibody levels among individuals with a prior infection, vaccinated individuals (with or without previous infection) and unvaccinated individuals.
Material and Methods: We retrospectively analyzed the medical records of patients admitted to the Sexually Transmitted Diseases Clinic at Sacco Hospital from August 1st, 2022, to February 25th, 2025, documenting their mpox vaccination and infection history. Serological tests were performed on blood samples collected during follow-up visits by means of PRNT in order to identify broadly neutralizing anti-mpox antibodies (bnABs). The antibodies levels were compared across groups. Data were then analyzed using descriptive statistics.
Results: A total of 435 consecutive males were included, with a median age of 37 years (IQR 29-40). Of these, 204 (46.9%) received at least one vaccine dose: 30 received one dose, 173 received two and 1 received three. Previous mpox infection was reported in 9 (2.1%) individuals, of whom only one (11.1%) was vaccinated. In this subgroup, 4 (44.4%) patients had reactive antibody titers, with a median titer of <1:10 and a maximum of 1:20. Serological tests were available for 387 out of 426 patients without prior mpox infection. Of those, 184 were vaccinated and 21 of them (11.4%) had reactive antibody titers. Overall, 28 non-infected individuals had reactive antibody titers, including 7 unvaccinated individuals with titers of 1:20 or 1:40.
Conclusions: Mpox cases were relatively infrequent among male users attending Sacco Hospital's STI Clinic. While vaccination uptake was substantial, serological response was limited, with only 11.4% of vaccinated non-infected individuals displaying reactive antibody titers. These findings highlight the need for further investigation into vaccine-induced immunity and potential booster strategies.

Challenges in prevention

SC 40 MACROLIDE-RESISTANT MYCOPLASMA GENITALIUM: EPIDEMIOLOGICAL INSIGHTS FROM A CLINICAL STUDY IN HIGH-RISK POPULATIONS

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Background: Mycoplasma genitalium (MG) infection is often asymptomatic, contributing to its silent spread. When complications arise, it can cause epididymitis, prostatitis, pelvic inflammatory disease, infertility, and spontaneous abortion. Treatment is challenging due to MG's intrinsic resistance to multiple antibiotics. Resistance to almost all therapeutic options (macrolides, quinolones, and tetracyclines) continues to rise at an alarming rate, likely driven by their widespread use for common infections. The aim of our study was to estimate macrolide resistance in subjects attending the STI center of the Infectious Diseases Clinic at San Paolo Hospital, Milan.
Material and Methods: Between June and November 2024, 1942 subjects (78.2% male) were screened for STIs at the Infectious Diseases Clinic of San Paolo Hospital, Milan. The population included PrEP users, PLWH, and STI clinic outpatients. Collected specimens were urine, rectal, cervical, oropharyngeal and urethral swabs, and seminal fluid. Nucleic acid amplification tests (NAATs), the gold standard for detecting MG and resistance identification, were used for sample analysis. Statistical analysis were performed to compare macrolide-resistant and sensitive MG: age differences were assessed with Student's t-test, categorical variables with chi-square test ($p<0.05$).
Results: Among 78 MG-positive individuals, 32 were tested for macrolide resistance, and 22 of them (69%) were found harboring resistant strains (Table 1). The median age was 35 years (IQR 28–42) in resistant cases and 38 years (IQR 32–52) in non-resistant. Most were men (90.6%), primarily MSM (84.4%), followed by WSM (9.4%) and MSW (6.3%). PrEP users accounted for 46.9% of cases, STI clinic outpatients 34.4%, and PLWH 18.8%. Regarding sexual behavior, 20.7% of MG-positive subjects reported more than 10 sexual partners in the past three months, while 48.6% engaged in more than 10 condomless intercourses, all linked to macrolide-resistant MG. Macrolide-resistant MG was more frequently detected in rectal swabs (59.4%) and urine (31.2%) compared to cervical swabs (9.4%), although this was a non-significant trend ($p=0.09$). Among symptomatic individuals (19.4%), 83.3% had resistant MG, with a trend linking urinary symptoms and macrolide resistance (3 out of 4 samples, Table 2).
Conclusions: Our findings confirm a high prevalence of macrolide-resistant MG, particularly among MSM and PrEP users. No statistically significant demographic or behavioral differences emerged between resistant and non-resistant cases, likely due to the limited sample size of our cohort. However, our data highlight a concerning trend associating high-risk sexual behavior with resistance: individuals with multiple partners and frequent condomless sex appear to be more likely to harbor resistant strains. Strengthening STI prevention strategies, including increased testing and targeted antimicrobial stewardship programs, could help to mitigate further resistance spread.

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Challenges in prevention

SC 41 ONE-YEAR EXPERIENCE IN HIV NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (NPEP) MANAGEMENT AT JENNER 44 STI CLINIC - LUIGI SACCO HOSPITAL, MILAN, ITALY: FOCUS ON ADHERENCE

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Background: The use of HIV non-occupational post-exposure prophylaxis (nPEP) is a secondary prevention measure to reduce infectious risk after a potential sexual exposure to HIV. It should be initiated within 72 hours after exposure. There are few recent data regarding adherence to this treatment, its effectiveness and tolerance. Our study aims to analyse these aspects in the cohort of subjects who received nPEP at our clinic.
Material and Methods: We conducted an observational study of individuals (aged > 18 years) who received HIV nPEP at our clinic from 1 December 2023 to 31 December 2024.
HIV nPEP protocol indicates specific follow-up by infectious diseases specialists with baseline, 6 weeks and 3 months post-treatment initiation laboratory testing: 4th generation HIV Ag-Ab test, serology for HBV, HCV, syphilis and other sexually transmitted infections (STIs) PCR screening according to exposure, kidney and liver function tests and pregnancy tests as recently requested by regional guidelines, published in August 2024.
Results: 147 individuals receiving HIV nPEP were followed and underwent initial baseline assessment. The prescribed regimen was B/FTC/TAF fixed formulation once daily in the 95% of cases.
Among the nPEP cohort, 71,4% completed the 28-day treatment course of therapy while 17,7% were lost to follow up after baseline evaluation and drug dispensing.
Only 49.5% of nPEP users completed follow-up assessment at 3 months, while 50,5% had only 6 weeks follow-up assessment.
Of the participants 96,5% were male, 87,8% Italian, 46,9% heterosexual male and 36,8% MSM*. The median age was 32 years. Baseline characteristics are detailed in table 1.
No cases of HIV, HBV and HCV infections were recorded at baseline or at subsequent assessments, 14 cases required a booster dose of HBV vaccine, and 25 cases started full cycle vaccination. We registered only one case of late latent syphilis. PCR for STIs yielded positive results in 7,6% at baseline and 1,9% at 6-week assessment.
The regimen was well tolerated and 3,8% experienced transient gastrointestinal side effects. The few cases of slight increase of creatinine at baseline (5/65) or ALT (10/73) all reverted at subsequent observations.
Conclusions: Compared to other published studies, our cohort is mainly represented by heterosexual males, probably due to reduced access to HIV pre-exposure prophylaxis programs.
HIV nPEP with B/FTC/TAF in our cohort demonstrated high efficacy and safety, while revealing important adherence problems. The adherence analysis noted: 17,7% of HIV nPEP lost to follow-up after baseline assessment and 50,5% reached only the 6 weeks follow-up; furthermore 7 users returned for a new nPEP within a few months. To increase adherence, we have implemented: counselling, step by step follow-up pathway, detailed written information about nPEP and recall if the scheduled follow-up visit was not attended.
Table 1
Table 2

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Challenges in prevention

SC 42 BURDEN OF ANAL HIGH GRADE DYSPLASIA IS HIGH AMONG AN UNDER-SCREENED POPULATION SUCH AS WOMEN LIVING WITH HIV

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Background: Screening for anal cancer (squamous cell carcinoma of the anus, SCCA) prevention is suggested is target high risk populations. Since access to such screening is still limited, men who have sex with men (MSM) are often prioritized given their very high risk of this neoplasm. Following current guidelines, women living with HIV should also undergo screening for SCCA prevention starting at age 45 as well as women NLH based on their history of genital histopathology.

Material and Methods: Here we present retrospective data on a cohort of 52 women (7 LWH and 45 NLH) that underwent screening with anal cytology, anal HPV test for high risk HPV genotypes (HR-HPV) identification and high resolution anoscopy (HRA).

Women LWH were referred for screening by their Infectious Diseases practitioners, while women NLH were directly referred by their Gynecologists following screening for HPV related genital lesions.

High grade lesions were treated with electrocautery.

Continuous variables are reported as median values.

Results: Median age of women LWH was 51±10, while median age of women NLH was 44±11 (p=0.52). All participants LWH showed undetectable HIV RNA, median CD4 count was 742±201 cells/uL.

No differences were observed between the two groups in regard to smoking habit (14.3% vs. 38.4%; p=0.22), BMI (26.1±3 vs. 23.8±2; p=0.73) and HPV vaccination rate (42.8% vs. 31.7%; p=0.56).

The presence of cervical HR-HPV infection was detected in 57.1% of participants LWH and 50% of women NLH (p=0.56). Similarly, prevalence of anal HR-HPV infection was comparable between women LWH and women NLH (85.7% vs. 77.7%; p=0.15), while, on the other hand, anal HPV16 was more frequently observed in women LWH (57.1% vs. 35.7%; p=0.02).

A higher prevalence of HSIL was observed among women LWH in respect to women NLH (87.5% vs. 40%; p=0.02).

Recurrence of treated HSIL was similar between the groups, while onset of metachronous lesions during follow-up was more frequent among women LWH (33.3% vs. 11.1%; p=0.06).

Conclusions: Access to screening for SCCA prevention is limited, thus a strict compliance to guidelines indications should be warranted to maximize prevention in high risk populations besides MSM.

Challenges in prevention

SC 43 IS DOXYPEP BEING OVERUSED? INSIGHTS FROM A PREP CLINIC COHORT

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Background: Doxycycline post-exposure prophylaxis (DoxyPEP) is effective in preventing bacterial sexually transmitted infections (STIs). In 2024, the CDC released prescribing guidelines emphasizing counselling and shared decision-making.
Concerns remain about its potential overuse, antimicrobial resistance, and its long-term microbiome impact. Ensuring appropriate use while minimizing unnecessary uptake is key to its implementation.
Methods: From June 2024, all patients attending our hospital's PrEP clinic received counseling on DoxyPEP. Its use was considered appropriate for patients major risk exposure (> 5 partners), chemsex sessions and group sex in the 72 hours preceding uptake, and patients were provided with a prescription.
We included all MSM patients attending the PrEP clinic who received dedicated counseling and a DoxyPEP prescription and attended at least one follow-up visit between June 2024 and March 2025.
At follow-up, participants reported their DoxyPEP use and number of sexual partners over the prior three months. We assessed post-counseling DoxyPEP uptake and usage trends over time, particularly in relation to recent STI diagnosis and other behavioral factors
Statistical analyses included Chi-squared, T-test, McNemar's test, and paired t-tests.
Results: A total of 240 individuals were included, of whom 55 attended a second follow-up visit. At first follow-up, 90 participants (37.5%) reported DoxyPEP use in the prior three months, with a median of two doses (IQR 1–3) and 20 sexual partners (IQR 10–30). Baseline STI diagnosis, chems usage and partner count were associated with increased DoxyPEP use ($p < 0.05$), however age did not show any statistical correlation with DoxyPEP use.
Among the 55 participants who attended a second follow-up, 23 (41.2%) never used DoxyPEP, 22 (40%) used it consistently, and 10 (18.2%) changed their uptake behavior. No significant differences were observed between visits in DoxyPEP use, partner count, or STI diagnoses.
Despite dedicated counseling, DoxyPEP uptake remained moderate, with only about one-third of participants reporting use at first follow-up. The association between prior STI diagnosis and DoxyPEP use suggests that individuals with a history of STIs may perceive a higher need for prevention. Similarly, the correlation between partner count and DoxyPEP use highlights engagement among those at higher risk. Longitudinal data indicate stability in DoxyPEP usage patterns and minor behavioral changes over time.
Conclusion: DoxyPEP uptake was moderate and primarily driven by individual risk factors, such as prior STI diagnosis chems usev and partner count. Usage patterns remained stable over time, with no evidence of overuse. These findings suggest that counseling supports appropriate DoxyPEP use but strategies may be needed to enhance adherence and long-term engagement in high-risk populations.
Table 1

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Ageing

P 1 AGEING IN HIV FROM A GENDER PERSPECTIVE: RESULTS FROM A SURVEY ASSESSING NEEDS AND PROVISIONS OF CARE

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Background: The process of ageing among people with HIV has become a matter of increasing interest, as it gives rise to a range of specific health requirements that are often not met. Older people with HIV (OPWH) have clinical, psychological and care needs that should be addressed to provide them with the best care possible.
HIV Outcomes Italy is the Italian session of the European initiative established in 2016 with the aim of improving the health-related quality of life (HRQoL) of people living with HIV. It developed a questionnaire, in collaboration with Plus APS and with the support of Fondazione The Bridge, that aimed to outline the state of the art in the management of aging people with HIV and highlight areas where targeted intervention is needed.
Material and Methods: The questionnaire was developed based on a previous year's project in which experts and various stakeholders discussed ageing from a gender perspective. It consisted of three pre-selection questions (living with HIV, age ≥ 55, living in Italy) and 36 other items (some specific to the sex assigned at birth), including single-choice, multiple-choice and open-ended responses. The survey investigated the respondents' biographical data, habits and lifestyles, stigma in healthcare and non-healthcare settings, experiences of receiving care and comorbidities, and unmet needs and facilitators in their care pathways. The survey was validated amongst OPWH, and then conducted by means of a self-completed online questionnaire (CAWI method).
Data analysis focused on basic descriptive statistical measures such as frequencies and percentages.
Results: The survey results are not fully representative due to the limited number of participants (n=135) and the prevalence of responses from Sicily. However, the data provides some interesting insights into access to health services for ageing PWH. In particular, the data reveals that ageing-specific follow-up visits are virtually non-existent: for instance, frailty screening and geriatric counselling were not performed at all for AFABs (0.00%) and only in very low percentages for AMABs (3.90% and 1.30%, respectively). Furthermore, 48% of AFABs report receiving no support for menopause management.
By contrast, cardiology screening is among the most prevalent visits (54.55% of AMABs and 50% of AFABs). For AFABs, mammography (79.31%) and pap smear and vitamin D monitoring (60%) are more common.
Finally, when asked what could facilitate their care pathway, 60.40% of respondents indicated the need for dedicated information and counselling on ageing issues.
Conclusions: Notwithstanding the importance of the provision of effective care for people with HIV in the context of ageing, it is evident that there is a scarcity of dedicated health services with a specific focus on the needs of the ageing population, particularly with a gender perspective.

Ageing

P 2 ATTITUDES TOWARD AGING AND HIV-RELATED STIGMA IN ELDERLY PEOPLE WITH HIV

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Background: Elderly people with HIV (EPWH) face many challenges, not only due to multimorbidity and polypharmacy, but quite often also to isolation and poor social interactions. Therefore, we decide to assess attitude to ageing and perceived stigma in a cohort of EPWH.

Material and Methods: Attitudes to Ageing Questionnaire (AAQ) and the HIV stigma scale were administered to all EPWH who consecutively accessed to our HIV Outpatient's clinic for their routine clinical check in February 2025. AAQ investigates the attitudes toward the process of ageing, by evaluating psychosocial loss (PL), psychological growth (PG), and physical change (PC). A PL higher score indicates a more negative attitude, while a higher score in PG and PC indicate a more positive attitude toward aging. HIV stigma was assessed by using personalized stigma (PS) subscale and the negative self-image subscale (NSI), with higher score indicating higher level of stigma. A multivariable analysis to test factors associated with worst survey outcomes was performed.

Results: We included 20 male Italian EPWH with a median age of 76 years (IQR: 75-79). All had an undetectable HIV RNA and the mean CD4+ count was 556 cell/mm3 (SD: ± 173 cell/mm3).The other main features are depicted in Table 1. In the AAQ questionnaire, PL, PG and PC scores ranged between 8 and 40. In our cohort the mean PL score was 15 (mean±SD, 15±7), the mean PG score was 25 (mean±SD, 25±5), the mean PC score was 25 (mean ±SD, 25±5). In the HIV stigma scale, PS scores range between 18 and 72 and NSI scores range between 13 and 52. In our cohort the mean PS score was 32 (mean±SD, 32±10), the mean NSI score was 21 (mean±SD, 21±6). The complete results are depicted in Table 2. In the statistical analysis we found a positive correlation between age and PS (p 0.033), and a negative correlation between NSI and PG (p 0.008) In addition, we find a higher PG score in EPWH who had ad AIDS's defining events in the past (p 0.022) and a higher score in NSI subscale in EPWH with a mild cognitive impairment (p <0.001).

Conclusions: In conclusion, our study, despite limited by the small sample size, reveals important insights into the interplay between aging, stigma, and self-perception in individuals living with HIV.

The correlation between personal stigma and age, as well as the impact of cognitive health on self-image, underscores the complexity of aging in this population. Interestingly, the positive relationship between past AIDS-defining events and psychological growth, suggest that EPWH may develop a more resilient psychological framework, enhancing their ability to cope with the aging process. Further studies with larger patient population are needed to validate these results.

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Ageing

P 3 THE GLASGOW MANIFESTO IN ITALY: A PLATFORM FOR CHANGE

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Background: Thanks to advancements in HIV treatment, it is estimated that by 2030 >70% of people with HIV will be aged >50, with >25% aged >65. They will face a range of physical, and psychosocial challenges negatively impacting their quality of life and care needs. This will require a radical change in clinical approach and pose substantial challenges for social welfare systems.
The Glasgow Manifesto is a crucial framework for addressing the evolving needs of people ageing with HIV. Developed to guide policies and interventions, it emphasizes core principles, i.e. equitable healthcare access, combating stigma, and adopting multidisciplinary approaches.
Our community-led project examines the implementation of the Glasgow Manifesto in seven European countries: Italy, Portugal, Spain, France, Romania, Turkey, and Georgia.
Here we present a comprehensive analysis of Italian policy documents addressing the needs of older adults with HIV.
Materials and Methods: The analysis examines the broader policy context of the care needs of the elderly and the specific needs of the elderly living with HIV, comparing these policies to the recommendations outlined in the Glasgow Manifesto. The methodology employs content analysis of relevant policy documents using NVivo software. The study follows the systematic review guidelines from the PRISMA statement and applies meta-analytic statistical techniques where appropriate.
Results: Italy has comprehensive policies in place to promote the dignity, autonomy, social inclusion, and active ageing of the elderly. These are cascaded into a wide provision of services. While these services are available to all Italian citizens, they may not be fully accessible to the HIV elderly population. Several factors pose barriers for older adults with HIV:
1. HIV stigma and discrimination within the broader healthcare system makes it challenging for this population to navigate different medical specialties beyond the HIV clinic, as they seek care for other age-related health conditions.
2. Older people with HIV may require support services and continuity of care in residential care homes, where HIV stigma is likely present, and healthcare workers' knowledge of HIV may be limited.
3. People with HIV may experience age-related health conditions at an earlier age yet be unable to access services intended for those over 65.
Conclusions: While Italy's policies aim to support the elderly, the unique needs of older adults with HIV warrant additional considerations to ensure equitable access to these services. There has been progress, as evidenced by the changes in national guidelines, progress largely due to the pioneering work of Italian clinicians and researchers on ageing with HIV. However, there remains room for advocacy placing: Greater emphasis on specific needs of women and transgender people; Earlier screening for common age-related comorbidities; Interventions to address the psychosocial needs and empower people in self-care.

Basic Science - Immunology

P 4 ELEVATED LEVELS OF INTERLEUKIN-15 IN NAÏVE PLWH NORMALIZE EARLIER FOR THOSE TREATED IN THE PRIMARY PHASE OF INFECTION

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Background: The delay between HIV infection and treatment (ART) start is strongly associated with risk of incomplete immune reconstitution and generalized inflammation, which in turn correlates with AIDS and non-AIDS events.
Seldom investigated, levels of interleukin-15 (IL-15), an inflammatory cytokine similar to IL-12 and involved in stem cell-like memory T cell (TSCM) proliferation, have been described to increase in acute HIV infection. We describe and compare pre-ART and post-ART IL-15 levels in primary and chronic HIV infection.
Materials and Methods: Sub-analysis of the GR-2018-12365699 study, which enrolled naïve and ART-experienced PLWH (>18y.o., without concurrent infections and non-pregnant) between 2019 and 2024 in Milan, Italy, aiming at better understanding the role of TSCM in establishing and maintaining the HIV reservoir.
Primary infection was defined through serologic (Fiebig 1-5) and clinical criteria (acute retroviral syndrome, negative HIV test up to 6 months prior); the rest was defined as chronic.
IL-15 levels were assessed through ELISA kits from R&D Systems (MN, USA).
HIV-negative controls were obtained from leftover buffy coats.
Comparisons through Kruskall-Wallis.
Results: A total of 160 samples were analyzed ex vivo: 21 naives with primary infection (AI; pre-ART and 12 months after ART start), 24 naives with chronic infection (CI; pre-ART and 12 months after ART start), 53 HIV RNA-suppressed individuals on ART for at least 24 months (EX), and 17 healthy donors (HD).
IL-15 levels were significantly elevated in untreated HIV infection compared to healthy donors (HD) in both AI and CI groups, with median values of 3.5 pg/mL and 3.3 pg/mL, respectively, versus a median of 2.5 pg/mL in HD (Panel A).
On the other hand, no significant difference was detected between pre-ART levels of IL-15 between AI and CI.
After 12 months of ART, the difference between AI (median 2.9 pg/mL) and HD was no longer detected, whereas IL -15 levels of CI, despite having decreased (panel B), remained significantly higher (median 3.0 pg/mL) than those of HD (panel C).
For CI, there was a correlation for pre-ART levels of IL-15 and levels at 12 months of ART, p=.0009 (panel D).
Cumulatively, IL-15 levels at 12 months remained higher than both those of HD and of EX (treated for at least 2 years, median 2.4 pg/mL). The latter, in turn, did not have significantly different levels than HD (panel E).
Conclusions: Levels of IL-15 were elevated in untreated individuals in different stages of infection, and remained high at 12 months in those who were treated in the chronic phase, whereas PLWH treated in the primary phase seemed to have a faster decay towards normalization at 12 months. Permanently HIV RNA suppressed PLWH (> 24 months) had levels comparable to HD, irrespective of treatment start. These observations support early diagnosis and early treatment to thwart inflammation and its consequences. T CD4 sorting and HIV DNA determination of samples are underway.

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Basic Science - Immunology

P 5 EVALUATION OF T CELL-MEDIATED IMMUNE RESPONSE AFTER DENGUE INFECTION: A COMPARISON BETWEEN PEOPLE LIVING WITH HIV AND HIV-NEGATIVE INDIVIDUALS

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Background: Dengue is the most widespread arboviral infection, with approximately half of the world's population at risk. In 2023, an autochthonous dengue outbreak occurred in Rome, highlighting the increasing relevance of this infection in non-endemic areas. People living with HIV (PLWH) are at an increased risk of developing severe dengue, particularly in cases of secondary infection. The aim of this study was to evaluate and compare the T cell-mediated immune response following dengue infection in PLWH and HIV-negative individuals.
Methods: In this cross-sectional study, we enrolled PLWH and HIV-negative individuals with a history of dengue infection, identified through DENV RT-PCR or NS1 antigen assays in a hospital setting. Interferon-gamma (IFN-γ) enzyme-linked immunospot assay (ELISPOT) was used to analyze T cell response, using peptide pools representing three structural proteins (prM/E/C) and non-structural proteins (NS3 and NS2A/B, NS4A/B, NS5).
Results: We enrolled 9 PLWH and 10 HIV-negative indiduals. All but one HIV-negative subjects showed a positive T-cell response to at least one stimulating peptide pool. Overall, HIV-negative individuals exhibited stronger ELISPOT responses than PLWH across all antigens, though without statistical significance, likely due to sample size limitations. The NS3 antigen showed the most pronounced difference (Mean: 23.5 in HIV-negative vs 2.0 in PLWH, p=0.223); prM/E/C responses were also higher in the HIV-negative group (14.3 in HIV-negative vs. 5.8 in PLWH, p = 0.327), while NS4/AB (5.4 in HIV-negative vs 2.5 in PLWH, p=0.451) and NS2/A/B (3.0 in HIV-negative vs 2.0 in PLWH, p =0.578) responses were only slightly elevated in the HIV-negative group. NS5 elicited the weakest response in both groups (0.5 in HIV-negative vs 0.0 in PLWH, p = 0.408).
Conclusion: The HIV-negative group demonstrated overall stronger responses, particularly to NS3 and prM/E/C, suggesting greater immunogenicity of these antigens. In contrast, PLWH exhibited lower and more variable responses, with some activation against NS4/AB but generally weaker reactivity across all antigens. The non-uniform antigen recognition pattern suggests potential differences in immune history, genetic background, or prior exposure between groups, influencing T-cell activation levels. Overall, our findings suggest that prior dengue exposure does not guarantee uniform T-cell reactivity, and HIV status may modulate the strength and pattern of antigen-specific immunity.

Basic Science - Immunology

P 6 IMMUNOMODULATORY EFFECTS OF HIV TAT'S N-TERMINAL SEQUENCE ON CD8+ T CELLS

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Background: The HIV Tat protein plays a crucial role in viral replication and spread, and it also contributes to the hyperactivation of lymphocytes in People Living With HIV (PLWH). Several studies have demonstrated that Tat influences the immune system by promoting the activation, proliferation, and functionality of cytotoxic T lymphocytes. Currently, Tat is being utilized in both preventive and therapeutic vaccines, showing promising results in primates and in clinical trials of phases I and II. Additionally, antibodies directed against the N-terminal region of Tat have been shown to protect monkeys from HIV infection.
In this study, we investigated the immunomodulatory activity of the N-terminal domain of Tat, specifically the amino acid region 1-40, as this region is targeted by most anti-Tat antibodies developed during natural infection.
Material and Methods: We analyzed peripheral blood samples collected from healthy donors across age groups ranging from 20 to 67 years. We examined the ability of Tat and its derivative peptides encompassing the amino acid sequence 1-40 to enhance clonal expansion and T-bet production, a key regulator of T cell functionality and development, in an in vitro priming process of CD8+ T lymphocytes directed toward an unrelated MHC-I presented epitope.
Results: The Tat protein displayed the ability to modulate heterologous responses generated from epitope-specific naïve CD8+ T cells. We observed that the amino acid region 1-40 of Tat exerts an immunomodulatory effect by enhancing priming capacity comparably to the full-length Tat protein. Indeed, the peptide aa 1-40 induced a statistically significant increase in T-bet production compared to the untreated control, indicating an immunomodulatory effect capable of hyperactivating CD8+ T lymphocytes. We further analyzed the sequence aa 1 -40 by examining two peptides composed of the sub-sequences aa 1-20 and 18-40. Only the sequence aa 1-20 induced a statistically significant increase in clonal expansion and T-bet production compared to the untreated control.
Conclusions: Our results highlight the immunomodulatory activity of the N-terminal region of the Tat protein, particularly the sequence aa 1-20, which enhances immunological priming process with higher specific T cell expansion and increased activation, measured by T-bet production.
We hypothesize that anti-Tat antibodies targeting this N-terminal portion may mitigate the immunomodulatory effects of Tat in PLWH. This could provide new insights for developing therapeutic approaches aimed at reducing immune activation typical of PLWH. At the same time, the Tat1-20 sequence itself could constitute a promising immunomodulatory tool.

Basic Science - Immunology

P 7 THE OPPOSITE TREND OF NEUROTROPHINS NGF AND BDNF DURING HIV PATHOGENESIS

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Background: Although cART suppresses HIV replication, many PLWH still experience chronic inflammation and immune activation, which can affect multiple anatomical districts, including the nervous system. Some individuals may exhibit HIV-associated neurocognitive disorders, due to both direct neurotoxic effects of the virus and to chronic immune activation status. The neurotrophins are involved in various neuroprotective or neuroinflammatory processes and their serum levels may fluctuate in PLWH. Nerve growth factor (NGF) is involved in the immune response and blood levels are increased in autoimmune diseases and chronic inflammatory conditions, while high blood brain-derived neurotrophic factor (BDNF) levels indicate better brain plasticity and mental health. Given this, understanding the relationship between NGF, BDNF and blood CD4+ T cells count could be useful as an indicator of neurological health according to immune status. Thus, the study aims to evaluate serum NGF and BDNF levels in cART-naïve and cART-treated PLWH and to assess their changes based on different blood CD4+ T cell levels.
Material and Methods: 38 serum samples were collected from cART-naïve (n = 9), cART-treated (n = 9) PLWH and HIV-negative healthy volunteers (n = 20), all male and age-matched. NGF and BDNF were detected in patient serum using enzyme-linked immunosorbent assay (ELISA). Statistical analysis was performed using GraphPad Prism and $p < 0.05$ was considered statistically significant.
Results: Increased serum NGF levels were observed in cART-naïve compared to cART-treated PLWH ($p = 0.0174$) and healthy volunteers ($p = 0.0029$), while no difference was found between these latter two groups of individuals (Figure 1). By contrast, serum BDNF levels were reduced in cART-naïve compared to cART-treated PLWH ($p = 0.0019$) and healthy volunteers ($p < 0.0001$), while no difference was found between treated PLWH and HIV-negative controls (Figure 2). Moreover, a negative correlation was found between NGF and BDNF serum levels ($r = -0.5487$; $p = 0.0005$), while blood CD4+ T cells count had a negative and positive correlation with NGF ($r = -0.3499$; $p = 0.0365$) and BDNF ($r = 0.6853$; $p < 0.0001$) serum levels, respectively.
Conclusions: The reduced NGF and increased BDNF serum levels in cART-treated compared to cART-naive PLWH and their similarity to the levels measured in HIV-negative healthy volunteers could suggest a reduced neuroinflammation. In addition, the negative correlation of serum NGF levels with both blood CD4+ T cell count and serum BDNF levels could indicate that recovery of immune and neurological health occurs in parallel after effective cART. Further studies and a larger study population are needed to better define these findings. Monitoring neurotrophins in the context of HIV treatment could provide valuable insights into the management of HIV-associated neurocognitive disorders and long-term immune recovery.

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Clinical HIV

P 8 ANAL CANCER SCREENING IN ITALY: A PILOT SURVEY

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Background: Recently, guidelines for anal cancer (AC) screening have been issued by the International Anal Neoplasia Society (IANS), NIH/CDC and European AIDS Clinical Society (EACS). AC screening strategies include anal cytology and HPV testing, either in single- or combination-test modalities. We thus conducted a pilot survey on the use of anal cytology to gain insight into AC screening in Italy, since anal cytology represents the screening tool in the Italian guidelines for the management of people living with HIV (LWH).

Materials and Methods: The questionnaire focused on screened populations; departments collecting the anal samples; use of conventional vs. liquid-based cytology; device used for anal sampling; professionals evaluating cytology and reporting system; use of anal cytology alone, in co-testing or triage modality; diagnostic procedure for screen-positive individuals; departments that perform the diagnostic procedure. The questionnaire was posted on the website of the Italian Society of Cytology (SICi) and was also sent in the monthly newsletter to the SICi members. Data were collected from October 2024 to February 2025.

Results: Eighteen centers participated: 9 (50.0%) from Northern, 7 (38.9%) from Center and 2 (11.1%) from Southern Italy. In 15 centers (83.3%), anal cytology is performed on more than one target population among those included in IANS Risk Category A or B: MSM/TW LWH in 13 centers (72.2%), women with a history of genital HSIL or cancer in 10 centers (55.6%), women LWH in 9 centers (50.0%), MSW LWH and MSM/TW not LWH in 8 centers each (44.4%). In the majority of the centers, samples come from infectious disease (9, 50.0%) and STI units (7, 38.9%). Between 5 and 700 anal samples are collected each year (median: 140; IQR 30-500). Conventional cytology is used in 11 centers (61.1%). Cytology is most frequently interpreted by histopathologists (12, 66.7%) followed by biologists (10, 55.6%). All centers use the Bethesda System for reporting anal cytology. Ten centers (55.6%) use cytology in co-testing with high-risk HPV or HPV genotyping. Only one center uses p16 staining in case of abnormal cytology. In five centers (27.8%), abnormal cytology cases are triaged with high-risk HPV, HPV genotyping or HPV mRNA. Three centers use cytology alone (16.7%), and only in one (5.6%) high-risk HPV testing is used as the primary test and cytology as the triage test. Most centers (12, 66.7%) perform high-resolution anoscopy (HRA), while the others perform standard anoscopy. The diagnostic procedure is performed in general surgery (8, 44.6%), gastroenterology (3, 16.7%), proctology (3, 16.7%), infectious disease unit (3, 16.7%), gynecology (2, 11.1%) or internal medicine (1, 5.6%).

Conclusions: In most of the centers that participated in this pilot survey, anal cytology is employed in PLWH, but scenarios of its use are extremely variable. The use of HRA is sub-optimal, most likely due to the lack of experts in this procedure.

Clinical HIV

P 9 ANAL CANCER SCREENING UPTAKE IN A COHORT OF WOMEN WITH HIV

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Background: According to the latest guidelines, anal cancer (AC) screening (ACS) is recommended in over 40's women with HIV (WWH) [1]. However, data about women's acceptability are scarce.
Methods: We performed a survey in all adult WWH in care at Padua University Hospital HIV outpatient's clinic to assess acceptability of ACS, after excluding women with a previous AC diagnosis. We recorded demographic and clinical information, adherence to ACS and reasons for refusal. Multivariate analysis to test for factors associated with rejection was performed.
Results: ACS was offered to 331 WWH (features in Table 1), mostly Caucasian (61.9%), with median age was 53 (IQR: 44-60) years. 95.2% of them had an undetectable HIV RNA, and median CD4+ T cell count of 574 (IQR: 431 -758) cell/mmc. Out of 331, 150 (45.3%) refused to receive ACS. There were no significant differences in terms of age, migrant status, level of education, HIV treatment and its outcomes (viral load, CD4+ T cell count) between women who accepted and those who refused ACS, but women who accepted were more likely to have multimorbidity (p=0.0235), a history of HPV-related diseases (p=0.0002), and to be vaccinated against HPV (p=0.0001). Main reasons for refusal were: "I do not want" in 28% cases, "I do not have anal sex" in 25% cases, and "I do not think to be at risk" in 16% cases. Interestingly, 12.7% and 2% women declared to refuse screening because of not having sex since HIV diagnosis and because of partner denial, respectively. Multivariable analysis showed years living with HIV (p=0.03) and multimorbidity (p=0.02) were significantly associated with ACS refusal.
Conclusions: Despite the increasing prevalence of AC in WWH, their availability to receive ACS is still poor, mainly due to the misperception of not being at risk. Urgent prevention and targeted campaigns are needed in this population, to increase awareness and screening uptake.
References
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Clinical HIV

P 10 BEMPEDOIC ACID AND EVOLOCUMAB IN PEOPLE LIVING WITH HIV: A REAL-WORLD STRATEGY FOR ACHIEVING LDL TARGETS IN STATIN-INTOLERANT OR RELUCTANT PATIENTS

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Background: People living with HIV (PLH) have up to twice the risk of cardiovascular disease (CVD) compared to the general population. Statins are the cornerstone of cardiovascular prevention due to their anti-inflammatory and lipid-lowering effects, with pitavastatin shown to reduce major adverse cardiovascular events (MACE) in PLH. However, in individuals who are statin-intolerant, have insufficient LDL reduction on the maximum tolerated statin dose, or are reluctant to use statins, alternative lipid-lowering therapies are needed. Bempedoic acid (alone or in combination with ezetimibe) and evolocumab have emerged as effective options, but data on their use in PLH remain limited. This study aimed to assess the real-world experience of bempedoic acid and evolocumab prescriptions at the Modena HIV Metabolic Clinic (MHMC).

Methods: We conducted a retrospective analysis including all PLH who initiated bempedoic acid and/or evolocumab at MHMC from January 2024 onward.

Demographic, clinical, and virological data were extracted from electronic medical records. Cardiovascular risk was assessed using ESC SCORE2 and classified as moderate, high, or very high according to ESC guidelines. LDL cholesterol targets were defined based on ESC risk classification.

Frailty was defined as Frailty index±0.30; Multimorbidity was defined as presence of ≥3 comorbidities among MACE, hypertension, diabetes, metabolic-associated fatty liver disease (MAFLD), cirrhosis, kidney failure, osteoporosis and cancer.

Participants were stratified by lipid-lowering therapy: bempedoic acid (alone or with ezetimibe) and evolocumab.

Results: A total of 56 PLH were included: 46 (82%) initiated bempedoic acid (alone or with ezetimibe), 10 (18%) received evolocumab. Thirtyseven (66%) were males, with a median age of 61.5 years (IQR 59–65.5). All participants were of Italian origin. Baseline characteristics are detailed in Table 1.

The majority (77%) were treated for primary prevention, particularly with bempedoic acid (p=0.027). According to SCORE2, the distribution of cardiovascular risk was: 16% moderate risk, 53.6% high risk, 30% very high risk. A total of 48 (85%) subjects did not reach ESC-recommended LDL cholesterol targets at baseline with “standard” therapy with statins (plus possible therapy with ezetimibe).

A third of the cohort had multimorbidity, and a fifth presented Frailty assessed with Frailty index, reinforcing the need for tailored lipid-lowering strategies.

Conclusions: Our preliminary data indicate that bempedoic acid (alone or with ezetimibe) and evolocumab are well-tolerated in PLH with moderate to very high cardiovascular risk. In particular, they could be useful in subjects unable or unwilling to use statins, or in the high proportion of subjects who did not reach LDL target with standard statins therapy.

Further studies with larger cohorts and longer follow-up are warranted to confirm these findings and refine the cardiovascular risk management strategies for PLH.

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Clinical HIV

P 11 BEYOND VIRAL SUPPRESSION: NAVIGATING THE POLYPHARMACY MAZE IN ELDERLY PEOPLE WITH HIV ON ANTIRETROVIRAL THERAPY

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Background: With advancements in antiretroviral therapy (ART), the life expectancy of people with HIV (PWH) has significantly increased, leading to a growing elderly HIV-positive population. This demographic shift introduces new clinical challenges, particularly related to polypharmacy, drug-drug interactions (DDI), and age-related pharmacokinetic and pharmacodynamic alterations. The study assesses the impact of ART optimization in elderly HIV patients (≥65 years), focusing on virological suppression, metabolic complications, and comorbidity burden.
Materials and Methods: A retrospective observational analysis was conducted on elderly PWH receiving bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF). Data from clinical records, including demographics, comorbidities, previous ART regimens, and laboratory outcomes, were extracted. Statistical analysis focused on comorbidities, pill burden reduction, and virological and metabolic parameters over 24 months. Key subgroups included patients with high cardiovascular risk (ASCVD Score >7.5%), renal impairment (eGFR <50 mL/min), and metabolic syndrome.
Results: Among elderly PWH (75 patients), the most prevalent comorbidities included:
• Hypertension (60%)
• Dyslipidemia (29%)
• Type II diabetes mellitus (17%)
• Ischemic heart disease (21%)
• Osteoporosis (11%)
• Central nervous system disorders (6%)
• Chronic obstructive pulmonary disease (COPD) (2%)
• Malignancies (5%)
• Cirrhosis (2%)
A significant proportion (40%) required polypharmacy (>5 daily medications), increasing the risk of DDIs. Previous ART regimens varied widely, including:
• Protease inhibitor-based regimens (DRV/r + ABC/3TC, ATV/r + TDF/FTC) (45%)
• Integrase inhibitor-based regimens (DTG/ABC/3TC, RAL + DRV/r) (35%)
• Other combinations with NNRTIs or multiple switches due to adverse events (20%)
Switching to BIC/FTC/TAF resulted in:
• Sustained virological suppression (HIV-1 RNA <50 copies/mL in 94% at W96)
• Reduction in pill burden from 13 to 3 tablets/day, enhancing adherence and quality of life
• Improved compliance, as the simplified regimen reduced daily medication complexity, minimizing missed doses and treatment fatigue
Conclusions: Elderly PWH require a tailored therapeutic approach prioritizing virological suppression while minimizing polypharmacy risks. BIC/FTC/TAF represents a well-tolerated and effective strategy, ensuring stability across renal, cardiovascular, and metabolic parameters. Routine geriatric assessments, including frailty evaluation and drug interaction screening, should be integrated into HIV care models to optimize long-term outcomes. Further longitudinal studies are needed to explore the impact of ART optimization on aging-related syndromes in this population.
Table 1
Table 2

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Clinical HIV

P 12 CARDIOVASCULAR MANAGEMENT IN PLWH: POOR ADHERENCE TO BLOOD PRESSURE AND LDL-C TARGETS

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Background: People living with HIV (PLWH) have an increased incidence of cardiovascular disease (CVD). Controlling modifiable risk factors is a critical element in achieving CVD risk reduction. The aim of this study was to assess blood pressure values and LDL-c target achievement in a cohort of PLWH, according to individual CVD risk, using the EACS guidelines.

Materials and Methods: We conducted a single-center, retrospective, observational study. We enrolled PLWH outpatients on cART for at least 12 months, followed at the Infectious Diseases Clinic of the Ss. Annunziata Hospital in Chieti. Clinical-demographic and laboratory data were collected. According to the EACS guidelines, cardiovascular risk for fatal events over 5/10 years was estimated for each patient by integrating risk factors, using the Framingham risk score, DAD risk score, For each cardiovascular risk category, we assessed whether the systemic blood pressure and LDL-c targets were achieved.

Results: A total of 258 PLWH were enrolled, including 203 men (78.7%) and 55 women (21.3%). Of the population, 56.9% (147/258) had hypertension, and 53.0% (78/147) were on antihypertensive drugs. The mean age was 52.6 years (± 11.2 years), with a BMI of 26.6 (± 4.7 kg/m²). Additionally, 3.5% (9/258) of the population had a previous major cardiovascular event. According to the EACS guidelines, 27.1% (70/258) had low CVD risk, 45.7% (118/258) had moderate risk, 21.3% (55/258) had high risk, and 5.8% (15/258) had very high risk.

The blood pressure target was met in only 41.9% (108/258) of PLWH. Among hypertensive patients, 96% (141/147) did not reach the target, and only 51% (72/141) were on antihypertensive therapy. The LDL-c target was not achieved in 81% (209/258) of the population, and only 27.27% (57/209) were on lipid-lowering therapy. Achieving both blood pressure and LDL-c targets was significantly negatively correlated with adherence to antihypertensive therapy and dyslipidemia treatment ($p < 0.01$).

Conclusion: A remarkably low percentage of PLWH achieve the established therapeutic targets for controlling blood pressure and LDL-c levels. The low awareness of cardiovascular risk in PLWH is evident from the fact that fewer hypertensive patients are receiving treatment than needed. This suggests multiple issues, including poor behavioral implementation, limited perception of treatment needs by healthcare providers, and suboptimal adherence to prescribed therapies. These findings underscore the need for intensified management of hypertension and dyslipidemia in PLWH. Enhanced attention to treatment initiation and ongoing therapy is critical to achieving optimal targets and improving cardiovascular outcomes in this population.

Clinical HIV

P 13 CAROTID AND FEMORAL INTIMA MEDIA THICKNESS (C-IMT AND F-IMT): RISK STRATIFICATION FOR CARDIOVASCULAR EVENTS IN PLWH

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In people living with HIV infection (PLWH), the risk of developing cardiovascular comorbidity is significantly higher than in uninfected population, despite the virosoppression of HIV. The chronic inflammation and immune activation associated to HIV disease, may promote the mechanisms that lead to atherosclerotic plaque formation, thus increasing the risk of CVD in these individuals. Whether the prevalence of subclinical atherosclerosis is even higher in PLWH is unclear. The aim of the study is to improve the risk stratification for cardiovascular events in people living with HIV, through the simultaneous evaluation of carotid and femoral IMT. Fifty-five HIV-positive patients, permanently virosoppressed with effective STR regimens, were scanned for IMT measurement, by vascular ultrasound of four vascular beds (right-left carotid artery and right-left femoral artery). For the study of the common femoral axis we analyzed the last portion of the vessel upstream of the bifurcation. All sonographic measurements were performed using a high resolution B-mode US with a 12-MHz linear transducer, by a single experienced investigator. All patients were assessed for both carotid and femoral intima media thickness (c-IMT and f-IMT) and for the presence of atherosclerotic plaques; and underwent blood tests at the time of instrumental evaluation. The IMT was defined as the distance between the media-adventitia interface and the lumen-intima interface. The presence of plaque was defined as a focal protrusion into the lumen >0.5 mm or IMT >1.5 mm. Patients were evaluated for cardiovascular risk factors, indices of cardiometabolic and vascular function (blood pressure, BMI). Demographics, HIV characteristics, cardiovascular risk factors and estimations are summarized in Table 1 -2. For statistical analysis we used the test t-student and Chi square test. Doppler analysis showed atheromatous plaques were more prevalent in the carotid axis than in the femoral axis (c-Plaque= 34.45% - 36/55 vs f-Plaque=12.72% - 7/55; p=0.0136). Regarding lipid profile, patients with c-plaque show significantly higher levels of total cholesterol (p=0,03), LDL-cholesterol (p=0,024) and % cholesterol >200 mg/dl (p=0,046) than those without plaque. Significantly higher total serum cholesterol values was also observed in f-plaque patients versus those without plaques (p=0,045). Concerning the relationship, plaque – cardiovascular risk estimator, the high risk of CV events with the use European score equation, is statistically significant in patients with c- plaque (p=0,008). No significant correlation was found between plaque and the Framingham risk score for risk prediction A statistically significant relationship was low CV risk in ASCVD and the absence of both carotid and femoral plaque (p=0,06 and p=0,046). The analysis of our data confirms that the control of cardiometabolic risk factors and the use of CV risk estimators prevent the clinical manifestations of CV comorbidity.

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Clinical HIV

P 14 CHALLENGING RETENTION IN CARE IN HIV-VERTICALLY ACQUIRED PEOPLE: A REAL LIFE EXPERIENCE

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The transition of people living with HIV (PLHIV) from pediatric to adult care centers presents a complex and multifaceted challenge, involving not only medical, but also psychological and social factors that needs a customized approach.
We focus on the transition of 14 young vertically-acquired PLHIV occurred in the last 12 months from Bambino Gesù Children's Hospital to A. Gemelli University Polyclinic Foundation.
All young people had a history of at least 20 years of antiretroviral therapy (ARV) and multiple ARV regimens.
At the first visit on the adult center one patient (7,1%) had a detectable HIV-viral load for reported poor adherence to antiretroviral treatment; CD4 count was < 100 cell/mm^3 in 1 patient (7,1%), between 100 and 300 in 2 patients (14,3%) and > 300 cell/mm^3 (median 659 cell/mm^3) in 11 patients (78,6%).
At the second check 12 patients (85,7%) were HIV undetectable, 2 patients (14,3%) were HIV detectable for poor adherence to ARV; CD4 count was similar to the first visit.
To overcome poor adherence, based on historical and available HIV genotypes, two patients started intramuscular long-acting therapy with cabotegravir and rilpivirine. They were cared for at home by dedicated medical and nursing staff, becoming HIV undetectable at the subsequent follow-up.
Young patients transitioning from pediatric to adult care may face difficulties in adapting to a more autonomous role in managing their health, navigating different healthcare systems, and dealing with the stigma often associated with HIV.
Healthcare providers must address the need for age-appropriate counseling, support in managing long-term health consequences, and fostering a positive therapeutic relationship to ensure continued engagement with care.

Clinical HIV

P 15 CHANGES IN BONE MINERAL DENSITY AND BONE TURNOVER MARKERS IN ANTIRETROVIRAL THERAPY-NAÏVE PEOPLE WITH HIV STARTING BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE OR DORAVIRINE/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE

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Background: Antiretroviral therapy (ART) including tenofovir disoproxil fumarate (TDF) has been associated with an increased risk of bone loss in people with HIV (PWH) compared to tenofovir alafenamide (TAF). However there is no a direct comparison about changes in bone mineral density (BMD) between naive PWH starting bictegravir/emtricitabine/TAF (BIC/F/TAF) or doravirine/lamivudine/TDF (DOR/3TC/TDF).
Methods: We performed a retrospective, observational, cohort study on adult PWH in our Division of Infectious Diseases who started as initial antiretroviral therapy (ART) the single tablet regimen BIC/F/TAF or DOR/3TC/TDF between January 2020 and December 2022. The inclusion criteria were as follows: individuals naïve to ART; age >40 years; individuals who had a dual-energy X-ray absorptiometry (DXA) scan before ART initiation and had at least one follow-up DXA scan 12 months or more after ART initiation. BMD changes and variations in bone turnover markers [bone alkaline phosphatase (ALP) and beta-crosslaps (cLP)] were evaluated in participants who had follow-up DXA scans after >12 months of ART.
Results: As a whole, 65 patients (59 males, mean age 48.5 years) were enrolled: 35 starting BIC/F/TAF and 30 DOR/3TC/TDF. Baseline characteristics were comparable between groups: median HIV RNA was 4.35 log10, median CD4 T lymphocyte count was 379 cells/mm3, and 6 patients (9.2%) had AIDS diagnosis. At baseline, 11 subjects (17%) were diagnosed with low BMD (T-score <-1.0 or Z-score <-2.0), without significant differences between groups. After a median follow-up of 14.4 months, decrease in median absolute BMD and changes in bone turnover markers were comparable between groups. The median reduction (IQR) in BMD at femur neck was -0.04 (-0.07, 0.00) g/cm2 in BIC/F/TAF group and -0.05 (-0.08, -0-01) g/cm2 in DOR/3TC/TDF group (p=0.198). The median change (IQR) in BMD at lumbar spine was -0.06 (-0.09, -0.01) g/cm2 in BIC/F/TAF group and -0.07 (-1.0, -0 -02) g/cm2 in DOR/3TC/TDF group (p=0.276). The median changes (IQR) in bone turnover markers were: +7.2 (+4.9, +9.3) ng/mL in BIC/F/TAF group and +8.1 (+4.2, +10.7) ng/mL in DOR/3TC/TDF group for ALP (p=0.403), and +115 (+82, +153) ng/L in BIC/F/TAF group and +106 (+77, +141) ng/L in DOR/3TC/TDF group for cLP (p=0.552). After the median follow-up, virological efficacy was comparable: HIV RNA <50 copies/mL was obtained in 32 patients (91.4%) in BIC/F/TAF group and in 27 (90%) in the DOR/3TC/TDF group. The median increase in CD4 T lymphocyte count was comparable between groups (+156 and + 132 cells/mm3, respectively), such as incidence of adverse events (<10% in each group). However, weight gain was significantly greater in the BIC/F/TAF group (weight change: +1.86 Kg vs +0.81 Kg; p=0.008).
Conclusions: In our study, initial antiretroviral regimen with BIC/F/TAF or DOR/3TC/TDF caused comparable reduction in BMD and similar changes in bone turnover markers after a median follow-up of 14 months.

Clinical HIV

P 16 CHANGES IN GLUCOSE HOMEOSTASIS IN PEOPLE LIVING WITH HIV NAÏVE TO ANTIRETROVIRAL THERAPY AND STARTING DOLUTEGRAVIR/LAMIVUDINE OR BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE

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Objectives: Large population cohort studies have yielded conflicting results about the risk of diabetes among integrase inhibitors users. An observational, prospective, cohort study was performed to assess changes in glucose homeostasis in people living with HIV (PWH) naïve to antiretroviral therapy and initiating dolutegravir/lamivudine (DOL/3TC) or bictegravir/emtricitabine/tenofovir alafenamide (BIC/F/TAF).

Methods. All non-diabetic PWH, naïve to antiretroviral therapy, and initiating DOL/3TC or BIC/F/TAF in our outpatients HIV clinic between January and December 2023 were enrolled into the study. Serum levels of glucose and insulin, and homeostasis model assessment of insulin resistance (HOMA-IR) index were evaluated every 6 months during a 12-month follow-up.

Results: Overall, 78 patients were enrolled: 38 treated with DOL/3TC (group A) and 40 with BIC/F/TAF (group B). The mean age was 48.5 years, 69 (88%) were males, and 71 (91%) were Caucasian. Mean concentrations (+SD) of glucose and insulin were 83.2 (+19.2) mg/dL and 10.8 (+7.6) mcrUI/mL; mean HOMA-IR index (+SD) was 2.11 (+0.88); mean body mass index (BMI) was 24.4 (+2.2) Kg/m2. Insulin resistance (HOMA-IR index >2.5) was present in 5 subjects (6.4%), and baseline characteristics were comparable between groups. Changes in mean values of glucose, insulin, and HOMA-IR index from baseline to month 12 were not significant in each group: +4.2 (+2.4) mg/dL, +1.48 (+1.12) mcrUi/L, and +0.32 (+0.14) in group A; +4.8 (+2.7) mg/dL, +1.51 (+1.33) mcrUi/L, and +0.35 (+0.15) in group B, respectively. Moreover, changes in glucose and insulin from baseline to month 12 were not significant in each group. After 12 months, insulin resistance was present in 4 subjects (10.5%) in group A and in 5 (12.5%) in group B (p=0.712). Mean increases (+SD) in body weight and BMI were also comparable: +2.03 (+1.51) Kg and +0.28 (+0.13) Kg/m2 in group A and +2.21 (+1.69) Kg and +0.32 (+0.17) Kg/m2 in group B, respectively. An increase >5% in body weight after 12 months was reported in 6 (15.8%) subjects in group A and 9 (22.5%) in group B (p=0.209). Only in these 15 persons with a >5% increase in body weight, a statistically significant increase in insulin and HOMA-IR index was reported at month 12: +6.13 (+4.02) mcrUi/L, and +1.24 (+0.87), respectively (p<0.001), and 14 out of 15 (93.3%) subjects developed insulin resistance. At the end of follow-up, 35 (92.1%) patients in group A and 37 (92.5%) in group B had HIV RNA <50 copies/mL, and mean change in CD4+ cell count was comparable between groups (+125 and +141 cells/mm3, respectively; p=0.309).

Conclusion: In antiretroviral therapy-naïve PWH starting DOL/3TC or BIC/F/TAF, no significant changes in mean values of glucose, insulin and HOMA-IR index were reported after 12 months. However, subjects with a significant increase in body weight (>5%) showed also a significant increase in insulin and HOMA-IR index, leading to the appearance of insulin resistance.

Clinical HIV

P 17 CHANGES IN LIPID PROFILE AND CARDIOVASCULAR RISK AFTER SWITCHING TO LONG-ACTING CABOTEGRAVIR/RILPIVIRINE

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Introduction: Life expectancy of PWH has increased over time, thus leading to an increase in the comorbidity rate. One of most important comorbidities is cardiovascular disease (CVD) since HIV infection has been shown to be a factor that increases CVD risk. To date, the role of antiretroviral therapy (ART) in influencing CVD risk is debated.
For people aged 40-69 years, without a history of diabetes and CVD, a score, called SCORE2, has been validated to determine fatal and non-fatal CVD risk. To date, there are no scores that determine CVD risk specifically in PWH.
Methods: At the AIDS Outpatient Clinic in S.M. Goretti Hospital in Latina, 40 patients are undergoing treatment with cabotegravir/rilpivirine long acting (CAB/RPV LA); 13 (33%) are women; the median follow-up since ART switch is 70 weeks [40-101].
18 (46%) are older than 40 years old(median age 51 years old [43-68]) and have at least 54 weeks CAB/RPV LA follow up; one of these has had an AMI, 5 were already on statin therapy and 2 had started statin therapy in the last year, both 6 months after switch. We observed lipid profile and weight before switch (T0) and after 52 weeks (T52) since CAB/RPV LA switch. Pre-switch treatment were: DTG/3TC(27,8%), RPV/TAF/FTC(25%), BIC/TAF/FTC (22,2%), DTG/RPV(11%), DRV/cobi/TAF/FTC(5,6%), TDF/FTC + RAL(2,8%), TDF/FTC/ABC(2,8%), DRV+RTV+3TC +ETV(2,8%).
Results: There were no significant changes in cholesterol (median T0: 194 mg/dl [113-266], T52:215mg/dl [141-295], p=0.18) HDL-cholesterol (median T0: 54mg/dl [27-91], T52:52 mg/dl [34-84], p=0.76), triglycerides (median T0 :106mg/dl,[40-357], T52:121, 27-376 , p0.41), weight (median T0: 75.5 Kg[47-98], T52: 75 kg [50-103] p=0.19)
If we look exclusively at the subpopulation over 40 years old, in which SCORE2 is applicable, there are no significant changes in lipid profile and in SCORE2, adjusted for age, (T0: 3.8 [1.1-15.3], T52: 5 [1-12.1]).
SCORE2 also did not correlate with CD8+ level or duration of infection (p=0,8 and p=0,9 respectively).
Conclusions: Switching ART to CAB/RPV LA does not alter the lipid profile or CVD risk of patients. It is necessary to increase the caseload in order to also be able to stratify according to the history of antiretroviral therapy.

Clinical HIV

P 18 COMORBIDITIES PREDICT LONGITUDINAL COGNITIVE CHANGES IN PEOPLE WITH HIV

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Background: Cognitive performance in people with HIV (PWH) has been studied, and several factors have been associated with low cognitive performance (LCP), such as older age, low CD4 at nadir, and HCV coinfection. Yet the predictors of longitudinal decline in CP are less characterized. This study aimed to assess the impact of traditional risk factors and seroprevalence of latent infections on the trajectory of CP.

Material and Methods: PWH enrolled in prospective studies (between 2015 and 2023) on CP and with at least two available neurocognitive evaluations were included in this analysis. The battery evaluated six cognitive domains: short- and long-term memory, visuospatial sensory and perception, speed and mental processing, attention and working memory, and executive and motor functions. Raw scores of individual measures were transformed into scaled scores and then into demographically adjusted T-scores using normative data correcting for age, education, sex, and race. A generalized linear mixed model was selected for predicting T-score change over time.

Results: We included 102 participants; they were mostly male (79, 77.5%) and of a median age of 51 years (45-58). Current and nadir CD4 cell count at baseline were 508 (255-696) and 106 (36-256) cells/mm3. HCV seroprevalence was 27.5%, while the most prevalent latent microorganisms were CMV (42.2%), EBV (25.5%), and HSV1/2 (22.5). Patients showed a median of comorbidities of 1 (0-2) and of coinfections of 2 (1-3). Participants had a median of 2 CP evaluations (2-3) with 12 (6-24) months between the first and last test. Global T-score was 0.74 (0.53-0.84) and its change over time was +0.03 (-0.05-0.10); 56 (55.4%) had higher T-scores over time. At bivariate analysis, several baseline factors were associated with T-score change over time: bictegravir use (OR 1.924, p=0.017) with its increase and depression (BDI-II score OR 0.984, p<0.001) and COPD (OR 0.389, p<0.001) with its decrease; HCV infection (OR 0.673, p=0.075) and IVDU status (OR 0.500, p=0.065) did not reach statistical significance. At the Multivariate model the age, HIV RNA, and number of comorbidities were independent predictors of NC change over time.

Discussion: In this longitudinal analysis the majority of study participants had improvement in cognitive function. While concomitant infections did not seem to be predicting the cognitive trajectory age, HIV RNA and comorbidities did: these data suggest to focus on optimal virological control and tailored comorbidities management for cognitive health in PWH.

Clinical HIV

P 19 CORRELATION BETWEEN LIPID PROFILE, SUBCLINICAL ATHEROSCLEROSIS AND HEPATIC FIBROSTEATOSIS IN PLWH: COMPARISON BETWEEN TAF/FTC/BIC AND TDF/3TC/DOR

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In persons living with HIV infection (PLWH), the risk of developing cardiovascular and metabolic comorbidity is significantly higher than in non-infected controls, despite the virosoppression of HIV with the use of effective antiretroviral therapies.

Patients and Methods: Eighty HIV-positive patients, permanently virosoppressed with effective STR regimens, forty treated with TDF/3TC+DOR and forty treated with TAF/FTC+ BIC, were compared by age, sex, duration HAART, to assess the impact of TARV on individual cardiovascular and metabolic risk factors (Table 1). All the patients were evaluated for carotid intima-media thickness (IMT) with sonographic examination of epiaortic vessels (ecoTSA) and for hepatic fibrosteatosis by fibroscan, and were evaluated with blood examinations 12-24 months after antiretroviral treatment. For statistical analysis we used the test t-student and Chi quadro.

Results: Analysis of the ecocolordoppler TSA, only 15% (6/40) of the patients treated with TDF/3TC+DOR, showed arterial wall intima-media thickness (IMT) between 0.9 and 1.3 mm, against 45% (18/40) of the patients treated with TAF/FTC+ BIC (p=0.0073); no difference between the two groups about the presence of carotid plates (IMT 1.3 mm). At laboratory tests, patients treated with TAF/FTC+BIC, showed a better lipid profile, lower serum triglycerides values (p=0.038); no statistically significant in absolute value of blood total cholesterol was detected between the two groups. On the elastometric examination, no statistically significant difference in fibrosis and steatosis was detected between the two groups. From the analysis of our data, the lipid-lowering effect promoted by the use of TDF/3TC +DOR, is not evident for the typology of patients treated proactively (dyslipidemic, cardiac and diabetic at baseline). The cardioprotective effect of the TDF/3TC+DOR regimen is evident in terms of IMT<1.3mm, as a surrogate marker of cardiovascular events.

Conclusions: The analysis of our data, supports as a pro-active approach, through the control of cardiometabolic - bone factors risk and the use of antiretroviral regimens with better safety profile, could be useful in preventing the clinical manifestations of the different comorbidities (myintimal damage, osteopenia-osteoporosis, steatosis). Our goal will be to confirm or disprove the statistical data by extending the study to a much more representative sample of patients.

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Clinical HIV

P 20 DISPARITIES IN CARDIOVASCULAR RISK MANAGEMENT FOR PLWH: A COMPARISON OF ESC AND EACS GUIDELINES

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Background: People living with HIV (PLWH) have a higher incidence of cardiovascular disease (CVD), making the correct management of modifiable risk factors essential for optimal patient care. This study aims to assess the alignment between the European Society of Cardiology (ESC) guidelines and the EACS guidelines in the management of cardiovascular risk in PLWH.

Materials and Methods: We conducted a single-center, retrospective, observational study enrolling PLWH outpatients on cART for at least 12 months, followed at the Infectious Diseases Clinic of the Ss. Annunziata Hospital in Chieti. Clinical-demographic and laboratory data were collected. Cardiovascular risk for fatal events over 5/10 years was estimated for each patient using the Framingham, DAD, SCORE, and SCORE2/SCORE2-OP risk scores, according to both the ESC and EACS guidelines. We compared the management of blood pressure and LDL-c control as defined by these two sets of guidelines.

Results: A total of 258 PLWH were enrolled, including 203 men (78.7%) and 55 women (21.3%). 56.9% (147/258) of the population had hypertension, and 53.0% (78/147) were on antihypertensive drugs. According to the ESC guidelines, 26.4% (68/258) had mild to moderate risk, 49.2% (127/258) had high risk, and 24.4% (63/258) had very high risk. In contrast, according to the EACS ones, 27.1% (70/258) had low risk, 45.7% (118/258) had moderate risk, 21.3% (55/258) had high risk, and 5.8% (15/258) had very high risk.

Regarding blood pressure control, 46.5% (120/258) of the entire population met the target according to the ESC guidelines, compared to 41.9% (108/258) according to the EACS ones. Among those with hypertension, 90.5% (133/147) were not at target according to the ESC guidelines, compared to 96% (141/147) in conformity to the EACS ones. Of those not at target, 48% (64/133) and 51% (72/141) were on antihypertensive therapy, respectively. Thus, 53.5% to 58.1% (138-150/258) of all patients, and 90.5% to 96% (133-141/147) of hypertensive individuals, did not reach their target blood pressure.

For LDL-c control, the target was not met in 88.0% (227/258) according to the ESC guidelines and 81.0% (209/258) according to the EACS ones. Only 26.9% (61/227) and 27.27% (57/209) of these patients were on lipid-lowering therapy, respectively.

Conclusions: This study highlights a significant gap in the management of blood pressure and LDL-c control in PLWH, regardless of the guidelines used. While there are some differences in the cardiovascular risk estimates between the ESC and EACS guidelines, both sets of guidelines demonstrate similar but not same, challenges in achieving optimal treatment outcomes for PLWH. These findings underscore the need for a more unified approach to managing cardiovascular risk in PLWH, with particular emphasis on improving adherence to treatment and integrating care across specialties to better meet established targets.

Clinical HIV

P 21 EVOLUTION OF LIVER FIBROSIS IN A COHORT OF PEOPLE LIVING WITH HIV WITHOUT ACTIVE HEPATITIS CO-INFECTIONS

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Background: Besides hepatitis coinfections, liver diseases are highly represented in people living with HIV (PLWH) and can be related to metabolic comorbidities, antiretroviral therapy (ART) or concomitant drugs, and to HIV itself. The aim of our study was to investigate the long-term evolution of liver fibrosis in a cohort of PLWH without active hepatitis B or C coinfection.

Methods: Retrospective single centre study enrolling PLWH who underwent longitudinal non-invasive liver fibrosis assessment by transient elastography (TE). Exclusion criteria were: age <18 years, active HBV or HCV coinfection, significant alcohol intake, previous HCC or liver transplantation. Patients were followed from baseline (date of first TE) to the last available TE. Liver fibrosis was categorized from Metavir stage F0 to F4 according to previously published liver stiffness (LS) cut-offs. We assessed the incidence and predictors of (i) LS increase >30% compared to BL and (ii) worsening of Metavir stage over time using KM analysis and Cox regression models.

Results: Overall, 137 PLWH were enrolled (81% males, median age 52 years, median CD4 689/mmc, 92.7% with HIV-RNA<50 cp/mL). At BL median LS was 4.6 (IQR 4.0-5.9) Kpa. Metavir F0-1, F2, F3 and F4 stages were observed in 112 (81.8%), 5 (3.6%), 7 (5.1%) and 13 (9.5%) patients, respectively. During a median follow-up of 4.2 (IQR 2.3-4.5) years, 37 (27.0%) patients showed a LS increase >30% compared to BL, with an incidence of 8.3 per 100 PYFU (95% CI 3.7-12.9). Among non-cirrhotic patients at BL (n=124), 7 (5.6%) were diagnosed with cirrhosis during follow-up. Moreover, 18/124 (14.5%) subjects showed worsening of Metavir stage, with an incidence of 3.9 per 100 PYFU (95% CI 0.5-7.3). The estimated incidence of outcomes (i) LS increase >30% compared to BL and (ii) worsening of Metavir stage was 7.6% (95%CI 2.7-12.5) and 3.6% (95%CI 0.1-7.1) at 2 years, 11% (95%CI 5.1-16.9) and 6.9% (95%CI 2-11.8) at 4 years, respectively. At multivariate analysis, NNRTI use (aHR 0.43, 95%CI 0.19-0.98, p=0.044) was independently associated with a lower risk of LS increase >30% compared to BL after adjusting for time from HIV diagnosis and therapeutic line. On the other hand, therapeutic line (aHR 1.25 per 1 line increase, 95% CI 1.08-1.44, p=0.003) and bilirubin levels (aHR 4.67 per 1 mg/dL increase, 95%CI 1.03-21.25, p=0.046) were independently associated with an increased risk of worsening of Metavir stage over time.

Conclusions: A slow progression of liver stiffness and a low incidence of worsening of Metavir stage were observed over time in PLWH without hepatitis coinfection. However, some patients developed liver cirrhosis during follow-up, suggesting that periodic assessment of liver stiffness can be useful in these patients. NNRTI use was associated with a lower risk of LS increase, suggesting that ART could play a role in the progression of liver fibrosis. Further studies and longer follow-up are needed to better understand predictors of liver fibrosis progression in non-coinfected PLWH.

Clinical HIV

P 22 GLUCOSE HOMEOSTASIS IN PEOPLE LIVING WITH HIV STARTING LONG-ACTING ANTIRETROVIRAL THERAPY

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Introduction: Insulin resistance in people living with HIV (PLWH) has become a growing concern. While modern antiretroviral therapy (ART) has reduced HIV-related morbidity and mortality, its effects on metabolic health remain critical.

Methods: A retrospective cohort study was conducted with outpatients at our clinic who initiated long-acting cabotegravir/rilpivirine (LA CAB/RPV) between January 2023 and December 2024. The study aimed to evaluate changes in glucose homeostasis after 32 weeks of treatment. Participants were assessed at baseline (T0) and after 32 weeks on ART (T1). Clinical and metabolic parameters were compared to identify significant changes over time.

Results: Forty-six participants were included, with a median age of 50 years (IQR 40.5–56.8), and 82.6% were male. At baseline, the cohort had a median BMI of 24.5 (IQR 22.2–26.1) and waist circumference of 90.2 cm (IQR 88.0–96.4). The prevalence of insulin resistance was 28.2%, while 36.9% had dyslipidemia. Baseline glucose was 84.9 mg/dL (IQR 77.0–91.3), median insulin was 8.8 µU/mL (IQR 5.1–11.3), and HOMA index was 1.9 (IQR 1.0–2.7). Previous treatments included mainly integrase inhibitors, with 3TC/DTG (28.2%) and TAF/FTC/BIC (15.2%) being most common.

After 32 weeks on long-acting ART, body weight remained stable (75.5 kg at both T0 and T1), and BMI increased modestly from 24.5 to 24.7 ($p>0.05$). Waist circumference decreased slightly by 0.3 cm ($p>0.05$). Glycemia increased by 2.2 mg/dL (from 84.9 to 87.1 mg/dL), and insulin levels rose by 1.4 µU/mL (from 8.8 to 10.2 µU/mL), with a marginal increase in the HOMA index of 0.4 ($p>0.05$). The prevalence of insulin resistance remained unchanged at 28.2%.

Lipid metabolism showed slight increases in total cholesterol (+9.3 mg/dL) and LDL (+7.5 mg/dL), while HDL decreased slightly by 0.5 mg/dL ($p>0.05$). Triglycerides decreased by 2.9 mg/dL ($p>0.05$). Additionally, 13.0% of participants experienced a weight gain >5%. Renal function showed no significant changes.

Immune function remained stable, with CD4+ count decreasing slightly from 824.5 to 809 cells/mm³, and the CD4+/CD8+ ratio improved from 1.09 to 1.92. Viral suppression was robust, with 100% of participants maintaining HIV RNA <50 copies/mL.

Conclusion: In our cohort, the switch to long-acting ART with cabotegravir and rilpivirine every 8 weeks led to a slight increase in insulin levels and HOMA-IR index, and these changes did not reach a statistical significance. Importantly, no significant alterations were found in body weight, glucose, or lipid parameters, and immunological and virological efficacy were preserved. These findings highlight the need for further research to explore the long-term effects of ART on glucose homeostasis and to determine optimal management strategies for potential metabolic changes.

Clinical HIV

P 23 HIV & MASLD BURDEN: LONGITUDINAL CHANGES, PREDICTIVE FACTORS AND PROGNOSTIC IMPACT IN PEOPLE LIVING WITH HIV FROM SOUTHERN ITALY

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Background: Optimal management of PWH with cardiometabolic disease has dramatically changed during latest years. Metabolic dysfunction-associated steatotic liver disease (MASLD), characterized by hepatic steatosis and at least one cardiometabolic risk factor (including obesity, dysglycaemia, hypertriglyceridemia, low HDL-cholesterol, hypertension), is increasingly recognized as a critical condition in PWH. This study aimed to evaluate the epidemiology, risk factors, and clinical outcomes of MASLD in PWH.

Methods: A retrospective analysis was led using electronic health records from PWH followed at the Infectious Diseases Unit of the "Federico II" Hospital in Naples, Italy, from 1996 to 2023. Cox regression models with time-dependent covariates were used to assess risk factors for incident MASLD.

Results: Data from 486 PLWH were evaluated during a mean follow-up of 108 months. At baseline, hypertriglyceridemia was reported in 22% of PLWH, elevated total cholesterol in 25%, and low HDL in 41% of participants. Hepatic steatosis increased from 11% at baseline to 37% at follow-up, with 26% new-onset cases. MASLD prevalence rose from 23% to 31%, with 10% new cases. Hypertension and obesity also increased significantly, from 17% to 50% and 8% to 19%, respectively(Table 1).

Demographic and clinical comparisons between PWH with and without MASLD revealed no significant differences in gender, age at diagnosis, or HIV acquisition risk factors (Table 2). However, Black ethnicity and foreign nationality were less common in the MASLD group (p=0.006 and p=0.011, respectively). Viro-immunological parameters, including median viral load and CD4 counts at diagnosis, were similar between groups(Table 2).

At last follow-up, PWH with MASLD were older (median age 49 vs. 44 years, p=0.027) and had higher CD4+ (p=0.044) and CD8+ counts (p=0.042), all surrogates of an iper-inflammated status; comorbidities, particularly central nervous system disorders (p=0.023) and overall cardiovascular events (p=0.041), were more frequent in the MASLD group (Table 2).

Treatment history revealed that PWH with MASLD were more likely to have received multiple antiretroviral regimens (p=0.007) and prior TAF-including combinations (p=0.043). Current most commonly used regimen was NRTIs +INSTIs, accounting for 69% of the total population, with lower rates in those with MASLD (62% vs 72%,p=0.046). NRTIs+NNRTIs were significantly more common among individuals with MASLD (22%) compared to those without (10%, p<0.001).

Multivariate analysis identified multiple antiretroviral regimens (aHR 1.188, p<0.001) and cardiovascular events during follow-up (aHR 6.457,p<0.001) as significant independent predictors of MASLD(Table 3).

Conclusions: MASLD is highly prevalent among PWH and is associated with adverse metabolic and clinical outcomes, including cardiovascular disease. Early identification and management of metabolic risk factors are essential to mitigate long-term complications in this population.

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Clinical HIV

P 24 HIV INDICATOR CONDITIONS PRIOR TO LATE PRESENTATION: A TEN-YEAR ANALYSIS IN A MAJOR CLINICAL CENTER—IMPLICATIONS FOR ADDRESSING MISSED OPPORTUNITIES IN ONE OF ITALY'S TOP FIVE MOST AFFECTED CITIES

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Background: Late presenters (LP) represent a significant challenge in HIV infection, with severe consequences on both individual health (reduced life expectancy) and public health (disease transmission). A key strategy to address late presentation is early HIV diagnosis based on clinical signs indicative of HIV infection (HIV indicator conditions, or HIC), which may appear months or even years prior to the HIV diagnosis. This study evaluates LP diagnosed over the past 10 years at our center, examining whether any HIC were present in the 5 years preceding diagnosis, potentially representing missed opportunities for earlier HIV detection.

Materials and Methods: LP is defined as a person with a new HIV diagnosis and a CD4 lymphocyte count <350/mm³. We considered five HICs that are particularly relevant and easily diagnosed, based on existing literature: recurrent pneumonia (RP), herpes zoster (HZ), thrombocytopenia (platelets <130,000/µl) (TP), psoriasis (PS), and generalized lymphadenopathy (involving >2 lymph node stations) (GLA). We analyzed data from patients diagnosed with HIV in the last 10 years at our center.

Results: Between 2014 and 2024, our center registered 707 new HIV infections, 411 of which were late presenters (58.7%). The mean age is 48.9 years (range 19-92). Of these, 277 (67.4%) are Italian, and 134 (32.6%) are foreign-born. The cohort consists of 321 (78.1%) males and 90 (21.8%) females. HIV transmission risk factors include: MSM (181, 44%), ETX (187, 45.5%), TD (30, 7.3%), and missing data for 13 (3.2%). The baseline average CD4 lymphocyte count is 160.3/mm3.

Among the 411 LPs, 83 (20.1%) had at least one HIC documented in the 5 years prior to their HIV diagnosis. Of these, 72/83 (86.8%) had a single HIC: 4 had RP, 16 had HZ, 16 had TP, 19 had PS, and 17 had GLA. 10/83 individuals (12%) had two co-occurring HICs: 5 PS + GLA, 2 HZ + GLA, 1 GLA + TP, 1 HZ + RP, and 1 HZ + PS. Only 1 (1.2%) had three conditions: PS + GLA + TP (figure1).

Conclusions: Approximately 20% of late presenters had one of the five selected HICs in the 5 years preceding diagnosis. Expanding the list of HICs may increase this percentage. Although it is unclear whether diagnosing HIV during the presentation of an HIC would have prevented late presentation, strategies to educate and raise awareness among general practitioners, specialists (particularly dermatologists), and emergency department physicians (including those handling white codes) are essential for earlier HIV detection. The HIV-HCV Free Project is an initiative aimed at supporting this direction.

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Clinical HIV

P 25 HIV STILL HIDING IN RESERVOIRS: FOUR CASES OF SYMPTOMATIC CSF ESCAPE WITH TENOFOVIR ALAFENAMIDE/EMTRICITABINE/BICTEGRAVIR

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Background: CSF escape, defined as detectable cerebrospinal fluid (CSF) HIV RNA with suppressed viremia or a level 0.5-1.5 log greater than the plasma HIV RNA, may present as symptomatic, asymptomatic, or secondary to other inflammatory processes. To date, only one case of CSF escape has been reported in a patient with tenofovir alafenamide/emtricitabine/bictegravir(TAF/FTC/BIC).
Material & Methods: PWH presenting neurological symptoms, receiving TAF/FTC/BIC, and meeting the criteria for CSF escape were identified at two major institutions in Italy. Clinical, demographic, radiological, and inflammatory characteristics of four identified cases are described.
Results: The Table summarizes patients' characteristics.
Patient 1 presented with decline in general condition, cognitive impairment, mood swings, behavioral disinhibition. CD4+ T-cells were 4/mm3. Plasma HIV viremia was 486 copies/mL with no resistance-associated mutations (RAMs), whereas CSF HIV RNA was 1400 copies/mL with T215S(92%), K70N(22%), and E138K(18%) at NGS analysis. No blood-brain barrier damage, intrathecal synthesis, or brain injury were detected. Plasma HIV RNA was undetectable at 3 months of intensified treatment with doravirine.
Patient 2 presented with lower limb pain and poor condition in HIV-associated dementia. CD4+ were 326 cells/mm3. Plasma HIV RNA was 7410 cps/mL and CSF HIV RNA was 88000 cps/mL. No RAMs were detected either in CSF or in plasma. No blood-brain barrier damage was observed, while biomarkers showed intrathecal immunoglobulin production and neuronal damage (high CSF tau). Treatment was intensified with doravirine, leading to a plasma HIV RNA <50 copies/mL one month later.
Patient 3 was admitted for mental confusion and fever. CD4+ were 133 cells/mm3. After 2 months of TAF/FTC/BIC, CSF HIV RNA was 1814 copies/mL and <30 cps /mL on plasma. Both proviral DNA and plasma showed identical RAMs in the protease gene (L63P, I93L); historical genotypes showed a K103. Antiretroviral therapy was switched to TDF/FTC/DOR, with an initial improvement of CSF viral load and CNS imaging till a rebound after 3 months (CFS HIV RNA 1098 cps/mL, plasma <30 cps/mL). Stable improvement over time was achieved with TDF/FTC + DRV/c bid + DTG.
Patient 4 presented with visual impairment 6 months after being on treatment for neurotoxoplasmosis and cART. Plasma and CSF HIV RNA were 22998 and 1360304 cps/ml. Similar RAMs were observed in the protease and retro transcriptase genes in both compartments, but R263R/K(R at 37% and K at 29%)was found on CSF only. TDF/FTC + DRV/r bid + DTG 50 bid with clinical and MRI imaging improvement.
Conclusions: This case series suggests that symptomatic CSF escape can occur even with modern antiretroviral combinations and that lumbar punctures may be necessary in cases of unexplained neurological or neuropsychological symptoms. These patients exhibited several risk factors, including advanced HIV disease, immune depletion, and incomplete adherence to cART.

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P 26 IMPLEMENTATION OF STATIN THERAPY IN AN HIV-POSITIVE COHORT: REAL-WORLD CHALLENGES AND INSIGHTS FROM THE REPRIEVE TRIAL

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Background: People living with HIV (PLWH) are at increased risk for cardiovascular diseases (CVD) due to a combination of chronic inflammation, antiretroviral therapy (ART) effects, and traditional risk factors. Statins have proven effective in reducing cardiovascular events, as demonstrated by the REPRIEVE trial. However, real-world adherence to statin guidelines and their application in clinical practice remain challenging. With this study, we aimed to assess the prevalence of statin use and adherence to cardiovascular risk management strategies in a cohort of PLWH in regular follow-up. Additionally, we analyzed the barriers to implementing evidence-based recommendations from the REPRIEVE trial and the ESC 2024 guidelines.

Material and Methods: We analyzed a cohort of 539 HIV-positive patients regularly followed at our Infectious Diseases outpatient clinic in Foggia. Data on demographics, comorbidities, cardiovascular risk factors, virological suppression, statin therapy, and adherence to lifestyle interventions were collected. Cardiovascular risk was assessed using SCORE2/2OP. Chi-square tests were used to compare virological suppression and statin eligibility versus use.

Results: Only 18.3% of the cohort was on statin therapy, despite 29.2% being eligible for primary prevention according to SCORE2/2OP (Fig. 1a). Only a portion of patients achieved optimal LDL cholesterol targets according to ESC recommendations. This may be attributed to several factors (Fig. 1b): suboptimal adherence to pharmacological therapy, assessed by age groups using the Morisky Medication Adherence Scale (MMAS-8); poor adherence to a healthy lifestyle, with 47.1% of patients being active smokers, only 18% engaging in adequate physical activity, and less than 50% adhering to Mediterranean diet, as assessed by the Mediterranean Diet Adherence Screener (MEDAS).

Conclusions: Our study highlights significant gaps in the implementation of statin therapy for cardiovascular risk management in people living with HIV. While the REPRIEVE trial demonstrated the efficacy of statins in this population, real-world barriers - such as poor adherence to therapy and lifestyle interventions - limit its application. Future research should focus on tailored strategies to enhance adherence and optimize cardiovascular prevention in HIV care. Bridging the gap between evidence-based guidelines and real-world practice requires greater efforts, including multidisciplinary interventions, patient education, and simplified treatment protocols to improve cardiovascular outcomes in this population.

Figure 1a
Figure 1b
Tabella 2

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P 27 LOST TO FOLLOW-UP: WHAT'S HAPPENED? A SINGLE CENTER ANALYSIS

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Background: Retention in care for People Living with HIV (PLWH) represents a critical challenge in the management of HIV. Covid-19 pandemic, one of the most impactful events of the XXI century, with its restrictions widened the gap between PLWH and healthcare centers especially for those patients (pts) not fully adherent.

Material and Methods: This study aimed to evaluate loss to follow-up rate in Covid-19 pandemic period at the Clinic of Infectious Diseases in Foggia, from January 2019 to December 2024, describing their socio-demographic and clinical features and tried to identify predictors of disengagement. The data about patients lost to follow-up (LFU) were collected using the digital healthcare platform of the Apulia Region. The definition of LFU patient refers to those patients who have missed a medical visit for medication collection for a minimum period of 12 months. Clinical and socio-demographic data were collected from clinical records and telephone surveys.

Results: We've analyzed data of 181 PLWH LFU from 1 January 2019 to 31 December 2024. The annual LFU rates, normalized to the number of patients followed at our center each year, were as follows: 7.5% (41 pts) in 2019; 4.5% (25 pts) in 2020; 6.7% (42 pts) in 2021; 5.2% (33 pts) in 2022; 4.7% (27 pts) in 2023; 1.2% (7 pts) in 2024.

Four main subgroups emerged as causes of LFU: 47 patients re-engaged in care elsewhere; 43 patients died, 15 of whom due to AIDS-related illnesses; 6 patients were lost due to bureaucratic issues; 85 PLWH were untraceable. Re-engagement elsewhere was driven by seeking care closer to home/work (19 patients) or in a more socially progressive city (28 patients). Among untraceable patients, the transmission factor (TF) was heterosexual contact for 56 pts, men who have sex with men (MSM) in 6 pts, injecting drug use in 10 patients and vertical transmission in 13 pts. Non-Italian nationality (63 pts) was a predictor of being untraceable.

Conclusions: Retention in care of PLWH is crucial to achieving the UNAIDS 95-95-95 goals. Non-Italian nationality and history of drug addiction were strong predictors of non-adherence to therapy and loss to follow-up. A small proportion of pts finds in the bureaucratic barriers the cause of care-discontinuation. A common denominator in these trends was the Covid-19 pandemic, which disrupted, hindered, and discouraged retention in care. However, we observed a reduction in the rate of patients lost to follow-up in the post-pandemic era.

According to our analysis, LFU remains a pressing issue that requires new strategies to improve patient retention in care, enhance survival rates, and, no less importantly, improve the quality of life of PLWH.

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P 28 MANAGEMENT OF PREGNANCY IN WOMEN LIVING WITH HIV: A TWO-WEEK NEONATAL PROPHYLAXIS AND BREASTFEEDING EXPERIENCE

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Background: Since 2022, our hospital has implemented a multidisciplinary protocol for the management of pregnant women living with HIV and their newborns.
In accordance with the latest international recommendations and available literature we have decided to reduce the duration of neonatal prophylaxis to two weeks in cases considered to be at very low risk for mother-to-child transmission (MTCT). Additionally, we have moved beyond the categorical ban on breastfeeding, instead placing women at the center of a shared decision-making process.
Materials and Methods: We included all women living with HIV who were referred to the Infectious Diseases Unit of Belluno and became pregnant after the introduction of the protocol. We collected demographic, clinical and viro-immunological data for both mothers and infants throughout pregnancy and breastfeeding.
Results: Four pregnant women living with HIV were included with a mean age at pregnancy of 36.3 years. All women came from African countries, and two had arrived in Italy a few months prior. Two women were diagnosed with HIV infection during the first trimester of pregnancy. One woman, who was aware of her HIV-positive status before pregnancy, had not been on antiretroviral therapy (ART) as she had independently discontinued treatment after a previous pregnancy. The three women who were not on ART were immediately started with emtricitabine/tenofovir disoproxil 200/245 mg plus dolutegravir 50 mg once daily, achieving rapid viral suppression. The remaining woman continued her ongoing therapy with emtricitabine/tenofovir disoproxil 200/245 mg once daily plus raltegravir 400 mg twice a day. Adherence to treatment was optimal in all cases, ensuring sustained virological suppression. Three women underwent C-section due to obstetric complications. Detailed data are shown in Table 1.
All newborns tested negative for HIV-RNA at birth and were immediately started with post-exposure prophylaxis with zidovudine for 2 weeks. Three women chose to breastfeed and underwent monthly medical check-ups, including HIV-RNA evaluation, maintaining virological suppression during all the breastfeeding period. During the study, an HIV-RNA assay was also implemented on breast milk, occasionally revealing slight discrepancy compared to plasma viremia (Table 2). One woman discontinued breastfeeding after two months due to the frequency of clinical and laboratory checks-up. The other two women breastfed for eight months, introducing complementary foods after six months of age; one of them is still breastfeeding her infant. All infants consistently tested negative for HIV infection.
Conclusion: Although limited, our experience supports the use of a short-course of neonatal post-exposure prophylaxis in settings with a very low-risk HIV MTCT, as already implemented in some European countries. Additionally our data provide further support for breastfeeding in the context of stable viral suppression, even in high-income countries.

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P 29 MENTAL HEALTH IN PLWH: PSYCHOPATHOLOGICAL VARIABLES AND PERSONALITY TRAITS IN PATIENTS COMPARED WITH NON-CLINICAL SUBJECTS IN ITALY

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Background: Medical advancements in HIV prevention and treatment have fostered aspirations to end the HIV epidemic. However, achieving this goal requires addressing mental health and substance use in a large subgroup of people living with HIV (PLWH) and those at risk of acquiring it. Such issues increase social and economic barriers to accessing healthcare, increasing vulnerability. While existing literature showed the comorbidity of HIV with depression and substance abuse, few studies have explored the interplay of multi-psychopathological variables, including stress vulnerability and personality traits, in PLWH compared to healthy subjects.
Methods: We conducted a cross-sectional study involving adult PLWH attending the HIV Outpatient Clinic Service of Infectious Diseases at the University Hospital Policlinico Umberto I in Rome, Italy. A total of 73 PLWH were enrolled alongside 33 non-clinical subjects. Participants completed a comprehensive questionnaire addressing socio-demographic and clinical variables, alongside various psychometric tools: the Montreal Cognitive Assessment (MoCA), Memory Impairment Screen (MIS), Mood Disorder Questionnaire (MDQ), Patient Health Questionnaire 9 (PHQ-9), Stress-related Vulnerability Scale 9 (SVS-9), alcohol and substance abuse indicators (M.I.N.I), and the MIDI Personality Trait Scales (BigFive).
Results: PLWH exhibited lower openness to experience (t=-2.456; p=0.016), nevroticism (t=3,174; p=0.002, χ^2 = 51.996, df = 25, p = 0.001) and agentivity (t=-3,133; p=0.002). Also, increased prevalence of depression (61%; χ^2 = 9.506, df = 4, p = 0.05), of life-time periods with higher mood causing daily life problems (18%, t=-2,226; p=0.028) and of substance abuse (18%; χ^2 = 6,508, df = 1, p = 0.011) were found as compared to the non-clinical subjects group. These results suggest that personality traits may shift following an HIV diagnosis, potentially impacting cognitive function and social interaction.
Conclusions: Addressing the HIV epidemic requires an integrated approach that encompasses community engagement, educational initiatives, social support, and psychological interventions. By implementing these strategies, stigma may be reduced and recovery of psychological and functional resources among PLWH may be promoted, ultimately fostering a more holistic response to the epidemic that could enhance the quality of life and outcomes for these patients.

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P 30 METABOLIC IMPACT OF SWITCHING TAF/FTC/RPV TO BIC/TAF/FTC IN A REAL-LIFE SETTING

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Background: In the aging HIV population, comorbidities such as cardiovascular disease, diabetes and dyslipidemia are increasing and with them, the need to take medications to manage them.
The need to take antiretroviral drugs lifelong implies on the one hand the importance of adopting effective, safe, well-tolerated and manageable drug combinations with few drug interactions and with a high genetic barrier to limit the risks of virological failure and the consequent development of resistance mutations and, on the other hand, since they themselves can affect metabolism and the risk of developing metabolic disorders, the choice of a regimen with a favorable impact on the metabolic profile.
Material and Methods: We retrospectively analyzed data in 126 people living with HIV (PWLH) on antiretroviral therapy switching from TAF/FTC/RPV to BIC/TAF/FTC between June 2020 and January 2025. We analyzed the efficacy, safety and tolerability of switch to BIC/TAF/FTC from TAF/FTC/RPV. We also studied the cardiovascular and metabolic effect of the switch through the change in FINDRISC score and ASCVD scores after 24 and 48 weeks, as well as changes in lipid profile and body weight. Statistical analyses were mostly descriptive, and association analysis was performed to assess changes in laboratory parameters from baseline to data cut-off.
Clinical, sociodemographic data are summarized in Table 1.
Results: 126 patients, 82 % males, median age 57 years (IQR 52-65) were enrolled. They had experienced a median of 3 therapeutic lines (IQR). At switch all of them presented an HIV-RNA <20 copies/ml and a CD4 mean count of 872 cells/mcL (IQR 646-1093) but 89,7% of them presented at least one co-morbidity mainly involving the cardio-vascular system (36.3%), bone (32.3%), CNS (18.6%), liver (16.2%) or lipids (25.7%) and glucose (10.9%) homeostasis, 20 (16%) had HBV co-infection. During the 48 weeks of follow-up no virological failure occurred. Treatment was discontinued in 4 (%) subjects because of death (1 prostatic cancer), of intolerance (3 cases: 1 insomnia, 1 intestinal disorder, 1 headache).
No difference in the FINDRISC score nor in the ASCVD score was observed 24 and 48 weeks from the switch. No significant overtime variation in mean cholesterol, triglycerides and glucose levels was observed at week 24 and 48. A slight increase in body weight and BMI was observed at wk 24 but the values did not change significantly at wk 48. No significant change in creatinine levels was observed (Table 2)
Conclusions: No significant differences in metabolic status were observed 48 weeks after the switch from TAF/FTC/RPV to BIC/TAF/FTC; this regimen has shown a positive impact both in terms of efficacy, safety and tolerability and in terms of the metabolic profile.

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P 31 MULTIDIMENSIONAL SCALE FOR THE DETECTION OF HEALTH NEEDS IN PEOPLE WITH HIV: PRELIMINARY RESULTS FROM THE MUSA STUDY

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Background: Advancements in treatment led to improvements in many aspects of the lives of people with HIV (PWH). However, viral persistence, continuous low-level immune activation and the prolonged use of antiretrovirals may contribute to an elevated risk of developing comorbidities, both physical and mental. For these reasons, the Mental Health Group of Coalition HIV developed a multidimensional questionnaire for rapid mental health screening in PWH. The efficacy of the test is currently being validated in nine Italian clinical centers and we herein present preliminary data from 4 of these.

Material and Methods: The survey consists of 23 questions exploring 12 domains: cognitive function, functional capacity, depressive and anxiety symptoms, sleep quality, quality of life, biological/nutritional status, socioeconomic factors, stigma, comorbidities, polypharmacy, and alcohol and substance use. Each question is designed to elicit a response on a scale ranging from 1 (best possible outcome) to 4 (worst possible outcome). Questions related to comorbidities are presented as multiple-choice lists, while the socio-economic inquiries are measured on a 2-point scale. The validation process involves the completion of a multidimensional self-administered questionnaire, followed by a longer diagnostic test for each area. Additionally, demographic and clinical variables are collected. Each center is expected to recruit consecutively 22 PWH. Statistical analyses were performed to evaluate the predictive power of depression and anxiety questionnaires in relation to the confirmation tests.

Results: To date, fifty-five PWH were included (key demographics/clinical data are reported in Table 1). The means of the domains (Figure 1) showed that, apart from stigma (mean >2), the remaining domains fall below the 2-point threshold - the midpoint between 1 (no problem) and 4 (very problematic). The social domain appears to be problematic, as it ranges from 1 to 2, and its mean is closer to 2. The domain of comorbidities was normalized on a scale from 1 to 4 as well. The statistical analysis suggested predictive validity, both when considered as continuous quantitative variables (depression: r=0.535, p= <0.001; anxiety: r=0.701, p=<0.001), and as categorical variables (depression: $\chi^2 = 5.063$, p=0.024; anxiety: $\chi^2=71.724$, p=<0.001), indicating an association between the two levels of questioning.

Conclusions: These preliminary findings, illustrated here by the categories of anxiety and depression, appear to demonstrate the predictive capacity of the first-level test developed by the working group. After the end of recruitment, the instrument's effectiveness evaluation will be completed.

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P 32 PREDICTORS OF HOSPITALIZATION IN HIV PATIENTS: IDENTIFYING KEY RISK FACTORS

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Background: Despite advances in antiretroviral therapy (ART), some patients with HIV remain at high risk of hospitalization due to comorbidities and unfavorable clinical factors. Identifying predictors of hospitalization may help implement targeted interventions to improve patient management and reduce the burden on the healthcare system.
Material and Methods: We conducted a retrospective study on 40 HIV patients discharged from our Day Hospital in December 2024. Demographic, clinical, and therapeutic data were collected, including age, CD4 count, presence of comorbidities (neurological disorders, diabetes, dyslipidemia, cardiovascular, gastrointestinal, hepatic, and renal diseases), ongoing ART regimen, psychiatric disorders, substance abuse, number and causes of hospitalization, treatment compliance, number of therapy changes, and duration of HIV infection. Statistical analysis included Spearman correlation and multiple linear regression to identify factors associated with a higher number of hospitalizations.
Results: Statistical analysis revealed that the factors most correlated with the number of hospitalizations were psychiatric disorders ($r = 0.36$, $p = 0.004$), renal insufficiency ($r = 0.32$, $p = 0.015$), and poor treatment compliance ($r = 0.35$, $p = 0.028$). Multiple linear regression confirmed that these three factors were
independent predictors of hospitalization. Age ($r = 0.29$, $p = 0.416$) and dyslipidemia ($r = 0.24$, $p = 0.258$) did not reach statistical significance. The primary causes of hospitalization were infections (19 patients), cardiovascular diseases (8 patients), and neoplasms (11 patients) (Figure 1).
Conclusions: Our findings indicate that psychiatric disorders, renal insufficiency, and poor treatment compliance are the main risk factors for hospitalization in HIV patients. These results highlight the need for multidisciplinary strategies to improve clinical management, with a particular focus on psychiatric and nephrology support and strengthening interventions to enhance adherence to therapy. Further studies on larger cohorts are needed to confirm these findings and identify additional preventive strategies.

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P 33 PREVALENCE AND PREDICTORS OF INCREASED CREATINE PHOSPHOKINASE (CPK) LEVELS IN A COHORT OF PEOPLE LIVING WITH HIV (PLWH) TREATED WITH MODERN ANTIRETROVIRAL REGIMENS

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Background: CPK elevations have been frequently observed in PLWH and have been previously associated with the virus itself, certain antiretroviral drugs (e.g. older PIs, NRTIs, InSTIs) and concomitant medications (e.g. statins). The present study aimed to investigate prevalence and predictors of increased CPK levels in a cohort of PLWH on modern antiretroviral regimens (ART).

Methods: Retrospective single centre study on a cohort of PLWH on stable ART, who had at least four CPK determinations across a minimum of two years' follow-up. Based on CPK values, patients were classified in two groups: (A) patients with normal CPK levels; (B) patients with hyperCKemia, if CPK levels were above the upper limit of normal (ULN, 170 U/L). The grade of physical activity was investigated through a structured questionnaire. Variables associated with hyperCKemia or CPK levels were explored by logistic or linear regression analysis.

Results: A total of 289 PLWH were included (71.6% male, median age 55 years, 8.7% of black ethnicity, 90.3% with HIV-RNA<50cp/mL, median CD4 752cell/mmc). ART included InSTI in 76.1%, NRTI in 86.9%, NNRTIs in 25.3%, PIs in 12.1% of cases. Overall, 19.7% patients were on a concomitant medication potentially associated with muscle toxicity (15.6% on a statin, 3.1% on fibrates). No regular physical activity was declared by 46% of patients, while 22.8% and 14.5% reported exercising once or ≥2 times per week, respectively. Abnormal CPK levels were observed in 40.5% (n=117) PLWH, of which 84 (29.1%) with transient and 34 (11.8%) with permanent CPK increase. Patients with hyperCKemia were younger (median 52 vs 56 years, p=0.032), most frequently male (78% vs 67%, p=0.047), of black ethnicity (17% vs 3%, p<0.001), and with a higher CD4/CD8 ratio >1 (52% vs 40%, p=0.045) than those with normal values. No significant differences between groups A and B were observed regarding physical activity, exposure to antiretroviral drugs or concomitant medications, viral load, absolute CD4 count and duration of HIV infection.

In a multivariate logistic regression analysis, we observed that males (p=0.001), patients of black (p<0.001) or Hispanic (p=0.017) ethnicity and those with a higher CD4/CD8 ratio (p=0.028) showed a higher risk of hyperCKemia, after adjusting for age (Table 1A). In a multivariate linear regression analysis, males (p=0.002), black/Hispanic ethnicity (p<0.001) and higher CD4/CD8 ratio (p=0.046) were independently associated to higher CPK levels, after adjusting for age and BMI (Table 1B).

Conclusions: HyperCKemia was frequent in PLWH and should be adequately evaluated when prescribing ART or statins (recently recommended in most PLWH >40 years based on REPRIEVE Trial's findings). Younger age, Black/Hispanic ethnicity and male gender were associated with hyperCKemia. The increased CK levels observed with increasing CD4/CD8 ratio might suggest an inflammatory mechanism, that should be investigated in further studies.

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Clinical HIV

P 34 PREVALENCE, PREDICTORS AND OUTCOMES OF POOR IMMUNOLOGICAL RECOVERY IN PLWH ON EFFECTIVE C-ART: A RETROSPECTIVE STUDY FROM A TERTIARY UNIVERSITY CENTER IN ITALY

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Background: Despite viral suppression, 10-30% of people living with HIV(PLWH) experience suboptimal immune recovery, increasing their risk of morbidity and mortality. This study evaluated the prevalence and determinants of poor immunological recovery and the association of this condition with incident AIDS and non-AIDS-related events.
Methods: The study enrolled virologically suppressed PLWH under active follow-up at the Infectious Diseases Unit of the Federico II University Hospital in Naples, categorizing them into three groups based on CD4 counts one year after ART initiation: immunological responders (IR, CD4 ≥350 cells/µl), incomplete immunological responders (ICR, CD4 200–350 cells/µl), and immunological non-responders (INR, CD4 <200 cells/µl).
Results: A total of 468 PLWH were enrolled: 92.73% were IR, 5.98% ICR, and 1.29% INR. Baseline and follow-up demographic characteristics, laboratory parameters, and clinical outcomes were compared between the IR group and those with inadequate immunological response (ICNR: ICR+INR) (Table 1). At diagnosis, PLWH with ICNR showed older age (43 vs 36 years, p=0.046), higher rates of advanced disease (82% vs 44%, p<0.001), and higher baseline HIV-RNA (>100,000 cp/mL, 76% vs 44%, p<0.001). At multivariate regression analysis, independent baseline predictors resulted CD4 <200 cells/µl (aHR: 1.950, p<0.001), use of additional medications (aHR: 1.933, p<0.001), oncological disease (aHR: 1.266, p=0.029), and chronic pulmonary disease (aHR: 1.278, p=0.047)(Table 2).
During follow-up, ICNR patients had lower CD4 recovery (118 vs 377 cells/µl, p<0.001) and more frequent persistent low-level viremia (pLLV, 29% vs 15%, p=0.011); full viral suppression (target not detected) was reached only in 29% of ICNR (vs 55% of IR, p=0.004)(Table 1). Follow-up predictors of inadequate immune response at multivariate Cox regression included HIV infection duration <5 years (aHR=2.380, p=0.015), single ART regimen (aHR=2.344, p<0.001), and pLLV (aHR=1.302, p=0.025) (Table 2). No impact of different ART classes on immune recovery was observed.
Notably, ICNR experienced earlier onset of AIDS-defining events (176 vs 242 months, p=0.001 log-rank test, Fig.1a), oncological diseases (182 vs 216 months, p=0.003 log-rank test, Fig.1b), CNS diseases (193 vs 233 months, p=0.002 log-rank test, Fig.1c), and chronic pulmonary diseases (185 vs 222 months, p=0.015 log-rank test, Fig.1d).
Conclusions: By identifying predictors of inadequate immune recovery and their association with adverse clinical outcomes, this study provides a foundation for tailored interventions to address persistent immune dysfunction in PLWH. Personalized approaches, such as optimizing ART to reduce pLLV and targeting HIV reservoirs, could help reduce the burden of AIDS- and non-AIDS-related diseases. The advent of LA drugs with high genetic barrier could represent attractive therapeutic options, overcoming forgiveness and adherence issues in a least a subset of PLWH with INR.

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Clinical HIV

P 35 PREVIOUS COBI-INCLUDING REGIMEN IS THE MAJOR DETERMINANT OF LIPID PROFILE MODIFICATION IN A COHORT OF PWH ON STABLE TAF TREATMENT SWITCHING TO DUAL TREATMENT

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Background: Our aim was to investigate the role of switching from emtricitabine/tenofovir alafenamide (FTC/TAF) based regimen to a dolutegravir (DTG) containing two-drug regimen (2DR) vs continuing FTC/TAF on metabolic parameters.

Methods: Consecutive people living with HIV infection (PWH), enrolled in a multicenter observational cohort (SCOLTA) project, on a stable (24 months at least) FTC/TAF based regimen with a HIV-RNA<50 copies/ml were included. Changes from baseline (T0) to follow-up (T1, week 24) were analyzed.

Results: Five hundred and thirty-seven PWH met the inclusion criteria, 415 (77.3%) were males, 290 (54%) were on a previous cobicistat (COBI)-including regimen (IR).

At T0 main characteristics were (mean ± standard deviation [SD]): age 49.5 ± 12.0 years, weight 75.6 Kg ±13.8, body mass index (BMI) 25.6 ± 4.2 kg/m2, total cholesterol (TC) 194.7 ± 40.7 mg/dL, LDL-cholesterol (LDL-c) 116.1 ± 35.5 mg/dL, median CD4+ cell count was 680 cell/µL (interquartile range [IQR] 500-901), triglycerides (TGL) 114 mg/dL (IQR 82.5-158.5). 366 (68.2%) PWH started FTC/TAF/bictegravir (BIC), 15 (2.8%) FTC/TAF/DTG, 128 (23.8) DTG/lamivudine (3TC) and 28 (5.2%) DTG/rilpivirine (RPV). Median observation time was 27.2 months (IQR 15.2 -77).

PWH switching to 2DR differed significantly by FTC/TAF for: INSTI, NNRTI and PI in previous regimen (62.8% vs 79.3%, 30.1% vs 6.3% and 7.7 vs 14.4%, respectively; p<0.0001), HCV coinfection (7.2% vs 25.1%, p<0.0001), baseline CD4 (median 730 and 646, p=0.0002) and CDC stage C (8.4% vs 19.5%, p=0.002), and previous COBI-IR (32.1% in 2DR vs 63.0% in TAF, p<0.0001). PWH with previous COBI-IR entered the study with higher levels of TC (200 vs 188 mg/dL, p=0.0005) and LDL-c (120.4 vs 111 mg/dL, p=0.002).

Evaluating 2DR vs continuing FTC/TAF, in strata of switch from a regimen with or without COBI, we observed no difference in lipid profile and weight (table 1).

On the other hand, irrespectively of the new treatment, a TC decline was observed in PWH on previous COBI-IR (-9.9 mg/dL, 95% confidence interval -13.6 to -6.2), as well as for LDL-c (-7.4 mg/dL [95% CI -10.8 to -4.1]) and TGL (-15.3 mg/dL [95% CI -23.6 to -7.0).

In a MM including sex, age, previous COBI and drug class, and 2DR vs FTC/TAF, no significant difference was found in terms of weight and blood lipid change between continuing FTC/TAF and switching to a 2DR.

Conclusions: In PWH already on TAF, stopping TAF does not impact lipid profile and BMI, while only switching by COBI is associated with amelioration of lipid profile. Weight and BMI were not influenced by switching TAF or COBI.

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Clinical HIV

P 36 RE-CALL, RE-TURN, RE-START: A CLINICAL PROJECT FOR RETENTION IN HIV CARE

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Background: Adherence is essential to improving the quality of life of people with HIV (PWH). Regular ART use helps maintain an undetectable viral load, while consistent follow-up at the care center contributes to better long-term health outcomes and reduces the burden of HIV. The Re-start Anti-Retroviral Therapy (Re-stART) clinical project was designed to systematically identify and re-engage individuals at risk of being lost to follow-up (LTFU).
Materials and Methods: Clinical project on PWH under care at the Infectious Diseases Unit of the San Raffaele Scientific Institute in Milan, Italy, who have recorded in their electronic medical records only one visit or laboratory test more than 12 months ago but less than 18. Since December 1, 2024, defined as baseline (BL), a monthly newsletter was created to highlight those who meet this criterion. The list was reviewed through the electronic health record to exclude those died or no longer receiving care in the Lombardy region. Subjects who can be contacted receive up to 3 phone calls to confirm their willingness to continue treatment and schedule an appointment at the Re-stART outpatient clinic. The participants' characteristics were recorded and reported as median (interquartile range, IQR) or frequency (%).
Results: Overall, 5074 PWH have been monitored. As shown in Figure 1, 152 PWH (3.0%) have recorded one visit or laboratory test more between 12 and 18 months ago. After verification, 79 were removed from the list due to confirmed transfer to another healthcare facility or recorded death. The proactive strategy enabled successful contact with 41 (56.2%) of the 73 remaining targeted individuals. Among them, 15 (36.6%) PWH scheduled an appointment at the Re-stART outpatient clinic, 26 (63.4%) PWH chose to schedule an appointment with their HIV specialist. In Table 1 have been reported the characteristics at BL of the 41 PWH returned in care. The median age was 51.0 years (IQR: 40.6-57.2), with 32 (78.0%) being male. The median duration of HIV infection was 17.6 years (IQR: 11.8 -24.3), the last available plasma viremia was 19 (0.9 - 41) cps/mL, nadir T-CD4+ count was 215 cells/mm³ (IQR: 93 -418), while the last available CD4/CD8 ratio was 0.71 (IQR: 0.48-1.05).
Conclusions: In the initial phase of the Re-stART clinical project (Re-CALL), 73 PWH out of 5074 under care (1.4%) were identified as requiring recall. More than half answered and agreed to schedule a new visit (Re-TURN). Less than 1% of PWH under care were unreachable and considered potential cases of LTFU. The next phase focuses on promoting adherence to care by identifying and addressing the underlying causes of non-adherence (Re-stART) and is currently under investigation.

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Clinical HIV

P 37 SCREENING WITH GAD-2 IN A REAL-LIFE OUTPATIENT SETTING IN MILAN. HIGH PREVALENCE OF ANXIETY, ASSOCIATED FACTORS AND ACCEPTANCE OF PSYCHOLOGICAL ASSESSMENT

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Background: Anxiety disorders, which have overall prevalence around 14% in adults in the EU, are reportedly frequent in persons living with HIV (PLH); in PLH, anxiety disorders in turn correlate with disability and poorer treatment (ART) outcomes, as well as substance use behavior. We screened outpatients with the Generalised Anxiety Disorder-2 (GAD-2) validated screening tool, 86% sensitive and 83% specific to diagnose GAD, and offered a psychologic consultation to people scoring ≥3; we describe prevalence in a real-life setting, acceptance rates and factors associated with testing positive.

Materials and Methods: Monocentric retrospective observational study. Outpatients on treatment for at least 6 months and without language barrier were consecutively screened with GAD-2 and substance abuse according to EACS guidelines in 01-02/2025; individuals with a positive score ≥3 were offered a free session with a qualified cognitive-behavioral psychologist, routinely provided by Anlaids Lombardia at our clinic. Chi-square and Fisher's exact tests were used for comparisons.

Results: A total of 100 outpatients were screened: 38% had a positive (≥3) GAD-2 score. Score distribution was as follows: 0 in 16, 1 in 29, 2 in 17, 3 in 18, 4 in 6, 5 in 3 and 6 in 11 patients respectively. Population demographic and clinical characteristics are summarized in table 1. Of note, 16% were currently seeing a psychologist (30% had seen one in the past). While 16% had a known psychiatric condition, 22% was on chronic medication for anxiety or depression. In regards to substance abuse, 14% reported alcoholism and 14% use of chemsex; when including previous cocaine and/or methamphetamine use the proportion rounded up to 30%. Optimal adherence to ART was 88% and adherence to visits 91%. Country of origin other than Italy (16/29 with score ≥3, vs. 22/71 Italians) and currently being on psychologic treatment (11/16 with score ≥3, vs. 28/84 not seeing a therapist) were associated to positive GAD-2. Of the 38 outpatients positive GAD-2, 7 were already on psychotherapy. The other 31 were offered a psychologic consultation: 20 accepted and 11 refused. Of the 33 who were not on psychiatric follow up, 19 were also offered a psychiatric evaluation: only 4 accepted. No item correlated with acceptance. Qualitatively, anxiety seemed to be related to everyday experiences like work and relationships rather than health.

Conclusions: A high proportion of outpatients screened positive to GAD-2, suggesting higher prevalence of anxiety disorder compared to the general population; a relevant proportion also reported substance abuse. Some were aware of anxiety and had already seeked psychologic consultation independently; however, most had not, and rate of acceptance for psychologic consultation was 65%, showing an unmet need uncovered by the screening. Foreigners living with HIV may face additional barriers, possibly explaining the higher proportion of anxiety and warranting further investigation.

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Clinical HIV

P 38 STATIN USE IN PEOPLE LIVING WITH HIV WITHOUT APPARENT CARDIOVASCULAR RISK FACTORS: OBSERVATIONAL STUDY OF AN OUTPATIENT COHORT

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Introduction: People living with HIV have greater risk to develop at atherosclerotic cardiovascular disease (CVD) because HIV determines chronic inflammation and persistent immune-activation.
The REPRIEVE study, a randomized phase III study (2015-2019), enrolled people living with HIV and with low-moderate risk of cardiovascular disease, showing a 35% reduction of cardiovascular major side effects (MACE) in people taking statins.
Methods: This retrospective and prospective study enrolled people living with HIV followed by Infectious Disease Clinic, Tor Vergata Polyclinic (Rome) aged ≥40 years, apparently good health and one of these criteria: 1) CV risk >5% at ten years (SCORE2/OP) and/or 2) CD4+/CD8+ <1. Demographic, clinical and laboratory data with lipid and inflammatory profile were collected.
The Shapiro-Wilk test was used for normality assessment, the Mann-Whitney test for comparing two groups, the Kruskal-Wallis test for multiple groups and Fisher's exact test for categorical variables. Statistical analysis was performed using STATA software; the significance level was set at p = 0.05.
Results: From January to November 2024, we enrolled 149 patients: 94/149 (63%) introduced statin when the study started, 31/149 (21%) already taking a statin and 24/149 (16%) refused statin.
Most participants were male and Italian origin, the median age was 54 years at study entry. At the time of enrollment, the median SCORE 2/OP was 7.1 and QRISK was 8.6. Most participants showed plasma HIV-RNA suppression (<50 copies/mL) [table 1]. All patients took on ART [table 2].
Among 149 participants, 44 (29.5%) had a SCORE2/OP > 5%, and 29 (19.5%) had a CD4+/CD8+ ratio < 1; 72 individuals (48.3%) had both criteria. Most participants took atorvastatin 10 mg and approximately 75% did not change the type of statin during the study [table 3]. The study describes lipidic and inflammatory pattern of population at baseline, 3 months, 6 months and final FU [table 4].
The statistical analysis was performed on 125 patients who, at the time of the final follow-up, were taking a statin. There were some statistically significant correlations between the decrease of SCORE2/OP (p-value 0.001), QRISK score (p-value 0.009), LDL cholesterol (p-value 0.00) and statin intake. During the analysis we also saw how the CD4 +/CD8+ ratio increased significantly (p-value 0.00) [table 5].
Conclusions: Statin therapy therefore has multiple benefits in people living with HIV by improving CVD risk scores, lipid and inflammatory profiles.

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Clinical HIV

P 39 TEMPORAL TRENDS, CLINICAL CORRELATES AND PROGNOSTIC POTENTIAL OF ADVANCED DISEASE IN NAÏVE PLWH AND IMPACT OF COVID-19 PANDEMIC: PRELIMINARY RESULTS OF A 20-YEAR RETROSPECTIVE COHORT STUDY

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Background: Late diagnosis in people living with HIV remains a key barrier to fully realizing the benefits of novel ART. Individuals diagnosed with HIV as advanced naïve (AN), characterized by a CD4+ count<200/μL or the presence of an AIDS-defining illness at presentation, continue to face a high risk of disease progression and mortality, even when achieving virological suppression.

Methods: This study aimed to analyse temporal trends in new HIV diagnoses and evaluate the characteristics and outcomes of AN PLWH under active follow-up at the Infectious Diseases Unit of the Federico II University Hospital in Naples, from 2001 to 2023.

Results: The preliminary cohort evaluated comprised 351 patients, with 116 (33%) classified as AN. The first time interval (2001-2006) showed a relatively low and stable number of diagnoses, followed by a gradual increase from 2006 to 2016 (Fig. 1). A significant rise of total diagnosis was observed from 2016 to 2020, with a sharp spike in 2021, a decline in 2022, and a slight increase in 2023 (Fig.1). For advanced PLWH, diagnoses remained low from 2006 to 2010, increased progressively from 2011 to 2015, and peaked in 2021-2023, with 16 and 17 cases, respectively (Fig.2). The prevalence of AN among total HIV diagnoses rose from 30% (2006-2016) to 45% (2020 -2023).

Demographic, clinical, virological, and immunological characteristics at diagnosis were compared between AN and non-AN groups (Table 1). AN were older (median age 42 vs. 36 years, p<0.001), more likely to have heterosexual transmission (64% vs. 47%, p=0.005) and had higher rates of coinfections (50% vs. 34%, p=0.005). AN exhibited significantly lower CD4 counts (median 120 vs. 442 cells/μL,p<0.001), higher HIV viral loads (median 281,518 vs. 46,432 cp/mL,p<0.001). Multivariate logistic regression analysis identified high HIV viral load (aOR 5.74, p<0.011), coinfections (aOR 1.777, p=0.039), and low monocyte counts (aOR 2.756, p=0.001) as predictors of advanced disease at diagnosis (Table 2).

At follow-up (Table 3), AN had lower CD4 counts (median 539 vs. 820 cells/μL, p<0.001), higher rates of nephropathy (15% vs. 6%, p=0.004), and more frequent coinfections (44% vs. 33%, p=0.049). Multivariate Cox regression analysis confirmed CD4 counts <500 cells/μL (aHR 1.401, p<0.001) and single-ART (aHR 1.577, p<0.001) as significant correlates of advanced disease status at diagnosis (Table 4).

Conclusions: This study highlights critical trends in HIV management, emphasizing the impact of late diagnosis on long-term outcomes. AN PLWH, often older and non-MSM, face stigma and delayed screening, leading to poorer immunological recovery and higher risks of comorbidities despite ART. Persistent immune dysfunction and chronic inflammation in AN necessitate tailored therapeutic strategies and close monitoring to reduce morbidity and mortality. The pandemic exacerbated late presentations, underscoring the need for improved screening and awareness to reverse this trend.

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Clinical HIV

P 40 THE ROLE OF INFLAMMATORY AND ATHEROGENIC MARKERS IN A GROUP OF YOUNG MEN LIVING WITH HIV WITH ERECTILE DYSFUNCTION: A CROSS-SECTIONAL STUDY

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Background: Inflammatory and atherogenic markers, such as the neutrophil-to-lymphocyte ratio (NLR), platelet-to-lymphocyte ratio (PLR), lymphocyte-to-monocyte ratio (LMR), neutrophil-to-lymphocyte-platelet ratio (NLPR), and atherogenic index of plasma (AIP), have been proposed as potential indicators of endothelial dysfunction and atherosclerosis. However, their association with erectile dysfunction (ED) have been extensively evaluated only in HIV-uninfected individuals, and data on young populations remain limited. The aim of this cross-sectional monocentric study is to investigate whether inflammatory and atherogenic markers may be associated with ED even in a group of young men living with HIV (yMLWH).
Materials and Methods: We enrolled all yMLWH, aged 18 to 50 years, who were followed in our outpatient clinic at ASST Spedali Civili di Brescia between December 2022 and December 2023. Clinical and laboratory data, including inflammatory and atherogenic markers, were collected. Descriptive analysis compared ED and non-ED groups using Mann-Whitney U tests and chi-square tests, as appropriate. Univariate and multivariate logistic regression (adjusted for age, number of comorbidities, CD4 and CD8 counts) were applied to assess potential associations between inflammatory or atherogenic markers and ED.
Results: A total of 308 people living with HIV (PLWH) were included, of which 63 (30.3%) reported symptoms of ED. The demographic characteristics of the two groups were similar. Descriptive analysis revealed that patients with ED had a significantly higher prevalence of comorbidities compared to those without ED (Table 1). However, no significant differences were observed in inflammatory and atherogenic markers between the two groups. Logistic regression models did not identify any statistically significant association between ED and inflammatory markers, although AIP, NLR and NLPR showed an odds ratio greater than 1 (Figure 1). Therefore, the clinical significance of these markers is still uncertain in PLWH under 50 years of age.
Conclusions: Our findings suggest that inflammatory and atherogenic markers are not significantly associated with ED in yMLWH. However, the presence of multiple comorbidities appears to play a relevant role, highlighting the need for a more comprehensive approach when evaluating ED in this population. The relatively young age of the included patients, and the relatively small sample size, may have limited the detection of potential associations, despite some inflammatory markers showing a tendency toward a positive correlation with ED.

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Clinical HIV

P 41 TRANSGENDER PEOPLE WITH HIV: CHALLENGES IN THE ART MANAGEMENT

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Introduction: Certain key population groups, such as transgender people (TGs), are at significant risk of acquiring sexually transmitted infections (STIs), including HIV, due to their involvement in high-risk behaviors such as unprotected sex, multiple partners, drug use, and limited access to healthcare facilities. The aim of the study is to present sociodemographic, clinical, and behavioral characteristics of TGs with HIV in an Italian cohort.
Methods: At the Policlinico Umberto I, Sapienza, University of Rome TGs with HIV were recruited. Sociodemographic and risk factor data were collected through questionnaires and visit.
Results: A total of 40 TGs with HIV women were enrolled in the study, with a median age (interquartile range, IQR) of 40 (31-46) years. It is noteworthy that all TGs were Latin American origin and engaged in sex work, with 40% of the cohort also exhibiting a history of drug abuse. Five out of 40 TGs with HIV exhibited at least one comorbidity. The majority of the study population (90%) received hormone replacement therapy. Furthermore, 33 out of 40 TGs with HIV were receiving ART, while 5 TGs with HIV were naïve and started ART as soon as possible. Thirty-six out 40 had undetectable viral load, with a median (IQR) CD4 count of 547 (254-724) cell/µl, despite only 22 TGs with HIV having regular to follow-ups. Sexually transmitted infections (STIs) were prevalent, with syphilis having the highest prevalence (27.5%). Hepatitis was common with a 28% prevalence of hepatitis B
Conclusion: TGs encounter obstacles in accessing healthcare due to administrative impediments and pervasive social stigma. These factors result in delays in the diagnosis and treatment of STIs, which is a significant public health concern on a global scale. It is imperative to address the needs of TGs with HIV by establishing appropriate structures that can effectively address their complex needs.

Epidemiology

P 42 A WALK ON THE WILD SIDE: AN OBSERVATIONAL RETROSPECTIVE SINGLE CENTER STUDY ON A COHORT OF TRANS* WOMEN COMING FROM LATIN AMERICA ACCESSING CLINICS FOR HIV AND STIS IN A TEACHING HOSPITAL IN ROME

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Although Trans* population is known to be burdened by adverse health indicators, study about this population worldwide and specifically in our country are lacking. Particularly critical is the condition of migrant Trans* people, a difficult to reach population, mostly invisible for institutions and health system for multiple and complex reasons.
We decided to conduct a retrospective observational study on 80 Trans* AMAB women coming from Latin America who attended the sexually transmitted infections(STI) and HIV clinics of Policlinico "Umberto I" in Rome from 2013 until December 2024, studying demographic characteristic, specific health problems and possible factors involved in the lost to follow up (LTFU).
The age range went from 22 years to 69 years, with a median age of 40. The main country of origins were Brasil (45%) and Colombia (31.3%), followed by Argentina, Perù, Venezuela, Paraguay and Uruguay. We observed a significant increase in first time visits over the last two years, with 72% of patients admitted in our clinic from 2023, when we began to collaborate with a cultural mediator.
We mapped our patients' origins within the province of Rome, identifying an higher concentration where sex work is more prevalent and where our center is more easily accessible by public transport. Of all patients, 63.5% accessed to our clinic for an HIV infection, 25% to get PrEP and 12.5% for other reasons.
Data regarding profession, drug consumption, hormones use, surgical intervention and noncommunicable diseases are summarized in table1 where we confronted PLWH and people using PrEP. Relevant is the high consumption of drugs and alcohol, and the high rate of syphilis infection in both groups. The only significant difference was the higher drug use among those living with HIV. We then focused on the population of PLWH, discovering that just 13.7% of them got a diagnosis in our hospital, while 86.3% was diagnosed in another clinic. Of these group, 50% presented to our hospital with a detectable viremia (defined as HIV-RNA > 200cp/mm3). This is a significant, as it stresses the difficulty to retain these patients in care. Of all PLWH, 25.5% presented at least one AIDS defining illness, whose more frequent were tuberculosis and neurotoxoplasmosis, consistently with the epidemiology of the countries of origin.
We calculated the rate of lost to follow up, defined as missing an appointment of failing to pick up ARV for more than six month. The LTFU rate was 42.1%, confirming literature data. We tried to correlate it with different factors as indicated in table2, but aside the low CD4+ number and the high viremia at presentation, there were no singular factors significantly involved.
Our study confirmed the fragility at many levels of this population, burdened by a high rate of STI and drug consume. We aim to deepen our knowledge of the specific problems and to create a net with other centers and other professions to better reach and retain in care this population.

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Epidemiology

P 43 AN HIV CLINIC IN BOUAR, CENTRAL AFRICAN REPUBLIC: THE CURE MOVES WHERE MEDICAL CARE IS MISSING

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Introduction: Central African Republic (CAR) is one of the high-burden countries for HIV and TB infection, according to World Health Organization data. The country has been affected by decades of conflict and humanitarian challenges, which make HIV and TB care and data collection especially difficult, with women and children being the most affected population. In CAR live 5.2 million people, the reported number of people with HIV (PWH) is 67627, of which 94% are on antiretroviral therapy (ART). It is difficult to establish how many PWH have a suppressed viral load (VL), and an estimate of ART coverage in children and adults living in CAR in 2023 is not available. We describe a cohort of PWH in follow up at a clinic and dispensary in Bouar.

Material and Methods: This is a retrospective cohort study, conducted at Centre Saint Michel (CSM) in Bouar on PWH attending the clinic. Participants data were collected over the period 2010 - 2023. To detect HIV infection ELISA test was used (Determine™ HIV-1/2 test Abbott) and confirmed by a Western-blot test (Uni-Gold HIV by Trinity Biotech). At the time of HIV diagnosis were collected HIVRNA on blood (cp/mL), and when available, a CD4 count test (cell/L) was performed. A screening for TB infection was performed by microscopy and/or GenXpert MTB/RIF on sputum sample or TB-LAM urine test, depending on the presence of symptoms (cough, adenopathy). All cohort was screened for viral hepatitis using HBsAg and HCV rapid tests.

Results: On 1 January 2024, 1238 PWH were on ART at CSM. This number expanded to 1440 one year later, with 202 new diagnoses , in an area with estimated 28000 habitants.

In our cohort, 119 (9%) were children (age < 18). The remaining 90% (1119/1238) PWH are adults, of whom 896 (80%) are female (tab.1). The mean of age was 38 years old (0-75).

A total of 1061 VL were collected, with a median of 47 copies/mL (0 – 43800000), and just for 195 PWH a CD4 count test was available, with a median of 305 cells/mm3 (0 – 1310). Among them, 58 (4,6%) people had less than 200 CD4 cells/mm3 at the diagnosis, and fifty-two of them (89%) had an active TB infection. After screening at the diagnosis, 222 PWH tested positive for active TB (18% of all tested, see Table 2), 18 (5%) were <18 years old. We diagnosed 97 (7,8%) cases of HBV hepatitis, of whom 23 (23%) had a TB coinfection. Twenty-three (1,8%) individuals had a positive HCV rapid test.

Conclusions: Centre Saint Michel follows a large population of PWH in an especially difficult setting like CAR. Most of our cohort is composed of women and children, and active TB is common, especially among those who are diagnosed with a CD4 cell count < 200 cell/L . More efforts and funds are needed to monitor HIV parameters (VL, CD4+ total count), to improve overall health outcomes and to better describe the CSM cohort (5). The Centre Saint Michel is playing a crucial role in providing HIV care, retaining patients and becoming a landmark for PWH in CAR, contributing to create antiretroviral coverage in an extremely fragile population.

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Epidemiology

P 44 ANTIRETROVIRAL THERAPY IN PREGNANT WOMEN LIVING WITH HIV: REAL-LIFE DATA FROM A TERTIARY CENTER CATERING TO THE GREATER MILAN AREA, 2019-2025

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Background: Appropriate use of antiretroviral therapy (ART) during pregnancy is crucial to prevent vertical transmission of HIV. We report real-life data from pregnant women with HIV referred in the last six years at our institution, which is a reference center for obstetrics for women living with HIV (WLWH) in Northern Italy, aiming at describing factors associated to suboptimal treatment, to improve the treatment and retention cascade in this key population.

Materials and Methods: Monocentric observational retrospective study (02/2019-02/2025) of WLWH referred to Policlinico, Milan, for pregnancy; infectious disease assessment is obtained after first ob-gyn visit.

For WLWH with >1 pregnancy, only first pregnancy referred to Policlinico was considered.

Adequacy of ART at referral was stratified according to EACS guidelines of year of pregnancy. Median was used for continuous and Fisher's exact test for categorical variables.

Results: Twenty pregnant WLWH were referred, 10 Italian and 10 foreign-born, median age at referral 34 years; 14 were primigravidas.

Three were not on ART and viremic at referral (two diagnosed at pregnancy, one for personal choice), had CD4 counts > 200/mcL, and were promptly started on first-line INSTI-based ART. All three achieved undetectable viral loads at third trimesters, 2/3 had natural delivery with intrapartum AZT prophylaxis and 1/3 cesarean section without AZT, 3/3 delivered healthy newborns.

Of the 17 on ART, median time on ART was 6 years, viral load was < 50 cp/mL at referral in all cases (undetectable in 13), median CD4 count was 674/mcL.

Eight of them had adequate ART (2 first line, 6 alternative agents): 2 were switched (1 on TAF/FTC/RPV and 1 on TAF/FTC/BIC) for HIV RNA blip 50-200 cp/mL at week 36.

Nine (52.9%) had inadequate ART: 1 was on PI monotherapy, 4 were on dual therapy (3 DTG/3TC, 1 DTG/RPV), 1 on ABC/3TC + NVP, 1 on TAF/FTC/DRV/c, 2 (before 2024) on TAF/FTC/BIC. Eight of them were switched to INSTI-based 3-drug regimens, one maintained her TAF/FTC/DRV/c regimen.

Being foreign-born was associated to inadequate ART (p .003).

Of 17, 2 pregnancies are still ongoing, 15 achieved undetectable viral loads at delivery (6 with c-section due to ob-gyn decision, 2 with intrapartum AZT despite guidelines). All infants were put on AZT prophylaxis and were HIV RNA and DNA negative.

Conclusions: There is an unmet need for screening in heterosexual women, at risk of being diagnosed of HIV only when pregnant. Moreover, when timely diagnosed, despite treatment success, suboptimal ART in pregnant WLWH – accounting for 50% cases in this analysis - poses unnecessary risks, and requires regime changes in a phase where switches themselves pose a risk.

A thoughtful regime selection for WLWH of childbearing age (with particular attention to migrant WLWH), as well as multi-disciplinary planning with ob-gyns and pediatricians, are warranted to improve the healthcare cascade for this key population and their newborns.

Epidemiology

P 45 ASSOCIATION OF NEUTROPHIL-TO-LYMPHOCYTE RATIO, MONOCYTE-TO-LYMPHOCYTE RATIO, AND PLATELET-TO-LYMPHOCYTE RATIO VALUES WITH MORTALITY AND THE OCCURRENCE OF NON-AIDS AND AIDS EVENTS

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Background: In people living with HIV (PWH) neutrophil-to-lymphocyte ratio (NLR), monocyte-to-lymphocyte ratio (MLR), and platelet-to-lymphocyte ratio (PLR) measured at antiretroviral therapy (ART) initiation have been shown to be predictive of mortality and the occurrence of serious non-AIDS (SNAE) and AIDS-defining events (ADE) but their role during ART remains poorly investigated.
This study assessed the association between current NLR, MLR and PLR levels with mortality and the occurrence of SNAE and ADE in PWH.
Methods: We conducted 3 separate matched case-control studies nested within the ICONA Foundation Study cohort. Cases were defined as PWH who died or experienced a SNAE or ADE and were matched for age and CD4+ cell count pre-ART initiation. ART initiation was considered the baseline.
In each matched set, the survival time of controls was censored at the time matching the date of death/SNAE/ADE of the case (index date). The association between the last NLR, MLR and PLR values before the index date and outcomes was assessed using univariable and multivariable conditional logistic regression models. Ratios were fitted as 3-way categorical variables (G1-G3) using the tertiles of the distributions in the samples.
Results: We included 539 (140 cases), 525 (124 cases), and 329 (109 cases) PWH for the three analyses of all-cause mortality, occurrence of SNAE, and ADE, respectively. In the analysis with the primary endpoint of death, median age was 48 (IQR 40-57) years, 22% females, current CD4+ count was 575 (387-846) cells/mm3, 93% with HIV-RNA < 50copies/mL, on ART for a median of 8.3 (5.0-16.8) years. G1-G3 for NLR, MLR and PLR were defined using the cut-offs: (1.4; 2.2), (0.2; 0.29), (88.8; 134.7), respectively. In the analyses of all-cause mortality and SNAE, the proportion of participants in the G3 was higher in cases than controls (45% vs 31%; p<0.001 for NLR and 48% vs 31% for MLR; p <0.001 respectively). After adjusting for confounding (Figure 1), NLR values G3 vs. G1 were still associated with a higher risk of both all-cause mortality [aOR= 3.14 (1.73, 5.68)] and the occurrence of SNAE [aOR= 1.74 (0.98, 3.08)]. In addition, still compared to G1, MLR values in G3 were associated with a higher risk of death/SNAE [aOR= 1.83 (1.06, 3.17) and 1.68 (0.95, 2.98), respectively]. No evidence of an association was observed for any of the ratios in the ADE analysis.
Conclusions: In our analysis, current higher levels of inflammation markers (namely NLR and MLR) were associated with a higher risk of all-cause mortality and SNAEs occurence. As these biomarkers are derived from routinely collected blood samples, they are promising prognostic tools for use in daily practice.

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Epidemiology

P 46 CHARACTERISTICS AND CLINICAL OUTCOMES OF INDIVIDUALS WITH HIV AND LATE DIAGNOSIS IN A HEALTHCARE SETTING IN EASTERN SICILY OVER THE PAST 15 YEARS

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Background: Late HIV diagnosis is defined as the initial detection of HIV when the patient's CD4 count is below 350 cells/μL, or when there is an AIDS-defining event, irrespective of the CD4 cell count. In 2023, the Italian Institute of Health (ISS) reported that 60% of new HIV diagnoses were late. Despite warnings about this issue, late diagnosis continues to be a public health concern, potentially affecting the survival and quality of life of individuals with HIV.
Materials and Methods: This study aimed to retrospectively analyze the impact of late HIV diagnosis at a single clinical center over the past 15 years. We reviewed data from 484 adults diagnosed between January 1, 2009, and December 31, 2023, including exclusively those whose clinical and immunological evaluations occurred within a month of their first positive HIV test. The analysis considered socio demographics, epidemiological, and clinical factors including sex, age, HIV infection risk factors, CDC stage, CD4+ T-cell count, HIV RNA levels at diagnosis, year of diagnosis, last follow-up, and survival. Late HIV diagnosis was defined as having a CD4 count <350 cells/μL at first detection of HIV infection, or experiencing an AIDS-defining event regardless of CD4 count.
Results: Globally, 386 individuals (79.7%) were male with a median age of 36 years (IQR 29-44). 422 (87.2%) were Caucasian, and 402 (83%) Italians. Among them, 287 (59.3%) were MSM, 185 (38.2%) heterosexuals, and 12 (2.4%) IVU. The median CD4+ T-cell count at diagnosis was 338 cells/μl (IQR 172-522), and HIV RNA was 4.98 log10 (IQR 4.4-5.5). 249 (51.4%) had a CD4+ T-cell count <350 cells/μl, and 138 (28.5%) <200 cells/μl. 75 (15.5%) were AIDS presenters, while 358 (73.9%) were asymptomatic. Finally 254 (52.5%) received their first HIV diagnosis late (PWHLD), 39 (8%) died. 344 (71%) had a follow-up visit in 2024, whereas 104 (21.5%) were lost to follow-up. Among migrants, 53.6% were lost to follow-up, most within 2 years from diagnosis (p<0.001).
Compared to PWH diagnosed with more than 350 CD4, PWHLD were older (p<0.001) with a median age of 40 (IQR 32-49) years, 22.8% of them were over 50 years old (p<0.001). Additionally, 44.9% were identified as heterosexual (p<0.001), while 47.6% were tested as symptomatic (p<0.001). Median CD4 cell count was 181 (IQR 68-263) cells/μl (p<0.001), median HIVRNA viremia log10 5.2 (IQR 4.77-5.73). 55 of them were lost to follow-up (51.8% were migrants). Furthermore, 35 individuals (13.8%) died during the follow-up period (p<0.001), with 17 (48.6%) of them dying within one year after a median survival of 61 (33-131) days.
Conclusions: Over fifty percent of patients in our setting were diagnosed late with HIV, leading to delayed treatment and a higher risk of death, often within the first year. Migrants, independently of time of diagnosis, are at high risk of being lost during follow-up. Implementing strategies for early HIV testing is essential to diagnose and treat infections promptly.

Epidemiology

P 47 CLINICAL CHARACTERISTICS AND MOLECULAR DYNAMICS OF DENGUE CASES OCCURRING IN LIGURIA IN 2024

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Background: Dengue virus (DENV) is a mosquito-borne RNA virus belonging to the Flaviviridae family causing dengue disease. The virus exists in 4 different serotypes, named DENV-1, DENV-2, DENV-3, DENV-4, displaying significant genetic diversity, categorized into well-defined groups known as genotypes. Different genotypes are often associated with varying disease severity, ranging from mild to severe outcomes. Typically, individuals infected with DENV are asymptomatic (80%) or have only mild clinical manifestations, such as uncomplicated fever. About 5% of patients go on to a more severe form of the disease, and only in a small proportion of them can dengue be life-threatening. While dengue is primarily associated with tropical regions, outbreaks in temperate areas are becoming increasingly common due to the spread of a competent vector.
Methods: This study investigates the clinical characteristics and molecular dynamics DENV strains isolated from 12 Dengue RNA positives samples detected by PCR in the laboratory of the U.O. Hygiene Unit of the San Martino Polyclinic Hospital in Genoa between January and September 2024. Serotypes were defined using a modified version of CDC DENV-1–4 Real Time RT-PCR Assay. All samples were amplified using distinct pool primer schemes for the 4 DENV serotypes and sequenced by NGS with the Illumina Miseq platform. NCBI BLASTn was used to perform multiple sequence alignments selecting an Identity Percentage from 99% to 98% in addition to Gisaid search. Phylogenetic trees were estimated using IQ-TREE v.1.6.12. Nexclade was used to assign genotypes.
Results: The descriptive analysis of the 12 positive patients studying was reported in Table 1.
Nine/12 (75%) were male and the median age was 39 years (IQR: 32.7-49). The nationality of the subjects was Italian for 75% of the cases. All subjects had travelled abroad. Regarding symptomatology, 100% of subjects developed fever, 75% arthromyalgia, 42% rash and 33% asthenia. Other symptoms such as nausea, cough, diarrhoea, and eye pain were observed in lower percentages. None of the study subjects had comorbidities. All serotypes were observed except for 4, the majority carried serotype 2 (66.7%). Genotypes were: 1V_E.1 (n=2) and 1V_D.1.2 (n=1), 2II_F.1.1 (n=7) and 2II_F.1.1.2 (n=1), 3III_B.3.2, for serotypes 1,2 and 3 respectively. Maximum likelihood analysis revealed a clear separation of genotypes into different subtypes. Italian strains clustered together with sequences isolated from countries of originating strains.
Conclusions: Our data confirmed the importation for studied cases from endemic areas. However in order to minimize the risk of importing the DENV into non-endemic areas, the continous monitoring of DENV is needed. It is crucial to implement effective measures to prevent both the introduction and the spread and importation of the viral infection during the period of high density and activity of Aedes mosquitoes such as summer months.

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Epidemiology

P 48 CLUSTER OF PRIMARY HIV INFECTIONS SUSTAINED BY CRF02_AG IN INTRAVENOUS DRUG USERS IN MILAN

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Background: An important share of HIV transmission events is sustained by undiagnosed individuals with primary infection, making early diagnosis and prompt treatment (ART) initiation critical; non-B subtypes have become established in Italy, contributing to epidemic diversity.
We describe a cluster of primary HIV infections sustained by CRF02_AG, occurring in intravenous drug users (IDUs) with ties to the Rogoredo area, one of the largest drug market hubs in Milan.
Materials and Methods: Retrospective monocentric observational analysis of CRF02_AG HIV-1 cases diagnosed at Policlinico, Milano 06/2023-12/2024. Baseline HIV-1 RNA NGS genotyping resistance tests processed through Stanford HIVdb, with NGS set at 20%. Consensus pol sequences were added to a final alignment of 157 CRF02_AG reference sequences (length 915 nt).
Subtype and transmission cluster were confirmed through Maximum Likelihood phylogeny based on the GTR+F +GAMMA model with 1000 replicates fast bootstrapping. Clusters were defined by intra-genetic distance ≤0.015 and bootstrap =100.
Results: Five unrelated individuals were admitted in our inpatient ward across 18 months due to injection site infection from heroin use, and diagnosed with primary HIV-1 infection (Fiebig 2/3 in three cases, Fiebig 5 in two cases).
Median age was 32y; 4 were male, 4 homeless, 2 foreign-born, 3 lost to follow up from distinct centers for drug addition, 4 had previously tested negative for HIV. All acknowledged a tie to the Rogoredo open-air drug market. Median HIV RNA load was 10^7. Median CD4 count was 360/mcL (24%). At GRT, all harbored CRF02_AG, with no drug resistance mutations. Three were HCV-positive, 2 newly diagnosed, 1 HCV RNA negative from previous treatment. All were started on ART while admitted, discharge to rehabilitation centers was possible for 2/6, and 5/6 were lost to follow-up in 2025.
By retrospective analysis of all new HIV-1 diagnoses posed at our unit between 06/2023 and 12/2024 (N=55), non-B subtypes accounted for 61.8% cases, and CRF02_AG alone for 21.8%. Both IDUs and primary infections were significantly more prevalent for CRF02_AG vs. other subtypes.
Phylogenetic analysis confirmed the transmission cluster, including all 5 primary HIV-1 infection cases, together with an IDU diagnosed in 2024, with Fiebig 6 infection. Genetic distance in the cluster was 0.0102 ± 0.0025 nt/substitution per site.
Conclusions: In line with reports of non-B clade increase in Italy, and limited effect of available harm reduction strategies, we observed a transmission cluster of CRF02_AG subtype HIV among IDUs in Milan with ties to the Rogoredo area, confirmed through phylogenetic analysis. Primary infection across the cluster allows for a snapshot of recent local dynamics, as estimated date of transmission lie within a limited timeframe. This aspect, along with missed opportunities for diagnosis, treatment and retention in care, calls for targeted public health interventions to reduce risk and prevent transmission.

Epidemiology

P 49 CO-CIRCULATION AND CO-INFECTION WITH DIFFERENT INFLUENZA VIRUSES IN THE 2024-2025 FLU SEASON

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Background: Surveillance of influenza (Flu) virus circulation is crucial for monitoring seasonal dynamics of the disease. In the regional reference laboratory of the Hygiene Unit of San Martino Hospital in Genoa, Italy, molecular diagnosis and Flu virus characterization is routinely performed. In the past years, out of the main 3 Flu virus strains currently present in epidemic form in the world (Flu A H1N1, Flu A H3N2, Flu B), the circulation of one single strain largely prevailed during pandemic outbursts in our country. Instead in the 2024-2025 Flu season a co-circulation of all 3 viruses was observed in similar proportions (Fig. 1). Moreover, routine tests detected the presence of a few Flu virus coinfections. Thus, an in-depth molecular approach was set up to better evaluate the cases.

Materials and Methods: Nasopharyngeal swabs were collected from patients presented to the hospital with flu-like illness, and tested using the routine diagnostic multiplex RT-PCR kit, which allows for Flu virus sub-typing. Four of the 6 samples in which a coinfection was detected, had suitable Cycle threshold values for NGS. Library preparation was performed using the Illumina Microbial Amplicon Prep-Influenza A/B kit (Illumina), sequenced on iSeq100 (Illumina) platform. FASTQ files were analyzed with DRAGEN Microbial Amplicon (Illumina) pipeline. Consensus sequences were evaluated on Nextclade website.

Results: During the 2024-2025 Flu season, 545 samples were found positive for one Flu virus (308 H3N2, 167 H1N1, 64 FluB), except for 6, in which 2 Flu viruses were detected.

Of these 6 co-infections (4/6 male, median age 82), 5 were H1N1-H3N2 co-infections while 1 was H1N1-Flu B. Symptoms were: fever (5), cough (3) and dyspnea (2); comorbidities were cardiovascular (5), endocrine (3), renal (2), cancer (1), HIV infection (1). All patients required hospitalization, resolved in 5 with discharge; 1 patient died. NGS confirmed all coinfections; however, in 2 cases, the sequences of the less abundant virus were only partially recovered due to its lower presence compared to the dominant strain. Nextclade analysis assigned to all H1N1 subclades C.1.9.3 and C.5.3.1, respectively for HA and NA; to H3N2, J.2 and B.4.2; and for B, C.5.1 and B.7 (Fig.2).

Conclusion: The presence of unprecedented co-infections in this season can be explained by the epidemiological context. In the 2022-2023 season, in fact, initially the H3N2 virus outburst strongly limited the circulation of other viruses, while later in the season a second separate B virus burst could be seen; in the 2023-2024 season the H1N1 virus dominated the entire Flu season. In these scenarios cocirculation of different viruses at the same time was very limited.

In contrast, in the 2024-2025 season we had the concomitant circulation in the population of all the 3 Flu viruses, thus making it possible that some individuals, likely among the most fragile, could be infected by two viruses at the same time.

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Epidemiology

P 50 CORRELATION OF SELF-TEST FOR HIV BOUGHT BY PHARMACIES AND REGIONAL INCIDENCE OF HIV IN ITALY: 2018-2023

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Background: HIV self-testing (HIVST) may serve as an additional strategy to increase the number of people tested for HIV, in particular among individuals currently unreached by services, thereby contributing to the achievement of the Continuum of Care (CoC) for HIV. Self-testing can help overcome barriers associated with conventional services, such as stigma, discrimination, and privacy. We evaluated the spread of self-tests purchased by Italian pharmacies, overall and by region, and its correlation with HIV incidence from 2018 to 2023.
Materials and Methods: For this study, we used 3 sources of information. IQVIA RID collected self-tests purchased by Italian pharmacies. New HIV diagnoses reported in Italy from 2018 to 2023, sourced from HIV surveillance system (ISS). Population data were extracted from the ISTAT website. The number of HIV self-tests purchased by pharmacies x100,000 (NHIVST) each year was computed as: (Amount of HIV self-tests purchased by pharmacies/resident population x100,000), overall and by region. To evaluate the correlation between HIV incidence x100,000 population and NHIVST across the Italian region by year, the Spearman correlation test was used. P-values <0.05 were considered statistically significant.
Results: A total of 250,082 self-tests were available through pharmacies in Italy from 2018 to 2023, 21.82% in 2019. NHIVST reached the greatest peak in 2019 (81.84x 100k people) and the lowest peak in 2020 with 51.23x100k people. By region, Lombardia recorded the highest NHIVST each year of the study period, with a maximum of 139.49 in 2019. The lowest NHIVST was observed through Basilicata from 2018 to 2020 and in 2022, with 15.63, 16.11, 13.56, and 12.38 NHIVST, respectively; through Calabria in 2021 and 2023, with 12.58 and 19.44 NHIVST, respectively. Except for Basilicata, Sicilia, and Toscana, NHIVST in the Italian regions peaked in 2019. A statistically significant positive correlation between HIV incidence x 100,000 and NHIVST was found in 2018 (p=0.000), 2019 (p=0.001), 2021 (p=0.002), and 2022 (p=0.004) (Figure 1).
Conclusions: Data on self-tests for HIV bought from pharmacies in recent years showed an increasing number of tests purchased in the first years (2018-2019), a subsequent decrease during the COVID-19 pandemic (2020-2021), partially recovered in the last two years considered (2022-2023), with higher amounts of HIV-tests available in those regions (namely Lombardia, Lazio, Emilia Romagna, Toscana and Piemonte) with a higher annual incidence of HIV in the population. However, given the heterogeneity of NHIVST among regions, the NHIVST available strongly correlates with annual HIV incidence. It could be relevant to investigate these findings further and explore the contribution of self-tests in discovering new HIV infections.
Project implemented with the technical and financial support of the Ministry of Health - General Directorate of Health Prevention" (ref 4023).

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Epidemiology

P 51 DRUG RESISTANCE MUTATIONS AMONG ART-NAÏVE INDIVIDUALS IN LECCO

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Background: Thanks to antiretroviral therapy (ART) people living with HIV (PLWH) can achieve viral suppression, thus preventing disease progression and transmission. However, the presence of drug resistance mutations (DRMs) may lead to viral failure and limit treatment options. DRMs may be acquired under treatment pressure, especially in case of suboptimal ART adherence. Nonetheless, transmitted DRMs may be present in ART-naive PLWH.
Material and methods: We evaluated the prevalence of DRMs in ART-naive genotypic resistance tests (GRT) of PLWH attending our infectious disease clinic in Lecco (Lombardy, Italy) as at December 2024. GRT were obtained from clinical charts review and were considered as ART-naive if performed before or within one month from ARV initiation. Stanford HIV DB summary tables (updated on 01/02/2023) were used to identify DRMs and classify them as major and minor. Mutations not listed in the tables were ignored.
Results: Among 790 PLWH attending the clinic, 251 subjects had an available ART-naive GRT. Median age at time of GRT was 41 years (interquartile range, IQR 34-50), 76,1% (N=191) were male. GRTs were performed from 2000 to 2024. GRT for reverse transcriptase was available in 238 subjects, for protease in 236 and for integrase in 29. Only 25% had an available subtype. Most prevalent subtype was subtype B (N=35, 57% among those with an available subtype), followed by F (N=6, 10%) and CRF02_AG (N=6, 10%). At least one DRM was present in 14,3% (N=36) of GRTs and 6,4% (N=16) had at least one major DRMs. In 2,8% (N=7) of GRTs were detected more than one DRMs, however only 1,2 % (N=3) revealed more than one major DRMs. Non nucleoside reverse transcriptase inhibitor (NNRTI) DRMs were detected in 8,8% (N=22), nucleoside reverse transcriptase inhibitor (NRTI) DRMs in 5,6% (N=14), protease inhibitors (PI) DRMs in 2,8% (N=251) (figure 1). Only one person had a DRM for integrase strand transfer inhibitor (INSTI). Overall, the most frequent major DRMs were K103N (N=6, 2,4%), M41L (N=4, 2%) and K70R (N=4, 1,6%). The most prevalent DRMs for NNRTI, NRTI and PI were K103N, M41L and Q58E, respectively (figure 2).
Conclusions: DRMs in ART-naive PLWH were relatively infrequent for PI and INSTI. NNRTI class was the most affected by transmitted DRMs, with K103N being the overall most frequent mutation.

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Epidemiology

P 52 EPIDEMIOLOGY OF ENTEROVIRUSES IN LIGURIA: ANALYSIS OF DATA FROM JANUARY 2024 TO FEBRUARY 2025

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Background: Enterovirus (EV), a member of the picornavirus family including polioviruses, coxsackieviruses, and echoviruses, commonly presents with flu-like symptoms affecting the respiratory and gastrointestinal systems. Severe manifestations, such as pleurodynia, encephalitis, and myocarditis, occur primarily in infants, children, and immunocompromised adults. Despite the clinical relevance, a standardized surveillance system for EV circulation is lacking in Europe. This study aims to describe the epidemiological trend of EVs in Liguria during 2024 and the first two months of 2025.

Materials and Methods: In the observation period, a total of 10675 nasopharyngeal swabs from individuals presenting with Influenza-like illness (ILI) symptoms were analyzed at the Hygiene Unit Laboratory of Policlinico San Martino Hospital in Genoa. Viral RNA extraction and RT-PCR were performed using the automated Seegene STARlet platform (Seegene Inc.) with amplification reagents from the Allplex™ Respiratory Panel 2 kit, achieving a turnaround time of approximately 4 hours. As a regional reference center for emerging pathogens, 18 positive EV samples collected randomly between August and November were typed by Sanger sequencing of the VP1 protein and analyzed with the Enterovirus Genotyping Tool Version 1.0.

Results: Of the 10675 samples collected from 7473 patients, EV positivity was detected in 132 individuals (1.76%). This numerical difference is due to continuous patient monitoring within hospital wards. Notably, only 9 positive cases were identified between January and July 2024, while the majority occurred between August and November, with peaks in September (38/128; 29.7%) and October (37/128; 28.9%). At the time of positivity, 32.6% of patients were in the emergency room, 15.9% in haematology, and 12.9% in nephrology. Patients' ages ranged from 23 to 102 years, with a median of 70.5 years (IQR 59.5–81.0), and 54.5% were female (72/132). All sequenced samples were identified as EV-D68, subtype A2.

Conclusions: This study underscores the necessity of integrating clinical and laboratory data on EV infections within respiratory surveillance systems for real-time monitoring of EV-D68, a strain associated with respiratory infections of varying severity, predominantly affecting adults. Effective surveillance systems are essential for timely outbreak detection, alerting public health authorities, and adapting public health strategies accordingly.

Epidemiology

P 53 EXPANDING HCV SCREENING IN HOSPITALIZED PATIENTS: PRELIMINARY DATA OF A SINGLE CENTRE EXPERIENCE IN MONZA, ITALY

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Background: World Health Organization targets for viral hepatitis elimination by 2030 include diagnosing 90% and curing 80% of people living with hepatitis C. Since 2015, direct-acting antivirals (DAAs) have offered a cure rate exceeding 95%, making early detection critical. In Italy, an estimated 1-2.2% of the population has been exposed to the virus, while 0.74-1.7% is currently infected. Moreover, a significant number of cases remains undetected, with up to 40% of individuals with HCV unaware of their infection.
The Italian Ministry of Health has introduced a nationwide HCV screening program for individuals born between 1969 and 1989. The Lombardy Region has adopted this initiative, offering free, voluntary screening in selected healthcare facilities. However, a large part of the population has yet to be tested. Here, we present the "Non solo Covid: Ospedale HCV Free" project, which expands systematic HCV screening to inpatients outside the national program's target age group. The initiative aims to enhance existing screening efforts in Lombardy by identifying undiagnosed cases among hospitalized patients.
Methods: Since February 2024, all inpatients in the department of Internal Medicine (Infectious Diseases, Internal Medicine, Geriatrics, Gastroenterology, Nephrology, Oncology) at IRCCS San Gerardo dei Tintori Hospital, outside of 1969-1989 cohort already covered by official regional screening, undergo routine HCV antibody testing upon admission. If the antibody test is positive, HCV RNA testing is automatically performed to confirm active chronic infection. If an infection is detected, eligible patients are referred for treatment.
Results: Out of 640 tests performed, 28 subjects (4%) tested positive for HCV antibodies, of those 9 had confirmed active chronic infection (HCV RNA detectable), corresponding to a rate of 1.4% (9/640). The mean (standard deviation) age of patients with chronic HCV infection was 87 (10) years. Patients with active HCV infection were detected in Geriatrics (n=5) and Medicine (n=4) wards.
Due to severe comorbidities and frailty, 4 patients (mean age 91 years) were excluded from treatment, 1 patient died during hospitalization and 1 was hold in follow-up for very low viremia.
Of the remaining three patients eligible for treatment, two are awaiting therapy initiation, while one discontinued treatment due to drug toxicity (jaundice).
Conclusion: The "Non solo Covid: Ospedale HCV Free" project demonstrates the feasibility of systematic inpatient screening for HCV beyond the existing national screening criteria. The findings highlight a significant prevalence of undiagnosed HCV infections among the older hospitalized patients. Addressing barriers to treatment in frail and elder population remains a challenge. Indeed, the exclusion of many patients from treatment due to their frailty raises questions about the cost-effectiveness of a widespread screening in this specific patient population.

Epidemiology

P 54 HIV INFECTION IN MIGRANTS FROM SUB-SAHARAN AFRICA IN THE NORTH EAST OF ITALY

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Background: In 2023, 36.9 % of new HIV diagnoses in Italy were among migrants, with 58% of those from Sub-Saharan Africa (SSA) being diagnosed late (CD4 count < 350 cells/mmc). Our region hosts a significant number of SSA immigrants, yet data specific to this population is limited.
Material and Methods: We conducted a retrospective analysis of sociodemographic, clinical and immunovirological data of adult migrant people living with HIV (MPLWH) from sub-Saharan Africa receiving care at 10 Italian Infectious Diseases Centers in the North East of Italy in 2020.
Bivariate analysis was performed to assess differences between groups. Univariate and multivariable logistic regression analyses were conducted to examine associations between socio-demographic and clinical variables concerning sex, risk of a low CD4 count (<350 cells/mmc), and detectable viremia (HIV RNA ≥ 20 copies/mL).
Results: We included 762 MPLWH (454 females, 308 males), coming from Nigeria (43.2%), and other 32 SSA states. No differences were found between males and females regarding country of birth, education and bureaucratic status. Females were younger than males at arrival in Italy (27.4 years old vs 30.8), and less employed than males (Table 1). The majority (629/670) of HIV infections were sexually transmitted through heterosexual contact, with 86.3% of women and 78.2% of men affected. Women were diagnosed at a younger age than men (30.7 vs 36.7 years old) and had a lower proportion of late diagnosis (70 vs 80%). 98.3% of patients were on antiretroviral therapy with no significant difference in regimens between genders. At last visit 55.4% of patients had HIV-RNA undetectable (< 20 copies/ml), 32.3% had low level viremia (20-199 copies/mL), and 12.3% had a virological failure (> 200 copies/mL) with no significant gender differences observed (Table 2).
Males had a higher prevalence of tuberculosis (14.9% vs 6.6%; p = 0.0002) and active hepatitis B (7.5% vs 6.4%; p = 0.023), while no significant differences were found for HCV and syphilis infection. Comorbidities were common (31.% hypertension, 23.0% dyslipidemia and 12.% diabetes mellitus) with no gender based differences.
In multivariable analysis a good immunological response (CD4 count > 350 cells/mmc at last visit) was associated with higher nadir CD4 count (> 200 cells/mmc) as expected (OR=0.32, p = 0.0009) and with dual therapy (OR=0.28, p = 0.004). Low level viremia and virological failure were associated with a fragile bureaucratic status (OR = 12.06, p = 0.038 in subjects with a short-term residence permit compared to those with Italian citizenship).
Conclusions: Late diagnoses among SSA MPLWH at our ID centers were prevalent, particularly among males, underscoring the urgent need for targeted HIV prevention and testing programs. Although over 98% received ART, only 55.4% achieved undetectable HIV-RNA levels. A stable bureaucratic status favours undetectability.

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Epidemiology

P 55 HIV TESTING IN ITALY: PRELIMINARY DATA FROM THREE PILOT REGIONS OF THE PRONTI STUDY, 2018 -2023

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Background: In 2021, UNAIDS proposed a new global strategy focused on addressing inequalities, aiming to reduce new HIV infections and AIDS-related deaths. The key three targets set in the strategy include reaching 95% of HIV diagnoses, ensuring at least 95% of people living with HIV receive treatment, and achieving undetectable viral status for 95% of individuals on treatment. This study presents preliminary results from the PRONTI study ("Number of Outpatient HIV Testing in Italy Project"), funded by the Italian Ministry of Health. The analysis is based on outpatient specialist data to assess the number of HIV tests performed in Italy and identify potential regional disparities. Data from three pilot regions Piedmont (North), Tuscany (Center), and Apulia (South) were reported.

Material and Methods: In this study, the code for identifying the first-level HIV screening test was determined according to the guidelines of the Italian Society of Clinical Microbiology, which recommend using a 4th-generation test that simultaneously detects HIV-1/2 antibodies and HIV-1 p24 antigen. Data on the number of HIV tests performed between 2018 and 2023 in residents aged 18 and older in each of the three regions were extracted from regional outpatient databases. The annual testing rate (number of tests per resident population) and the testing coverage rate (number of people tested per resident population) were calculated.

Results: Between 2018 and 2023, an average of 119,377.8 HIV tests/year were performed in Piedmont (annual testing rate - ATR 3.3%), 62,269.3 tests/year in Tuscany (ATR 1.9%) and 48,414.8 tests/year in Apulia (ATR 1.5%).
The average annual testing coverage rates were 2.4% in Piedmont, 1.6% in Tuscany and 1.2% in Apulia. A reduction in the coverage rate was observed in 2020 in Piedmont with a subsequent increase in the following years and a peak in 2023. A similar but less pronounced pattern was observed in Tuscany while data from Apulia were more stable over time (Figure 1).
An average of 1.2 tests per person tested per year was recorded across the three regions.

Conclusions: The study revealed a higher HIV testing rate in Piedmont compared to Tuscany and Apulia, both in the number of tests per resident population and the number of individuals tested per resident population. The decline in HIV testing coverage rate in 2020 in Piedmont is most probably associated with COVID-19 pandemic that affected more strongly north-Italian regions. The data presented in this study are preliminary, as a more comprehensive analysis will be conducted using data from all Italian regions and on second-tier tests, such as immunoblotting and HIV-RNA testing.
Understanding HIV testing is crucial for interpreting HIV trends, planning targeted prevention strategies and allocating adequate financial resources for HIV prevention.

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Epidemiology

P 56 INTERVENTIONS TO SUPPORT BREASTFEEDING AMONG MOTHERS LIVING WITH HIV: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Mother-to-child transmission (MTCT) of HIV remains a major public health challenge, particularly in low- and middle-income countries where breastfeeding is essential for infant survival. While antiretroviral therapy (ART) has significantly reduced transmission rates, adherence to exclusive breastfeeding and retention in care among mothers living with HIV remain suboptimal. Several interventions, including healthcare-based support, peer-led programs, nutritional counseling, and remote support strategies, have been proposed to enhance breastfeeding practices and improve maternal and infant health outcomes. However, the effectiveness of these interventions remains unclear.

Methods: We conducted a systematic review and meta-analysis following PRISMA guidelines to assess the impact of non-pharmacological interventions on breastfeeding practices among mothers living with HIV. A comprehensive search of PubMed, Embase, and the Cochrane Library (from inception to January 2025) identified randomized controlled trials (RCTs) evaluating psychosocial interventions, counseling, peer support, health education, and remote support strategies. The primary outcomes included exclusive breastfeeding rates, maternal and infant retention in care, and maternal viral suppression. Data extraction and quality assessment were conducted independently by two reviewers, with a third resolving discrepancies. A random-effects meta-analysis was performed to account for anticipated heterogeneity.

Results: Out of 360 screened studies, eight RCTs (n = 3,715 mothers) met the inclusion criteria. Studies were conducted in South Africa, Uganda, Kenya, and India, primarily in resource-limited settings. Healthcare support interventions showed no significant effect on maternal viral suppression (RR 1.21, 95% CI 1.00–1.47) or maternal-infant retention in care (RR 1.07, 95% CI 0.95–1.19). Peer support, nutritional interventions, and remote interventions similarly failed to demonstrate significant improvements in breastfeeding outcomes. However, integrated Mother and Child Health (MCH) support showed a positive impact on exclusive breastfeeding rates (RR 1.38, 95% CI 1.06–1.80), although the certainty of evidence was low due to the high risk of bias in the included trials.

Conclusion: Our findings suggest that single-component interventions, such as peer or healthcare support alone, may not be sufficient to improve breastfeeding outcomes among mothers living with HIV. Instead, multifaceted, integrated approaches that address medical, psychosocial, and structural barriers simultaneously may be more effective. Future research should focus on scalable, context-specific interventions that holistically support HIV-positive mothers and their infants, ensuring sustainable improvements in breastfeeding adherence and maternal-infant health outcomes.

Figure 1. Integrated Mother and Child Health (MCH) support compared to standard care in breastfeeding mothers living with HIV for exclusive breastfeeding.

Epidemiology

P 57 INVESTIGATION ON THE CONTINUUM OF CARE IN PEOPLE WHO INJECT DRUG IN ITALY: THE ITALIAN NGOS CONTRIBUTION

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Background: In Italy, there are few data on the Continuum of Care (CoC) for HIV in Key-Populations such as people who inject drugs (PWID) which often remain "invisible" in surveillance system. Aim of the study was to investigate the CoC for HIV in PWID in collaboration with Italian non-governmental organizations (NGOs) devoted to the fight against HIV/AIDS.

Materials and Methods: We conducted an on-site survey aimed at PWID during outreach unit/drop-in and other activities with the collaboration of NGOs interviewing PWID for asking about HIV testing, result of last HIV test and eventual ARV therapy with detectable/undetectable viremia. The survey was conducted for a period of 14 consecutive days within Nov-24/Jan-25. Descriptive statistics were performed as well as multivariate logistic regression to identify factors associated with referred HIV seropositivity.

Results: With the support of 21 NGOs, 278 PWID were contacted (80.6% M, 80.2% born in Italy; 54.7% ≥ 45 years; 15.5% Sex-Workers) (Figure 1) mainly in drop-In setting (51.8%) or by outreach unit (45.7%). About HIV testing history, 204 (73.4%) ever performed an HIV test, 53 (19.0%) reported never been tested for HIV (21, 7.6%, did not answered). As of 204 subjects tested for HIV, 147 (53.0%) declared to be HIV-negative: the last negative test for 102 (69.4%) was in 2023/24, but 18 (12.3%) were tested before 2020. 57 people (21%) declared to be HIV-positive, of which 49 (86%) on ART, while 7 (12%) not on therapy. Regarding those in treatment, 20/49 (40.8%) reported an undetectable viremia, while 13 (26.5%) a detectable one (N=16, 32.7%, didn't know or didn't respond) (See Figure 2). In the multivariable logistic analysis, factors significantly associated with referred HIV-positivity are to be female (aOR: 3.33, 95% CI 1.50-7.47, p=0.003) and increasing age (for those aged >60 vs 18-29 years: aOR: 10.7, 95% CI 2.38-61.2, p=0.004), while being also a sex-worker resulted to be 2.16-times more likely to be HIV-positive even if close to significance (p=0.077) (see Table 1).

Conclusions: Data reported highlighted a sub-optimal proportion of PWID tested (N=204, 73.4%, including 18 who referred to have performed a test more than 4 years ago) and among PLWH on ART (86%), also suggest problems in maintaining treatment (26.5% PWID on ART reporting a detectable viremia). To achieve the CoC objectives, it is essential to implement interventions that promote PWID empowerment and their active involvement. NGOs' work is able to promote health of often marginalized people such as PWID, given the more acceptable intervention of low threshold service, contributing to the feasibility of producing CoC estimates. We suggest to extend investigation in this setting, which in this setting could be extended and periodically replicated.

Project implemented with the technical and financial support of the Ministry of Health - General Directorate of Health Prevention" (ref 4023).

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Epidemiology

P 58 LOW ADHERENCE TO POST-EXPOSURE PROPHYLAXIS FOR HIV IN PEOPLE WHO UNDERWENT SEXUAL ASSAULT: IMPLEMENTATION OF A RE-CALL STRATEGY

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Background: Post-exposure prophylaxis (PEP) is an important measure to reduce risk of HIV transmission, but it is effective if properly completed. In our cohort study APE, we observed that people who started PEP after a sexual assault (SVS) had higher loss-to-follow up, likely due to multiple reasons including trauma and social determinants. We implemented a re-call strategy for this high-risk group to improve adherence to follow up.

Methods: Monocentric observational cohort study (APE) analyzing clinical and serologic data from consecutive infectious diseases (ID) consultations for PEP at IRCCS Policlinico, Milan, from 01/02/2023 to 31/01/2025 (24 months). Patients'evaluations were performed at STI center, a general ER and an ob-gyn ER. Patients not undergoing HIV testing at day-28 and not showing up at end-of-PEP visit were categorized as lost to follow up. A recall before end-of-PEP visit for people who received PEP for sexual assault (SVS) was performed starting 01/2025. Frequencies for categorical variables and medians with inter-quartile range [IQR] for continuous variables were used; Chi-squared, Fisher's exact and Mann-Whitney tests were used for categorical and continuous variables, respectively.

Results: A total of 467 patients received ID evaluation for non-occupational PEP that was started in 433/467 cases (92.7%) according to guidelines and specialist's opinion. Of them, 208/433 (48%) reported SVS and received additional antimicrobial prophylaxis and emergency contraception where indicated at ob-gyn ER. Their median age was 27 years [IQR 22-35], 184/208 (88.5%) were female and 74/208 (35.6%) were extra-UE citizens [Table 1].

Until 12/2024, 304/412 (73.8%) patients were adherent to follow up; all tested negative for HIV, HCV and T. pallidum-Ab at day-28. On the other hand, 108/412 (26.2%) patients were lost to follow up. Of them, 78/108 reported sexual assault, as opposed to 119/304 adherent patients ($p<0.00001$). Therefore, only 60.4% (119/197) of people receiving PEP for SVS adhered to follow up. [Figure 1]

From January 2025, a telephone recall was implemented before end-of-PEP visit for people who started PEP for SVS. At the moment, 15 recalls were performed with 5 resulting in no response and 10 successful contacts. Of those contacted, 8/10 (80%) respected follow up [Figure 2]; adherence to follow up after recall implementation rounds up to 10/15 (66%) at time of writing.

Conclusions: In our cohort, people reporting non-occupational exposure completed PEP and follow up in 73.8% cases. Sexual assault was associated to loss-to-follow, up with only 60% individuals of this group adhering to PEP follow up. A recall strategy was started for this high-risk group with promising preliminary results on improving adherence which encourages prosecution of this policy.

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Epidemiology

P 59 MEASLES OUTBREAK IN LIGURIA: MOLECULAR SURVEILLANCE AND TRANSMISSION DYNAMICS IN 2024 -2025

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Background: Measles is a highly contagious RNA virus (genus Morbillivirus, family Paramyxoviridae) causing a potentially severe disease. The WHO declared a global epidemiological alert in 2024 due to a resurgence of measles, with over 1,000 cases reported in Italy, reflecting a broader trend of increasing cases worldwide. This situation, worsened by declining vaccination coverage and failure to meet WHO targets, underscores the urgent need for enhanced surveillance and continuous monitoring.
Material and Methods: The Hygiene Laboratory of Policlinico San Martino Hospital in Genoa, a subnational MoRoNet network reference centre for Liguria, conducted molecular tests on urine samples from patients with suspected measles. Nucleic acid extraction was performed using the ELITe InGenius® system (ELITechGroup) and amplification with the Real-Cycler Chic-Out test (Progenie Molecular). Positive samples underwent Sanger sequencing of the N-450 region in the N gene's C-terminal part. Genotype identification was performed using the Nextclade v3.10.0 platform, and phylogenetic analysis was conducted using the Neighbour-Joining method, aiming to accurately identify transmission pathways.
Results: From February to October 2024, 35 measles cases were confirmed in Liguria (mean age: 31 years; 74% men). Most cases presented complications such as diarrhea, pneumonia, thrombocytopenia, or hepatitis, with 7 hospitalizations. Four cases were classified as imported based on travel history. Of the 35 patients, 32 were unvaccinated, while three had received a single dose of vaccine. Genotyping identified 29 samples as genotype D8 (99.9% sequence identity; 100% BLAST identity with strains isolated in Moscow, 2023). Six samples, including four imported cases and two epidemiologically related cases, were genotype B3 (99.7% BLAST identity with strains from Florida, 2016).
Between late February and mid-March 2025, 14 measles cases were confirmed in Savona, west Liguria; 12 were linked to hospital exposure. Patients were 64.3% men, with a mean age of 39 years (median 37; IQR 27.5-50). Eight patients were healthcare workers; 12 were unvaccinated (85.7%), one had a single vaccine dose (7.1%), and one had two doses. Genotyping, performed on the 11 samples received to date by the laboratory, revealed samples as genotype B3.
Conclusions: The 2025 outbreak, unlike the broader 2024 epidemic, was predominantly hospital-associated, affecting healthcare workers and their contacts, most of whom were unvaccinated. Molecular characterization and sequencing were essential for accurately identifying transmission routes, supporting epidemiological investigations, clarifying transmission dynamics, and effectively interrupting transmission chains. These findings emphasize the importance of molecular tools in measles outbreak management and highlight the need for targeted preventive measures in healthcare settings.
Figure 1

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Epidemiology

P 60 NEAR FULL-LENGTH SEQUENCING IS ABLE TO ENSURE A MORE ACCURATE HIV-1 SUBTYPING: COMPARISON WITH COMMONLY USED METHODS

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Background: HIV-1 is characterized by extensive genetic diversity due to various mechanisms driven by its evolution within an infected individual, thus leading to a broad viral heterogeneity. Tracking HIV-1 subtypes is crucial for disease surveillance. Next-generation sequencing (NGS) is gradually replacing Sanger for HIV genotypic drug resistance testing (GRT) for protease/reverse transcriptase (PR/RT) and/or integrase (IN) regions. To investigate phylogenetic accuracy of subtypes, NGS near full-length (NFL) sequences were used in comparison with NGS PR/RT and PR/RT/IN (pol), and with the performance of 4 commonly used automated subtyping tools.

Material and Methods: Thirteen plasma samples from people with HIV-1 (PWH) were initially sequenced by NGS with Ion AmpliSeq for the Ion GeneStudio S5 prime System (Thermo Fisher) for the pol resistance region (nt:2253–5250 in the HXB2 genome). The same samples were also sequenced with Ion AmpliSeq WGS HIV-1 custom panel (Thermo Fisher; nt:1–9719) to obtain NFL sequences. Phylogeny (phy) was performed with MEGAv11, using the most recently available HIV-1 reference sequences, by performing three different phylogenetic trees with PR/RT, pol and NFL sequences to determine subtypes. Then, PR/RT, pol and NFL sequences were submitted to COMETv2.4, REGAv3, Geno2Phenov3.5 (G2P) and Stanfordv.9.8 subtyping tools, and results were compared to phylogenies results.

Results: Table 1 shows results of phy and subtyping tools based on PR/RT, pol, and NFL sequences. In particular, the most concordant tool with PR/RT phy was Stanford (92.3%), followed by COMET, REGA, and G2P (all 61.5%); by using pol sequencing, Stanford remained the best performing tool (100%), followed by COMET, G2P (both 69.2%), and REGA (46.1%). A further increase in nucleotide lengths with NFL sequencing proved again Stanford as the most concordant tool (92.3%), followed by COMET (61.5%), and REGA (38.5%). G2P was not able to accept NFL sequences. Comparison of the three phy showed that three samples were reclassified as more complex subtype (sample 4: CRF02_AG to CRF06_cpx; sample 7: G to CRF02_AG; sample 13: F1 to CRF46_BF1). All pure subtypes were correctly identified by all the subtyping tools, except for REGA that mistakenly identified samples belonging to A6 as sub-subtype A1.

Conclusions: Phy remains the gold standard method for an accurate HIV-1 subtyping. In case phy cannot be used in routine practice due to its complexity, online subtyping tools can be a valid option for the subtype characterization. Outputs of different tools are usually in disagreement, because their algorithms are not regularly updated. Nevertheless, Stanford appears more reliable for rapid subtyping of both pure and recombinant strains. This work highlights as the increased nucleotide sequence lengths are directly correlated with more consistent subtype classification, which could be fundamental to understand genetic diversity and identify new recombinant forms.

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Epidemiology

P 61 OCCUPATIONAL AND SEXUAL EXPOSURES: ANALYSIS OF POST-EXPOSURE PROPHYLAXIS (PEP) PRESCRIPTION AND SURVEILLANCE PROGRAM IN A LARGE HOSPITAL, NORTHERN ITALY

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Background: Occupational and sexual exposure to sources that may transmit bloodborne pathogens define a challenge for public health. PEP is a key strategy to prevent the risk of HIV transmission after percutaneous or mucocutaneous blood exposure. However, it has been associated with insufficient compliance and difficulty in proper prescription. This study aims to evaluate the management of biological risk exposures, comparing PEP prescription and adherence to the surveillance program among occupational and sexual exposure to identify critical issues.
Methods: A retrospective monocentric study has been conducted at the ASST Spedali Civili General Hospital of Brescia, gathering data about occupational and sexual exposures from the post-exposure surveillance program at the Infectious Diseases Unit between 01/01/2022 and 31/12/2024. Collected data included demographic information, details about exposure, PEP prescription, and adhesion to surveillance protocol. We compared the two groups through chi-squared tests.
Results: The study population included 688 subjects who were evaluated in our clinic because of accidental or occupational exposure (OE) (203 in 2022, 244 in 2023, and 260 in 2024) and 273 subjects evaluated for sexual exposure (SE) (72 in 2022, 102 in 2023, and 109 in 2024). In OE females were 488 (70.1%) and the mean age was 38.8 (SD 14.2) years, while in SE we observed 94 (34.3%) females and a mean age of 34.0 (SD 13.6) years. Subjects got to clinical evaluation more than 72 hours after the exposure in 16 (2.3%) OE, while it was more frequent in SE (48, 16.9% with p-value<0.001). Surveillance was activated in 548 (79.7%) cases of OE vs 243 (86.6%) of SE (p-value 0.297), while it was more frequently considered unnecessary in OE (137, 20.0%) vs SE (7, 3.1% with p-value<0.001). PEP was prescribed in 179 (26.0%) OE and 191 (67.5%) SE (p-value<0.001). It resulted in an overprescription in 7 (1.0%) OE and 27 (9.9%) SE (p-value<0.001), while it was underprescribed in 10 (1.5%) OE and 6 (2.2%) SE (p-value 0.59). Considering the PEP prescribed, the planned medication pickups were not completed in 25 (3.6%) OE and 52 (19.0%) SE (p-value 0.0026). The surveillance was interrupted by the patients in 69 (10.0%) OE, way lower than SE (126, 45.9% with p-value<0.001). It was interrupted after assessing the negativity of the source in 460 (66.9%) OE, but only in 13 (4.6%) SE (p-value<0.001).
Conclusions: Our study highlights an increasing rate of occupational and sexual risk exposures. Moreover, it clarifies the differences between occupational and sexual exposures, in terms of patterns in access, prescription, and adherence to PEP and surveillance programs. Our data underline the strong need to implement strategies to improve the adherence to surveillance programs after the first evaluation.

Epidemiology

P 62 PREVALENCE AND INCIDENCE TRENDS OF AIDS EVENTS IN PEOPLE NEWLY DIAGNOSED WITH HIV INFECTION BEFORE AND AFTER COVID-19 PANDEMIC: EXPERIENCE FROM THE PISAN COHORT

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Background: Monitoring trends in prevalence and incidence of new AIDS diagnosis is important for targeted public health approaches, as well to assess individual patients' risks. According to official data from Italian National Institute of Health, new AIDS diagnosis have constantly declined since early 2000s, with a sharper decrease between 2019 and 2020, followed by a progressive increase in more recent years. We assessed trends of AIDS events in the cohort of people diagnosed with HIV infection in the University Hospital of Cisanello, Pisa, from 2019 to 2024.

Material and Methods: Trends in the yearly prevalence of AIDS diagnosis in newly diagnosed HIV infections (baseline) were assessed by joinpoint regression using Joinpoint Regression Program 4.9.1.0. A joinpoint represents the time point when a significant trend change is detected. Time changes are expressed in terms of Expected Annual Percent Change (EAPC). Incidence rate (and 95% confidence interval) of new AIDS events after HIV diagnosis was then calculated, and predictors of new events were assessed through Poisson regression, by including variables associated with the outcome at univariable analysis (at a p-value of ≤0.05).

Results: One hundred and forty-six participants were diagnosed with HIV between 2019 and 2024 (30, 20.6% in 2019; 22, 15.1% in 2020; 28, 19.2% in 2021; 24, 16.4% in 2022; 21, 14.4% in both 2023 and 2024). Most participants were Caucasian males (119, 81.5%), with a median age of 42 years. Being MSM was the most common risk factor for HIV acquisition (63, 43.2%). At diagnosis, CD4 count and HIV-RNA were 236 cells/μL and 5.31 log10 cp/ml, respectively. No difference in population characteristics at diagnosis was found before and after 2020 (see table 1).

Forty-one (28.1%) people had at least one AIDS-defining event at diagnosis, mainly represented by: Pneumocystis pneumonia (19/41, 46.3%), CMV disease (16/41, 39.0%) and Kaposi's sarcoma (11/41, 26.8%). Joinpoint regression identified an EAPC of -69.8% between 2019 and 2020, and a subsequent increase in EAPC of 9.3% between 2020 and 2024, even if the model selection (null hypothesis of 0 joinpoint versus alternate hypothesis of 1 joinpoint) did not reach statistical significance (p=0.065).

Only 6 persons presented a new AIDS events during follow-up, with an incidence of 1.3 new events per 1000 person-years follow-up (95%CI 0.6-2.9), all of which occurring from 2022 to 2024. Baseline CD4 count (per 100 cells/μL, IRR 0.25; 95% CI 0.09-0.69; p=0.007) and the count of previous AIDS events (per one event more, IRR 1.71; 95% CI 1.20-2.45; p=0.003) predicted the onset of a new AIDS event, after adjusting for gender and baseline viral load.

Conclusions: An increasing prevalence of AIDS events at HIV diagnosis in the period 2020-2024 after a sharp drop between 2019 and 2020 could not be demonstrated. Overall, new AIDS events were rare after HIV diagnosis and mainly occurred in people with more advanced disease at baseline.

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Epidemiology

P 63 RESPIRATORY PATHOGEN PROFILE AND ITS ASSOCIATION WITH HOSPITALIZATION RISK IN PAEDIATRIC PATIENTS WITH ACUTE RESPIRATORY INFECTION (ARI): INPATIENT AND OUTPATIENT COMPARISON

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Background: This study aims to evaluate the types and prevalence of pathogens associated with acute respiratory infection (ARI) and their association with Hospitalization Risk in Paediatric Patients attending the emergency department of Bambino Gesù Children's Hospital in Rome.
Materials and Methods: A retrospective analysis on paediatric patients with ARI admitted to the Emergency Department, who had positive respiratory samples screened with the BioFire FilmArray Respiratory 2.1 panel (BioMérieux) between January 1, 2024, and November 30, 2024, was conducted.
Results: A total of 1,008 samples were collected; 568 (56.3%) from patients who did not require hospitalization, and 440 (43.7%) from those who required. Hospitalized patients were younger than non-hospitalized (0.22 [0.11-1.14] vs 1.16 [0.24-4.80] years, p<0.001), and had higher rate of lower respiratory tract infection (64.1% vs. 26.6%, p<0.001). The analysis of pathogen detection revealed a trend towards higher mono-detection in non-hospitalized patients compared to hospitalized patients (77.5% vs. 72.7%, p:0.09). Adenovirus, Influenza A, Influenza B, Parainfluenza virus 1, and Mycoplasma pneumoniae were more common in non-hospitalized patients (p<0.005), while Metapneumovirus, respiratory syncytial virus (RSV), and Bordetella pertussis were more frequent in hospitalized patients (p<0.005). The distribution of only viral and only atypical bacterial infections was similar between the two groups, but hospitalized patients had a slightly higher frequency of mixed infections (virus+atypical bacteria; 3.3% vs. 6.1%, p:0.047). Considering clinical manifestation, pneumonia in hospitalized patients was mainly associated with only viral infections (38.5% vs 76.7%, p:0.006), while non-hospitalized pneumonia patients were more likely to have infections with atypical bacteria, particularly M. pneumoniae (61.5% vs 13.3%,p<0.001). A similar trend was seen in bronchiolitis, with RSV being the predominant viral infection in hospitalized patients (18.8% vs 48.1%, p<0.001). Logistic regression analysis showed that neonates (adjusted odds ratio, AOR [95%CI]: 7.27 [2.39-22.11], p<0.001), infant (1.64 [1.01-2.66], p:0.044), respiratory failure (14.99 [1.96-114.59], p:0.009), mixed infection (2.62 [1.05-6.58], p:0.039) and RSV (2.57 [1.46-4.52], p:0.001) were positively associated with hospitalization, while a negative association was observed with M. pneumoniae (0.17 [0.06-0.0.50], p:0.001).
Conclusions: This study revealed significant differences in the respiratory pathogens distribution between hospitalized and non-hospitalized paediatric patients. These findings highlight the complex relationship between pathogens and clinical outcomes and provide insights to improve strategies for the diagnosis, treatment and management of paediatric respiratory infections, particularly in the hospital setting.

Epidemiology

P 64 TESTING FOR HIV AND OTHER SEXUAL TRANSMITTED DISEASES OFFERED IN THE CONTEXT OF COMMUNITY BASED VOLUNTARY COUNSELLING AND TESTING SERVICES IN THE LAST YEARS IN ITALY (2019-2023)

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Background and Objectives: In the recent years, a profound re-organization of Community Based Voluntary Counseling and Testing (CBVCT) activities took place as a response to the rearrangement healthcare settings during the COVID-19 pandemic period. Our aim was to assess Counselling and Testing (CT) activities offered in non-healthcare setting in the last years (2019-2023) in terms of tests offered for HIV and other sexual transmitted diseases (STD, namely HCV and Syphilis), number of active centers and their geographical distribution.
Materials 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 and/or other STDs was collected, in terms of number of accesses to CT for HIV or other STDs, the number of HIV rapid tests performed and proportion of reactive results, as well as the percentage of subjects with a reactive result linked to a clinical center.
Results: Sixty-seven organizations from all over Italy participated to the survey, 59 (88.1%) offering testing for HIV and other STDs within the period of consideration. Overall, 56629 tests for HIV were performed during the investigated period, starting from 10k tests performed in 2019, almost doubling in 2023 (18.6k tests performed), with a relevant reduction in 2020 (4.8k tests) and in 2021 (8.6k) due to COVID-19 restrictions. (see Table 1 and Figure 1). In the same period 25k and 35k test for HCV and Syphilis were performed, showing a similar trend during the period. Overall, the percentage of reactivity for HIV, HCV and Syphilis was 0.45%, 1.49% and 2.04% respectively (cases substantially all linked to a clinical center for confirmation tests and therapy).
Figure 1 shows the number of tests and organizations active in HIV, HCV e Syphilis testing, where is evident that during the period the number of tests performed more importantly the number of active organizations increased sensitively in all Italian areas considered.
Conclusions: Even if the COVID-19 pandemic has determined an early negative impact on CBVCT activities, a gradual growth was observed in the number of Associations that resumed testing activity, as well as in the number of monthly tests offered, exceeding, in the first months of 2022, pre-pandemic levels and doubling them in 2023.
Project supported and financed by Italian Ministry of Health: CCM (ref 4393) and General Direction for Health prevention (ref 4023).

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Hepatitis and Liver Diseases

P 65 A MODEL OF SCREENING AND CASCADE OF CARE FOR CHRONIC VIRAL HEPATITIS IN ASYLUM SEEKERS AND REFUGEES IN ROME

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Background: Viral hepatitis B (HBV) and C (HCV) are a global public health challenge and a leading cause of morbidity and mortality worldwide.Migrants from endemic countries are a high-risk population for hepatitis, although they face healthcare barriers to vaccination,testing and treatment.Screening and access to dedicated healthcare programs for viral hepatitis is a priority in migrants arriving in low-prevalence(high income)countries.The aims of the study were to estimate the prevalence of HBV and HCV infection and the rates of linkage and retention in care in asylum seekers(AS)and refugees in Rome.

Material and Methods: The study is a single-center retrospective study that systematically included AS and refugees hosted in extraordinary and ordinary reception centers located in Rome.A multi-diseases screening programme was implemented at the National Institute of Infectious Diseases “Lazzaro Spallanzani”, which included the screening for viral hepatitis through testing for hepatitis B surface antigen (HBsAg), anti-hepatitis B core (HBcAb) and surface (HBsAb) antibodies and anti-HCV antibodies (HCV-Ab).Subjects who tested positive for HBsAg or HCVAb were referred to the hepatology unit according to complete disease staging and starting treatment when indicated.The observation period was 1 year (February 2024 - January 2025). A descriptive analysis was performed, percentages and medians(interquartile ranges)were used for categorial and continuous variables, respectively.

Results: During the study period 247 AS and refugees were screened for viral hepatitis.The median age was 28 years [IQR 24-35] and most of them were male (89%). According to the WHO region of birth, most participants originated from the East Mediterranean Region (39.7%, EMR), followed by the South-east Asia Region (33.6%, SEA) and the African Region (26.7%, AFR).The median time from arrival in Italy to access in the programme was 4 months [IQR 0.9-8]. Overall,the prevalence of HCV-Ab was 0.4% and the prevalence of HBsAg was 4.9%.The prevalence of HBsAg was higher in people from AFR (13.8%) compared to those coming from SEA (2.06%) and EMR (1.02%).The linkage to care (individuals who attended the first hepatologic visit) was 76.9% and the retention in care (individuals who had at least 6 months follow-up) was 90%. All HBsAg positive subjects tested negative for hepatitis delta virus antibodies (HDV-Ab).The rate of participants without evidence of immunity against HBV was 59%. Vaccine or infection-induced immunity against HBV was found in 37.7% of subjects,while 2.3% tested isolated anti-HBc positive (Table).

Conclusions: The study confirms the high prevalence of HBV infection in AS and refugees,mainly in those coming from the African region, and the low prevalence of HCV infection.The study highlights the high rate of migrants who could benefit from HBV vaccination and emphasize the key role of new programmes of screening and cascade of care in order to achieve the WHO elimination target for viral hepatitis.

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P 66 BULEVIRTIDE TREATMENT IN PEOPLE LIVING WITH HIV/HBV/HDV COINFECTION

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Introduction: HDV is a small RNA defective virus that needs HBsAg for its propagation (HBV/HDV coinfection). HDV causes the most severe form of chronic viral hepatitis and its complications such as cirrhosis and HCC are higher in people living with HIV (PLWH). Bulevirtide (BLV) is a novel treatment, an entry inhibitor that targets NTCP and inhibits intrahepatic viral spreading. It's approved by EMA in 2020-2023.

Study Design: We analyzed retrospective data from 4 patients with HIV/HBV/HDV coinfection treated with BLV 2mg/die sc injection up to 48 weeks in HIV Outpatient Clinic of Infectious Diseases Unit of IRCCS Policlinico San Matteo, Pavia. (Table 1). All patients were on antiretroviral therapy with anti HBV activity and coincidental HBV suppression. Treatment safety and tolerability, virological and biochemical response, and HIV-RNA and CD4 count were assessed during the treatment.

Results: In three patients ALT rapidly decreased until normalization. (Figure 1) On the contrary HDV-RNA slowly decreased. In particular, in one of the four patients analyzed, HDV-RNA was undetectable after week 48 (Figure 2). HIV-RNA remained undetectable with no changes in CD4 count. No drug interaction with antiretroviral therapy were observed and no liver-related events were reported. Biliary acids were elevated in all patients asymptomatic as expected following blockade of the HBV/HDV receptor sodium taurocholate co-transporter polypeptide (NTCP), preventing HBV/HDV entry into hepatocytes.

Conclusions: According to this case series BLV monotherapy as long term suppressive therapy appears to be safe, effective and well tolerated in PLWH. Biochemical and virological response were observed in all patients.

Without prejudice to the indications of real-life clinical trials on HBV/HDV coinfected patients which show that the continuation of treatment still guarantees a functional hepatic benefit in at least 75% of patients, without however giving precise indications in which specific type, the availability of new data to indicate the stopping-rules of therapy and in particular specific studies and longer follow-up to analyze if this kind of therapy works in HIV/HBV/HDV coinfected patients.

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Hepatitis and Liver Diseases

P 67 CHARACTERIZATION OF A COHORT OF LIVER TRANSPLANT PATIENTS FOR HBV AND/OR HBV/HDV RELATED COMPLICATIONS: RESULTS OF A CAMPANIA MULTICENTER STUDY

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Introduction: Liver transplantation is a life-saving treatment option for patients with complications related to HBV and/or HBV/HDV-related liver disease.
Methods: A multicenter retrospective study was conducted including 5 infectious disease or hepatology units in Campania. Patients receiving liver transplants for HBV and/or HBV/HDV-related complications were enrolled in post-transplant follow-up from 1 to a maximum of 20 years. The characteristics of patients with monoinfection were compared with those of HBV/HDV coinfected patients.
Results: We enrolled 257 patients, 162 of whom had confirmed HBV/HDV coinfection. Patients were predominantly male (75.5%), with a median age of 55 years, of whom 10.3% were HCVAb positive and 0% HIVAb positive; the median years of liver transplantation was 7 years. 59.9% of patients had a diagnosis of HCC at the time of transplantation. The comparison between the subjects transplanted for HBV and HBV/HDV did not show statistically significant epidemiological and demographic differences (table 1). During follow-up, 32.7% of patients had a clinical event: 7.4% liver-related and 28.0% not liver-related. Renal failure and cancer were the most frequent new-onset clinical events, with similar incidence between HBV patients and those with HBV/HDV coinfection (table 2). Patients in whom an adverse clinical event occurred were mostly men (77.4%, n.s.) (table 3). Only 12.1% of patients died during follow-up and 3.5% of them died because of an hepatic event (table 2). Comparing the characteristics (Table 4): most of them were men (96.8% vs 72.2%; p = 0.002), they had been transplanted for shorter (4 years vs 7; p = 0.006), 51.6% of them were HDV coinfected (51.6%vs64.6%;p=0.160).
Conclusions: our study highlights a good outcome during follow-up and does not show different clinical evolution between liver transplant patients for HBV monoinfection and HBV/HDV coinfection.

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Hepatitis and Liver Diseases

P 68 CLINICAL AND INSTRUMENTAL CHANGES OF LIVER FUNCTION AFTER ONE YEAR OF BULEVIRTIDE TREATMENT IN CHRONIC HEPATITIS DELTA WITH ADVANCED HEPATIC DISEASE: INSIGHT FROM A MONOCENTRIC COHORT STUDY

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Background: Hepatitis delta virus (HDV) leads to a severe and rapidly progressing form of hepatitis with high risk of liver cirrhosis, decompensation and hepatocellular carcinoma (HCC). This study evaluates clinical and instrumental outcomes of patients with HDV receiving bulevirtide (BLV) 2mg/die, after 12 months of treatment, with a focus on liver function, fibrosis progression, and cirrhosis-related parameters.

Methods: We analyzed clinical and laboratory data from HDV patients followed at our clinic with moderate-advanced liver disease, defined as a Child Pugh score (CPS) of at least 6 or a MELD score higher than 9, who started BLV between June 2022 and December 2023. Baseline data were collected prior to treatment initiation and compared to data collected after 12 months of therapy, with a focus on liver function, fibrosis progression (measured by elastography with FibroScan®), and cirrhosis-related parameters.

Results: Six patients were included, the mean age was 57 years and 50% were male. 50% were HIV coinfected, with a stable immune-virological control. At baseline all presented with advanced liver fibrosis (F4), with a mean stiffness of 16.4 kPa. Notably, 2 patients had previous episodes of decompensated ascites, with undergoing diuretic therapy, and two of them presented esophageal/gastric varices (with a F1 RCS grade). Liver function markers showed mild improvement, with albumin median levels increasing (from 39,1 to 39,8 g/L) and bilirubin and liver enzymes stabilizing (ALT values from 141,3 to 60,8 U/L). The mean MELD score decreased slightly from 12.8 to 10.7, and the CPS improved in four out of six patients.

Ascites remained stable and two patients showed a decrease in the presence of esophageal varices. Notably, there were no HCC cases. A virological response was observed in five out of six patients, with a combined biochemical response of 80% and two patients with HDV RNA under the limit of detectability.

Conclusions: One-year treatment with bulevirtide in HDV-infected patients demonstrated a favorable trend in liver function, with improvements in liver stiffness and liver enzymes. While cirrhosis-related parameters such as ascites and portal hypertension remained largely stable, the reduction in liver stiffness and HDV RNA suggests potential long-term benefits. Further studies with larger cohorts and extended follow-up are needed to confirm these findings and determine the long-term impact of bulevirtide on liver disease progression in HDV patients.

Hepatitis and Liver Diseases

P 69 CLINICAL AND VIROLOGICAL FEATURES OF CHRONIC HBV INFECTED PATIENTS WITH GENOTYPE E

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Background: Hepatitis B virus (HBV) genotype E is the predominant strain in sub-Saharan Africa, accounting for 97% of regional and 17.6% of global HBV infections. Despite its prevalence, its clinical impact and response to antiviral therapy remain under-researched. This study investigates its virological, mutational, and clinical characteristics, as well as treatment responses and phylogenetic relationships in our cohort.
Methods: This monocentric retrospective study was conducted at ASST Spedali Civili di Brescia, Italy (2015- 2023), including all HBV genotype E infected patients who underwent genotypic resistance testing. HBV viral loads were quantified using the COBAS HBV assay. Genotyping and molecular characterization were performed by direct sequencing of the S/POL region, and resistance-associated and immune escape mutations were analyzed using Geno2pheno [hbv] 2.0 and Stanford HBV resistance tools.
Results: Among 102 HBV-infected patients, eight (7.8%) were identified as genotype E. Most were male (62.5%) and of African origin (87.5%), with a median age of 38.5 years. Sexual transmission was identified in 37.5% of cases. No co-infections with HCV or HDV, cirrhosis or hepatocellular carcinoma were detected. Chronic HBV infection was observed in 75% of patients, with one case of active hepatitis and one case of occult HBV infection. Genotypic resistance testing (GRT) was performed due to persistent viremia despite antiviral treatment, with five cases occurring in HIV/HBV coinfected individuals with detectable HIV-RNA and immune compromission. Lamivudine resistance mutations (L180M, M204V) were found in one patient with prolonged exposure, tenofovir resistance-associated mutations (M267L/I) in two patients. Mutations in the HBV surface region were found in three cases (37.5%), with one showing three immune escape mutations (T126I, D144E, G145R). Additional immune escape variants spanned the major hydrophilic region (MHR), including P105R, I110L, T115N, and E164D/G. Following GRT, 50% of patients maintained their initial treatment due to suboptimal adherence and absence of resistance mutations, while the remaining patients modified their therapy, leading to viral suppression in 37.5% of cases. However, 50% continued to experience persistent viremia, and one patient was lost to follow-up (Table 1).
Conclusions: The presence of HBV genotype E in Italy highlights the need for targeted screening programs, especially among migrants from endemic regions. While nucleos(t)ide analogs are effective, low adherence remains a major barrier to viral suppression, increasing the risk of persistent viremia and resistance mutations. Strengthening adherence monitoring and targeted screening is essential for improving disease management.

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P 70 COMPARATIVE INVESTIGATION ON THE IMPLEMENTATION OF THE NATIONAL SCREENING PROGRAM FOR HCV IN ITALIAN REGIONS

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Background: Viral hepatitis represent an important public health issue. In recent years, hepatitis C has become a curable disease, so much so that the WHO has defined a strategic line aimed at its elimination.
In 2020 in Italy a dedicated fund for free HCV screening was established; however, in 2023, few Regions had outlined the actions to be implemented, as well as very different the strategies used.
Due to the strong diversification between the Italian regions, the Association decided to create a platform completely dedicated to HCV screening.
Material and Methods: The goal was to create a portal that would be an encouragement to export, imitate, replicate and incentivize any activity aimed at eliminating HCV, to create a sort of “healthy competition” between the Regions.
To achieve these objectives, we have carried out a rational and in-depth research phase to identify all the regional documentation relating to the implementation of national screening.
We also directly contact the Regional Health Departments, to request any documentation relating to screening activities, analyzed data released by the Regions themselves and/or illustrated in public events.
Subsequently, we analyzed the documentation to extrapolate all the most relevant and useful information for citizens.
Finally, we carried out a comparative analysis, published on the portal in different specific sections.
Results: We created a portal dedicated to HCV screening, with the dual purpose of: 1)providing all citizens with precise indications and information, Region by Region; 2)developing a platform in which we can highlight strategies, procedures and model organizations, such as virtuous examples, compare the different strategies and monitor the progress of the activities.
All the information developed was widely disseminated through all the Association's communication channels (websites, social media - more than 6.000 people reached - forums, newsletters, magazine) and shared with the Regions and the main stakeholders, in order to offer interesting ideas to decision makers.
Conclusions: We have created a sort of comparative summary of the “state of the art” regarding HCV screening, which aims to be not only informative but above all a spur for a “healthy competition” between the Regions, showing which are “on-track”, which not, which have implemented effective activities, programs and actions, which are still struggling, with the obvious aim of further stimulating the Institutions to take action to carry out screening actions for hepatitis C in the most effective way possible.
The portal is and will be constantly updated with all the initiatives that are launched or identified over time, all the useful information and all the available and retrievable data relating to the progress of screening activities.
Thanks to an unconditional Community Grant by Gilead Sciences (Community Award 2021 e 2023).

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P 71 EVALUATING INTEGRATED HEALTHCARE PATHWAYS FOR HCV ELIMINATION: A PILOT STUDY FROM A LARGE ITALIAN REGION

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Background: Despite effective treatments, Hepatitis C virus (HCV) remains a significant global public health issue. Achieving WHO's elimination goals requires optimized and integrated healthcare pathways. This study aimed to design, implement, and evaluate a structured, patient-centred care pathway for HCV within the Tuscany Region, Italy, using key performance indicators (KPIs) aligned with WHO guidelines. To the best of our knowledge, there are few examples of care pathways designed for communicable diseases in the literature, and none of them are for hepatitis. Therefore, our work aims to develop a methodology to measure and evaluate the care pathway for hepatitis based on a pilot study conducted in the Tuscany region.

Methods: The study adopted a multi-stage design, combining administrative data linkage and patient-reported measures. Fifteen KPIs were selected and categorized across four care pathway dimensions: prevention, linkage to care, treatment, and outcomes. These indicators were developed from WHO recommendations and literature reviews and validated through expert consultations. Administrative healthcare databases were linked using anonymized patient identifiers. Concurrently, patient-reported experience (PREMs) and outcome measures (PROMs) were collected through longitudinal surveys administered at baseline, three months, and one-year post-treatment initiation. Performance visualization utilized a stave graph method, accurately identifying areas requiring intervention.

Results: Significant variability across pathway dimensions was identified. Despite the regional variation, prevention metrics indicated reduced screening services provision, with population screening coverage declining across Tuscany. Linkage to care indicators highlighted disparities, with increasing delays in treatment initiation despite good general access to specialist services. Treatment adherence remained relatively high, though the proportion of patients receiving antiviral prescriptions declined. PROMs demonstrated improved patient health perceptions post-treatment, yet regional disparities persisted. Enhanced communication with specialists correlated strongly with higher patient satisfaction and better outcomes.

Conclusions: The structured, KPI-driven care pathway provided actionable insights, facilitating targeted interventions to improve patient-centred care. This approach underscores the importance of comprehensive monitoring and patient involvement, contributing meaningfully toward regional and global hepatitis C elimination targets.

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P 72 EXPERIENCE FROM A SINGLE CENTRE ON HBV SEROCONVERSION IN PEOPLE LIVING WITH HIV AND HBV: THE RELEVANCE OF INDIVIDUAL CLINICAL HISTORY AND CAREFUL MONITORING OF VIRAL MARKERS

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Background: In PLWH with chronic HBV coinfection (HIV/HBV), tenofovir-containing cART represents the standard of care. Serum HBV RNA is an emerging biomarker reflecting the activity of intrahepatic HBV reservoir.
The aim of the study was to describe HBV seroconversion (HBV-S) rate in HIV/HBV subjects under HBV-active cART attending Modena HIV Clinic and to analyse markers of HBV activity after achieving HBsAg loss.
Material and Methods: We included HIV/HBV subjects attending Modena HIV Clinic (Italy) with a follow-up above 6 months. Clinical and biohumoral data were collected retrospectively from electronic records. HBV-S was defined as HBsAb development (>=10UI/ml) in presence of HBsAg loss.
In a subset of subjects with HBsAg loss, HBV-DNA and -RNA was also quantified by highly-sensitive assays (HS-A) based on digital droplet PCR (LLOQ: 1IU and 2IU/ml, respectively) at last blood examination.
Antiviral therapy (tenofovir disoproxil fumarate TDF, tenofovir alafenamide TAF, lamivudine 3TC) was recorded at HBV-S and as cumulative exposure.
Subjects were compared according to the HBV-S outcome with Mann-Whitney U and Chi-square test and with logistic regression to evaluate associated factors.
Results: A total of 163 HBV/HIV subjects included and described in table 1: 77% male, 31% intravenous drug users, with median HIV duration of 16(IQR 9-25) years.
Among them, 32(19.6%) presented HBsAg loss and 19(11.7%) had HBV-S during follow-up (incident rate 0.26 per 10,000 PYFU), after a median time from HBV diagnosis of 10(IQR 5-19) years.
HBV-S rate was higher in subjects with positive HCV Ab (p=0.004), liver transplant (p=0.016) and undergoing TDF-based regimen at seroconversion (p=0.013). On the contrary, history of AIDS diagnosis (p=0.011) and a lower cumulative exposure to TAF (p=0.025) were more frequent in non HBV-S.
By applying HS-A for HBV-DNA and RNA quantification (see Figure 1) to a subset of 15 individuals with HBsAg loss, a residual HBV activity was revealed in 80%(12/15) of PLWH, despite HBsAg loss. Among them, 4(33.3%) had a positivity to both HBV-DNA and -RNA and 8(66.7%) to HBV-RNA alone. Notably, a higher rate positive HBV-RNA was found in HBV-S (100% vs 57.1%, p=0.038).
At logistic regression for HBV-S, history of AIDS diagnosis reduced likelihood of HBV-S (OR 0.11, 95%CI 0.02-0.93, p 0.043), while positive HCV Ab (OR 4.03, 95%CI 1.48-10.92, p 0.006) and liver transplant (OR 8.35, 95%CI 1.10 -63.19, p 0.040) favoured it. Any correlation with antivirals was confirmed.
Conclusion: One out of 10 individuals with HIV/HBV co-infection in our cohort reached HBV-S, in line with literature. Previous AIDS-related events did not favour seroconversion, while HCV co-infection seemed to be associated with the outcome.
A residual HBV activity persisted despite HBsAg loss during active HBV therapy: tenofovir discontinuation should be carefully evaluated in those patients and, if pursued, a proper monitoring of HBV markers should not be missed.

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P 73 LONG-TERM OUTCOMES AND INCIDENCE OF CLINICALLY SIGNIFICANT EVENTS AFTER HCV ERADICATION IN PEOPLE WITH HIV: DATA FROM ICONA/HEPAICONA COHORTS

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Background: Direct antiviral agents (DAAs) revolutionized the management of HCV-related liver disease even in presence of advanced fibrosis/cirrhosis. While it is established that people with cirrhosis remain at high risk of liver-related outcomes after sustained virological response (SVR12), long-term data on incidence and relevance of non-liver related clinical significant events (CSE) are lacking.

Methods: We retrospectively assessed the incidence and type of CSE (solid and haematological cancers, cardiovascular diseases, hypertension, diabetes, liver-related events, and death) in PWH after SVR12 with DAA over 2014-2023 in the Icona/Hepaicona cohorts. The "liver-related events" outcome was a composed outcome including liver decompensation, hepatocellular carcinoma, and liver transplantation. Incidence risks (with 95% CI) of events past SVR were calculated as number of events per total number of participants. We used an outcome-wide analysis approach with a single exposure (liver disease stage at SVR), 6 CSE outcomes and the same set of confounders in separate Poisson regression models for all outcomes. Liver disease stage at SVR was classified using the Baveno VII consensus definition.

Results: Overall, 2,034 people who achieved SVR12 were included: they were mostly males (76%), with a median age of 53 (IQR:50-56) years, 95% had an undetectable HIV RNA, and median CD4+ T cell count was 632 (IQR:431 -865) cell/mm3. Median follow up was 5.20 (IQR: 3.07-6.29) years.

years (IQR). Participants' main characteristics are shown overall and by liver disease stage in Table 1A. Over follow up, we observed a total of 467 incident CSE, the most frequent ones were diabetes (n=205, incidence risk=12.1%, 95% CI: 10.5-13.7) and death (n=100, incidence risk=4.9%, 95% CI: 4.0-5.9).

The outcome wide analysis (Table 1B) showed that people with compensated advanced chronic liver disease (cACLD) and clinically significant portal hypertension (CSPH) as by Baveno VII had a significantly higher incidence of liver-related events (IRR: 11.7, 95% CI 4.1 -33.5) and diabetes (HR: 1.3, 95% CI 1.0-1.6) while we found null results for all other CSE. Of note, there was no evidence that participants with cACLD "grey zone" (i.e., minimal risk of transitioning to further stages of liver disease) were at higher risk of CSE compared to those with no or low stage liver disease.

Discussion: In our large cohort of HIV/HCV positive individuals who achieved SVR12 we observed a concerningly high incidence of CSE over 5 years after viral eradication. Individuals with cACLD/CSPH showed a significantly higher risk of developing further liver events and diabetes compared to those with lower liver disease stage but, after controlling for confounding there was no evidence that liver disease stage at SVR was predictive of other CSE. These data provide innovative insights on the natural history of liver disease after viral eradication.

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P 74 OPTIMIZING HEPATITIS C TREATMENT: THE IMPACT OF PATIENT REPORTED MEASURES IN VARIED HEALTHCARE SETTINGS IN A LARGE ITALIAN REGION

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Despite significant advancements and the efficacy of direct-acting antivirals (DAAs) in treating hepatitis C, substantial barriers remain, impacting patient experiences and clinical outcomes. Investigating patient-reported experiences across diverse healthcare pathways is critical for enhancing quality, adherence, and successful HCV eradication.
A multicenter longitudinal survey was conducted among 953 adult patients diagnosed with HCV infection in Tuscany, Italy. Patient-reported experiences (PREMs) and outcomes (PROMs) were collected at baseline (treatment initiation), three months, and six months post-treatment using the validated SF-12 questionnaire alongside specifically designed items to assess patient experience comprehensively (Table 1). Participants were stratified by their care access pathways: general practitioners (GPs), specialist healthcare providers, prison doctors, or Dependency Services (Ser. D.). Statistical analysis included repeated measures ANOVA, non-parametric tests, and chi-square tests to determine variations in patient experiences across pathways and over time.
The study identified significant variability in patient experiences associated with each healthcare pathway. Patients managed primarily by specialist healthcare services consistently reported the highest satisfaction levels, particularly valuing clear and effective communication with clinicians. In contrast, individuals accessing care through prison or Ser.D. faced several barriers, such as administrative burden, poor coordination among healthcare providers, logistical difficulties, and stigma perceptions. These factors were strongly associated with lower levels of treatment adherence and a higher incidence of treatment interruptions. Patients receiving initial care from GPs praised the accessibility and convenience but expressed dissatisfaction with inadequate coordination and delays in referral to specialist care. Across all pathways, administrative inefficiencies and perceived stigma notably hindered timely diagnosis and treatment initiation, underscoring broader systemic challenges. At three- and six-months post-treatment, positive patient experiences significantly correlated with improved adherence and self-reported health outcomes, as measured by PROMs. Conversely, those within prison or Ser.D. pathways frequently reported unmet clinical needs due to fragmented service delivery, contributing to overall dissatisfaction and poorer health outcomes.
Patient-reported measures provide essential insights into barriers and facilitators within different HCV care pathways, highlighting areas where targeted interventions could enhance the patient experience. Prioritizing improvements in coordination, reducing stigma, and streamlining administrative processes are critical steps toward achieving more equitable, patient-centered care. These strategic enhancements could improve adherence, clinical outcomes, and progress toward regional and global HCV elimination goals.

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P 75 QUANTIFICATION OF PLASMA HDV RNA IN UNTREATED AND BULEVIRTIDE-TREATED PATIENTS WITH CHD: A COMPARISON BETWEEN ROBOGENE 2.0, EUROBIOPLEX EBX071 AND ALTOSTAR

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Background and Aim: Accurate quantification of HDV-RNA is essential for diagnosing and managing chronic hepatitis Delta (CHD), but there is considerable variability between different assays. In this study, we compared three methods for HDV-RNA quantification in both untreated and Bulevirtide (BLV)-treated CHD patients.
Methods: Frozen plasma samples from untreated and BLV–treated CHD patients were tested in a single-center retrospective study by 3 different assays: Robogene HDV-RNA Quantification Kit 2.0 [Roboscreen GmbH; Lower Limit of Detection (LOD) <6 IU/mL, Lower Limit of Quantification (LOQ) 60 IU/mL on 7500 Fast Real-Time PCR System (Applied Byosystem)], EurobioPlex HDV PCR quantitative EBX071 [Eurobio Scientific, LOD <20 UI/mL, LOQ 50 UI/mL on CFX96™ real-time PCR detection system (Bio-Rad)] and AltoStar HDV RT-PCR RUO Kit 1.5 (Altona Diagnostics, estimated LOD <10 IU/mL estimated LOQ 20 UI/mL on AltoStar®AM16).
Results: 112 plasma samples from 79 CHD (10 untreated and 69 BLV-treated) patients were studied by 3 different assays (total 336 tests). All patients were HDV genotype 1 (available in 70). Median HDV RNA was 3.05 (-0.04-6.69) Log IU/mL with Robogene 2.0, 3.78 (-0.83-7.78) IU/mL with EurobioPlex EBX071, 3.22 (-0.31-7.03) IU/mL with AltoStar (Robogene vs. EurobioPlex p=0.005; Robogene vs. AltoStar p<0.0001; EurobioPlex vs. AltoStar p=0.5; overall p<0.0001). Compared to Robogene 2.0, EurobioPlex EBX071 reported higher (>0.5 Log IU/mL) HDV RNA levels in 33% samples, similar levels (<+/-0.5 Log IU/mL) in 55%. Likewise, compared to Robogene 2.0, AltoStar reported higher HDV RNA levels in 18% of positive samples, similar levels in 82%. Robogene tested target not detected (TND) or <LOQ in 33% samples, EurobioPlex in 36%, AltoStar in 20%, the difference in identifying as either positive or negative samples being statistically significant (p<0.01).
Conclusions: HDV-RNA levels quantified by EurobioPlex EBX071 and Altostar were similar to Robogene 2.0 in most samples. However, HDV-RNA undetectability rates significantly differed across assays.

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P 76 THE SUBSTANTIAL BURDEN OF HDV CHRONIC INFECTION AND THE GAPS IN HDV SCREENING ACROSS EUROPE RISE THE NEED TO IMPLEMENT HDV DIAGNOSTICS AT PAN-EUROPEAN LEVEL

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Background and Aims: Hepatitis D virus (HDV) infection is often underdiagnosed, despite the severity of the related liver disease. Here, we investigate the rates of HDV screening, HDV seroprevalence and the rate of HDV RNA positivity among antiHDV+ individuals in routine care across Europe and parts of the Middle East, as well as the characteristics of individuals with active HDV infection.

Method: We collected data from 15,200 HBsAg+ people attending 16 tertiary centres during 2021-2023: Northwestern Europe (NWE: UK, Switzerland, Luxembourg, Germany, Sweden; N=3596, 23.6%), Southern Europe (SE: Spain, Italy, Slovenia, Croatia; N=3203, 21.1%), and Eastern Europe (EE: Romania, Serbia, Slovakia; N=4136, 27.2%) and the Middle-East (ME: Israel, Turkey; N=4265, 28.1%).

Results: Participants were predominantly males (59.5%), HBeAg-negative (90.7%) with a median (IQR) age of 49 (39-60) years and only 28.6% were receiving nucleos(t)ide analog treatment. The rate of HDV screening varied widely across regions: 23.9%, EE; 59.3%, NWE; 71.5%, ME; 79.1%, SE.

Overall, HDV seroprevalence was 5.9% (523/8801) with the highest rate of anti-HDV positivity in EE (9.9%), followed by ME (7.0%), NWE (5.8%) and SE (3.3%). By country, anti-HDV positivity peaked in Romania (10.4%), Turkey (8.7%), Germany (7.9%) and Italy (6.8%).

Compared to individuals with HBV infection, anti-HDV+ people had significantly higher HBsAg levels (median [IQR]: 3225 [591-9784] vs 2568 [242-11163] IU/ml, p<0.001), lower HBV-DNA (3.1 [2.2-3.9] vs 2.4 [1.6-3.7] log IU/ml, p<0.001) and a more advanced liver disease (Ishak score >4: 25.7% vs 4.6%, HCC: 5.9% vs 1%, p<0.001 for both). HIV coinfection was also more common (10.8% vs 4.1%, p< 0.001).

Overall, among 523 individuals with anti-HDV positivity, 82.6% were tested for HDV-RNA and 46.9% showed an active HDV infection with a median (IQR) HDV-RNA of 5.7 (4.2-7.1) log IU/ml and ALT of 92 (58-171) U/L. Strikingly, large regional variations were noted in both HDV-RNA detection (ME: 39.6%, NWE: 40%, SE: 56.1% and EE: 71.6%, p= 0.0002) and HDV-RNA levels (median [IQR] log IU/ml: 6.4 [4.9-7.2] in ME, 5.4 [3.9-6.7] in EE, 5.4 [4.0-7.4] in NWE and 4.0 [3.2-4.7] in SE, p=0.001).

Remarkably, among 344 participants tested for HDV-RNA despite anti-HDV negativity, a total of 7 (2%) from EE (N=5), SE (N=1) and Africa (N=1) had detectable HDV-RNA with median levels of 5.4 (5-6) log10 IU/ml.

Conclusions: Despite the substantial burden of HDV infection and related liver disease, significant gaps in HDV screening still remain across Europe, particularly in specific regions. Notably, we observed a small but appreciable proportion with HDV RNA despite lack of anti-HDV, underscoring the need for greater standardisation of HDV diagnostics. Overall, the data supports the urgent need to improve and harmonize HDV screening measures and promote the access to antiviral treatment at pan-European level.

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P 77 TREATMENT OF CHRONIC HDV HEPATITIS WITH BULEVIRTIDE: PRELIMINARY RESULTS OF A BEHAVIOR-DRIVEN INVESTIGATION ON PATIENTS AND CLINICIANS

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Background: Adherence to treatment is universally recognized as a key determinant for achieving expected clinical outcomes, and in the case of HDV infection, it is further complicated by barriers that patients, often migrants, face in terms of vulnerability and emargination.
Ongoing clinical practice studies assessing determinants of adherence and persistence to bulevirtide (the only approved antiviral for HDV) are showing initial positive results.
Materials and Methods: In order to assess adherence to daily injectable HDV treatment in various Italian regions, a questionnaire based on a validated behavioral sciences model was developed to analyze barriers and facilitators towards therapy.
The questionnaire, developed in two versions for patients and clinicians, was administered between June and September 2024 at 5 specialized Italian centers treating HDV, in either digital or paper format, in Italian, English, French, or Romanian. Results were collected anonymously and analyzed, taking into account demographic characteristics and duration of treatment of respondents.
Results: A total of 13 clinicians and 83 patients answered the questionnaire. Of these latter, 65% (54/83) were >50 years old, and 48% were of Italian origin (40/83). Most patients were >40 years old (86.6%) and had been on treatment for more than 6 months (81.5%); no correlation was noted between age and treatment duration (Figure 1).
Despite limitations related to the sample and the nature of the survey, both target groups reported high levels of adherence to HDV treatment, even if foreing patients reported problems with regularly assuming the medication more often than Italians.
Of relevance, notwithstanding the eterogeneous nature of the sample, almost all of the patients reported a positive relationship with their clinician and nearly all respondents agreed that effectiveness of treatment is motivating and important (99% and 100%) and translates into a strong optimism towards its ability to improve daily activities and life expectancy expressed by the respondents who believe that reaching treatment goals is important.
Key concerns included underestimation by patients of the severity of their disease (13.5%) and the intention by some patients (~10%) to discontinue treatment. In any case, the high percentage of positive responses to the questionnaire should be interpreted as an indirect signal of the effectiveness and safety of the treatment, as well as an appropriate patient counseling process.
Conclusions: Adherence to HDV treatment in Italian clinical practice, and the factors that can either facilitate or hinder it, are still poorly studied. However, the results of this survey, which will be presented in more detail in the future, are encouraging and indicate a good quality of care, attributable to the effectiveness of the therapies currently available and their correct integration into a therapeutic pathway that appropriately involves, motivates, and empowers the patient.

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Hepatitis and Liver Diseases

P 78 TRENDS IN THE PREVALENCE AND EPIDEMIOLOGICAL CHARACTERISTICS OF HDV INFECTION IN HBSAG + PERSONS WITH OR WITHOUT HIV IN ITALY: IS HIV STILL A KEY FACTOR FOR HDV CO-INFECTION?

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Background: HIV infection is often associated with hepatitis D virus (HDV) in HBsAg-positive individuals due to shared transmission routes, such as injection drug use (IDU) and unprotected sex. However, most available data come from historical cohorts of people with HIV (PWH), and recent trends in HDV prevalence and epidemiological characteristics among HBsAg-positive PWH compared to HIV-negative individuals remain unclear.
Materials and Methods: We conducted two cross-sectional analyses assessing HDV prevalence and epidemiological characteristics among HBsAg-positive PWH tested for anti-HDV in the ICONA cohort in 2009–2012 (n=257) and 2019–2023 (n=289). These data were compared with two cohorts of HIV-negative HBsAg-positive individuals: MASTER (n=1938, enrolled in 2009–2012) and PITER (n=3813, enrolled in 2019–2023). Descriptive statistics were used to compare continuous and categorical variables.
Results: In 2009–2012, anti-HDV prevalence was 19% in ICONA vs. 8.3% in MASTER (p<0.01). Among PWH, 20.0% reported IDU. Compared to HIV-negative individuals, HBsAg/anti-HDV-positive PWH had a similar median age (48 vs. 47 years), but a higher proportion of males (89.8% vs. 64.6%) and Italians (89.8% vs. 63.4%). HBeAg prevalence was higher in PWH (23.5% vs. 14.4%), as was HCVAb positivity (67.3% vs. 19.7%) and NUC therapy use (85.7% vs. 26.7%). The proportion of patients with FIB-4 > 3.25 was similar (35.4% vs. 34.2%, p=0.928) [Table 1].
In 2019–2023, anti-HDV prevalence was 12.5% in ICONA and 11.8% in PITER (p=0.729). The proportion of IDU among PWH decreased to 11.8%. Demographic and clinical differences between HIV-positive and HIV-negative individuals remained similar. The proportion of patients with FIB-4 > 3.25 was lower in PWH (20.0% vs. 42.0%, p<0.01) [Table 2].
Conclusion: Over time, anti-HDV prevalence among HBsAg-positive PWH has declined, now aligning with HIV-negative individuals. The reduction in IDU among PWH may have contributed to the decreasing prevalence of HDV.
Although the cross-sectional design prevents establishing causality between HIV co-infection and liver disease severity, factors such as competing mortality and cirrhosis progression in PWH observed in 2009–2012, may have influenced the differences in liver disease severity over time.

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Hepatitis and Liver Diseases

P 79 UNEXPECTED HBV REACTIVATION FOLLOWING DISCONTINUATION OF ANTIVIRAL PROPHYLAXIS IN IMMUNOSUPPRESSED SUBJECTS WITH PREVIOUS HBV EXPOSURE

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Introduction: People with serological status of previous hepatitis B virus (HBV) exposure and iatrogenic immunosuppression are at high risk of HBV reactivation. Guidelines recommend antiviral prophylaxis with lamivudine for potential occult B infection (pOBI, HBcAb+/HBsAg-) or entecavir/tenofovir for chronic HBV infection (HBsAg+, HBV DNA <2,000 UI/mL, normal transaminases), according to the degree of immunosuppression, with indefinite stopping rules. Here we describe a case series and investigate risk factors of HBV reactivation after prophylaxis discontinuation.

Methods: Data on patients referred to Infectious Diseases from 2008 for prophylaxis of HBV reactivation were retrospectively retrieved. All HBcAb+ patients starting prophylaxis and stopping it after the end of immunosuppression were included. People with HIV were excluded, as lamivudine and/or tenofovir are often continued as part of antiretroviral regimens. Reactivation was defined as seroreversion of HBsAg (from negative to positive) and/or increase of serum HBV DNA (>20,000 UI/mL if already HBsAg+, or >10 UI/mL if pOBI). Flare was defined as serum transaminases >100 U/L. Descriptive statistics are reported.

Results: Out of 85 patients who received prophylaxis for a median (IQR) time of 60 (40-75) months, we observed 12 HBV reactivations: 10 after prophylaxis discontinuation, 2 under prophylaxis with lamivudine. We observed 5 flares of transaminases, of which 4 after lamivudine and 1 after entecavir discontinuation. Prophylaxis duration was >= 18 months in 81/85 (95.3%) patients. The median (IQR) lag time between the stop of prophylaxis and HBV reactivation was 6 (3.5-20.5) months.

In Table 1 we compared patients' characteristics between those who experienced HBV reactivation and those who did not. Of note, there were no differences in age, gender, HBV/HCV serology. Hematologic malignancies were the most frequent cause for requiring HBV prophylaxis. The risk of reactivation was higher in subjects with a history of bone marrow transplant (BMT). At multivariable logistic regression analysis, adjusted for age, gender, antiviral drug, HBsAg serologic status, and duration of prophylaxis, only a history of BMT (OR 53.09, 95%CI 4.96-567.73, p=0.001) was independently associated with HBV reactivation.

Treatment with entecavir or tenofovir was resumed in all the patients with HBV reactivation, obtaining successful control of HBV replication and normalization of transaminases in case of flare.

Conclusions: HBV reactivation is still a considerable risk in patients with haematological malignancies undergoing chemotherapy. Proper discontinuation of prophylaxis after currently recommended length of time could not be enough to avoid HBV reactivation, possibly due to the profound immunosuppression of immuno-chemotherapy or bone marrow transplant. Further studies are needed to identify subsets of patients in whom long-lasting prophylaxis or at least strict and prolonged monitoring should be envisaged.

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Hepatitis and Liver Diseases

P 80 UTILITY OF THE FIBROSIS-4 INDEX FOR 10-YEAR RISK OF ALL-CAUSE MORTALITY IN PEOPLE WITH HIV: A RETROSPECTIVE LONGITUDINAL COHORT STUDY

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Background: The Fibrosis-4 (FIB-4) index is a non-invasive tool for assessing liver fibrosis. It has been employed to predict long-term all-cause mortality in people with high cardiovascular risk and in those with obesity or type-2 diabetes. This study investigated the association between FIB-4 and all-cause mortality in people with HIV (PWH).
Methods: We included 3,066 PWH aged 40 to 75 years seen in routine clinical practice at the Unit of Infectious Diseases, San Raffaele Hospital, Milan, Italy with FIB-4 measurements after January 2007 (data freezing February 2025). FIB-4 score was categorized as low (<1.30) indeterminate (1.30–2.67) or high (>2.67) risk for advanced fibrosis. PWH were followed from baseline (their first FIB-4) until death, their last visit to the center, or for up to 10 years. Comparisons between FIB-4 groups were conducted using Kruskal-Wallis test, Chi-square test, or Fisher's exact test, as appropriate. Cumulative probabilities of mortality were estimated using Kaplan-Meier curves, and differences were assessed by log-rank test. A multivariate Cox regression model was used to assess the impact of FIB-4 on mortality adjusting for age, sex, CD4 count, nadir CD4, type 2 diabetes, smoking, hepatitis C virus (HCV) infection, prior cancer, statin and antihypertensive use, and total cholesterol levels.
Results: Characteristics of PWH stratified by FIB-4 classes are described in Table 1. The low FIB-4 group was younger (p<0.0001), while the high FIB-4 group had a longer HIV infection duration (p<0.0001) and lower CD4 count and nadir, compared to the other 2 groups (p<0.0001). Smoke was prevalent in the high FIB-4 group (p=0.003). A total of 242 deaths occurred over the 10-year follow-up: 63/239 in the high group, 73/674 in the indeterminate group, and 106/2153 in the low group. The main causes of death were non-AIDS related cancers (59/242), liver-related (26/242), and AIDS-related (25/242), with 78 missing data. The cumulative probability of death in the high FIB-4 group was significantly higher than in the other two groups (at 10-year: 28.8% [22.5%–34.6%] in the high group, 11.6% [9.1%–14.1%] in the indeterminate group, and 5.3% [4.3%–6.2%] in the low group; p<0.0001, Figure 1). In the multivariate model, the high FIB-4 group had a higher risk of death compared to the low group (adjusted hazard ratio [aHR]:2.40; 95% CI: 1.63–3.53; p<0.0001 Table 2). Other factors associated with increased mortality risk included age (for 5-year increase aHR: 1.34; 95% CI: 1.22–1.47; p<0.0001), smoking (aHR: 1.50; 95% CI: 1.14–1.97; p=0.0036), HCV infection (aHR: 1.86; 95% CI: 1.36–2.54; p = 0.0001), and antihypertensive treatment (aHR: 1.68; 95%CI: 1.23–2.28; p=0.0009) while CD4 count (per 100 cells increase) was protective (aHR: 0.86; 95% CI: 0.80–0.92; p<0.0001).
Conclusion: Besides traditional risk factors, a high FIB-4 score appears to be an independent predictor of all-cause mortality over a long-term observation period in PWH aged 40–75 years.

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HIV: Antiretroviral therapy

P 81 ACCEPTANCE RATE AND REASONS FOR REJECTION OF LONG-ACTING INJECTABLE CAB/RPV IN AN ITALIAN CENTER

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Background: Cabotegravir (CAB) and Rilpivirine (RPV) long-acting (LAIs) have been approved as the first bi-monthly injectable regimen for treating HIV. LAI antiretroviral therapy (cART) represents an innovative and promising alternative to daily oral therapy, aiming to enhance treatment outcomes and alleviate pill fatigue, as well as reduce adherence burden for people with HIV (PWH).
Methods: Between January 31 and March 1, 2025, we proactively offered patients attending our clinics the option to switch their current antiretroviral therapy to the LAI CAB/RPV. We assessed the acceptance rate along with the reasons for declining the switch to LAI-cART and non-eligibility. Univariate comparisons were conducted between groups and explanatory variables (Pearson $\chi 2$, Fisher's exact test, Student's T-test, and Wilcoxon Mann-Whitney test as appropriate), and statistical significance was set at <0.05. Crude odds ratios (ORs) and corresponding 95% confidence intervals (CIs) were calculated to quantify the risk of rejection based on age, gender, 2DR, 3DR, nationality, years of HIV infection, years of ART exposure, or polypharmacy.
Results: Overall, 200 PWH were included in the analysis: the mean age was 51.4 (12.3) years, 21% female, 27 (13.5%) participants accepted switch to LAI CAB/RPV, n=138/200 PWH (69%) declined to switch, and 35/200 (17%) were non-eligible. The main characteristics of study participants by acceptance/rejection decision are shown in Table 1. The main reason for rejection was a preference for oral therapy (65%), followed by personal logistical issues [(17.4%) the need for frequent clinical visits and/or work-related constraints affecting injection scheduling]; uncertain PWH (11%) reported thinking about it and to postpone their decision. Among those non-eligible, physicians' reported motivations were: i) absence of viral genotype or HBV serology (n=15), presence of resistance-associated mutations (RAMs) (n=6 of which E138A in NNRTI, E138K in INSTI, L79D in NRTI constitutive of subtype A6) (42.5%); occult B infection (HBsAb/HBcAB +)(15%), silicone gluteal implants (15%), HIV RNA > 50 cp/mL (7.5%), motherhood desire (5%), gluteal hydra-adenitis (2.5%). Antiretroviral regimens of participants who accepted or declined to switch to LAI are in Figure 1A-C. No significant risk factors for rejection were found (Figure 2).
Conclusions: This analysis highlights a limited acceptance of CAB/RPV LAI (13.5%), with the main rejection reason being a preference for oral therapy (65%). Ineligibility was primarily due to incomplete viral genotype history, HBV serology, or RAMs. These results emphasize that the primary motivation for switching to LAI therapy is the patient's desire, and the need for more comprehensive testing before transitioning to LAI could delay or inhibit the successful implementation of LAI cART. Clear communication, personalized care, and thorough patient evaluation are crucial in transitioning to such innovative treatment options.

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HIV: Antiretroviral therapy

P 82 ANTIRETROVIRAL THERAPY IN PATIENTS WITH SWALLOWING DISORDERS: AN OPEN ISSUE

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There are an estimated 37.8 million people living with HIV worldwide (1). In Italy it is estimated that there are 120 -130,000 (2). With the advent of combined antiretroviral therapy, the life expectancy of people with HIV is comparable to that of the general population. The average age of people living with this infection is increasing: in 2010 it was 44 years old and it is estimated that in 2030 it could reach 57 years old (3).
This means that later in life people may develop non-HIV-related conditions requiring prolonged hospitalization without the ability to swallow for a long time or for life. Among the possible causes of impaired swallowing there are: acute neurological pathologies, neurodegenerative, neoplastic pathologies, pathologies of the gastrointestinal tract. If it is possible to guarantee the nutritional requirements enterally, in these cases, the use of devices such as the nasogastric tube or nosejejunal tube, gastrostomy or jejunostomy is necessary.
The pharmaceutical formulation of the antiretroviral drugs currently used in Italy (4) consists of tablets (22 out of 59), coated tablets (27 out of 59) and capsules (7 out of 59). The exceptions are Epivir (lamivudine) available in oral solution and slow-release intramuscular injectable formulations (Rekambys and Vocabria).
The recommendation number 19 of the Ministry of Health (5) on the handling of oral drugs advises against the division / shredding / pulverization of the tablets, where not clearly specified by the manufacturer, due to a possible alteration of the pharmacokinetic properties of the drug, reduced absorption and therefore reduced plasma concentration, toxicity. Gelatin capsules and coated tablets cannot be handled. Furthermore, the interaction between the manipulated drugs and enteral nutrition solutions in terms of absorption and/or pharmacokinetic alterations is not known.
The international literature does not seem to reveal data of unequivocal interpretation (pharmacodynamics, pharmacokinetics, dosage adjustments, etc.) on the manipulation of antiretroviral drugs to be administered through sng/peg/pej. In perspective, the HIV-positive population will be increasingly older (the current average age is 44 years) more affected by non-HIV-related pathologies of the elderly or, being in any case an adult population, to be hospitalized for a long time in the ICU/ordinary hospitalization wards/rehabilitation for traumatic events, of an anti-conservative nature. It would be important for the scientific/hospital/territorial community to address this topic through clinical pharmacology research and the hypothesis of new liquid or semi-liquid, orodispersible, intravenous, subcutaneous, etc. formulations and to structure multidisciplinary protocols/guidelines that can be reproducible on the national territory, in order to make the pharmacological assistance homogeneous for patients unable to swallow.

HIV: Antiretroviral therapy

P 83 B/F/TAF AS A SWITCH THERAPY IN A COHORT OF WOMEN LIVING WITH HIV: A 24-MONTHS OBSERVATIONAL STUDY ON DURABILITY, EFFECTIVENESS AND METABOLIC PROFILE

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Background: HIV has a substantial impact on women's health and quality of life, and women account for the majority of diagnoses worldwide. In 2022, the number of people living with HIV globally was approximately 39 million; girls and women make up more than half people living with HIV .Despite bearing a significant burden, women remain underrepresented in clinical trials, including those for antiretroviral treatments (ART).
We aimed to assess in our real-life an analysis similar to BICSTaR cohort, evaluating virological and immunologic effectiveness, safety ,weight gain and lipid profile modification real-life cohort of women with HIV (FWH) over a period of 24 months who stared B/F/TAF as a treatment switch.
Methods: We conducted an observational retrospective study in two peripheral hospitals (S.M. Goretti Hospital, University "La Sapienza" Polo Pontino, Latina and University Hospital Sant'Andrea, Rome), including all female (FWH) that switched to a B/F/TAF regiment during the follow-up on our Centers and of whose all the required virological, immunological, metabolic and weight alterations data were available both at baseline and after 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: This study involved a cohort of 28 FWH completed measurements, with a median age of 46 years (34 -66y). The median duration of HIV infection was 13 years (6-36y), 29% women received the diagnosis in a CDC C3 state; CD4 count Nadir of 172 cells/mmc (3-738 cell/mmmc) and an HIV-RNA Zenith of 145000 cp/ml (4275 -5407656). At baseline, 89,2% had undetectable HIV-RNA, which increased to 96,4 at 24 week (p=0.29). The CD4 count at 24 months increased from 684.5 cell/mmc to 737 cell/mmc (p 0.45). The CD4/CD8 ratio showed an improvement from 0.88 to 1.02, although not statistically significant (p = 0.63). Only 3,6% discontinued therapy.
No statistically significant changes in the metabolic profile has also been found, with a total cholesterol, LDL, HDL , triglycerides and fasting glucose levels.
Furthermore, we observe only minimal change in body weight from 63 Kg (41-107) to 65,5 Kg (47-106)p=0.78, and no significant changes in BMI (p= 0,37).
Conclusions: In conclusion, B/F/TAF regimen as a switch therapy in FWH is a valuable option that grants the achievement of a better virological suppression and an increase of the immunological profile. Our findings offer valuable insights into its use among women, a population historically underrepresented in clinical trials.

HIV: Antiretroviral therapy

P 84 BICTEGRAVIR/TENOFOVIR ALAFENAMIDE/EMTRICITABINE: A REAL-LIFE EXPERIENCE IN WOMEN LIVING WITH HIV (WLWH)

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Background: According to the World Health Organization (WHO) data published in 2024, more than half of people living with HIV (PLWH) are women (WLWH). However, in most studies WLWH are underrepresented. Aim of this study was to describe a real-world cohort of WLWH in antiretroviral therapy (ART) with bictegravir-emtricitabine-tenofovir alafenamide (BIC-STR).

Material and Methods: We retrospectively analyzed data of WLWH on ART with BIC-STR followed by the Clinic of Infectious Diseases of Perugia (Perugia, Italy) from September 2019 to September 2024. The study aimed to evaluate changes in CD4+ cell count, viral load and metabolic profile after BIC-STR introduction. Furthermore, variables that influence the residual viremia (defined as detectable HIV-RNA) and immunological recovery (defined as CD4 cell count >500 cell/mm3), were evaluated.

The study was conducted according to the declaration of Helsinki and approved by the local Ethics Committee; all patients had signed a consent to use their anonymized data when admitted to our department.

Results: Seventy-five WLWH were enrolled, with a median age of 50.8 years (IQR 45.2–59.1) and a median follow-up of 2.3 years (IQR 1.7–3.9) on BIC-STR. During follow-up, 13/75 (17.3%) patients discontinued therapy due to a switch to dual therapy (9/13, 69.2%), adverse effects (3/13, 23.1%), or drug-drug interactions (1/13, 7.7%). Furthermore, six were lost to follow-up (6/75, 4.0%) and three died (3/75, 4.0%). No virological failures occurred.

As shown in Table 1, CD4 count improved in absolute number, percentage, and CD4/CD8 ratio after BIC-STR initiation, with an increase in patients achieving HIV-RNA <50 cp/mL. Post-switch, total cholesterol and triglycerides significantly decreased, while LDL and HDL remained unchanged. BMI showed a significant increase.

Among WLWH, 58 (77.3%) achieved HIV-RNA <20 cp/mL, though the small number of viremic cases prevented identifying contributing variables. Additionally, 45 (60%) had a CD4 count >500 cells/mm³. Multiple factors - including age, sex, therapy duration, pre-switch ART duration, past opportunistic infections, HCV/HBV coinfections, comorbidities, nadir CD4, zenith HIV-RNA, and prior ART - were analyzed for associations with immunological recovery. However, none were significantly linked to the outcome in multivariate logistic regression (Figure 1).

Conclusions: Further and larger studies focused on WLWH will certainly be needed, however, our real-life study contributed to showing that the BIC-STR regimen is effective and safe in women.

This therapy showed an improvement in virological control and immunological recovery and a neutral metabolic modification after the switch. Therefore, it could be a valid option for the therapy switch and simplification, such as initial ART in WLWH.

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HIV: Antiretroviral therapy

P 85 CAUSES OF DISCONTINUATION OF CO-FORMULATED DOR/TDF/3TC IN ART-EXPERIENCED ADULTS WITH HIV-1 AFTER THREE YEARS OF FOLLOW-UP: REAL-WORLD DATA FROM A SINGLE CENTER IN FLORENCE, ITALY

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Introduction: Doravirine (DOR) is a non-nucleoside reverse transcriptase inhibitor (NNRTI) also available co-formulated with tenofovir disoproxil fumarate (TDF) and lamivudine (3TC). Real-life data on DOR/TDF/3TC are lacking. The study aims to evaluate the discontinuation rate of DOR/TDF/3TC and its causes in a cohort of people living with HIV (PLWH) treated in a single center in Florence, Italy.
Materials and Methods: This is a retrospective, monocentric cohort study. We included PLWH >18 years old, antiretroviral therapy (ART) experienced, switching to DOR/TDF/3TC with at least one follow-up visit at the Infectious and Tropical Diseases Unit in Careggi Hospital, Florence. Study entry was the date of DOR/TDF/3TC initiation; exit was the discontinuation date, the date of loss to follow-up, or the end of follow-up (February 2025). Virological failure (VF) was defined as two consecutive HIV-RNA >50 copies/mL detections or a single HIV-RNA >50 copies/mL followed by ART switch. Those lost to follow-up weren't considered treatment discontinuations.
Results: We included 119 patients with a median FU of 2.8 years [IQR 1.7–4] with a total observation time of 333.2 years. At the switch, (n=100, 84.1%) had undetectable HIV-RNA, while (n=19, 15.9%) did not. Patients included have shown a median of 11 [IQR 5-17] years of HIV. Demographic and clinical details are elucidated in Table 1. Over half of the cohort (N=75; 63,1%) had at least one comorbidity, mostly dyslipidemia, followed by psychiatric disorders and hypertension (Figure 1). The majority (n=109; 91.6%) were on a three-drug regimen before switching, with tenofovir alafenamide (TAF) included in 56.3% of cases, while 6.7% came from a simplified dual therapy (Table 2). We found 25 (21.0%) discontinuations with an overall rate of 7.5 per 100 patient-years [95% 5.0 – 11.1] due to: VF (N=4; 3.4%), Grade 1 toxicity (N=8; 6.7%), physician's choice (N=7; 5.9%), patient's will (N=5; 4.3%), others (N=1; 0.8%). Details are listed in Table 3. The virological failure rate alone is 1.2 per 100 person-years (0.4 - 3.1). Notably, 2 out of the 4 VF occurred due to pre-existing mutations for TDF and 3TC or other NNRTI (179E), in one case new mutations for NRTI developed. Instead, in one subject with VF and wild type genotype at baseline mutations for NRTI and NNRTI (138K) developed. The majority (n=16 84.2%) of those starting with detectable viremia obtained undetectable levels after the switch. Figure 2 shows the probability of maintaining DOR/TDF/3TC up to 4 years.
Conclusions: Our study showed that switching to DOR/TDF/3TC was effective even with baseline HIV-RNA levels not perfectly controlled. The overall discontinuation rate was higher than in other studies with shorter FU. (1-2). About half of the discontinuations were due to patient or physician choice, probably reflecting a preference for simpler regimens or long-acting options.

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HIV: Antiretroviral therapy

P 86 CHANGES IN BODY WEIGHT IN PEOPLE LIVING WITH HIV SWITCHING THERAPY FROM TAF/FTC/RPV TO TAF/FTC/BIC

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Background: Weight gain in people living with HIV (PLWH) on antiretroviral therapy (ART) has become a topic of increasing interest in recent years, as it may have metabolic, cardiovascular, and prognostic implications. Traditionally, in the pre-ART and early years of the combined antiretroviral therapy (cART) era, the main problem used to be weight loss and infection-related wasting syndrome. However, with the introduction of increasingly effective and less toxic drugs, the phenomenon has been reversed, and today weight gain, sometimes excessive, is frequently observed in PLWH on treatment.

TAF/FTC/BIC is a combination antiretroviral drugs including bictegravir (BIC), emtricitabine (FTC) and tenofovir alafenamide (TAF), used for the treatment of HIV infection. Recent studies have shown a correlation between TAF/FTC/BIC use and weight gain in PLWH on antiretroviral therapy.

The aim of this study was to evaluate the changes in body weight of PLWH followed at our center after discontinuation of TAF/FTC/RPV therapy and initiation of TAF/FTC/BIC.

Methods: We conducted a retrospective monocentric observational study on PLWH who discontinued TAF/FTC/RPV therapy to initiate TAF/FTC/BIC therapy, collecting demographical, clinical and viroimmunological data at baseline (BL, time of switch) and at every follow-up.

The analysis included self-reported weight at BL and measured weight at the conclusion of the median follow-up period of 152.6 weeks.

Results: We enrolled 100 PLWH. At the start of TAF/FTC/BIC treatment, PLWH had a median body weight of 74 kg [IQR 65-85]. Following a median follow-up period of 152.6 weeks, a slight increase in weight was observed, with a median value of 75 kg [64-85], however, this change was not statistically significant in the overall population (p = 0.626).

Further subgroup analysis revealed no significant change in weight when stratified by previous AIDS event (+0 kg [-5, +2], p=0.377), sex (+0 kg [-3, +2], p=0.550), age (p=0.693), CD4 nadir (p=0.716), HIV-RNA zenith (p=0.387).

Conclusions: These results suggest that switching to TAF/FTC/BIC does not result in substantial modifications of body weight in the general population or specific patient subgroups.

Analysis of weight change in patients who discontinued TAF/FTC/RPV and started TAF/FTC/BIC showed no significant impact of the introduction of bictegravir (BIC) on body weight. These data do not seem to support the hypothesis that BIC is associated with weight gain in this patient population.

HIV: Antiretroviral therapy

P 87 DUAL VERSUS TRIPLE AS OPTIMIZATION ANTIRETROVIRAL THERAPY IN PEOPLE WITH HIV WITH STABLE VIROLOGICAL SUPPRESSION: LONG-TERM EFFECTIVENESS FROM THE MOSAICO STUDY

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Background: The optimal antiretroviral regimen (ART) for people with HIV (PWH) with undetectable HIV-RNA remains a subject of ongoing debate, as both dual therapy (DT) and triple therapy (TT) demonstrated efficacy in maintaining viral suppression. DT has emerged as a potential alternative to TT, offering benefits such as reduced drug exposure, lower toxicity, and improved adherence. However, concerns persist regarding its long-term effectiveness and safety, particularly in specific populations. This study aimed to compare the effectiveness and safety of DT vs TT in virologically suppressed patients undergoing a treatment switch, providing real-world evidence to support clinical decision-making.

Materials and Methods: We conducted a retrospective, multicenter, observational study including adult PWH on stable virological suppression who switched ART either to DT or TT between 2017 and 2019, and recorded viroimmunological data 12-, 24-, 36-, and 48-months after the switch. The two treatment groups were balanced using propensity score weighting for the following variables: age over 50, Caucasian ethnicity, at least one coinfection (excluding HBV), at least one comorbidity, CD4+ T cell count > 500 cell/m3, and CD4/CD8 ratio > 1. Effectiveness was assessed using a multivariate logistic regression at the four timepoints. The analyzed variables included virological load (VL), CD4+ T cell count and CD4/CD8 ratio, with single tablet regimen (STR) and integrase strand transfer inhibitor (INSTI)-based therapy as covariates. Safety was evaluated through a Kaplan-Meier analysis up to 24 months of follow-up, with therapy discontinuation as the outcome. Discontinuation reasons included virological failure, toxicity, drug-drug interactions, resistance, and poor adherence. Cox regression was performed to assess factors associated with treatment discontinuation.

Results: 419 patients from 20 centers were enrolled (75 and 344 receiving DT and TT, respectively; Table 1). No statistically significant differences were observed between the two regimens, according to the study outcomes at all four timepoints. Similarly, Kaplan-Meier analysis revealed no significant differences in therapy discontinuation rates between the two groups (p-value >0.05). Even Cox regression results showed no significant differences (p-value > 0.05) on comparison between DT and TT. However, STR therapy emerged as a protective factor against treatment discontinuation in the Cox regression analysis (HR 0.33; CI 95%: 0.20-0.56; p-value < 0.01).

Conclusions: Our findings demonstrated that DT and TT exhibit comparable effectiveness and safety in optimization strategy for PWH on a stable virological suppression. The consistent outcomes observed over a 48-month follow-up indicate that physicians can confidently view DT as a viable option for managing HIV treatment. This, in turn, supports more personalized approaches aimed at improving the overall quality of life of PWH.

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HIV: Antiretroviral therapy

P 88 EFFECTIVENESS AND DURABILITY OF SIMPLIFICATION STRATEGIES WITH ORAL DOLUTEGRAVIR/LAMIVUDINE VS LONG-ACTING INJECTABLE CABOTEGRAVIR/RILPIVIRINE IN VIROLOGICALLY SUPPRESSED PEOPLE LIVING WITH HIV

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Background: The INI-based two-drug regimens (2DR) represent an appealing option for simplification in treatment-experienced people with HIV (PWH). Specifically, in addition to the known efficacy and tolerability of oral 2DR, long-acting injectable (LAI) strategies showed several advantages both in reducing the pill burden and in enhancing therapeutic adherence; however, comparison data with 2DR are currently lacking. We aimed to compare the effectiveness, tolerability, and durability at 12 months of oral dolutegravir/lamivudine (DTG/3TC) vs LAI cabotegravir/rilpivirine (CAB/RPV) for simplification strategy in ART-experienced virologically suppressed PWH in a real-life setting.

Materials and Methods: In this retrospective observational study, we included virologically suppressed PWH (HIV-RNA <50cps/mL) aged>18 years who switched from three-drug regimens to DTG/3TC or to LAI CAB/RPV between 2022 and 2024 in our hospital in Rome. Kaplan-Meier analysis estimated the probability at 12 months of both virological failure (VF) (two consecutive HIV-RNA>50cps/mL determinations or a single determination of HIV RNA>200cps/mL) and treatment discontinuation (TD) for any reason. Cox analyses assessed the potential factors associated with both VF and TD. Moreover, reasons for discontinuation have been examined.

Results: Our analysis included 34 participants in the CAB/RPV and 40 in the DTG/3TC group. The two groups were similar for most of the characteristics at baseline (Table 1). However, participants in the CAB/RPV group were more likely to be Caucasian (p=0.025), more frequently diagnosed with CDC C (0.020), with higher Log zenith HIV-RNA (p=0.020), and with lower probability to have the undetectable rather than detectable viremia but <50 cps/mL (p=0.048). A significant difference was also observed in triple therapies before the switch (p=0.005). By Kaplan-Meyer analysis, the overall probability of VF at 12 months was not statistically significant between the CAB/RPV and the DTG/3TC group (5.9% and 5.0%, respectively, p=0.930); the overall probability of TD at 12 months was 14.7% and 5%, respectively, (p=0.154). By adjusted Cox regression analysis, no factors were found to be statistically associated with either VF or TD. Reasons for discontinuation in the CAB/RPV group were injection-site pain (3/5), participant decision (1/5) and initiation of anticoagulant therapy (1/5), while for the DTG/3TC group they were intention of the participant to switch to LAI therapy (1/2) and unspecified reason (1/2).

Conclusions: Although participants in the CAB/RPV group showed a worse initial virological profile, the effectiveness of the two dual therapies was comparable. However, due to a slightly higher rate of adverse events, the durability of LAI CAB/RPV could be lower in comparison to oral DTG/3TC. However, such trend needs to be confirmed by further studies in a larger population.

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HIV: Antiretroviral therapy

P 89 IMMUNOVIROLOGICAL EFFICACY OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE THERAPY AND PERCEPTION OF WELL-BEING IN PEOPLE LIVING WITH HIV. EXPERIENCE OF THE INFECTIOUS DISEASES CLINIC OF PERUGIA

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Background: Advances in HIV therapeutics have transformed this infection into a chronic disease, but adherence, pill burden/fatigue, drug-food interactions, and personal stigma remain a notably burden, often significantly impacting the quality of life. Like other chronic diseases, HIV infection can currently be treated with long-acting injectable drugs such as the combination of cabotegravir+rilpivirine (CAB + RPV LA), administered monthly or bimonthly im. Aim of our report is to describe the experience at Perugia Infectious Disease Clinic in switching from an oral daily therapy to CAB + RPV LA i.m, both in terms of effectiveness and patient satisfaction.

Material and Methods: From March 2023 to December 2024, available patients who met the criteria for switching to CAB+RPV LA bimonthly were enrolled. Demographic, immunovirological, clinical and therapeutic history data of the patients were obtained from electronic medical records and at each injection a blood sample was taken to verify the immunovirological state: all subjects were interviewed about the pain at the injection site or adverse events. Data from all patients for each administration were recorded in an Excel database for the follow-up. Immunovirological efficacy of CAB + RPV LA and perception of well-being were analyzed in patients who completed 1 year of therapy and they were asked about the quality of life compared to baseline, quantifying it as a percentage from –100 to +100.

Results: CAB/RPV LA was started in 50 patients, 46 metting the switching criteria, 2 compassionate rescues for advanced terminal carcinoma, 1 with a viremic blip and 1 with a pre-switch viremia of 6.7x105 cp/ml due to a very poor adherence to ART. The baseline demographic and clinical characteristics are shown in table 1. There were 6 treatment interruptions in the follow up (table 2). The 2 patients treated on a compassionate basis for advanced cancers in the first months of LA therapy died. In 4 LA therapy was subsequently suspended. One, the rescue therapy for poor adherence, showed high viremia from M8 onwards (showed a complete resistance to INI), the one for a viremic blip for other blips without resistances. Moreover, in two (4.3%) of the 46 patients metting the enrollment criteria the treatment was discontinued, one by personal choice (disconfort, asthenia, nausea) and one due to a reactivation of HBV infection (he had been treated before with tenofovir). Overall, 35 patients completed the follow up of 12 months (M12). All patients showed an absolute immunovirologic control and no alterations in the metabolic profile (table 3). The perception of pain at the injection site progressively decreased and the quality of life significantly improved (average + 70) (fig.1).

Conclusions: In our experience the CAB/RPV LA has been shown to be effective in maintaining immunovirological control and well tolerated. Moreover it improved the quality of life and patients satisfaction.

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HIV: Antiretroviral therapy

P 90 IMPACT OF 2 DRUG ANTIRETROVIRAL REGIMENS ON IMMUNE RECOVERY

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Background: Two-drug antiretroviral regimens (2DRs) have emerged as a viable alternative to three-drug regimens (3DRs). While the virological efficacy of 2DRs in ART-naïve PLWH is well established, their impact on immune recovery compared to 3DRs remains less clear. This study aims to compare the effectiveness of 2DRs vs. 3DRs in promoting immune recovery among ART-naïve PLWH.

Methods: We conducted a monocentric retrospective study including ART-naïve PLWH diagnosed between 2015 and 2024. Virological and immunological data were collected at baseline (BL, time of diagnosis) and up to 24 months post-baseline. Immune recovery was assessed as a composite endpoint, defined as achieving CD4 count ≥500/μL, CD4% ≥30%, and CD4/CD8 ratio ≥0.7.

BL characteristics between 2DR and 3DR groups were compared using chi-square tests and t-tests, as appropriate. Kaplan-Meier survival analysis was used to assess the probability of immune recovery over time. Finally, a Cox regression model was used to identify independent predictors of immune recovery. To assess a potential selection bias related to the preferential use of 2DR in patients with a better immunological profile at diagnosis, a sensitivity analysis was performed including only patients with CD4<350 cells/μL at BL.

Results: A total of 414 patients were enrolled, including 29 (7%) treated with 2DRs and 385 (93%) with 3DRs. The characteristics of the population are summarized in Table 1. Kaplan-Meier survival analysis showed that the probability of achieving immune recovery was 23.9% in the 3DR group and 69.0% in the 2DR group, with a statistically significant difference (LogRank<0.001). Multivariate Cox regression analysis (Table2) showed that a higher CD4 count at baseline (HR=1.005, 95% CI 1.004–1.006, p<0.001), a higher CD4/CD8 ratio (HR=11.26, 95% CI 6.00 – 21.11, p<0.001) and being on a 2DR (HR=2.07, 95% CI 1.25–3.43, p=0.005) were independent predictors of immune recovery.

The sensitivity analysis (Tables 3 and 4), conducted on the subset of patients with CD4<350 cells/μL at BL, confirmed that higher CD4 count at diagnosis (HR=1.005, 95% CI 1.004–1.006, p<0.001), a higher CD4/CD8 ratio (HR=26.96, 95% CI 8.11-89.62, p<0.001) and 2DR use (HR=5.02, 95% CI 1.86-13.56, p=0.001) remained significant predictors of immune recovery, suggesting that the association observed in the full cohort was not driven by selection bias.

Conclusion: In ART-naïve PLWH, the use of 2DRs was associated with a higher probability of immune recovery compared to 3DRs, even after adjusting for potential confounders. Additionally, a higher baseline CD4 count emerged as an independent predictor of immune recovery. The sensitivity analysis confirmed these findings in patients with CD4 <350 cells/μL at diagnosis, suggesting that the observed association was not influenced by selection bias. These results support the immunological efficacy of 2DRs as a viable alternative to 3DRs in first-line ART.

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HIV: Antiretroviral therapy

P 91 IMPACT OF BASELINE PLASMA HIV-1 RNA AND VIRAL SUBTYPE ON THE ACHIEVEMENT OF VIROLOGICAL SUPPRESSION IN PWH TREATED WITH BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE IN CLINICAL PRACTICE

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Background: Bictegravir, co-formulated with emtricitabine and tenofovir alafenamide and (B/F/TAF), is approved for the treatment of HIV-1 in antiretroviral (ART)-naïve people with HIV (PWH). While its efficacy has been demonstrated in several trials, there is a paucity of data in PWH with high HIV RNA loads and non-B subtypes. The aim of this study is to describe the efficacy of B/F/TAF in an unselected population of naïve PWH.

Material and Methods: This two-center retrospective study included ART-naïve PWH starting B/F/TAF between 01/02/2020 and 31/12/2024. Time to virologic success (TVS) was defined as days between HIV diagnosis and first HIV RNA load below 50 cp/mL. The outcome assessed at 6, 12 and 24 months was virologic suppression, defined as HIV RNA <50 cp/mL. Baseline characteristics were summarized as count and percentage or as median with interquartile range (IQR).

Univariate and multivariate gamma regression analyzed associations between viral subtype and resistance profile with TVS, adjusting for gender, age >50 years, CD4+ <200 cells/mm³ and HIV RNA >10^5 cp/mL. Logistic regression assessed factors associated with failure to suppress viral load at 6 and 12 months using the same covariates. A p-value ≤ 0.05 was deemed statistically significant. Analyses conducted with SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results: 128 PWH were enrolled, 88 (68.8%) male, with a median age of 39 years (IQR: 30-52). HIV subtype B was found in 79 (61.7%), wild-type 100 (78.1%). At diagnosis, 52 (40.6%) had CD4+ <200 cells/mm³, and 75 (58.6%) had HIV RNA >10^5 cp/mL (Table 1).

The median TVS was 115 days (IQR: 45-605). TVS was not associated with neither HIV subtype (aRR for B-subtipe vs non-B 0.85, 95% CI: 0.63-1.14, p = 0.3) nor with resistance profile (aRR for wild-type virus vs any resistance mutation 1.24, 95% CI: 0.89-1.72, p = 0.2). On multivariate analysis, male sex (aRR 1.37, 95% CI: 1.01-1.85, p = 0.0400) and HIV RNA >10^5 cp/mL at diagnosis (aRR 2.2, 95%CI 1.6-2.3, p<0.0001) were significantly associated with longer TVS (Table 2a and 2b).

At 6 months, 18 (14.1%) PWH failed to achieve viral suppression, with HIV RNA >10^5 cp/mL at diagnosis being a significant predictor (aOR = 17.01, 95% CI: 2.07-100, p = 0.008). At 12 months, 4.8% of 104 PWH with available data did not achieve viral suppression. HIV RNA >10^5 cp/mL at diagnosis showed a strong trend towards failure (aOR = 9.02, 95% CI: 0.70-100, p = 0.092), but was not statistically significant (Table 3).

At 24 months, HIV RNA data were available for 60 PWH, three of whom failed to achieve suppression (all with wild-type virus at baseline, all with HIV RNA < 105 cp/mL and two with non-B subtypes).

Conclusions: In this cohort of ART-naïve PWH treated with B/F/TAF, HIV subtype and resistance mutations did not significantly affect TVS. High HIV RNA viral load at baseline was the strongest predictor of delayed viral suppression, but not of long-term virological failure.

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HIV: Antiretroviral therapy

P 92 IMPLEMENTATION OF A SAME-DAY ART START MODEL IN A REAL-LIFE SETTING: EXPERIENCES FROM A CLINICAL CENTRE IN ITALY

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Background: Rapid ART initiation, ideally within 7 days and including on the same day as diagnosis, is recommended by most guidelines for all people diagnosed with HIV (PWH) who are ready to start treatment. Evidence of effectiveness, reduced mortality, and increased retention in care has been cumulating in trials in resource-limited countries. To date, few data are available in high-resource settings, and comparative data between same-day and <7-day approaches are lacking. We present preliminary results of a single-centre rapid start program, focusing on the same-day start.

Methods: All adult PWH starting ART within 7 days from HIV diagnosis from January to September 2024 were included. A baseline standard laboratory assessment was ordered but not typically available before ART. Follow-up visits were scheduled 1, 3, 6, and 12 months after ART initiation. Co-primary outcomes were the proportion of PLWH with HIV RNA<200 cp/ml (transmission threshold) and the need for regimen modification once a complete laboratory evaluation was available. Secondary outcomes were the proportion of PWLH with HIV RNA<50 cp/ml, mean viral load change from baseline at 3-6-12 months, and retention in care at 6-12 months. Fisher's test for categorical variables and Wilcoxon rank sum test for continuous variables were used as appropriate, and predictors were investigated by fitting a multivariate logistic regression.

Results: 107 PLWH were included (Tab1). 61(57%) PWH were in the same-day group, and 46(43%) started ART from 1 to 7 days (median 3 [2-4]). A 3-drug 2nd generation INSTI-based (TDF/FTC+DTG or B/F/TAF) was prescribed in 99% of participants. The baseline median CD4 count was 277/mm3 [IQR 147, 446], and the median HIV-1 RNA was 5.22 log10 copies/mL [4.51, 5.89]. 1.9% were HBsAg positive. 4 were previously exposed to oral PrEP. No treatment modification occurred after laboratory results became available. At 3 months, 29(97%) attained HIV-1 RNA <200 copies/mL in same-day vs 28 (87%) in other rapid starts (p=0.35), while 23(77%) had HIV-1 RNA <50 copies/mL in same-day vs 26(81%) in other rapid starts (p=0.76). For those for whom a 6-month follow-up was available (n=70), 35(92%) were <50 copies/mL in the same-day group vs 25(78%) other rapid start (p=0.13). Fig1 shows the proportion of viral suppression at each follow-up timepoint by baseline HIV-1 RNA. Mean viral load (log) change at 3 and 6 months is reported in Tab2 and Fig2. Baseline CD4 count <200/mm3 was significantly associated with lower viral suppression at 3-6 months (Tab3).

Conclusions: Same-day ART start was a safe and feasible strategy. However, in our high-income country setting, no evidence for a difference in short-term virological outcomes was found between same-day and other rapid-starting strategies. Longer follow-up is needed to evaluate retention in care and sustained viral suppression.

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HIV: Antiretroviral therapy

P 93 LIPID PROFILE IMPROVEMENT AMONG ART-EXPERIENCED PLWH SWITCHING TO BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE ACCORDING TO PRIOR INSTI EXPOSURE AND LATEST ART REGIMEN

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Background: The impact of Integrase Inhibitors (INSTIs), with or without TAF/FTC, on weight gain and lipid profile in People Living with HIV (PLWH) remains controversial. This retrospective cohort study assessed the long-term metabolic effects of BIC/FTC/TAF in ART-experienced PLWH switching from different ART regimens.

Material and Methods: We included all ART-experienced PLWH followed in our Center who switched to BIC/FTC/TAF between January 1, 2019, and December 31, 2023, with at least 12 months of follow-up. Based on their treatment history, patients were classified as INSTI-experienced (INSTI-exp) or INSTI-naive. The latter were further stratified based on the latest regimen before the switch (NNRTIs vs boosted PIs). Total (T-Chol), HDL and LDL cholesterol, and Triglycerides (Tgl), were collected 6 months before (T-6), at the switch (T0), 6 (T+6), and 12 months (T+12) after. T-Col/HDL ratio, log10(Tg/HDL Chol) (Atherogenic Index of Plasma, AIP) were calculated at the same time points.

The Mann-Whitney U-test compared T0 values between INSTI-exp and INSTI-naive PLWH and between those switching from NNRTIs vs PIs. Lipid profile changes over time were analyzed overall and by subgroup using non-parametric ANOVA with Durbin-Conover pairwise comparisons.

Results: Among 441 PLWH (74% male, median age 57 [48-61] years), 318 were INSTI-exp. Of these, 193 (60%) were on TAF/FTC/EVG/c, 35 (11%) on RAL + TAF/FTC or ABC/3TC, and 54 (17%) on DTG + TAF/FTC, TDF/FTC, or ABC/3TC. The remaining used INSTI + boosted PIs or NNRTIs. Among the 123 INSTI-naive PLWH, 58 switched from boosted PIs (40 from TAF/FTC/DRV/c) and 65 from NNRTIs (56 from TAF/FTC/RPV). No significant differences in immune, virologic, or metabolic parameters at T0 were observed based on INSTI exposure. However, INSTI-naive PLWH switching from PIs had higher liver disease, AIDS, IDU history, lower CD4+ nadir, shorter virologic suppression, and higher T-Chol, T-Chol/HDL ratio, and Tgl at T0 (202 vs 183 mg/dL, p=0.01; 4.16 vs 3.52, p=0.01; 155 vs 118 mg/dL, p=0.006) compared to the other subgroup.

T-Chol decreased in the whole cohort at T+6, persisting at T+12 (Figure 1, a.). This trend was observed in both INSTI-exp and INSTI-naive PLWH (Figure 1, b.), particularly in those switching from boosted PIs, but not from NNRTIs, whose parameters remained stable (Figure 1, c.). Significant improvements in HDL and LDL Chol, Tgl, and AIP were seen overall and among INSTI-exp, while in INSTI-naive only T-Chol decreased. Changes similar to those of the whole cohort were noticed among PLWH switching from PIs. Among PLWH switching from NNRTIs, all metabolic parameters remained stable.

Conclusions: Lipid profile improvement was observed among ART-experienced PLWH switching to BIC/FTC/TAF, particularly in those previously on other INSTIs or boosted PIs-based regimens. Conversely, a neutral effect was noted among PLWH switching from NNRTI-based regimens. Larger studies are warranted to confirm these findings.

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HIV: Antiretroviral therapy

P 94 LONG-ACTING INJECTABLE ANTIRETROVIRAL THERAPY (LAI-ART) WITH CABOTEGRAVIR (CAB) AND RILPIVIRINE (RPV) FOR THE TREATMENT OF HIV INFECTION: ANALYSIS NEARLY TWO YEARS IMPLEMENTATION IN A UNIVERSITY HOSPITAL

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Background: Several studies conducted worldwide reported that People Living With HIV (PLWH) a less frequent therapy administration is an unmet need not fully considered by current therapeutic options. Despite the wide range of fixed-dose regimens, adherence to daily lifelong antiretroviral therapy (ART) is still a challenge for many patients. Therefore, one of the aims of HIV research is focused on developing long-acting injectable (LAI) drugs. In this work, we analyze the data collected over a period of nearly two years of administration of LA therapy with cabotegravir (CAB) and rilpivirine (RPV) injectables at a University Hospital in Northern Italy.

Materials and Methods: We analyzed data from a cohort of patients from 07/03/2023 to 28/02/2025. The data were collected using a spreadsheet recording the number of LAI treatments, administration days, the induction phase with oral CAB plus RPV, if prescribed, the reports of potential adverse drug reactions (ADRs) and any therapy interruptions.

Results: Throughout the analyzed period, 40 patients were treated with LAI-ART. Only 23 started a four weeks an oral induction phase with CAB+RPV before receiving the first injection. The majority of patients (85%) responded optimally to the injectable therapy leading to better adherence among those facing stigma. In 6 cases (15%) treatment was discontinued due to various reasons: pregnancy (1 patient), death from cancer (1 patient), preference for oral regimen (1 patient) and 3 ADRs. The reported ADRs included widespread musculoskeletal pain with increased inflammatory markers, intense and persistent pain in the gluteal area and bruising at injection site in a hemophilic patient.

Conclusions: Nearly two years after the first administration of LAI-ART with CAB and RPV, results positive have emerged in terms of efficacy, acceptability of the injection site reaction and overall tolerability. Most patients have reported a favorable impact on their lifestyle. It is evident that simplifying and optimizing ART is a fundamental goal in HIV infection. LAI-ART might therefore represents an important advancement in HIV care as it considerably reduces dosing frequency and therefore improves patient satisfaction and adherence.

HIV: Antiretroviral therapy

P 95 METABOLIC AND IMMUNOLOGICAL OUTCOMES AFTER SWITCHING TO LONG-ACTING CABOTEGRAVIR + RILPIVIRINE: A 44-WEEK MULTICENTER OBSERVATIONAL STUDY (LAHIV)

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Background: Since its introduction in Italy in June 2022, the combination of cabotegravir (CAB) and rilpivirine (RPV) — a long-acting, bimonthly intramuscular regimen — represents the inaugural long-acting treatment to maintain virological suppression in HIV-1. This study investigates changes in creatinine, total cholesterol, triglyceride levels, CD4 and CD4/CD8 ratio from baseline to 44 weeks after the switch.

Methods: We conducted a multicenter observational study across 11 centers in Tuscany. The study included all virologically suppressed people living with HIV (PLWH) aged 18 and older (HIV-RNA <50 cp/mL) who initiated CAB +RPV and had creatinine, cholesterol, triglycerides, and CD4 levels measured at baseline and at week 44. Individuals with missing lab tests or insufficient follow-up were excluded. Dyslipidemia was defined as total cholesterol: > 200 mg/dL or Triglycerides: > 150 mg/dL.

Results: A total of 73 PLWH were evaluated at week 44. Most participants (n=61; 83.6%) were male, with a median age of 51 years (IQR 43-57). At baseline, nearly 40% had dyslipidemia but only 24.6% were on statin therapy. At week 44, no significant changes were observed in triglycerides, cholesterol, or CD4 count and CD4/CD8 ratio (Figure 1). We observed a statistically significant reduction in creatinine, although by only a few points, with a likely minimal clinical impact. However, among the participants, 31 individuals had a CD4/CD8 ratio <1 at the time of switching, despite a median duration of antiretroviral therapy of 10 years [IQR 7-13]. In this subgroup, we observed at week 44 an increase in the CD4/CD8 ratio by 0.2 (P=0.0120). This increase was not observed in individuals with a baseline CD4/CD8 ratio greater than 1.

Conclusion: Preliminary findings suggest that switching to CAB+RPV has neutral metabolic effect. Among individuals on stable ART, a significant increase in the CD4/CD8 ratio was observed at week 44, as also suggested by recent studies [1]. To confirm these results and enhance patient stratification, further research with larger sample sizes and longer follow-up periods is needed.

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HIV: Antiretroviral therapy

P 96 MINOR REVISION: SIMPLIFICATION THERAPY WITH DOLUTEGRAVIR, A RETROSPECTIVE OBSERVATIONAL STUDY WITH 96 WEEKS FOLLOW-UP

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Background: Dolutegravir (DTG)-based dual-drug combinations are widely used as antiretroviral therapy (ART), both as first line and switching strategy. DTG is an inhibitor of organic cation transporter-2 on the renal proximal tubule cells which uptake substrates like creatinine from the blood. As a result, one of the side effects of DTG is the increase in serum creatinine levels and the consequential reduction of estimated glomerular filtrate rate (eGFR). Such decrease in renal function has been described to occur in the first weeks after DTG initiation and to be non-progressive. This study analyses the efficacy and safety of DTG-based dual ART, with a special focus on people living with HIV (PWH) older than 55 years.

Methods: We present data from a longitudinal observational retrospective real-life cohort of ART-experienced PLWH who switched to a DTG-based dual therapy. The primary objective was virologic control (HIV-RNA < 50 copies/mL) 96 weeks after the switch. Secondary objectives were to identify the changes in immunological and metabolic profiles. Baseline characteristics are described as median values and interquartile ranges (IQR) or as simple frequencies and percentages. Changes from baseline of continuous variables were assessed by the paired samples Wilcoxon test. All tests were two-sided and p-values <0.05 were considered statistically significant, with false discovery rate correction for multiple comparisons applied when appropriate.

Results: 139 PLWH were included into the study and their demographics are shown in Table 1. We identified a subpopulation of 61 PLWH older than 55. After 96 weeks from the switch, at the per-protocol analysis virologic control was 97,14% (IC 91,88-99,41%) in the overall population, and 93,88% (IC 83.13-98.72%) among PLWH older than 55. These results are shown in table 2 and figures 1 and 2. During 96 weeks of follow-up, we observed 2 virological failures in 2 PLWH that discontinued ART for a few weeks. Both of them started the same dual therapy again and achieved virological suppression in two months, without developing RAMs. Then they No relevant changes in immune (CD4+, CD8+ and CD4+/CD8+ ratio) and metabolic (total cholesterol, HDL, LDL, body weight, BMI, AST, ALT) markers were detected along the study period.

We observed a significant increase in serum creatinine at week 24 and a parallel decrease in eGFR at week 24 and 48 among the overall population (figures 3-4), which were not observed in the subgroup of elderly PLWH when considered alone (figures 5-6). There was not significant change in the stage of chronic kidney disease among both the overall and the elderly population.

Conclusion: DTG-based dual-drug combinations are effective and safe, even in a population of PLWH who is getting older. A small decrease in renal function at week 24 and 48 has been observed, but it is not progressive and doesn't seem to affect elderly PWH.

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HIV: Antiretroviral therapy

P 97 NEXT GENERATION SEQUENCING (NGS) OF PROVIRAL HIV DNA AND ANALYSIS OF APOBEC-INDUCED MUTATIONS TO ASSESS SUITABILITY FOR LONG-ACTING CABOTEGRAVIR/RILPIVIRINE THERAPY

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Background: Genotyping Resistance Test (GRT) of HIV DNA in NGS is a useful tool for clinical treatment optimization, especially when GRT on RNA is unavailable and/or unfeasible and treatment history unreliable, and is particularly relevant when considering the prescription of long-acting (LA) therapies based on cabotegravir (CAB) and rilpivirine (RPV). However, NGS data interpretation, along with APOBEC-related mutations discrimination, remains complex and its clinical implications are still under investigation. This study evaluates NGS-GRT on DNA in individuals not eligible to standard enrolment criteria for CAB-RPV LA treatment, highlighting its potential in the challenges in HIV care.

Materials and Methods: A retrospective observational study was conducted at a single tertiary hospital, in individuals who underwent NGS-GRT on DNA and later started LA therapy. Library for NGS was prepared using the commercial kit AD4SEQ HIV-1 Solution v2 (Arrow Diagnostics). Consensus sequences were analyzed on HIV Drug Resisting Database (Stanford University). Mutations were considered APOBEC-induced if they appeared at low frequency and especially if associated with unusual mutations and/or stop codons. Data were described using the mean and standard deviation (SD) for normally distributed continuous variables and the median and interquartile range (IQR) for non-normally distributed continuous variables. Virological failure (VF) was defined as the occurrence of two consecutive viral load measurements >50 copies/mL.

Results: Our study included a cohort of 82 people living with HIV (PLWH) receiving LA therapy. Of these, 51 had NGS-GRT on DNA, 22 had mutations or stop codons, 10 had APOBEC-related mutations at sites that could potentially confer drug resistance (4 NRTI, 2 PI, 4 NNRTI, 6 INSTI).

Among the nine individuals with APOBEC-associated INSTI or NNRTI mutations, none experienced VF. Only one study participant was switched to an oral INSTI-containing regimen due to the historical detection of E138Q in GRT on RNA, a low-level resistance mutation for RPV. Comparing individuals with (n=22) and without (n=29) APOBEC-associated mutations, the mean time from diagnosis to virological suppression was 10.2 (±7.9) vs. 3.2 (±5.3) years (p=0.002) and the mean duration of infection was 25.4 (±10.1) vs. 2.1 (±5.6) years (p=0.001). This suggests that a longer duration of unsuppressed viral replication may be associated with a higher likelihood of APOBEC- related mutation emergence.

Conclusion: As the presence of mutations attributed to APOBEC activity is associated to defective virus, it does not preclude the efficacy of LA therapy with CAB/RPV; in fact, their correct identification in the INSTI and NNRTI drug classes should rather encourage clinicians in the use of LA therapy, in a setting of reduced viral fitness and growing capability. An accurate interpretation of NGS-GRT on DNA is therefore crucial to avoid unnecessary exclusion of individuals from LA therapy with CAB/RPV.

HIV: Antiretroviral therapy

P 98 PATIENT-REPORTED OUTCOMES IN HIV: A STUDY ON QUALITY OF LIFE IN PLWH ON LONG-ACTING ANTIRETROVIRAL THERAPY

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Background: HIV infection has evolved into a chronic condition requiring lifelong adherence to virosuppressive therapy. The introduction of long-acting antiretroviral therapy (LA-ART) with cabotegravir and rilpivirine has revolutionized treatment by replacing daily oral regimens with bimonthly intramuscular injections. This study evaluates changes in quality of life (QoL) among People Living With HIV (PLWH) receiving LA therapy compared to those on oral treatment through Patient-Reported Outcomes (PROs).

Materials and Methods: We conducted a single-center study at the Infectious Disease Department of Campobasso between January 2024 and February 2025. PLWH meeting the inclusion criteria and providing informed consent completed a four-section questionnaire assessing demographic characteristics (Section I), ongoing ART (Section II), general health and mental well-being (SF-12 survey, Section III), and LA therapy personal perceptions (Section IV, administered only to LA recipients).

Results: Sixty-three PLWH participated (81% male, 19% female; mean age 50 ±12.8 years). Of these, 20 (31.75%) were on LA therapy with bimonthly intramuscular cabotegravir-rilpivirine injections, while 68.25% remained on oral ART.

SF-12 scores showed no significant differences in MCS-12 and PCS-12 between groups (the SF-12 produces two main summary scores, the Mental and Physical Component Summary) [Table 1], but the LA group reported significantly better perceived health status (p=0.033) [Figure 1] and greater emotional well-being, as indicated by the question "In the past week, have you felt calm and peaceful?" (p=0.004).

Section IV, targeting LA recipients, revealed a significant reduction in perceived treatment burden. Before switching, patients rated the difficulty of balancing daily oral ART with personal and work life at a median of 7/10 (IQR 4-8), which dropped to 1/10 (IQR 1-1) after one year on LA therapy (p<0.001) [Figure 2].

Conclusions: Our results suggest that LA-ART can significantly reduce the burden of treatment management, translating into a greater sense of ease in balancing personal and professional life, improving QoL and emotional well-being in PLWH.

The overwhelmingly positive shift in patient-reported outcomes underscores the transformative potential of LA regimens in optimizing adherence and overall well-being.

PROs play a crucial role in clinical practice, as they provide a comprehensive understanding of patients' experiences, enabling a more tailored therapeutic approach. Integrating PROs into routine HIV care can enhance patient engagement, optimize treatment adherence, and improve long-term outcomes.

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HIV: Antiretroviral therapy

P 99 PROXIMITY-BASED LONG-ACTING THERAPY: A REAL-WORLD MODEL AT A CLINICAL CENTER FOR HIV/AIDS CARE IN TURIN

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Introduction: The so-called fourth 90 for people living with HIV/AIDS (PLWHA) encompasses factors related to quality of life, particularly health-related aspects but not exclusively. Reducing travel distances and time required for managing both HIV infection and comorbidities is highly valued and frequently requested by patients, especially those facing greater vulnerabilities or logistical difficulties, whether temporary or permanent. This report describes the administration of long-acting antiretroviral therapy (LA-ART) at home or in healthcare facilities close to the patient's residence.

Materials and Methods: A working group was established to analyze the characteristics of PLWHA progressively considered for LA-ART in an outpatient setting, assess feasibility, train nursing staff for administration (where applicable), and provide specialized home care services when necessary. The protocol requires the first administration to take place in a hospital outpatient clinic or to begin with an oral lead-in phase.

Results: As of February 2025, 10 patients (7 males, 3 females) with a mean age of 56.8 years (range 29–69) have been included. Among them, 2 reside in a group home, 4 at their own residence, 3 are referred to the appropriate local healthcare service, and 1 to the relevant addiction treatment center (SERD). The administration period ranges from 5 years to 3 months. There has been only one dropout (due to myocardial infarction), no treatment discontinuations due to adverse events, 100% adherence in all 10 patients, excellent acceptability, and no virological failure.

Conclusions: Outpatient administration of LA-ART is feasible within a structured pathway and thanks to a well-organized network of motivated and dedicated healthcare providers.

HIV: Antiretroviral therapy

P 100 REAL-LIFE USE OF BICTEGRAVIR/TAF/EMTRICITABINE IN A COHORT OF PEOPLE WITH HIV WITH MORE THAN 50 YEARS OLD

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Background: Aging people with HIV (PWH) face unique challenges in antiretroviral therapy (ART) management due to multimorbidity and polypharmacy. Few real-life studies have evaluated the long-term effectiveness and safety of bictegravir/TAF/emtricitabine (B/F/TAF) in this population. We investigated the virological, immunological, and metabolic outcomes of B/F/TAF as a switch strategy in PWH aged ≥50 years.
Methods: We conducted a multicenter retrospective study within the SHiNe-SHiC cohort, including data from four centers in Sardinia and Sicily, Italy. We analyzed PWH ≥50 years who initiated B/F/TAF while maintaining HIV-RNA <50 copies/mL. Clinical, viro-immunological, and biochemical parameters were assessed at baseline, 12, and 24 months. Treatment discontinuation (TD) and virological failure (VF) rates were evaluated.
Results: We included 135 PWH aged ≥50 years (median 59, IQR 55-64), of whom 29 (21.5%) were over 65 years. The majority were cisgender men (65.9%), and the most common HIV acquisition route was heterosexual transmission (80.0%). Comorbidities were frequent: dyslipidemia (69.6%), hypertension (43.7%), and psychiatric disorders (17.0%). More than half (56%) were on at least one non-ART medication, and 5.1% were prescribed five or more.
Before switching to B/F/TAF, 92.1% of PWH were on triple-drug regimens, mainly INSTI-based (60.0%), and only 4.4% were on dual regimens (Table 1). During 5284 person-months of follow-up (PMFU), we observed 11 treatment discontinuations (TD), corresponding to an incidence rate of 2.08 per 1000 PMFU. The probability of discontinuation was 2.97% (95% CI 1.12-7.72) at 12 months and 6.1% (95% CI 3.1-11.8) at 24 months (Figure 1). Reasons for TD included adverse events (4 cases, including CNS, gastrointestinal, asthenia, and neutropenia), patient choice (3 cases), simplification to long-acting therapy (3 cases), and one virological failure).
Virological suppression was sustained, with HIV-RNA <50 copies/mL in 93.9% at 12 months and 93.2% at 24 months (Figure 2). The incidence of HIV-RNA >50 copies/mL was 4.06 per 1000 PMFU, with only one associated treatment discontinuation (HIV-RNA 548 at 18 weeks). CD4 count improved significantly (738 to 825 cells/μL, $p<0.05$), along with the CD4/CD8 ratio ($p<0.05$). A significant reduction in total cholesterol, LDL, and triglycerides was observed over 24 months ($p<0.05$), whereas creatinine increased slightly without clinical significance (Table 2).
Conclusions: Among PWH aged ≥50 years, B/F/TAF demonstrated sustained virological suppression, immunological improvement, and metabolic benefits over 24 months, with a low discontinuation rate mainly due to adverse events. These findings support B/F/TAF as a safe and effective switch strategy for ageing PWH, including those with multimorbidity and polypharmacy.

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HIV: Antiretroviral therapy

P 101 REAL-WORLD DURABILITY, SAFETY, AND CHANGES IN LIPID AND BODY WEIGHT PROFILES WITH B/F/TAF IN ART- NAIVE ADULTS: A 24-MONTH OBSERVATIONAL STUDY

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B/F/TAF is the preferred Initial Combination Regimen for ART-naive adults. This study aimed to evaluate the real-world durability,effectiveness, safety, weight gain, and lipid profile changes over a 24-month period in ART-naive PLWH initiating B/F/TAF, conducting an analysis similar to the BICSTaR cohort.

An observational retrospective study was conducted in two hospitals (S.Maria Goretti, Latina, and University Hospital Sant'Andrea, Rome) with a 24-month follow-up. We included all ART-naive PLWH who started B/F/TAF and collected data on viro-immunological outcomes, adverse events, discontinuation, body weight, and lipid profiles at baseline and after 24 months. The primary endpoint was treatment discontinuation for any cause, and secondary endpoints included virological suppression, immunological recovery, and changes in body weight and lipid profile. Descriptive analysis was performed using JASP 0.19 software.

The study included 34 ART-naive PLWH, with a median age of 46.5 years (23–75y). The majority of the subjects were male (91%), and 76% were classified as advanced naive (CD4 <350 cells/mm³). All participants started ART therapy at diagnosis. Only 2 subjects (5.8%) discontinued treatment, one due to weight gain and another due to switching to long-acting ART. No adverse events were reported.

At 24 months, 91.2% of subjects achieved virological suppression (HIV-RNA <50 copies/mL), and 8.8% had HIV-RNA levels between 50 and 100 copies/mL. The CD4 count significantly increased from 180 cells/mm³ (1–714) to 491 cells/mm³ (101–1396) ($p < .00001$), indicating substantial immunological recovery. Although the CD4/CD8 ratio improved from 0.18 (0.01–1.67) to 0.65 (0.14–2.09), this change was not statistically significant, even when stratifying in the advanced naive.

Body weight increased from 75 kg (52–100) to 83 kg (57–127) ($p = .01$), with 38% of patients experiencing a >10% increase in body weight. Notably, 84.6% of those with significant weight gain were advanced naive. No significant difference in weight gain was found between advanced naive and others. Total cholesterol increased from 146 mg/dL (67–238) to 179 mg/dL (122–275) ($p < .00001$), LDL cholesterol rose from 88 mg/dL (20–152) to 115 mg/dL (64–181) ($p = .001$), and HDL cholesterol increased from 33 mg/dL (6–53) to 44 mg/dL (28–75) ($p = .00008$). No significant changes were observed in fasting glucose or triglyceride levels.

Only 3 out of 34 patients were prescribed statin therapy during the study period.

In conclusion, B/F/TAF was generally well-tolerated, with a low discontinuation rate of 5.8%. A high rate of virological suppression and significant immunological recovery were achieved. Body weight increased during the study period, likely reflecting the recovery process, particularly among advanced naive patients. These findings support the durability, effectiveness and safety of B/F/TAF in ART-naive adults, but also highlight the need for further management of weight and lipid-related issues in this population.

Table 1

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HIV: Antiretroviral therapy

P 102 SCULPTING LONG-TERM SUCCESS IN HIV THERAPY: THE SYNERGISTIC DYNAMICS OF DOLUTEGRAVIR AND DORAVIRINE IN A PRECISION-DRIVEN DUAL REGIMEN

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Background: Advances in antiretroviral therapy have spurred the development of two□drug regimens (2DR) that aim to reduce long□term toxicity while maintaining potent virological suppression. In this context, dolutegravir (DTG) and doravirina (DOR) emerge as a powerful combination. DTG, an integrase inhibitor with a high genetic barrier, and DOR, a novel non□nucleoside reverse transcriptase inhibitor with an excellent pharmacokinetic and metabolic profile, complement each other by minimizing drug–drug interactions and reducing pill burden. This dual therapy is particularly valuable for patients with extensive treatment histories and multiple comorbidities, where conventional triple therapy may pose challenges.

Material and Methods: We performed a retrospective analysis of 36 patients who transitioned from triple therapy to the DTG-DOR regimen. Data on immunovirological parameters, metabolic profiles, and safety markers were extracted from clinical records and an associated database. Patients were assessed at baseline, 12 months, and 24 months. The Wilcoxon test was used to evaluate changes over time, with statistical significance defined as $p < 0.005$. Parameters analyzed included liver enzymes, FIB-4 scores, CD4+ T cell counts, and viral loads.

Results: Virological suppression was robustly maintained, with 91.7% of patients suppressed at baseline, rising to 97.1% at 12 months and 97% at 24 months. Most immunovirological and metabolic parameters remained stable ($p > 0.005$). However, unexpected statistically significant increases in transaminases and FIB-4 scores were observed at 24 months ($p < 0.005$). Although unanticipated, these findings may be attributed to age-related factors such as immunosenescence, subclinical inflammation, and metabolic dysregulation—all of which can independently affect liver biomarkers in an aging population.

Conclusions: In the ongoing discourse between 2DR and 3DR regimens, the debate often falls into binary simplifications, overshadowing the nuanced pharmacological and clinical interplay of individual components. Rather than adhering to rigid classifications, it is the intrinsic properties of each agent—genetic barrier, pharmacokinetics, pharmacodynamics, toxicity profile, and drug-drug interactions—that define the overall robustness of a regimen. The efficacy observed in our cohort reinforces the notion that regimen strength is not merely a sum, but a dynamic synergy of its constituents, sometimes exceeding linear expectations through pharmacological forgiveness.

Beyond the molecular framework, patient-centric variables—ranging from intrinsic biological responses to psychological acceptance—emerge as pivotal in determining therapeutic success. Personalized treatment strategies should therefore transcend traditional dichotomies, acknowledging the multifactorial determinants of treatment sustainability. It is time to shift the narrative: not 2DR vs. 3DR, but the right drugs, in the right combination, for the right patient.

Table 1

Figure 1

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HIV: Antiretroviral therapy

P 103 SWITCHING BOOSTED PROTEASE INHIBITOR-BASED ANTIRETROVIRAL THERAPY TO FOSTEMSAVIR PLUS AN OPTIMIZED BACKGROUND IN PEOPLE WITH HIV WITH LIMITED THERAPEUTIC OPTIONS: A CASE SERIES FROM THE FOST SWITCH STUDY

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Background: People with limited HIV treatment options may have significant comorbidities and are often treated with complex antiretroviral therapies because of viral resistance, intolerance or both. A significant proportion of these people are treated with boosted protease inhibitor (bPI), a drug class associated with worse metabolic outcomes and significant potential for clinically relevant drug-to-drug interactions. Fostemsavir (FTR) has been approved for the treatment of people with multidrug-resistant HIV but real-life data are limited.
Methods: The FOST Switch study is an ongoing phase IV proof of concept, prospective, non-randomized, single-arm, multi-center study in virally suppressed, ART-experienced (lenacapavir-naïve) people on bPI. All participants are switched from bPI-containing regimens to an optimized background regimen (OBR) plus FTR. The primary endpoint is to assess the proportion of participants with HIV viral loads ≥50 copies/mL at week 48; several secondary endpoints are measured at weeks 24 and 48. We describe the features of the first study participants who were in follow-up at the time of DSMB analysis. Data are shown as median (range) values.
Results: 11 participants were included in this interim analysis; all were white males with a median (range) age of 63 (53-76) years. After a median of 26 years (2-33) all participants had a viral load <50 copies/mL. The table below describes baseline (BL) CD4 and cART, cumulative resistance, new cART regimen, week 12 (W12) HIV RNA if available and whether they were still on treatment at the time of analysis. No loss of virological suppression was observed. FTR was combined with TAF/FTC/BIC (10) or TAF/FTC and DTG (1). We observed one treatment interruption (participant's decision) and two OBR changes (from BIC to dolutegravir for mood changes). The most common drug-related adverse events were grade 1 or 2, e mostly mood changes (4/11 low mood, 1/11 anxiety); one suicide attempt, judged not to be drug-related, led to treatment discontinuation.
Conclusion: In the first FOST SWITCH Study participants, a compact optimized regimen plus FTR showed good short-term tolerability and was associated with maintained virological suppression.

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HIV: Antiretroviral therapy

P 104 SWITCHING FROM 3 OR 2-DRUG ORAL REGIMEN TO LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN PEOPLE WITH HIV: REAL-WORLD EXPERIENCE FROM ASST LECCO

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Background: Long-acting cabotegravir and rilpivirine (LA CAB/RPV) is a revolutionary antiretroviral treatment (ART) option for virologically suppressed people with HIV (PWH). Our aim was to investigate the role of switching from 2 or 3-drug oral regimen to LA CAB/RPV on immuno-virological and metabolic parameters in a real-world setting.
Methods: We conducted a retrospective study on 43 PWH on stable ART who switched to LA CAB/RPV between 05/2023 and 08/2024, followed at Alessandro Manzoni Hospital, Lecco. We defined as baseline (BL) the start of LA CAB/RPV. BL demographic and clinical characteristics were reported as mean (m, ± standard deviation, SD) or frequency (%). We performed a comparative analysis of lab and metabolic parameters at BL (T0) and 6 months after switch (T1), considering statistically significant a threshold of p value <0.05. Adverse events (AEs) and treatment interruptions were also collected.
Results: Baseline demographic and clinical characteristics are shown in Table 1. We evaluated 43 PWH for an average follow-up of 14 months. Overall, 13/43 (30%) PWH were female, and mean age was 54. Five of 43 (12 %) PWH had African origins, while 38/43 (88 %) PWH were Caucasian. Epidemiologically, most PWH were heterosexual (26/43, 60%). The most prevalent metabolic comorbidity was dyslipidemia [26 (60%) PWH].
Before switch, 31/43 (72%) PWH were on a tenofovir alafenamide fumarate-based 3-drug ART regimen (49% including non-nucleoside reverse transcriptase inhibitors, 21% including integrase strand transfer inhibitors and 3% including protease inhibitor), 4/43 (9%) PWH were on an abacavir-including 3-drug ART regimen, while 8/43 (19%) PWH were on an INSTI-based 2-drug ART regimen. No PWH was on a regimen containing tenofovir disoproxil fumarate. After switch, 9/43 (21%) PWH reported AEs (mostly pain in site of injection) and 3/43 (7%) PWH discontinued LA CAB/RPV before T1 (Table 1).
At T0, mean CD4+ count was 862 cells/μL and 100% of PWH had undetectable HIV-1 RNA. The average body weight was 76 Kg, abdominal circumference 90 cm, total cholesterol (TC) 179 mg/dL and low-density lipoprotein-cholesterol (LDL-c) 106 mg/dL. At T1, 40/40 (100%) PWH maintained undetectable HIV-1 RNA and no significant changes of CD4+ cell count were reported. No statistically significant changes of body weight, abdominal circumference and TC were observed. There was a decrease in LDL count despite it did not reach statistical significance (95 vs 106 mg/dl, p 0.067) (Table 2).
Conclusions: In our cohort, switching to LA CAB/RPV was safe and effective, as widely documented in clinical trials and real-world studies. Discontinuation rate was similar to the ones reported in clinical trials (3-7%) and real-world data (2.5-10%). No significant impact on body weight and lipid profile has been found. Longer follow-up and larger cohorts are needed to assess durability, long-term safety and metabolic outcomes of LA CAB/RPV in PWH.

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HIV: Antiretroviral therapy

P 105 TREATMENT INTERRUPTION AMONG PWH ON LONG-ACTING-INJECTABLE (LAI) CABOTEGRAVIR/RILPIVIRINE: EXPERIENCE FROM AN ITALIAN HIV OUTPATIENT CLINIC

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Background: LAI CAB/RPV is a two-drug intramuscular regimen for PLWH with stable virological suppression. Clinical trials have confirmed its efficacy, safety, and non-inferiority to oral regimens. However, up to date real-world data are needed to optimize its use in clinical practice.

Materials and Methods: We conducted a retrospective observational study on patients switched to LAI CAB/RPV at the Infectious Diseases Unit of IRCCS Policlinico San Matteo, Pavia. Data were collected from May 2023 to February 2025. We analyzed eligibility criteria, clinical and epidemiological profiles, HIV-RNA levels, and adverse events after one month (4W), 6 months (24W), and 12 months (48W) of injectable therapy.

Results: We analyzed 100 patients: 21 who have been on LAI for at least 12 months, 27 who reached 6 months, and 52 who were on LAI for less than 6 months. Characteristics of study population are shown in Table 1. All patients met eligibility criteria. At baseline (BL), all had virologic suppression for at least 6 months (VL ≤ 20 cps/ml; median TCD4: 806 cells/mm³, IQR 556.5–966.5), no virological failure, and a median BMI of 24.75 (IQR 21.65–26.95). Oral ART difficulties were reported by 52 patients, mainly due to pills fatigue burden (47%) rather than stigma (5%). Overall, 98% received injections within the scheduled time window.

Figure 1 presents adverse effects at 4W, 24W, and 48W in all patients.

Despite 3 cases of persistent injection site pain at 48W, adherence remained high. There were eight discontinuations: three due to injection site pain, two patients lost to follow-up, one non-related death, one for work-related reasons, and one due to a viral blip (92 copies/ml). In this case HIV-RNA and DNA genotypic testing were performed documenting no resistance mutations; however, while awaiting the outcome, the patient was switched to triple oral therapy. No cases of virological failure were recorded, and 99% maintained viral suppression. Figure 2 shows Kaplan-Meier analysis of non-discontinuation probability for LAI therapy.

We also evaluated the impact of CAB/RPV LAI therapy on BMI, lipid metabolism (total cholesterol and LDL), and CD4+ T lymphocyte levels in 21 patients who completed 48W of treatment, confirming no significant effects.

Conclusions: Our real-life results confirm that CAB/RPV LAI was safe, well-tolerated and effective in PLWH who met the eligibility criteria, with high adherence and minimal discontinuation. In our opinion, pending more solid data and based on our experience, it would seem necessary both a careful selection of eligibility for LAI, to reduce the risk of therapeutic failures (due to adverse events/lost at follow-up) associated with close virological monitoring in the first six months of therapy, to minimize the risk of VF. Furthermore, although sometimes apparently excessive, a return to oral therapy in the case of repeated virological blips could be the most precautionary choice to avoid virological failure.

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HIV: Antiretroviral therapy

P 106 UP TO HALF OF GERIATRIC PEOPLE LIVING WITH HIV ARE TREATED WITH 2-DRUG INSTI-BASED REGIMENS

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Background: People with HIV (PWH) are aging and may have a long history of HIV infection, long exposure to antivirals, increasing comorbidities and polypharmacy. We aim to assess the use of two drug regimens (2DR) in geriatric population of PWH.
Materials: This is a cross-sectional study in PWH older than 64 years and currently followed up in 3 HIV centers in northern Italy. Data were collected from medical reports or electronic database in February 2025 and subjects with the last visit within 9 months and currently receiving ARVs were included. Polypharmacy (PP) was defined as 5 or more non-HIV drugs. The primary endpoint was the use of 2DR, secondary end-points were prevalence and characterization of comorbidities, polypharmacy and viroimmunological status. Multiple cox regression model was used to assess factors associated to 2DR treatments
Results: 655 PWH were included (80%, males, median (IQR) age was 70 (66-75), 54% heterosex, 23% MSM, 13% past-IVUs, 95% were Caucasians. A total of 315 (48%), 243 (37%) and 42 (6.4%) subjects had received <3, 3-6 and more than 6 lines of HIV therapy, respectively. Median (IQR) duration of HIV infection was 25 (19-33) years, median (IQR) nadir and current CD4 count were 146 (3-50) and 689 (504-926) cells/mL, respectively, while 611 (93%) subjects had plasma HIV RNA <50 copies/ml. A total of 18 (3%), 212 (36%), 304 (53%) and 43 (7.5%) individuals had 0, 1-2, 3-5 and ≥6 comorbidities, respectively. A total of 266/525 (50.6%) had polypharmacy, while 21/570 (3.7%) were HBsAg positive. Overall, primary RAMs were documented in 159 subjects in NRTI- (124), NNRTI- (103), PI- (68) and INI- (10) regions, respectively.
A total of 329 (50.2%) and 322 (49%) were on 2DR and ≥3DR, respectively; 4 were on DRV-monotherapy. 2DRs were as follows: DTG/3TC (175/329, 53.2%), boosted PI+X (57, 17%), DTG/RPV (53, 16%), CAB/RPV (17, 5%), DTG/DOR (13, 4%) and others (15, 4.5%). The most used 3DRs were BIC/F/TAF (160/322, 49.6%), RPV/F/TAF (65, 20.2%) and DTG/ABC/3TC (22, 6.8%) and DRVc/F/TAF (20, 6.2%). Overall, boosted PIs were used in 100 (15.2%) individuals, in different combinations. At Cox regression analysis, factors associated with a higher probability of being on 2DR were the number of comorbidities (HR of ≥ 6 comorbidities compared to 0-2: 0.52, 95% CI 0.3-0.9, global p <0.001), the presence of major mutations (HR = 0.67, 95%CI 0.48-0.94; p = 0.02) and the value of nadir CD4+ count (increase of 50, HR = 1.08, 95%CI 1.02-1.15; p = 0.015). Table 1
Conclusions: 2DRs, INSTI-based and in different combinations, are used in up to half of geriatric PWH, with DTG/3TC being the most frequent, while CAB/RPV LA underused.

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HIV: Antiretroviral therapy

P 107 USE OF PROLONGED-RELEASE INJECTABLE CAB/RPV IN OUTPATIENTS

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Background: Since 9 May 2022 the first antiretroviral (ARV) drugs by intramuscular injection (IM) cabotegravir + rilpivirine (CAB/RPV) entered the market in Italy. Since November 2022 these drugs have been present in our Hospital Pharmacy and are in use in our Outpatient clinic. The aim of the work is to describe the cases observed in 2 years of use of these drugs.

Material and Methods: We prospectively collected data of patients who, since November 2022, underwent CAB/RPV administration, initially orally (28 days) and subsequently by the IM route. For each patient (pts), the following were collected: epidemiological data, evaluation of immunovirological staging and blood chemistry tests, possible onset of adverse events.

Results: 54 pts were observed, 43 males (80%) and 11 females (20%) whose mean age was 46 years, mean BMI 24.4; risk factor for HIV: 30 MSM (55%), 17 ES (32%), 7 TD (13%). 27 pts (50%) had metabolic risk factors such as diabetes, overweight, arterial hypertension, dyslipidemia. Anamnestically, 18 pts (33%) had a history of more than 15 years of ARV, 9 pts (16%) with an average age of 31 years underwent the first therapeutic simplification after 1 or 2 years from the start of ARV, 27 pts(51%) had been taking ARV for at least 9 years. 33 pts (61%) had previously received triple ARV therapy, 21 pts (39%) had already received dual oral ARV therapy. 6 pts (11%) stopped CAB/RPV: one pt for fever and arthralgias that occurred three days after the first CAB/RPV-IM (Injection Site Reaction-ISR); one pt for allergic rash (even if not related) that occurred three days after the first CAB/RPV-IM, one pt for the onset of acute pancreatitis (hospitalization required) 4 days after the first CAB/RPV-IM (even if not related); one pt for ISR after the second CAB/RPV-IM, one pt for ISR after the third CAB/RPV-IM, one pt for intention to become pregnant.40 pts have taken CAB/RPV-IM for at least 52 weeks and are continuing treatment, bimonthly HIV-RNA determinations have recorded the presence of only 5 viremic blips <70 cp/ml.

Conclusions: Despite the need for a larger sample size and a longer observation time, our work shows that CBV/RPV injection therapy has excellent virological efficacy in multi-treated and non-multi-treated patients, with good safety after the first administrations.

HIV: Antiretroviral therapy

P 108 VIROLOGICAL FAILURES IN A REAL-WORLD COHORT: A RETROSPECTIVE ANALYSIS OF POPULATION CHARACTERISTICS AND RESISTANCE MUTATIONS

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Background: virological failure is a significant challenge in HIV management, as it can be associated with disease progression, increased risk of transmission, and the emergence of drug resistance mutations (DRMs).
Materials and Methods: we conducted a retrospective study analyzing all cases of virological failure identified through resistance tests (NGS resistance test set at 10%) performed at our center in 2023 and 2024. Treatment-naïve people were excluded. Our objective was to characterize the population in terms of immuno-virological parameters, treatment history, and comorbidities, as well as to identify the most frequent DRMs and the affected drug classes.
Results: a total of 76 resistance tests were analyzed, of which 48 were from male PLWH. Subtype B was the most common (73.6%). At the time of testing, viral load was >1,000 copies/mL in 81.5% of cases, between 200 and 1,000 copies/mL in 10.5%, and <200 copies/mL in 7.8%.
Of the 76 tests, 39 (51%) showed no DRMs. Among the tests showing DRMs, 62% had NNRTI mutations, 51% had NRTI mutations, 29% had primary INSTI mutations, and 16% had primary PI mutations.
The most relevant DRMs identified were: K65R, L74V, M184V, L210W and T215Y for NRTIs; K103N, Y181C, G190S followed by V106A and K101E/P for NNRTIs; I54V, V82A, I84V, L90M for PIs; N155H followed by G140S, Q148H, Y143R, S147G and E138K for INSTIs.
Regarding ART regimens, 59% of tests were from individuals on INSTI-based regimens, 10.5% on PI-based regimens, 14.4% on NNRTI-based regimens, 11.8% on regimens containing both INSTI and PI, and 3.9% on other regimens. Most PLWH were on high genetic barrier regimens, primarily containing second-generation INSTIs.
On average, people had been exposed to 2.9 previous ART regimens. Multimorbidity was observed in 47% of cases, and polypharmacy (≥5 chronic medications) in 14%. A history of prior virological failure was documented in 57% of cases. Regarding HIV acquisition, the risk factor was unknown in most cases; however, intravenous drug use accounted for 25%, and vertical transmission was reported in 7.8%. The mean duration of HIV infection was 16.6 years, with a mean latest CD4 count of 394 cells/μL and a mean nadir of 216 cells/μL.
Concerning ART adherence, 30% of individuals had discontinued therapy, 43% showed partial adherence, and only 13% reported good adherence, while adherence data were unavailable in 13% of cases.
Conclusions: our analysis suggests that virological failure was primarily driven by poor adherence and treatment discontinuation. DRMs were detected in 49% of cases, with NNRTI and NRTI mutations being the most common, while primary PI and INSTI mutations were less frequent. Additionally, the high prevalence of multimorbidity in this cohort underscores the need for close monitoring of PLWH experiencing virological failure to optimize long-term clinical outcomes.

Infections in the Immunocompromised Host

P 109 CIRCULATING AUTOANTIBODIES TARGETING G-PROTEIN-COUPLED NEUROTRANSMITTER RECEPTORS: RELIABLE BIOMARKERS FOR LONG COVID DIAGNOSIS?

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Background: Emerging evidence suggests that IgG transfer from Long-COVID (LC) patients induces symptoms in mice. Auto-Abs against G-protein-coupled (GPCR Abs) neurotransmitter receptors are linked to chronic fatigue syndrome, which overlaps with LC. This study investigates these Auto-Abs in LC patients to identify potential biomarkers and therapeutic targets.
Methods: A prospective, pilot, single-center case-control study was conducted at the LC clinic in Rome. Fifteen participants were enrolled: four asymptomatic post-COVID (APC) individuals and eleven with severe LC, defined as the presence of at least four symptoms—fatigue, cognitive deficits, poor exercise tolerance, dyspnea, arthralgia, or dysautonomia—more than three months post-SARS-CoV-2 infection. Fatigue was assessed using the Fatigue Assessment Scale (FAS ≥ 22; severe: FAS ≥ 35). Auto-Abs against multiple receptors, including AT1R, endothelin receptor A, adrenergic (α1, α2, β1, β2), and muscarinic (M1-M5) receptors, were measured. Blood samples were analyzed for stress hormones (cortisol, ACTH). SARS-CoV-2 specific T cell response to Spike and Nucleocapsid antigens were assessed by Elispot assay.
Results: LC patients were younger than the APC, had more comorbidities (p=0.007), received fewer vaccine doses (p=0.04), and were more likely to engage in sports (p<0.001). Median FAS score was significantly higher in LC than APC (33 vs 12; p=0.001). The median levels of the studied Auto-GPCR Abs showed a higher trend in LC patients compared to APC individuals (8398 pg/ml vs 5637 pg/ml; p=0.2), as was the case for each specific Auto-Ab studied (Figure 1). We were able to make use of these differences in antibodies between APC and LC and we developed a diagnostic method for identifying LC with no false positives based on the Auto-Abs normalized levels. Median blood morning cortisol was statistically higher in APC than LC (17mg/dl vs 12.7mg/dl; p= 0.01). There was also a trend toward a better specific T-cell response to the S and N antigens in APC compared to LC (Figure 2). Correlations between the studied variables are shown in Figure 3.
Conclusions: Our pilot study suggests GPCR Abs help identify LC patients who may benefit from IV immunoglobulin or plasmapheresis. Further research is needed to assess treatment effectiveness.

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Infections in the Immunocompromised Host

P 110 EARLY MANAGEMENT OF COVID-19 INFECTION IN SOLID ORGAN TRANSPLANT RECIPIENTS: OUR EXPERIENCE WITH ANTIVIRAL TREATMENTS

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Background: in the last 4 years SARS-CoV-2 worldwide impact has changed thanks to the natural and vaccine-induced immunization, the availability of antiviral therapy and the virus mutation that led to the shift from pandemic to endemic infection. However for immunocompromised individuals it may still be a dangerous and compromising disease and it's vital to reach a prompt diagnosis and start an early treatment to avoid COVID-19 pneumonia and respiratory failure. We describe our experience as an Infectious Disease Center in ARNAS Civico-Di Cristina-Benfratelli Hospital consulting for 2 transplant centers: ISMETT (IStituto MEditerraneo per i Trapianti e Terapie ad alta specializzazione) and CRT (Centro Regionale Trapianti).

Methods: We describe 99 SOT recipients diagnosed with SARS-CoV-2 infection between 1st January 2022 and 31st December 2024. These patients were brought to our care and were eligible for early treatment for COVID-19. Comorbidities, vaccination data, antiviral management and outcome are described.

Results: Amongst the 99 patients the majority underwent kidney transplantation (n=81), then we had 10 heart recipients, 3 lung recipients, 3 liver and 1 with kidney and liver transplantation. 92/99 were not vaccinated against COVID-19. The most common comorbidities were chronic renal failure (74/99) and cardiovascular disease (65/99). 38 patients were treated with monoclonal antibodies infusion (6 with tixagevimab/cilvagimab and 32 with sotrovimab), 39 were treated with molnupiravir and 22 with 3-day course of remdesivir (early treatment protocol). The mean age of the patients was 60 years. 9/38 receiving monoclonal antibodies, 1/39 in the molnupiravir group and 3/22 of the early remdesivir group required inpatient management but none of them underwent to severe respiratory failure and required invasive ventilation. The immediate outcome was good for 100% of the patients. The 14 hospitalized patients were discharged without chronic respiratory failure.

Mean time between the positive swab and the antiviral therapy prescription was 0.8 days.

Conclusions: Solid organ transplant recipients are at high risk for severe SARS-CoV-2 disease, these patients have limited treatment options because the presence of chronic renal disease and for the drug-drug interactions with nirmaltrelvir/ritonavir and the calcineurin inhibitors. The antiviral treatment for COVID-19 should start as soon as possible to maximize the results. Our patients received the treatment within a mean delay of only 0.8 days from the positivity of the nasal swab thanks to a working network between the transplant centers and our infectious disease center For the future we should work for a national registry for COVID-19 infection in SOT recipient with the aid of the National Transplant Center.

Infections in the Immunocompromised Host

P 111 LONG COVID: LOOKING FOR A DEFINITION

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Background: According to WHO and the most recent NASEM definition, Long COVID (LC) is an infection-associated chronic condition that can affect one or more organ systems. Symptoms can fluctuate or relapse over time and impact quality of life. The clinical manifestations are so varied that they make the diagnosis difficult. For these reasons, the RECOVER study proposed two scores, in 2023 and the most updated in 2024, to help clinicians in the diagnosis of LC.
The aim of this study was to evaluate the concordance of these scores with the clinical diagnosis of LC.
Material and Methods: Patients discharged from the hospital with the diagnosis of SARS-CoV-2 pneumonia and followed in Long COVID Clinic at San Gerardo Hospital in Monza, were reevaluated after 4 years from acute infection. According to patients' reported symptoms and referring to WHO and NASEM definitions, we defined the diagnosis of LC as confirmed, excluded or possible (if there were few symptoms that appeared post-COVID). Subsequently, we applied the 2023 score (LC for score >12) and 2024 score (LC for score >11). We evaluated the concordance between clinical evaluation and both scores (2023 and 2024) with Cohen's K coefficient and estimated sensibility, specificity, positive predicted value (PPV) and negative predictive value (NPV) of the two scores with respect to the clinical evaluation considering possible LC both as confirmed LC and as excluded LC.
Results: From January to February 2025, we evaluated 43 patients. The median time from hospital discharge to the visit was 4.8 (4.4-4.8) years. Median age was 65 (59-71) years old and 65.1% (28/43) were male. 86% (36/43) of individuals required non-invasive ventilation with CPAP during hospitalization. 46.5% (20/43) of patients were vaccinated against SARS-CoV-2 with three doses. According to a clinical evaluation, LC was confirmed in 13 of 43 patients (30%) and it was a possible diagnosis in 7 of 43 patients (16%). Applying the scores, the 2023 score identified as LC 10 of 13 patients (76.92%) clinically evaluated as LC, while the 2024 score identified as LC 8 out of 13 (61.54%) patients clinically diagnosed as LC. Both scores correctly identified the individuals without LC (23/23, 100%). Regarding the possible LC diagnosis, none patient (0/7) was identified as LC with 2023 score, while 1 of 7 (14.29%) with 2024 score. Both scores had specificity and PPV of 100%. Test sensibility, NPV and concordance was better for 2023 than 2024 score, and all parameters improved if the possible LC was not considered as LC (see table1). The data were preliminary and the study is still ongoing.
Conclusions: Although the data are partial, the RECOVER scores, particularly the 2023 score, seem to have a good sensibility and specificity to identify patients with more symptoms and involving more organs. Instead, individuals with fewer symptoms, regardless of severity, might not be detected by the scores.

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Infections in the Immunocompromised Host

P 112 LONG-TERM NEUROLOGICAL OUTCOME IN PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY SURVIVORS

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Background: Progressive Multifocal Leukoencephalopathy (PML) is a demyelinating disease caused by the JC virus (JCV), generally affecting immunocompromised subjects. It typically follows a rapid and often fatal course with a one-year survival of 50% due to immune recovery and disease stabilization. This study aims to evaluate overall survival and neurological sequelae in PML long-term survivors.

Materials and Methods: This is a retrospective multicenter Italian study including PML subjects diagnosed between 1996 and 2022 who survived at least 2.5 years. Diagnosis was achieved by JCV-DNA detection in cerebrospinal fluid (CSF) or by histological examination. PML remission was defined as stabilization or improvement of neurological symptoms, lack of lesion activity at Magnetic Resonance Imaging (MRI), and, when available, negative JCV-DNA in CSF. We assessed the degree of disability by modified Rankin Score (mRS) at PML diagnosis, after 1 year (± 3 months), and 3 years (± 6 months). We used Kruskal-Wallis and Chi-square tests to compare continuous and dichotomic variables and Kaplan-Meier curves to estimate overall survival probability. A p-value of <0.05 was considered statistically significant.

Results: This study included 65 patients, with demographic and clinical characteristics detailed in Table 1. The median time from symptoms onset to PML diagnosis was 31.5 days (25th-75thIQR 15.8-89.3), with a median JCV-DNA level of 3.15 Log c/mL (IQR 2.5–3.9). Median follow-up was 2552 days (IQR 1568-3721), and median survival was 2403 days (IQR 1,467-4,109). Of 47 patients, 36 (76.6%) survived ≥4 years, with a median survival of 3151 days (IQR 2184-4771), but only 13 patients (27.7%) survived 10 years. There was no statistically significant difference in survival probability across the periods 1996-2004, 2005-2012, and 2013-2022, although survival was the highest in the most recent period (Figure 1). The median mRS score at diagnosis was 3 (IQR 2–3), with no significant changes at 1 year (median 3, IQR 2-4) and at 3 years (median 2, IQR 2-4) (p=0.51), and no significant variation in scores distribution over time (p=0.09) (Figure 2). Motor deficits were the most common neurological sequelae 3 years after PML diagnosis, followed by verbal deficits and gait impairment (Figure 3). Following initial remission, PML relapse, as new JCV-DNA positivity in CSF, and clinical and radiological worsening occurred in 3, 1, and 1 cases at year 1, 3, and 9 from diagnosis, respectively.

Conclusions: Long-term prognosis for PML survivors remains poor, with substantial persisting morbidity and mortality. The long-term degree of disability is similar to that observed at diagnosis reflecting either early disease stabilization or initial progression followed by improvement. The median survival was 2403 days (approximately 6.5 years). While relapse was rarely observed, its possible occurrence reinforces the importance of continued vigilance during patients' management.

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Infections in the Immunocompromised Host

P 113 NON-TUBERCULOUS MYCOBACTERIA (NTM) IN PEOPLE WITH HIV (PWH) IN RECENT CART ERA: CLINICAL PRESENTATION AND MORTALITY

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Background: Non-tuberculous mycobacteria (NTM) represent opportunistic pathogens that primarily cause disease in immunocompromised individuals or those with chronic pulmonary conditions, resulting in rather heterogeneous clinical presentations. Before the introduction and in the earlier years of universal cART NTM represented one of the most frequent opportunistic infections in people with HIV (PWH). Which is the current burden of NTM in PWH is largely unknown.

Material and Methods: A retrospective cohort study on patients diagnosed with NTM to a reference University Hospital between 2018 and 2024 was conducted. Demographic and clinical characteristics were collected for all patients and descriptive statistics were run. KM estimates were used to evaluate crude survival and Cox regression analysis to identify factors correlated with the risk of death.

Results: One hundred and thirty patients with NTM were identified, 65 male (50%), median age 67 years (IQR 57 -75). Detailed descriptive characteristics are shown in table 1. Overall, a progressive increase in occurrence of new NTM cases during the study period was observed. Ten (7.7%) out of 130 NTM cases were diagnosed in PWH. The other most frequent comorbidities were: cardiovascular diseases (39, 30.0%), oncological conditions (39, 30.0%), chronic pulmonary diseases (40, 30.8%) of witch 24 (18.5%) bronchiectasis and 16 (12.3%) COPD, autoimmune disorders (25, 19.2%). NTM isolates was achieved in 68 (50.8%) cases from bronchoalveolar lavage (BAL) samples and in 48 (36.9%) cases from sputum, primarily through culture examination (95.8% positivity vs. 58.2% molecular testing and 13.3% microscopy), 1 (0.77%) were isolated from blood. The most frequently isolated Mycobacterium species were Mycobacterium avium complex (MAC) (35, 28.2%), M. chimaera (32, 25.8%), and M. intracellulare (25, 20.2%), while M. abscessus, M. fortuitum, and M. kansasii were each isolated in 6 (4.8%) patients. Among the study cohort, 79 individuals underwent antibiotics of which 79.7% were symptomatic at presentation, with a median treatment duration of 411 days (IQR 226-529) and cure achieved in 41.9% of cases. During 565 PYFU we observed 10 deaths (mortality 1.77 per 100PYFU). At Cox regression analysis male sex at birth (versus female, aHR: 6.23, 95% CI 1.10-35.32; p=0.039), age (per 1 year more, aHR: 1.06, 95% CI 1.01-1.12; p=0.033), and HIV infection (vs HIV negative serostatus aHR: 8.09, 95% CI 1.03-63.67; p=0.047) were independently associated with higher mortality, after adjusting for others comorbidities and therapy.

Conclusions: Despite a persistent occurrence of NTM infection cases in recent years, this burden affects other comorbidities compared to HIV. Nevertheless, a higher mortality in PWH compared to other immunodeficiency causes is still reported. Moreover, considering the consistence number of NTM other than MAC, continuous efforts in terms accurate diagnostic approaches should be warranted.

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Infections in the Immunocompromised Host

P 114 PROLONGED CLINICAL MONITORING OF COGNITIVE PERFORMANCE AND PSYCHIATRIC SYMPTOMS AMONG PACS

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Background: To date, follow-up neurocognitive evaluations in Post-acute COVID-19 Syndrome (PACS) indicate that some degree of impaired performance persists in at least one cognitive domain, typically affecting the same functions initially compromised. In the present study, we aim to enrich longitudinal evidence on cognitive dysfunction and psychiatric symptoms in an Italian sample with PACS.
Material and Method: We included patients enrolled in “NeuroCOVID Study” (EC approval:119/2020). All pts signed informed consent and performed a neurocognitive assessment (NCA) of 20 tests across 5 cognitive domains (memory, attention, language, executive functions, speed of psycho-motor processing) and neuropsychiatric symptoms questionnaires (anxiety, depression and sleep quality) to evaluate their possible influence on neurocognitive performance (NP) at three time points (t0 at approximately 3 months after acute infection, t1 and t2 at 6 and 12 months from t0). The raw scores were adjusted for age, gender and level of education and then converted into equivalent scores (es), on an ordinal scale ranging from 0 to 4 (es=0 below normal NP,es=1 borderline NP,es=2 -3 normal NP,es=4 above normal NP). Impairment was defined by scores below the normative reference value (<cutoff- es = 0). Categorical variables were analyzed using Chi-Square or Fisher's exact tests, and quantitative variables were compared using the non-parametric Friedman test.
Results: Overall, 42 patients, 35.7% female, with a median age of 57 years (IQR 38-81) and 13 years of education (IQR 8-18) performed NCA (Table 1). NP of six cognitive functions improved over time (verbal short-term learning, p=0.032; short-term memory for visuo-spatial stimuli, p<0.0001; working memory, p=0.002; constructional praxis, p= 0.018; phonological verbal fluency, p= 0.05; speed of psychomotor processing, p= 0.002). Also sleep quality improved over time, p<0.0001 (Table 2). Furthermore, we found worsened performance in verbal episodic short-term learning, visuo-spatial short-term memory, visuo-spatial working memory and in speed of psycho-motor processing from t0 to t3 (9.5%, 16.7%, 4.8%, 14.3%, Figure 1). Finally, anxiety-depressive symptoms showed time-varying associations with cognitive performance (Figure 2A-B-C).
Conclusion: This study shows improvement over time in memory, executive functions and language during over the 18-month follow-up period in PACS. However, specific areas of neuropsychological performance may remain stable or decline during the follow-up period. Moreover, cognitive impairments can exacerbate neuropsychiatric symptoms, creating a self-perpetuating cycle. Early interventions to treat symptoms present in the months following hospital discharge could prevent further symptoms and the development of a more complex syndrome.

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Infections in the Immunocompromised Host

P 115 SARS-COV-2 INFECTION IN HOSPITALIZED ONCOHEMATOLOGICAL PATIENTS: A COMPARISON BETWEEN TWO YEARS

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Background: Subjects with oncohematological conditions represent the more fragile patients with the highest risk of developing a more severe form of COVID-19 disease, including a higher risk of hospitalization, a lower response to pharmacological therapies and a higher risk of developing complications (e.g. ARDS, multi-organ failure and nosocomial infections). In the last two years, entering in the endemic phase of SARS-CoV-2 infection, the impact on oncohematological patients is still controversial.
Methods: In this retrospective study we recruited patients admitted with a diagnosis of SARS-CoV-2 infection to the Units of Infectious Diseases of two hospitals in Latium, Italy: the "Santa Maria Goretti" Hospital in Latina, and the "Sant'Andrea" Hospital in Rome, from January 2023 to December 2024. These patients were divided into two groups: the first group comprising patients admitted in 2023 and the second group with patients admitted in 2024. We compared patients considering several factors such as age, comorbidities, underlying hematological disease, vaccination status at the time of hospitalization, absence or presence of pneumonia at admission, type of therapy administered (either early therapy or during hospitalization, considering monotherapy, combination therapy and triple therapy). Statistical analysis was performed with non parametric analysis.
Results: 70 patients (47.1 %F) were enrolled in the study. The 2024 group had an older median age (78 y.o.[IQR 70.5;85] vs 72 y.o.[IQR 64.5;79.5], p = 0.02) (table 1), with more than 95% of patients in both groups being older than 65 y.o. There were no significant differences in underlying oncological and hematological conditions or other comorbidities except advanced age. Nearly all patients were treated with remdesivir, with regimens of 3, 5, or 10 days depending on pneumonia status. Most patients in 2024 did not receive early therapy, as they were typically admitted within 24 hours of diagnosis. While there was no statistically significant difference in the average length of stay (18 days vs 17 days), the 2024 group showed a shorter time to viral clearance, both in absolute terms (10 days [IQR 7;16] vs 16 days [IQR 10;24], p = 0.03) and after antiviral therapy initiation (6 days [IQR 5;9] vs 12 days [IQR 7;20], p = 0.01). Regarding mortality, the 2024 group exhibited a lower absolute mortality rate (9.5%) compared to 2023 group (26.5%).
Conclusions: Our findings suggest that oncohematological patients admitted in 2024 had a better outcome, with shorter viral clearance times and lower mortality, possibly due to several factors: more timely antiviral treatments, evolving therapeutic strategies and attenuation of viral variants. However, the length of hospital stay was similar across groups, indicating a persistent clinical impact of COVID-19 in the last year. The importance of early initiation of antiviral therapy in this high-risk population within the first days of symptom onset remains a crucial point.

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Infections in the Immunocompromised Host

P 116 SPECIFIC T-CELL RESPONSE TO CMV, EBV AND VZV IN PEOPLE WITH MULTIPLE SCLEROSIS UNDER DISEASE-MODIFYING THERAPIES

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Background: People with multiple sclerosis(pwMS) treated with disease-modifying therapies(DMTs) are at high risk of reactivation by CMV, EBV and VZV. An effective T-cell response ensures host control over viral infections. The aim of this study was to characterize the specific T-cell response to CMV, EBV and VZV in pwMS.
Materials and Methods: pwMS and healthy donors(HD) were enrolled. Intracellular cytokine(IFNg, IL2 and TNFa) production by CD4 and CD8 T-cells after in vitro stimulation with CMV, EBV and VZV peptides was assessed. The cells were identified as responding if they produced at least one of the cytokines, and as triple-positive if they produced IFNg, IL2 and TNFa simultaneously. The pwMS were stratified both by CMV seropositivity(CMV+ and CMV-) and by treatment: those receiving anti-CD20(anti-CD20), those receiving anti-alpha-4 integrin(anti-a4), those receiving sphingosine-1-phosphate receptor modulators(S1P), and other treatments(Other).
Results: 46 pwMS and 15 HD(median age of 48[39-59] and 60[52-62] years, respectively) were enrolled. In the pwMS, previous infections with CMV, EBV and VZV were observed in 65%, 81% and 80% of subjects, respectively. In contrast, 93% of HD had anti-CMV antibodies and 100% had anti-VZV and anti-EBV antibodies.
A downward trend in the percentage of CMV-specific CD8 triple-positive T-cells was seen in pwMS compared to HD (p=0.0590). No differences in the cell-mediated responses to EBV and VZV were seen between pwMS and HD. Furthermore, no differences in T-cell specific responses to the three viruses were seen between pwMS subgroups. Interestingly, when looking at the different T-cell subsets, a predominance of only TNFa, followed by IFNg+TNFa+ T-cells, was seen in response to CMV and EBV in both pwMS and HD, as well as in pwMS subgroups. Conversely, a predominance of only IFNg producing-T-cell only was observed in response to VZV stimulation. According to CMV serostatus, a decreasing trend in the percentage of EBV-specific CD4 triple-positive T-cells was seen in CMV-pwMS compared to CMV+pwMS(p=0.0647). In addition, lower percentages of EBV-specific CD4 and CD8 responding T-cells(p=0.0016, p=0.0006) and lower percentages of CD8+ triple-positive T-cells(p=0.0026) were seen in CMV-Other compared to CMV+Other. No differences in VZV-specific T-cell responses were observed. Finally, a prevalence of only TNFa-producing T-cell was observed in all pwMS subgroups in response to EBV, although a more heterogeneous cytokine-producing T-cell subset was observed in CMV-subjects.
Conclusions: Our preliminary data suggest how the response to viruses that can reactivate in pwMS after immunomodulation is influenced by the mechanism of action of DMTs. Furthermore, the polyfunctional T-cell profile varied between pathogens, suggesting that a strong T-cell response may be present against CMV and EBV. Finally, in agreement with literature data, the response to EBV in pwMS appeared to be influenced by previous CMV infection.

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P 117 TRAJECTORIES AND PREDICTORS OF POST-COVID-19 CONDITION PERSISTENCE: A PROSPECTIVE EVALUATION IN THE EUCARE STUDY

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Background: Post-COVID-19 condition (PCC) is defined as ongoing symptoms lasting ≥4 weeks after acute infection. Symptoms may last for months, but data on long-term PCC evolution and persistence are lacking. In this study, we followed patients with PCC to assess the rate of symptoms resolution over time and predictors of PCC persistence.

Materials and Methods: Multicenter cohort study involving patients diagnosed with PCC followed over a maximum of 3 visits for up to 2 years. Patients not returning to their scheduled appointments for more than 1 year were assumed to have resolved symptoms. Predictors of PCC persistence were identified by means of univariable and multivariable logistic regression models. A mediation analysis was used to test if CRP, D-dimer and PLT count at time of hospital admission were intermediates in the comparison between the Wild Type (WT) and all other variants for risk of PCC persistence. The Controlled Direct Effect (CDE) was calculated to assess whether these factors acted as effect modifiers, amplifying persistence risk. All models were controlled for sex, age, comorbidities and calendar time of PCC diagnosis.

Results: Overall, 1,073 patients (906 hospitalized, 167 outpatients) diagnosed with PCC were included. Median age was 58 years (IQR 48-68), 51% were female, median follow-up time was 12.0 months (IQR 10.3-12.0). Overall, 302 patients (28%) exhibited persistent PCC symptoms. WT was the most common variant (666/1073, 62%). At entry in hospital, WT patients were more likely to have heart disease and metabolic syndrome (diabetes, obesity). CRP, PLT count, and D-dimer levels were significantly higher in WT (PLT 223×10^9/L, CRP 73 mg/L, D-dimer 534 ng/mL; p<0.05) and Gamma (PLT 215×10^9/L, CRP 90 mg/L, D-dimer 650 ng/mL; p< 0.05). Being cisgender female was associated with a higher risk of PCC persistence (vs. male OR 1.46, 95% CI 1.12-1.91). After controlling for confounders, WT (when compared to Delta - aOR 0.20; 95% CI 0.09-0.42; Gamma - aOR 0.26; 95% CI 0.09-0.72; and Omicron aOR 0.39; 95% CI 0.14-1.06), smoking (vs. not smoking; aOR 1.67, 95% CI 1.15, 2.42), and obesity (vs. BMI<35; aOR 1.93, 95% CI 1.35, 2.74) were all associated with PCC persistence (Table 1). CDE indicated that CRP, D-dimer and PLT at hospitalization may act as strong modifiers (high levels of CRP and D-dimer and low levels of platelets exacerbated the difference in risk of PCC persistence between WT and other VOCs, Table 2). There was no evidence that any of these markers could mediate this effect (proportion mediated <1%).

Conclusions: Despite the decline in PCC prevalence over time, 1/3 of patients still reported persistent symptoms by 1 year. Risk factors for PCC persistence were infection with the WT strain, female sex at birth, obesity, and smoking. Our data also suggest that a hypercoagulable/inflamed phenotype and low PLT at the beginning of the acute phase may exacerbate the effect of WT in enduring PCC.

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Infections in the Immunocompromised Host

P 118 UNRAVELING THE ROLE OF PERIPHERAL AND MUCOSAL SARS-COV-2-SPECIFIC CD8 T CELL RESPONSES IN SHAPING DISEASE SEVERITY

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Background & Aims: Most of the available knowledge of the cellular immunity to SARS-CoV-2 is limited to peripheral blood T cells showing the crucial role played by the early engagement of multispecific CD4 and CD8 virus-specific T cell responses in the prevention and containment of severe forms of SARS-CoV-2 infection. The aim of our study was twofold: first, to compare acute phase peripheral blood SARS-CoV-2-specific CD8 T cell responses in patients with different severity of disease enrolled in two different epidemic waves of SARS-CoV-2 infection, namely the one sustained by the omicron variant and the first original wave before omicron emergence; second, to compare peripheral blood and nasal-resident total and SARS-CoV-2-specific CD8 T cells in the acute phase of SARS-CoV-2 omicron variant infection.

Material and Methods: Peripheral blood dextramer+ SARS-CoV-2-specific CD8 T cells were analyzed from patients with severe (n=15), weak (n=37), or asymptomatic (n=20) acute omicron variant SARS-CoV-2 infection and from 14 patients with severe acute SARS-CoV-2 infection during the first epidemic wave. Paired peripheral blood and mucosal samples were available from the acute phase of 22 SARS-CoV-2 omicron variant infected patients. Blood and mucosal samples were analyzed ex vivo for co-expression of activation markers and effector molecules. Cytokine production was evaluated only on peripheral blood SARS-CoV-2-specific CD8 T cells by both ex vivo FluoroSPOT and intracellular cytokine staining assays based on PBMC stimulation with Spike peptides of optimal length for CD8 T cell recognition.

Results: A large predominance of circulating spike-specific CD8 T cells with high expression of the activation markers PD-1 and CD38 and cytotoxic granule production was detected in all symptomatic patient categories compared to asymptomatic patients. Importantly, spike-specific CD8 T cells from the first wave of acute severe SARS-CoV-2 infection appeared to be the most severely dysfunctional showing a reduced cytokine secretion capability and low levels of CD39 expression compared to mild and severe symptomatic patients infected during the most recent omicron wave. SARS-CoV-2-specific CD8 T cells in the nasal mucosa of patients with acute omicron SARS-CoV-2 infection exhibited higher frequencies and broader multi-specificity compared to PBMCs, while their activation state was similarly elevated in both compartments.

Conclusions: Our study identifies distinct phenotypic and functional profiles of the circulating SARS-CoV-2-specific CD8 T cell population during the initial and the omicron waves that may have significantly shaped the evolution of the disease.

Multi-specific anti-viral CD8 T cells are enriched in the nasal mucosal compartment, where they likely play an important role in first-line defense from infections and in prevention of their severe evolution.

Infections in the Immunocompromised Host

P 119 VARICELLA ZOSTER VIRUS VACCINATION IN PATIENTS WITH HAEMATOLOGICAL DISEASES AND PRIMARY IMMUNODEFICIENCIES. ASSESSMENT OF SPECIFIC T AND B-CELL RESPONSES

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Background: The reactivation of varicella-zoster virus (VZV) causes herpes zoster (HZ) and is more frequent in subjects with primitive or acquired impairment of the immune system. An adjuvanted recombinant subunit vaccine (HZ/su) has been approved for the prevention of HZ in adults with immune impairments, although limited data on HZ/su immunogenicity in this specific group are available. We aimed to investigate VZV-specific immunity in haematological patients (HE) and individuals with primitive immunodeficiency (PrID) after HZ/su vaccination.
Material and Methods: HE and ID patients were administered two doses of HZ/su 2 months apart (T0 and T1 respectively), with a follow-up visit 1 month after the second dose (T2). T-cell responses were assessed at T0 and T2 with an in-house Interferon Gamma Release Assay (IGRA), consisting of heparin whole blood stimulation with VZV gE peptide libraries (JPT). Each test included a negative (NC) and positive (phytohemagglutinin, PHA) control. IFN-gamma production was measured with the automated ELLA platform. Anti-gE antibody concentration were assessed with a commercial Elisa kit (DBA). Data were presented as median (interquartile range, IQR). Medians were compared using the Wilcoxon rank test.
Results: We enrolled 25 HE patients (13F/12M, mainly with Non-Hodgkin Lymphoma) and 16 PrID patients (6F/10M, mainly with common variable immunodeficiency or ipogammaglobulinemia). Median age was 67 [59-72) years and 59 [34-65) years, respectively. Median IFN-gamma production after gE stimulation significantly increased after HZ/su vaccination in both HE and PrID subjects (Wilcoxon $p<0.0001$ and $p=0.002$, respectively) (Figure 1A). However, considering as effective a vaccinal response greater than 4-fold increase in IFN-gamma production from T0 to T2 for the gE stimulated condition, 8/25 (32%) HE and 6/16 (38%) PrID patients were considered as non-responder. Concerning B-cell response, a significant increase in anti-gE antibody concentration were observed in both HE and PrID subjects (Wilcoxon $p=0.0004$ and $p=0.0012$, respectively). However, 10/25 (40%) HE and 9/16 (56%) PrID patients showed less than 2-fold increase in anti-gE concentration from T0 to T2.
Conclusions: VZV gE IGRA is a sensitive and specific tool to assess CMI after HZ/su vaccination in HE and PrID patients. A significant amount of HE and PrID patients had an impaired cell-mediated and humoral response after HZ/su vaccination. The implications of the reduced immunogenicity of HZ/su vaccination in terms of protection from HZ need to be further investigated in wider cohorts of immunocompromised patients with longer observation periods. We can speculate that a different vaccination schedule with supplementary booster doses could be advisable for these subjects. Multi-cytokine assessment of VZV gE-specific T-lymphocyte responses is currently ongoing in our group, to better characterize CMI in immunocompromised subjects.

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Infections in the Immunocompromised Host

P 120 VIRAL RESPIRATORY INFECTIONS IN IMMUNOCOMPROMISED AND IMMUNOCOMPETENT PATIENTS: A CASE-CONTROL STUDY

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Background: Respiratory infections may be more severe in immunocompromised patients, although their impact is not fully understood. This study aimed to compare the distribution and viral load of respiratory infections in immunocompetent versus immunosuppressed patients.

Material and Methods: A case-control study was conducted in immunocompetent and immunocompromised patients at Bambino Gesù Children's Hospital (January-December 2024). The first respiratory sample was analysed with the Allplex-Respiratory-Panel and Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2) tests. Some samples were tested for Mycoplasma pneumoniae by qPCR. Case-Controls were matched for collection date, age and sex.

Results: Of the 292 patients, 146 were immunocompromised and 146 were immunocompetent. The most common immunocompromised condition was Hemopoietic-Stem-Cell-Transplantation (HSCT,N=39), followed by leukaemia/lymphoma (N=39), neonates in sub-intensive care unit (ICU,N=37) and solid-organ transplantation (SOT, N=25).

Overall, 68.8% (N=201) tested positive for at least one virus with no difference in distribution between the two groups (63.7% cases vs. 74.0% controls;P-value:0.077). Human Enterovirus (19.4% vs. 8.6%;P:0.043) showed the highest prevalence in immunocompetent patients, while SARS-CoV-2 (9.7% vs. 1.9%;P:0.025) was more prevalent in immunocompromised patients.

Viral mono-infections were observed more frequently in immunocompromised patients than in immunocompetent (76.3% vs. 63.0%, P:0.047). Except for SOT (56.2%), a higher rate of mono-infection was observed in all other immunosuppression categories (80.0%;P:0.053).

In the immunocompromised-group, SARS-CoV-2 was associated with HSCT (20.7%;P:0.024), Adenovirus with SOT (18.8%;P:0.034) and Respiratory Syncytial Virus (RSV) with neonates in the sub-ICU (45.8%;P <0.001).

No differences in viral load (measured by cycle threshold, CT) were observed between cases and controls. However, when considering the type of infection (mono-infection vs co-infection) within each group, only Human Rhinovirus (HRV) CT value was statistically significant (P:0.019). Among the two groups, HRV CT value was significantly lower in mono-infection (median[IQR]: 26.5 [22.9-36.9]) than in co-infection (36.6 [27.1-38.2]) in the immunocompetent patients (P:0.025), while there was no statistically significant difference in the immunocompromised ones (P:0.810).

Notably, 100% of immunocompromised pneumonia patients had a viral mono-infection compared to 48.3% of immunocompetent patients, who had 12 viral mono-infections, 11 viral-viral, and 6 viral-M.pneumoniae co-infections.

Conclusions: This study shows that immunocompromised paediatric patients have a higher frequency of isolated viral infections due to specific virus depending on their immunocompromise. This highlights the distinct patterns of viral infection in these patients and the need for targeted surveillance and management strategies in this vulnerable population.

Infections in the Immunocompromised Host

P 121 WHAT REMAINS OF LONG COVID AFTER FOUR YEARS FROM HOSPITALIZATION FOR SEVERE COVID PNEUMONIA

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Background: Long COVID (LC) is an infection-associated chronic condition. It is multisystemic and negatively impacts on quality of life. Symptoms are various and can overlap with syndrome such as myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), dysautonomia, and mast cell activation syndrome. The aim of this study was to describe the prevalence of symptoms at four years from discharge in hospitalized population.
Material and Methods: Patients discharged from the hospital diagnosed with SARS-CoV-2 infection, were evaluated in a Long COVID clinic created in 2020 at the San Gerardo Hospital in Monza. In this analysis we described symptoms present at follow-up visit. We evaluated the prevalence of ME/CFS using CDC definition. According to WHO and NASEM definition of Long COVID, we described the prevalence of LC in our cohort. Finally, we evaluated the quality of life at four years after COVID pneumoniae through EuroQol VAS questionnaire.
Results: From January to February 2025, we visited 43 patients. The median time from discharge to follow-up visit was 4.8 (4.4-4.8) years. Median age was 65 years old (59-71) and 65.1% (28/43) were male. The median BMI was 27 (25-31.1) and remained stable from discharge to follow-up. 85.7% (36/43) of individuals required non-invasive ventilation with CPAP during hospitalization. The most prevalent symptoms at four years of follow-up were: fatigue (24/43, 55.8%), brain fog (18/43, 41.9%), sleep disorder (17/43, 39.5%), dyspnea (17/43, 39.5%), muscular and joint pain (14/43, 32.6%). Criteria of MF/CFS were met in 4 patients of 43 (9.3%), of whom 3 patients had had a diagnosis of fibromyalgia post-COVID. Dysautonomic symptoms (orthostatic intolerance, palpitation, blurred vision) were present in 7 individuals of 43 (16.3%). Allergy-type symptoms were reported in 7% of patients (3/43). According to NASEM definition, LC syndrome was diagnosed in 46.5% of patients (20/43). Compared to patients without LC, the former were mostly female (LC 11/20, 55%; no LC 4/23, 17.4%), had two or more comorbidities (LC 14/20, 70%, no LC 6/23, 26.1%) and were more frail (Clinical frailty scale >4: LC 5/20, 25%, no LC 1/23, 4.3%). Regarding the quality of life, only 40% (8/20) of individuals with LC reported to have fully recovered the autonomy in daily life. However, both individuals with LC and no LC had a good perception of their health status (VAS in LC 70, 50-80; no LC 80 (75 -90). The data were preliminary and the study is still ongoing.
Conclusion: In our small cohort, LC was still present at four years in about half of the patients with previous severe COVID pneumonia. Although there was not a full restoration of health conditions pre-COVID, the positive side of our data was that this condition might have no impact on the perception of quality of life.
Table 1

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PrEP

P 122 ASSESSMENT AND MONITORING OF PSYCHOLOGICAL, SEXUAL, AND RELATIONAL STATUS IN INDIVIDUALS ACCESSING A PRE-EXPOSURE PROPHYLAXIS (PREP) PROGRAM

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Background: Access to pre-exposure prophylaxis (PrEP) may influence, and may also be influenced by, users' psychological, sexual, and relational characteristics. The primary objective of this study is to evaluate and monitor factors related to the psychological, sexual, and relationship status of individuals accessing PrEP.
Material and Method: We included patients (pts) enrolled in the "VAMOS-PrEP Study" (EC approval:16/2024). All pts signed informed consent and performed the following psychological questionnaires (PQ) three times: baseline (T1) and at six (T2) and twelve months from T1 (T3): the Sexrelation Evaluation Schedule Assessment Monitoring questionnaire (SESAMO), which investigates dysfunctional aspects in sexuality (social, environmental data, motivation, and conflicts, medical anamnesis, previous sexual experiences, masturbation, sphere of pleasure, desire, psychosexual identity, and body image) and the Symptom Checklist-90-R questionnaire (SCL-90-R), which assesses the psychological status through 9 indices (anxiety, phobic anxiety, depression, paranoid ideation, interpersonal sensitivity, obsessiveness/compulsiveness, hostility, psychoticism, and somatization). Statistics were assessed by the Wilcoxon rank-sum test and Fisher's exact test. The impact of PrEP at t2 was investigated for each item by quantifying the intervention's effect size using Cohen's d and its significance using the Wilcoxon signed-rank test.
Results: 91 pts performed PQ: 89 (98%) identified as male, with a median age of 37 (IQR 30-45). 12 (13%) on chemsex, 73 (80%), and 77 (85%) declared themselves single and homosexual, 55 (60%) had a university degree, and 46 (53%) were employed (Table 1). Only 44 (48%) pts completed the questionnaires at T2 and 9 (9.9%) T3. Among the reasons for PrEP discontinuation, stable relationships, and personal and work-related reasons were the most commonly reported.We found a small effect size (>0.2) of PrEP initiation in SCL-90-R for depression (m=81.1 at T1 and 78.2 at T2, p=0.071, cohens=0.3),paranoid ideation (m=79.9 at T1 and 75.9 at T2,p=0.081,cohens=0.2). interpersonal sensitivity (m=80.4 at T1 and 77 at T2,p=0.042,cohens=0.3),and psychoticism (m=99.6 at T1 and 95.9 at T2,p=0.054,cohens=0.3);similarly,for motivation and conflicts (m=31 at T1 and 39.8 at T2,p=0.048,cohens -0.4) of SESAMO (Figure 1a,b), where scores increased from T1 to T2 (Table 2 and 3).
Conclusion: Our data suggest that PrEP use has minimal effect on individuals with altered psychological status. In addition, social reference context, personal motivation, and conflict with relational figures represent influential characteristics in PrEP use. However, the lack of normative baseline and longitudinal data does not allow us to consolidate these hypotheses. The results obtained can help improve the healthcare provided to PrEP treatment patients by identifying any psychological or sexual problems and adopting targeted interventions to address and overcome them.

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PrEP

P 123 EXPLORING THE ATTITUDE ABOUT USING TELEHEALTH IN PERSONS ON PRE-EXPOSURE PROPHYLAXIS (PREP)

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Background: After the COVID-19 pandemic, telehealth gained popularity for remote consultations, medications, and follow-up care, potentially enhancing access to PrEP. However, to date in Italy there is limited data on the acceptance of telehealth services for PrEP. The aim of the study was to explore attitudes toward telehealth among PrEP users through a self-administered paper questionnaire.

Materials and Methods: We conducted a cross-sectional, single-center survey of persons on PrEP between March and December 2024. An Italian adaptation of a questionnaire based on validated instruments used in the HIV population (1) was constructed. It consisted of closed multiple-choice questions, allowing for single or multiple answers. It comprised 10 items, all focused on the participants' perspectives. The survey assessed the availability of digital tools, the willingness to adopt telehealth, the expected frequency of use, and the benefits and concerns related to telehealth. Additionally, we collected demographic and clinical variables including personal information such as age, gender, country of origin, level of education, distance from the hospital, occupation, PrEP regimen, presence of co-infections and comorbidities. Descriptive statistics have been used to assess patients' propensity to use telehealth and explore the reported benefits and concerns.

Results: A total of 450 participants were included in the study. 246 (54.7%) were < 40 years old, 440 (97.8%) were male, 407 (90.4%) homosexual, and 415 (92.2%) were Italian. 281 (62.4%) were using PrEP on demand. Participants' characteristics are described in Table 1. Regarding the propensity to telehealth, most of the samples (91.3%) expressed a preference for video calls with their doctor instead of visiting the clinic. When asked about the desired frequency of video calls, responses were generally positive: 29.1 % answered "always", 38% chose "often", 24.7% said "sometimes" and only 2.2 % said "never". Reported benefits mainly related to better schedule organization (89.7%) and the convenience of not having to go to the clinic (85.8%) Conversely, concerns were mostly about maintaining privacy at home (24.8%) and the doctor's ability to accurately assess the patient's condition (24.2%). Detailed answers are shown in Fig.1.

Conclusion: Preliminary results of this survey indicated a high propensity to use telehealth services, with a significant portion expressed a willingness to engage regularly. However, the study also highlights important concerns that need to be addressed, particularly related to privacy at home and the potential limitations of remote assessments by healthcare providers. By understanding both the benefits and challenges of telehealth, healthcare providers can better support PrEP users and improve health outcomes within this population.

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PrEP

P 124 HIV PREP AND STI SURVEILLANCE: INSIGHTS FROM A TERTIARY HIV UNIT

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Background: robust evidence has demonstrated that HIV pre-exposure prophylaxis (PrEP) represents a crucial tool in reducing HIV acquisition in populations at risk of acquiring HIV through unprotected sex. In addition, persons receiving PrEP are usually offered the opportunity to get tested also for other sexually transmitted infections (STIs). The recent increase of new HIV infections after the COVID-19 pandemic, combined with the persistent incidence of STIs, underscores the need for continuous monitoring based on real-world data, to evaluate the long-term effectiveness of this strategy. We aimed to assess PrEP effectiveness, adherence, and safety in adults using PrEP as well as the acquisition of other STIs.

Material and Methods: since 2019, we have established a comprehensive service for PrEP prescription and STIs testing at our Infectious Diseases Unit. This service includes screenings for HIV, Hepatitis A, B, C, syphilis, as well as pharyngeal, urethral, and rectal swabs every 3 to 4 months, along with safety blood tests. Access to our services is guaranteed with no waiting list, supported by a dedicated phone line and email address, allowing for both in-person visits and telemedicine consultations. For this study, we reviewed the medical records of all individuals who initiated PrEP at our Infectious Diseases Unit from January 2019 to March 2025. Demographic, laboratory, clinical, and risk exposure characteristics and outcomes were described.

Results: a total of 515 persons were enrolled in our PrEP program (figure 1). Mean age was 40 years (range 21-76); 485/515 (94%) were MSM. On demand PrEP was preferred by 58% of users, compared to 27% who chose daily PrEP and 15% who opted for a mixed approach of on demand and daily PrEP. Adverse events (AE) were reported by 138 PrEP users (26%), with 96 (70%) experiencing gastro-intestinal discomfort, 32 (23%) headache, and 9 (6%) weakness. During the follow-up, 120 subjects (23%) discontinued PrEP: 2% due to PrEP related AEs, 64% were lost to follow up, 15% moved to another city and 19% stopped using PrEP. One case of acute HIV infection was observed and related to self-discontinuation of PrEP. 132/515 PrEP users (25,6%) developed STIs, including 48 cases of syphilis (9%), 20 cases of gonorrhea (4%), 56 cases of chlamydia (20%), and 8 cases of mixed infections (2%). No acute viral hepatitis cases occurred. As of March 2025, 21 users moved from oral to long acting cabotegravir PrEP experiencing no significant AEs after the first injection.

Conclusions: our study, which predominantly included MSM, demonstrated a consistent increase in access to PrEP, likely associated with its reimbursement starting in September 2023. PrEP has proven to be highly effective and well-tolerated. Notably, on-demand PrEP, which was the preferred option among our participants, has shown to be a valid alternative to daily PrEP for MSM. However, we have noted a worrying rise in other STIs, with no current evidence of antibiotic resistance. A critical area for further research is the relatively high discontinuation rate of PrEP among users.

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PrEP

P 125 IMPLEMENTATION OF PREP IN ITALY: HIGHLIGHTS AND CHALLENGES. FINDINGS FROM THE PRIDE SURVEY

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Background: The implementation of pre-exposure prophylaxis (PrEP) in Italy has expanded significantly from 2023 to 2024, reflecting a growing awareness of its effectiveness in preventing HIV transmission. The authorization of PrEP reimbursement by the Italian Medicines Agency (AIFA) in May 2023 played a pivotal role in improving access. However, regional disparities in uptake persist, necessitating further investigation into accessibility and service delivery across the country.
Methods: A nationwide survey (PrIDE) was conducted across 62 centers in 2023 and 2024 to assess trends in PrEP uptake, user demographics, and regional distribution. Data were analyzed to compare new and active PrEP users, the impact of reimbursement policies, and the ratio of People With HIV (PWH) to PrEP users across different regions. Factors influencing PrEP accessibility, such as structural and organizational barriers, were also examined.
Results: The number of PrEP users increased by 43.2% nationally, reaching 16,220 individuals in 2024 (Figure 1). The highest growth was observed in Emilia-Romagna (+54.67%), Friuli (+65.43%), and Trento Province (+51.09%), while regions such as Campania (+10.00%) and Puglia (0.00%) showed slower progress.
Though disparities remain, the PWH/PrEP ratio decreased in most regions, indicating improved PrEP coverage. Despite the expansion of services, access is still centralized in HIV clinics, potentially limiting reach to marginalized populations.
Conclusions: While Italy has made substantial progress in PrEP implementation, regional inequalities and structural barriers remain. To achieve equitable access, decentralization of services, broader provider involvement, and targeted interventions in underserved areas are essential. Addressing these challenges will be crucial in advancing Italy's goal of reducing HIV incidence.

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PrEP

P 126 INCREASE PREP UPTAKE TO REDUCE HIV INCIDENCE IN ITALY: THE CASE FOR SIMPLIFIED PREP DELIVERY

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Background: The incidence of new HIV diagnoses in Italy has increased in the last three years. At the same time, PrEP is largely under-utilized, with robust PrEP uptake only in Milano and Roma. High PrEP uptake among people at substantial risk for HIV is essential to reduce new infections. The current PrEP delivery model is defined by national HIV guidelines, last updated in 2017, and guidelines for PrEP dispensation adopted by the Italian Medicines Agency (AIFA) in 2023. Access to PrEP may be improved by simplifying PrEP delivery in line with EACS and WHO recommendations. WHO guidance on PrEP and EACS guidelines were last updated in 2024.
Material and Methods: WHO guidance on PrEP and EACS guidelines were reviewed to identify recommended procedures for PrEP delivery. National HIV guidelines and AIFA guidelines were reviewed to assess alignment of the Italian PrEP delivery model with the recommended procedures identified.
Results: Procedures for PrEP delivery recommended by both EACS and WHO were grouped into five thematic areas: eligibility, initiation visit, follow-up visits, simplified service delivery and sexual health. EACS and WHO guidance are broadly aligned, with minor differences (Table 1). Italian guidelines are not aligned with EACS and WHO guidance, with major gaps observed for eligibility, initiation procedures and simplified service delivery (Table 1). Individuals with a possible exposure to HIV in the previous 30 days are not eligible for PrEP, contrary to EACS and WHO recommendations. PrEP initiation is delayed until lab results are ready. Dosing schedules are outdated and not in line with EACS and WHO indications. PrEP is reimbursed within the national health system only when prescribed and dispensed at HIV clinics. WHO recommends community-based PrEP delivery and task-sharing with peer and lay providers in service delivery, which are not mentioned in Italian guidelines.
Conclusions: This review highlights several and serious gaps in Italian PrEP guidelines, which should be addressed by an update. Restricted eligibility, delayed initiation and quarterly follow-ups are major barriers to PrEP access and broader uptake. Addressing these issues would also support more efficient use of financial and human resources, allowing a significant increase in PrEP users that can be followed by each centre without allocating additional resources. Same-day PrEP initiation following a negative rapid HIV test, simplified clinical monitoring, twice-yearly follow-ups for experienced PrEP users and telehealth, in line with EACS and WHO guidance, are safe and acceptable solutions that would reduce the number of visits needed. Integrating community-based delivery into the national health system, and task-sharing with peer and lay providers would further increase the accessibility and cost-effectiveness of PrEP services. Simplified and differentiated delivery of PrEP is needed for increased PrEP uptake and reducing new HIV infections in Italy.

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PrEP

P 127 PREP - WHERE ARE WE NOW? UNDERSTANDING PROVIDERS' PERSPECTIVES ON CURRENT PRACTICES AND LONG-ACTING PREP IN SOUTHERN ITALY

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Background: Despite the lack of official statistics on PrEP uptake in Italy, community-based surveys highlight significant barriers and regional disparities. Considering PrEP reimbursement in 2023 and long-acting (LA) formulations forthcoming, we assessed the organizational structure and prescribing patterns of Infectious Diseases (ID) providers in Southern Italy, where PrEP prescription rates are the lowest.

Material and Methods: Semi-structured, open-ended question interviews were conducted with representatives of ID centers offering PrEP service in Apulia, Molise, and Basilicata, as per the Plus Onlus newsletter.

Results: Across the regions,11 ID centers actively provide PrEP: 10 hospitals (1 in Molise, 2 in Basilicata, 7 in Apulia) and 1 territorial outpatients service (Apulia).

On average, PrEP prescriptions started 17 months ago, but 4 centers began in 2022 (Bari, Lecce, Taranto, Potenza), 4 in 2023 (Campobasso, Bisceglie, Foggia, Brindisi), 1 in 2024 (Altamura), and 2 in 2025 (Foggia outpatients service, Matera). Typically, one physician provides PrEP in each center, with an uneven geographic distribution and doctor-to-population ratio (Figure 1). Visits are joined to general ID (5/11), HIV (5/11), or STI (1/11) services, with shared nursing staff.

Only 3/11 centers offer walk-in PrEP visits. Furthermore, only 2 provide comprehensive laboratory screenings, including microbiological tests, while the others only offer free HIV testing.

Since 2022, 294 PrEP requests have been recorded, with Lecce and Bari demonstrating the highest prescribing rates (38% and 22%, respectively). Four centers mainly prescribed continuous PrEP, five preferred PrEP on demand, and the remaining offered a combination of both.

During 2024, there were 202 active PrEP users (Table 1). In the same centers, 4,205 PLWH had been under care, and 145 of them had a diagnosis in 2023 (user-to-diagnosis and user-to-PLWH ratios of 1.39 and 0.05, respectively). Overall, 66 losses to follow-up were reported from the start.

From the providers' side, the main challenges were generic medication shortages (6/11) and a lack of dedicated staff (5/11). From the patients' side, 7/11 centers mentioned test costs, 2/11 had issues with microbiological screening, 1/11 had long waiting lists, and 1/11 had medication shortages, shifting costs to patients

Eight providers supported LA PrEP, 2 were uncertain, and 1 opposed. Concerns included organizational difficulties (4/11), fear of increased HIV/STI incidence (4/11), and high medication costs (1/11). The adherence to follow-up and the utilization of continuous PrEP were identified as pivotal criteria for candidacy for LA therapy.

Conclusions: PrEP in Southern Italy is a growing reality, despite disparities in access, resource allocation, and prescribing patterns. LA PrEP is supported, although there are economic and organizational concerns. Policies that optimize HIV prevention nationwide and ensure equitable access are urgently needed.

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PrEP

P 128 THE ROLE OF ANCONA CHECKPOINT IN COUNSELING AND FACILITATING PREP ACCESS THROUGH TELE-VISITS

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Background: The three pillars for achieving the 95-95-95 UNAIDS targets are providing early ARV treatment to all PLWH, increasing HIV testing to detect undiagnosed infections and implementing knowledge and adoption of preventive measures, such as pre-exposure prophylaxis (PrEP). Barriers to widespread PrEP access include geographic isolation, stigma, and lack of knowledge. Providing PrEP through tele-visit (an approach known as "tele-PrEP"), could help to overcome these barriers. Through a partnership agreement with Azienda Ospedaliero Universitaria delle Marche, since June 2023 the Ancona Checkpoint provides access to "tele-PrEP", consisting in online face-to-face consultation with a clinical immunologist. The present study aims to evaluate the degree of knowledge of PrEP among Ancona Checkpoint users and the effectiveness of tele-visit in facilitating access to PrEP.
Material and Methods: Questionnaires collected from Ancona checkpoint users from March 2022 to February 2025 were examined using COBATEST database. Gender, age, sexual orientation and PrEP knowledge were considered for the analysis.
Results: During three years of Ancona Checkpoint activity, 2.151 subjects accessed the service and filled out COBATEST questionnaire. Only 35% of them had heard about PrEP previously; of them 70,6% identified as males, 27,4% as females, 1% as transgender and 1% as other. Median age was 27,7 yrs, 60.8% being in the age group 18 -30 yrs, 34.4% in the 31-50 yrs, 4.8% over 50 yrs. Most of them (99.1%) were Italian. Regarding sexual orientation, 42.5% defined themselves as heterosexual, 40.1% as homosexual, 10.8% as bisexual, and 6.6% as other non-binary. The vast majority of subjects (92.3%) had never taken PrEP. 47.4% of them said they were not interested for the following concerns: need to take medication on a daily basis (34.2%), possible side effects (10%), need for frequent medical check-ups (11.9%), need to go to the hospital for drug supply (6.6%). Between June 2023 and February 2025, 49 individuals accessed "tele-visit" through Ancona Checkpoint and 36 of them (73.5%) entered PrEP program: two in 2023 (3.8% of new 2023 PrEP), twenty-nine in 2024 (37.7% of new 2024 PrEP) and five in the first two months of 2025 (50% of new 2025 PrEP).
Conclusions: Proportion of people who access PrEP through tele-visit is increasing over-time. This result indicates that checkpoint services can be a powerful instrument to facilitate access to PrEP. In addition, the amount of counseling and testing provided by Ancona Checkpoint in the first three years of activity further highlights the potential role of this service in terms of sexual health education and prevention of HIV/AIDS and other STI.

Social Science, PROs

P 129 ACCEPTABILITY AND AVAILABILITY TO CHANGE CARE FOR PEOPLE LIVING WITH HIV FOLLOWED BY HOME CARE ASSISTANCE (HCA)

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Background: Poor adherence to antiretroviral therapy (ART) and regular outpatient follow-up in people living with HIV (PWH) present considerable management challenges in multi-morbid and vulnerable populations, which are also numerous in high-income countries. Home care assistance (HCA) is an innovative system for re-integration and maintenance of care for PWH lost to follow-up. For a considerable proportion of the population, home care constitutes an essential service, as they are unable to attend outpatient services. The aim of this study is to assess the acceptability of home care and to explore the willingness of patients to return to outpatient services, in addition to identifying their real impediments and needs.

Methods: In the period from February to the 10th of March 2025, a comprehensive anonymous questionnaire was administered to PWH under the care of HCA in Policlinico A. Gemelli in Rome, who had consented to the administration of the questionnaire. The questionnaire consisted of 6 closed questions and 2 questions rated from 1 to 10. Ten PWH were excluded from the study due to their inability to complete the questionnaire independently, because of a neurological impairment.

Results: Of the total number of PWH followed by the home care service (n. 52), we administered and analyzed 42 specific and anonymous questionnaires. Most subjects (26.2%) had been under the care of the HCA for one year, 21.4% for three years, and 4.8% for more than ten years. The satisfaction of the PWH with the service was recorded at the highest rating for 86% of the study population. The majority of subjects (14 PWH, 33.3%) required and received between three and five monthly nursing and medical home visits, while 7.1% required more than five home visits [Figure 1]. It is noteworthy that 100 % of PWH expressed the opinion that they were unable to return to the outpatient service. In addition, 50% of subjects stated that they were physically unable to attend the outpatient clinic, while 38.1% stated that they had other impediments to attending the clinic. The most prevalent reasons cited were physical disability, the necessity for walking aids, and the absence of autonomy in terms of domestic mobility. Furthermore, 5 % of respondents expressed feelings of abandonment in the context of the cessation of home care services. It is noteworthy that none of the subjects in this study have claimed to have experienced a breach of privacy related to HIV infection in the context of receiving home visits. The relationship between the patients and the nurses was given the highest rating by 93% of the PWH.

Conclusions: As our survey of PWH showed that home care is a service of paramount importance for many frail PWH with high care needs. The implementation of this model of services, in conjunction with the establishment of supportive social networks, is absolutely crucial for the management of fragile populations.

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Social Science, PROs

P 130 ANALYSIS OF THE FINAL DATA AND FUTURE PROSPECTS OF THE "FRAGIL/MIND" PROJECT

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Introduction: On 20.10.2023, the project "FRAGIL/mind" approved by the Apulia Region - WELFARE DEPARTMENT - through the Public Notice "PugliaCapitaleSociale 3.0" for local programs of actions of general interest under the ministerial funds ex art. 72 and 73 of Legislative Decree 117/17, aimed at supporting, at the regional level, activities promoted by ETSs, was launched. The data we will report refer to the entire duration of the planned activities (20.10.2023 - 20.02.2025).

Methods: The recipients of the project were: people living with HIV, or in AIDS or other STIs; Households in poverty even with minor children; People undergoing alternative sentences to prison; Migrants without residence permits or residing in the Region. The idea for the project arose from having detected the absence of a structured counseling and psychological support service aimed at the recipients described above, people, almost always, left alone in dealing with psychological distress. The team, consisting of a Coordinator, 3 Psychologists and a Social Worker, through supportive and informative activities, provided social and psychological assistance, so as to process and scale back fears and guilt. In addition, they fostered the creation of a good therapeutic alliance from the new diagnoses; supported the recipients to enhance the ability to manage the psychological reaction towards everyday life; improved emotional well-being in order to better cope with stress. Finally, they sought to prevent phenomena of discrimination and offered personalized information on resources in the area, increasing the possibilities of "welcoming" through the establishment of a privileged territorial point.

Results: During the period we listened to 34 people, of whom 10 were female and 24 male through 664 individual meetings. Of these 34 people, 10 suffer from depression, 11 from anxiety disorder, 4 from mood disorder, 6 from personality disorder, and 3 from difficulties related to the acceptance of HIV status. As for origin, one is a foreigner, 28 reside between Bari and its province, and the rest are from Foggia, Brindisi, Taranto, Matera and Potenza. The average age is 47 years.

Conclusions: Compared to the last survey, the data are all up, both in the number of individual encounters and in the average age of service afferents. In conclusion, the benefits brought to those served, at the end of this project, were as follows: excellent psychological therapeutic relationship that developed more confidence in taking ART; improved communication with their family environment, having our professional figures as a "bridge" to deal with various contexts; improved perception of themselves as persons worthy of value and respect; development of awareness of their rights; improved quality of life. All this was possible mainly due to the free service, having intercepted the difficulties in accessing public social and health services in a direct, quick and concrete way. Looking forward, the project, dealing with frailty, will not have a conclusion, but an enhancement, such that it will be even more structured.

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Social Science, PROs

P 131 ANLAIDS COMMUNITY-BASED HIV SCREENING AS A TOOL TO IMPROVE HIV DIAGNOSIS AMONG ASYMPTOMATIC INDIVIDUALS

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Background: HIV testing is the first essential step on the path of reaching the UNAIDS global goal of ending AIDS as a public health threat by 2030. Since HIV-related stigma remains a key barrier to test access, Community Based Voluntary Counselling and Testing (CBVCT) may be more effective in addressing this issue. Anlaids has ever been committed to provide people with knowledge and skills to prevent HIV infection and other sexually transmitted infections (STIs). Following the availability or rapid HIV tests, many of the regional offices of Anlaids started to offer out-of-hospital HIV counselling and testing initiatives, often provided in conjunction with other infectious disease tests.

Material and Methods: Aim of the study was to evaluate the number of HIV tests conducted (testing volume) and the percentage of HIV-positive results obtained (positivity) in 12 different Anlaids offices located in 10 Italian regions, from northern to southern Italy. Five sites collected data on yearly basis from 2018 to 2024, 7 sites from 2020 to 2024. The data collection form allowed extrapolating subjects who received their first HIV test ever.

Results: From 2018 to 2024 11,424 rapid HIV test were done (41.9% salivary test, 58.2% blood test). Overall, male to female ratio was 61,1% to 38,9%; age distribution was: 43% 18-24 yo, 28% 25-30, 16% 31-40, 7% 41-50, 5% 51 -64, 1% 65 or over; sexual behaviour was: 61% heterosexual, 34% MSM, 2.5% bisexual, 2.5% other/no response; Italians were 75%, foreigners 25%. The total number of positive tests was 87, with a positivity rate of 0.73%. Six out of 12 sites were able to extrapolate data on “first-ever-HIV-test”. The number of “first-ever-HIV-test” was 4,185/8,989 (46.5%); the number of positive “first-ever-HIV-test” was 15 out of 4,185, with a positivity rate of 0.36%.

Conclusions: In Italy, 8,000-10,000 individuals are estimated to be unaware of their HIV infection. Most of them are presumably asymptomatic, since national data on new HIV diagnoses in 2023 confirm the high frequency (35%) of people undergoing HIV test only when symptoms develop. Our data show that the positivity rate in a small sample of asymptomatic young individuals undergoing HIV test for the first time in their life in CBVCT setting is 0.36%. By applying this rate to the estimated number of people unaware of their HIV status, we can assume that at least 2.5 million tests should be carried out in a limited period of time (i.e. one year) to increase the chances of HIV diagnosing among asymptomatic individuals with medium-low risk profile and/or limited risk perception. By providing adequate counselling and prevention information (including pre-exposure prophylaxis) to all the people undergoing HIV testing, we could mark a key step towards the end of the epidemic in Italy.

Social Science, PROs

P 132 ANLAIDS FORUM CHALLENGES ARTIFICIAL INTELLIGENCE: CAN ALGORITHMS ACT AS A COUNSELLOR?

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Background: Anlaids Forum is a platform where registered users can pose questions about HIV or risks they may have taken during their sexual experiences seeking counselling or possible remedies. Answers are provided by trained volunteers acting under the supervision and advice of a doctor.

Materials and Methods: Ten Frequently Asked Questions (FAQs) and ten user Forum questions were randomly selected from the Anlaids website1 and posed to three accessible AI algorithms2. Each AI response arbitrarily received a maximum score of 10 points, based on objective criteria (4 points for scientific evidence; 3 for pertinence and 1 for adherence to UNAIDS Terminology Guidelines3) and our subjective criteria (1 point for completeness and 1 for clarity). Scores were then converted into percentages to make comparisons among the three AI systems.

Results: Overall average score for all AI responses ranged from 59.5% to 70.0%.

The results of reply to each AI system varied widely, with one AI scoring the lowest clarity (20.0%), while another showing the best completeness (96.6%).

By analyzing a single criterion through the median responses of all AI methods the highest performance was observed in pertinence (84.4%), followed by compliance with UNAIDS terminology (69.2%), scientific evidence (66.2%), completeness (44.2%) and clarity (43.3%). AIs performance was average higher when compared to FAQs (66.5%) than to Forum submitted questions (55.1%). This difference was observed for all criteria, with a higher variation in scientific evidence (70.5% for FAQs vs. 55.0% for user questions) and clarity (53.3% vs. 33.3%).

By considering all posed questions, the AI system with the highest score concerned the concept 'U=U' (Undetectable =Untransmittable) (90.0%), while the lowest score (43.3%) was associated with an answer of a Forum question about risk assessment in protected occasional sex. In this case, all AIs identified an HIV risk not considering the condom use.

Conclusions: Although the tested AIs demonstrated some ability answering questions about HIV, their performance showed important limitations. Lower scores for questions posted on the Forum suggest difficulty in responding to complex real-world situations. The wide range of performance of individual AIs highlights variability and current limitations of these tools. This report indicates that AIs, even so evolving, are still not able to replace expert HIV counseling, as algorithms have difficulty in understanding the context, adhering to reference guidelines, and ensuring scientific accuracy. At present, the role of expert counsellor remains crucial in providing careful, personalized, and comprehensive HIV education and support.

1) https://www.anlaidsonlus.it/cosa-devi-sapere ; https://www.anlaidsonlus.it/forum/
2) ChatGPT-4 (OpenAI); Gemini (Google AI); Copilot (Microsoft). AIs consulted in December 2024 and January 2025
3) https://www.unaids.org/en/resources/documents/2024/terminology_guidelines.

Social Science, PROs

P 133 ASSESSING AWARENESS OF HIV AND PREVENTION STRATEGIES: A CROSS-SECTIONAL STUDY FROM TWO FREE RAPID TESTING EVENTS IN ROME

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Background: HIV prevention remains a critical public health challenge. While Treatment as Prevention (TasP) plays a vital role in curbing the spread of HIV, rapid HIV testing and raising public awareness are essential for early diagnosis and identifying undiagnosed cases. Despite improved access to testing, a substantial portion of the population remains underinformed about HIV transmission and prevention strategies, particularly regarding tools like PrEP (Pre-Exposure Prophylaxis), PEP (Post-Exposure Prophylaxis) and the concept of U=U (Undetectable equals Untransmittable). This cross-sectional study aimed to assess participants' awareness of HIV and prevention strategies during two free HIV rapid testing events in Rome.

Material and Methods: A total of 228 individuals were tested for HIV, 102 at "Policlinico" metro station on 28th of November 2024 and 126 at "Sapienza" University on 10th of December 2024. Additionally, 143 participants completed a survey (49% at the metro station and 51% at the university) to assess knowledge about HIV and prevention strategies. The survey consisted of twelve questions including items on relationship status, knowledge of HIV, previous HIV and sexually transmitted infection (STI) testing experiences, sexual behaviors and awareness of PrEP, PEP, and U=U. Age and gender were recorded for each participant who completed the survey. Data were analysed quantitatively and reported as absolute and relative frequencies for categorical variables and median and interquartile range (IQR) for continuous ones. Differences between data collected in the two locations were analysed using Chi-Square test for categorical variables and Mann-Whitney test for continuous ones.

Results: The results are shown in Table 1. All rapid HIV tests conducted were non-reactive. The median age of participants was 22 years (IQR: 20-24) with 55.9% identified as male, 36.4% as female and 7.7% as non-binary. While 97.2% of participants had elementary knowledge of HIV, only 44.8% were aware of PrEP and 33.6% of PEP. Awareness of U=U was even lower, with just 18.2% familiar with the concept. Although 64.3% of participants were aware that HIV testing in Italy can be requested anonymously and for free, only 42.7% had previously tested for HIV and 66.4% had never tested for any other STI. Comparison between testing locations showed a statistically significant difference in age (P-value = 0.001) and in the answers to question eleven (P-value = 0.036). After the events, 17 (7.5%) participants contacted the Sexual Health Clinic of Policlinico Umberto I to get information about PrEP and STI testing.

Conclusions: While there is a sufficient level of basic knowledge about HIV, significant gaps in awareness of modern prevention strategies like PrEP, PEP and U=U remain. These findings highlight the need for tailored educational campaigns, particularly aimed at younger individuals, to raise awareness of these tools and reinforce the importance of regular screening.

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Social Science, PROs

P 134 BEYOND A STANDALONE CHECKPOINT: THREE YEARS OF COLLABORATION AND GROWTH AT IOC'ENTRO, GENOA, ITALY

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Low-threshold STIs screening centers are essential in meeting the needs of high-risk populations, particularly those who live in vulnerable or marginalized conditions and often encounter significant barriers to accessing hospital-based testing services.

To better understand the characteristics of those accessing low-threshold facilities and identify gaps in service provision, this study assessed the socio-demographics and risk profiles of individuals attending IOC'ENTRO HIV Checkpoint between Dec. 2021 and Feb. 2025. Located in Genoa (Liguria, Italy), IOC'ENTRO is part of COBATEST, a European network of community-based testing facilities aimed at standardizing data collection practices. Data were collected using the COBATEST questionnaire.

A total of 896 rapid HIV tests and 80 syphilis tests (introduced Nov. 2024) were carried out. Within our cohort, 133 (14.8%) had a foreign nationality. Regarding gender distribution, the majority were cisgender men (499, 55.7%) and women (368, 41.1%), non-binary people (15, 1.7%), transgender women (10, 1.1%) and men (4, 0.4%). 219 (24.4%) men had sex with men, and 73 (8.1%) women had sex with women. The most represented age groups were 25-39 years (456, 50.9%) and 18-24 years (327, 36.5%). Additionally, 101 users (11.3%) were aged 40-59, and 9 (1%) were 60+.
Among our users, 17 (1.9%) engaged in sex work (SW), and 23 (2.5%) reported having unprotected sex with SW. Regarding substance use, 80 (8.9%) reported drug use, with 8 (0.9%) injecting drugs and 16 (1.8%) engaging in chemsex. The most commonly used substances were cocaine/crack (56.2%), followed by cannabis (50%), heroin (11.2%), amphetamines (10%), and other drugs (6.2%). Additionally, 7 users (0.8%) reported using pre-exposure prophylaxis (PrEP).
37 (4.1%) reported a STI in the past year, with 9 having a history of HCV, 7 of syphilis, and 2 of HBV. Overall, 5 tested positive for HIV and 1 for syphilis. While statistical analysis on factors associated with test results is limited due to small sample size and privacy concerns, preliminary observations suggest that those receiving a positive diagnosis in our setting often come from vulnerable backgrounds, including migration routes, sex work, or experiences of abuse. These users often encounter structural barriers to accessing the Italian National Health System, from a lack of clear information to near-total exclusion from healthcare, further delaying diagnosis and care.

In response, IOC'ENTRO has strengthened its role within the community, fostering collaborations with LGBTQ+ organizations, services for survivors of violence and trafficking, and services for people who use drugs or experience homelessness. These partnerships have led to a growing number of contacts and have strengthened the personalized care pathways available to users.
Building a strong, interconnected network is crucial for effective linkage to care and follow-up, ensuring a person-centered approach that improves health outcomes.

Social Science, PROs

P 135 BRIDGING GAPS IN HIV CARE: AN OUTREACH SCREENING PROGRAM FOR STREET-BASED SEX WORKERS

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Background: HIV prevalence remains high among key populations such as sex workers. The double stigma of HIV and sex work, compounded by socioeconomic challenges and migrant status, often creates significant barriers to screening and healthcare access. To address these challenges, we implemented an outreach screening program through a collaboration between our Infectious Diseases unit and a non-governmental organization (NGO) with extensive experience in low-threshold interventions for sex workers.

Methods: A multidisciplinary team, including two trained street outreach workers from the NGO and a nurse or physician from the Infectious Diseases unit, conducted fortnightly nighttime outreach (22:00–02:00) using a recognizable NGO vehicle. The team provided counseling, condoms, refreshments, and rapid oral HIV and HCV antibody testing (OraQuick) to sex workers along established urban routes in northern Milan and Monza province. Individuals with reactive test results were accompanied the following day to an HIV referral center for confirmatory testing and linkage to care.

Results: Between March and December 2024, 20 outreach sessions were conducted, during which 63 HIV tests and 54 HCV tests were offered and accepted by 49 individuals: 23 cisgender women, 25 transgender women, and one cisgender man. Transgender women were primarily from South America (Peru, n=18; Brazil, n=7), while cisgender women were predominantly from Eastern Europe (Romania, n=14; Albania, n=4; Moldova, n=1), with additional representation from Nigeria (n=2), Venezuela (n=1), and Italy (n=1). The cisgender man was from Brazil. The mean age was 33 years.

HIV prevalence was 14.3% (7/49), with four individuals already diagnosed and three newly identified cases (6.7%). All seven were successfully linked (or re-linked) to HIV care in referral clinics in the Milan metropolitan area. Notably, all HCV tests were negative.

Beyond HIV screening, the outreach initiative provided additional benefits, including assistance in escaping human trafficking, education on risk reduction, and referrals for pre-exposure prophylaxis (PrEP) for those interested. Additionally, linkage to care was facilitated for other individuals within sex workers' social networks (e.g., friends and roommates).

Conclusions: Despite the relatively small sample size, HIV prevalence among sex workers was high, highlighting the critical need for ongoing screening and linkage-to-care efforts in this population. Consistent outreach fosters trust and facilitates access to preventive strategies such as PrEP, particularly given the upcoming availability of long-acting injectable antiretrovirals. Further studies are needed to evaluate the feasibility, acceptability, and long-term impact of such interventions.

Social Science, PROs

P 136 CHALLENGES ON RECRUITING FOR THE HIV-CORE 007 CURE TRIAL: THE PERSPECTIVE OF INFECTIOUS DISEASE DOCTORS

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Background: HIV cure clinical trials often involve a monitored analytical treatment interruption (ATI) of antiretroviral therapy (ART). A previous survey of individuals with HIV who were eligible for cure trials revealed that 40% of respondents expressed interest in participating in ATI-based studies for altruistic reasons (Lee et al, J Virus Erad., 2023).
This study aims to describe challenges encountered by infectious disease (ID) doctors on proposing HIV-CORE 007 trial, a phase I/II, randomized study that involves the administration of two therapeutic vaccines or placebo, followed by an ATI phase.
Methods: Assessment of perceptions was collected by means of a questionnaire submitted to ID doctors working at the Infectious Diseases Unit of San Raffaele Hospital in Milan, Italy, where the study HIV-CORE 007 is conducted. HIV-CORE 007 is a phase I/II randomized, placebo-controlled, single-blind trial enrolling people with HIV (PWH) who began ART during primary HIV infection (Protocol information available at EudraCT number 2019-003102-26).
Anonymized data from the Infectious Diseases Department's database at the IRCCS San Raffaele Scientific Institute (CSL HIV Cohort) were used. Data were analyzed using descriptive statistics.
Results: Among the 11 medical doctors interviewed, 55% reported encountering difficulties when proposing participation in the HIV-CORE 007 study.
The most common challenge was related to ineligibility due to factors beyond the inclusion criteria (e.g., high risk of transmission, willingness to change ART) (Figure 1).
Seventy percent of medical personnel indicated that the potential participants expressed interest in the study. However, the primary reasons for not agreeing to participate, as reported during consultations, were related to the time commitment required for the study and the ATI phase (Figure 2.A).
Numerosity was also a considerable challenge: among 5034 PLWH in care, 134 PLWH were eligible for screening, as per inclusion and exclusion criteria. Twenty-six (19.4%) were then excluded as they were receiving long-acting ART.
Providing participants with easily accessible informative materials was identified as the most important action to improve acceptability, followed by involving the community (Figure 2.B).
Conclusions: Our data suggest that ID doctors encountered challenges when proposing the cure study CORE-007. Despite a considerable interest in participation, primary concerns identified by potential participants were related to time-demanding design of the study and ATI phase. Recruiting for HIV cure clinical trials remains challenging in the current era, as concerns about ATI, potential risks and availability of long-acting therapy, may hinder participation, despite the critical importance of advancing cure research. A collaborative approach with the community, new strategies of communication and a multi-center design may contribute to recruitment success outcomes.

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Social Science, PROs

P 137 DEGREE OF APPROPRIATENESS AND ORGANIZATION OF SERVICES DEDICATED TO THE ADMINISTRATION OF CAB+RPV: PWH OPINIONS FROM AN ITALIAN MULTICENTER COHORT

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Background: Following the introduction of long-acting cabotegravir plus rilpivirine (CAB+RPV) for the treatment of virologically suppressed people with HIV (PWH), clinicians are facing the challenge of a radical renewal, implementation, of outpatient clinics. Inspired by validated questionnaires and based on evidence from clinical trials (CUSTOMIZE and SOLAR), we aimed to investigate the extent to which dedicated facilities have been implemented and preference of PWH.

Methods: Between January and February 2025, a complete anonymous questionnaire was administered to a cohort of PWH undergoing long-acting CAB+RPV, at the outpatient services of Policlinico A. Gemelli, ASST of Legnano and Niguarda Hospital, who consented to the administration of the questionnaire. The questionnaire consisted of 8 closed questions and 2 questions (one rated from 1 to 10; one rating from excellent to inadequate) and one open-ended section to explore suggestions for improving the quality of the service.

Results: We distributed 80 questionnaires, 38 PWH agreed to complete them. The median time since the switch to CAB+RPV injectable was 18 months (IQR 12-24). The overall level of satisfaction was quantified with the highest rating by the 63.2% of partecipants. The most used channel for communicating with the service is the telephone (68.4%), with only 5.3% reporting difficulties communicating with the doctor. With respect to the participants' perception of the service's organization, 55.3% of the PWH assigned a rating of 10 while 3/38 allocated a rating ≤6 [Figure 1]. The designated area allocated for administration was deemed satisfactory by 58% of the PWH, whereas 13.2% regarded it as unsatisfactory, primarily due to the presence of concomitant activities. Furthermore, 81.6 % of the patients assessed the preparation of the dedicated staff as excellent [Figure 2]. A positive correlation was identified between individuals who expressed favorable opinions regarding the spaces and those who considered the staff preparation to be adequate (p 0.03). In addition, 78% of respondents expressed satisfaction with the level of privacy respect, with a positive relationship observed between this sentiment and the extent of perceived inadequacies in staff training ($p < 0.001$). Concerning the doctor-patient relationship, most (84.2%) did not notice any changes, while 15.8% reported it. The open-ended part of the survey showed that patients would not return to oral therapy (94.7%). The most prevalent recommendations for enhancing the standard of service delivery were focused on the necessity for increased allocation of time and spatial resources for the facilitation of injection administrations.

Conclusion: Despite the elevated rating of PWH within our cohort, the evaluation of service organization according to PWH opinions remains inadequate. This essay requires expansion on a larger scale, including higher numbers and incorporation of implementation strategies.

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Social Science, PROs

P 138 DEGREE OF CURRENT KNOWLEDGE AND AWARENESS REGARDING LONG-ACTING INJECTABLE ANTIRETROVIRAL THERAPY IN PEOPLE LIVING WITH HIV WHO ARE UNDERGOING ORAL THERAPY

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Background: In the landscape of antiretroviral therapy, the combination of injectable cabotegravir and rilpivirine (CAB+RPV) has prompted interest among not only clinicians but also between people with HIV (PWH). We investigated the level of knowledge and awareness among people with HIV undergoing oral treatment about antiretroviral injection therapy and new treatments.
Methods: Between January and February 2025, a complete anonymous questionnaire was administered to a cohort of PWH undergoing oral therapy followed in the outpatient services of Policlinico A. Gemelli and ASST Ovest Milanese, who consented to the administration of the questionnaire. The questionnaire consisted of 7 closed questions and 2 questions rated from 1 to 10 and one open-ended question. Subjects who had been transitioned to CAB+RPV and had discontinued before the date of completion of the questionnaire were excluded.
Results: The study was conducted on 284 PWH who had consented to complete the questionnaire. The results indicated that 198 PWH (69.7%) reported awareness of the existence of injectable therapies. The predominant method of awareness among the study participants was through referrals from their Infectious Diseases doctor, accounting for 86.9% of responses. Additionally, 35.86% of respondents reported acquiring knowledge through social media, 17.2% through friends and 3.5% through associations. Furthermore,191 PWH stated that they considered themselves adequately updated by their doctors on therapeutic innovations and 42.6% reported being proactive in asking their doctor for updates on new therapies on the market. Furthermore, 50.3% of PWH would agree to initiate long-acting injections if, following a comprehensive evaluation, they were deemed eligible. The most common reasons reported for the unwillingness to initiate CAB+RPV were the custom of taking the oral therapy (40.2%) fear of injections (15%), and the need for more information on the subject (26.5%), with no specific reason expressed in most cases (18.3%). Potential benefits were reported by 64% of PWH, while 36% reported no benefit [Figure 1]. Amongst those who would accept,141reported disadvantages, yet this did not preclude their decision to proceed suggesting that the perceived benefits of the therapy outweigh the concerns expressed by the participants. Conversely, those who refused therapy cited few disadvantages, with only 24 cases reported, suggesting that their refusal may be rooted in personal preferences or concerns. Analysis of the data showed that those informed by their doctor are more likely to want to start CAB+RPV (p=0.02).
Conclusions: Our study shows that knowledge of injection therapies remains insufficient. Doctors' communication is crucial to provide information for the extension of these novel injectable formulations. In this context, the role of associations could be crucial to facilitate the expansion of the network of information.

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Social Science, PROs

P 139 EVOLUTION OF HIV TESTING ACCESS IN THE MSM COMMUNITY: A COMPARISON OF THE 2005/2015 AND 2015/2025 DECADES WITH A FOCUS ON THE USE OF THE INSTI TEST IN MEETING PLACES (OUTREACH)

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Access to HIV testing in the MSM community has undergone a significant evolution over the past twenty years, with an increase in the adoption of rapid tests and a broader distribution of testing services. This study analyzes data on HIV testing access during the 2005/2015 and 2015/2025 decades, with particular focus on the introduction and dissemination of the INSTI test in meeting places and community-based centers such as Milano Checkpoint, Brescia Checkpoint, and Bologna Checkpoint.

During the 2005/2015 period, testing was predominantly based on rapid tests with response times of about 15 minutes, mainly offered in community-based centers. However, access to testing in meeting places was limited due to the need for adequate facilities and the time required for results, often delaying communication of outcomes to the following days. This delay carried the risk of losing contact with the tested person in case of a reactive result, compromising follow-up and rapid access to care. The following decade (2015/2025) saw a significant increase in the use of the INSTI test, which provides almost immediate results (<60 seconds), enabling peer operators to conduct screenings directly in MSM community meeting places (Fournier et al., 2013) [https://pubmed.ncbi.nlm.nih.gov/23480561/].

The comparison between these two testing models highlights the greater accessibility and timeliness of the INSTI test compared to traditional 15-minute rapid tests. The introduction of instant-result tests has encouraged broader participation in testing, reducing logistical and psychological barriers (Bowles et al., 2023) [https://pubmed.ncbi.nlm.nih.gov/37160925/]. However, implementing tests with a shorter window period (30 days) remains crucial to ensuring early infection detection in high-risk populations.

This study emphasizes the need to further promote the dissemination of next-generation rapid tests, combining the immediacy of the INSTI test with improved diagnostic sensitivity within the first 30 days of exposure. The comparison between the two decades demonstrates that the future of HIV prevention in the MSM community relies on the continuous innovation and adaptation of testing strategies to meet real user needs (MacGowan et al., 2017) [https://pubmed.ncbi.nlm.nih.gov/28764661/].

Social Science, PROs

P 140 FROM SCREENING TO CARE: STRENGTHENING LINKAGE TO SERVICES FOR MARGINALIZED POPULATIONS IN GENOA, ITALY

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High-risk populations often face structural barriers to accessing hospital-based sexual health services. Low-threshold STI screening centers offering free, anonymous testing and counseling, play a crucial role in bridging these gaps and improving access to care. Since late 2021, IOC'ENTRO Checkpoint (Genoa, Italy) has provided a stigma-free, informal environment, recording 1000+ contacts and conducting 895 HIV and 80 syphilis tests.

Many users diagnosed with STIs in our setting come from vulnerable backgrounds, including migration routes, sex work, or experiences of abuse. These individuals frequently face barriers to accessing healthcare, from a lack of clear information to near-total exclusion from services, which can delay diagnosis and treatment. To address this, IOC'ENTRO has reinforced its role as a bridge to care, fostering collaborations with local healthcare and social support providers. While a detailed analysis of linked cases is limited due to small sample and privacy concerns, here we provide an overview of the theoretical framework, interventions, and strategies adopted.
In the event of a reactive screening test, users first engage in a conversation with a health worker and health educator who explain the need for confirmatory testing, offer reassurance and emphasize the availability of effective treatment and positive long-term health outcomes. Confidentiality is ensured, and emotional support is offered. Immediately after, users are accompanied to the Outpatient Clinic at Ospedali Galliera, where comprehensive and confirmatory testing are conducted. If HIV is confirmed, psychological support is provided.
However, in line with the governance and socio-healthcare integration frameworks outlined in the United Nations Agenda 2030, linkage to care at our checkpoint extends beyond STI diagnoses. It is provided whenever a user requires a personalized, multidisciplinary care approach. In complex cases of individuals facing social instability, with mental health challenges, or who reach out following an experience of trauma or abuse, health education interventions are implemented to enhance autonomy, support treatment compliance, and improve health outcomes. Where needed, individuals are referred to specialized centers for victims of violence or sex trafficking. In case of concomitant substance use disorder, users are linked to local addiction services and a drop-in center where medical personnel and legal assistance are available. All these services are located within 1km of our checkpoint.

In total, 9 users from diverse backgrounds were linked to care. Despite foreigners showing inconsistent adherence to follow-up care, highlighting the need for targeted retention strategies (eg. language and cultural mediation), the majority of users linked to services remain in follow-up, continuing to receive support and treatment. This suggests that the adopted framework and collaborative network may facilitate sustained engagement in care.

Social Science, PROs

P 141 GETTING TO THE FIRST 95: INTRODUCING RECOMMENDED BEST PRACTICES IN NATIONAL HIV TESTING GUIDELINES

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Background: In Italy, the national strategic plan for HIV/AIDS was last updated in 2017 and the HIV testing guidelines in 2011. The plan declared a commitment to implement the most recent international guidelines issued by the ECDC and the WHO. Those guidelines were updated respectively in 2018 and 2024. These updates are based on emerging evidence for more cost-effective approaches and strategies to expand testing outside clinical settings. However, the Italian authorities failed to follow suit, widening the divide between Italy and comparable states in Western Europe.

Methods: Recommended best practices on HIV testing were extracted from the WHO (2024) and the ECDC (2018) guidelines. The latest HIV testing guidelines of France, Italy, Spain and the UK were reviewed to assess the adoption of these best practices. France, Spain, and the UK were selected for their similarity to Italy in terms of economic and demographic parameters, Human Development Index and HIV incidence rate.

Results: Recommended best practices were extracted from the WHO or ECDC guidelines (Table 1). The Italian guidelines do not include many of them (Table 2). Notably, Italy still prevents general practitioners and pharmacists from performing HIV testing. Moreover, extensive and cost-effective innovative solutions, such as ER testing and opportunistic testing are also not envisaged by Italy. Spanish guidelines, dating back to 2014, share most of these shortcomings, albeit providing for opportunistic testing, while the more recent French and British guidelines are broadly aligned to international guidelines. To reduce the stigma tied to HIV testing, the WHO and ECDC strongly recommend removing differences in obtaining consent. Italy and Spain show significant shortcomings in this field (Table 2). Moreover, some provisions included in the Italian strategic plan, such as lowering the age of consent, have not been implemented due to lawmakers' immobilism.

Conclusion: The findings of this review indicate that the Italian HIV response is burdened by persisting delays in the alignment with consolidated international guidelines. These delays are even more evident as other Western European countries have repeatedly updated their guidelines in the same timespan: the UK in 2016 and again in 2020; France in 2017 and 2024. Delays in implementing evidence-based best practices may hinder efforts to expand access to testing for all people at substantial risk of getting HIV and to reach the UNAIDS 95-95-95 targets. Italian health authorities should include these best practices in their guidelines in concert with international recommendations. The full and comprehensive implementation of guidelines should be ensured after their adoption to continue making progress towards the 95-95-95 targets.

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Social Science, PROs

P 142 HIV AND STI TESTING BEYOND KEY POPULATIONS: BRESCIA'S FIRST COMMUNITY-BASED EXPERIENCE

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Background: Despite Brescia's high HIV incidence rates and its participation in the Fast-Track Cities initiative since 2021, HIV and STI testing services in community-based settings had never been available. This lack left a critical gap in prevention services, both for key populations and for groups that are non conventionally considered as key populations.

Materials and Methods: In 2024, the organization Brescia Checkpoint was established, to address this gap through a community-based testing service. The organization leveraged on expertise in HIV and sexual health services gained within other LGBTQIA+ and HIV organizations. Thanks to municipal funding, Brescia Checkpoint offered free and confidential rapid HIV and syphilis testing once a month between November 2024 and February 2025 at Spazio Lampo, a community space located near the heart of Brescia.

Alongside testing, peer providers offered counseling on combination prevention strategies, and facilitated linkage to care at the local STI clinic as needed. All clients completed an anonymous questionnaire assessing STI services awareness, PrEP knowledge, and use of barrier methods for HIV/STI prevention. Data collection aimed at understanding testing behaviors and STI services accessibility across different population groups.

Results: Out of 61 individuals who tested for HIV and syphilis, 20 (32.8%) got tested for the first time for HIV and 28 (45.9%) for syphilis. The majority of clients who had never tested before were heterosexual (65% for HIV and 60.7% for syphilis).

39.3% of clients reported not being aware of the local STI clinic, which offers HIV and STI services free of charge and without requiring a medical prescription. Additionally, only 54.1% had heard aboutPrEP before, with awareness gaps particularly pronounced among heterosexual clients (Table 1).

65.6% of clients indicated inconsistent use of barrier methods for HIV/STI prevention in the past year, with no notable variation across groups (Figure 1). Furthermore, 56.9% chose to test at Brescia Checkpoint explicitly due to its community-based approach (Figure 2).

2 clients had a reactive test result for syphilis, all were linked to care.

Conclusions: These preliminary findings highlight the crucial role of community-based services in improving access to HIV and STI testing for key populations and the general population. The results also highlight a considerable demand for testing services offered outside of facility-based settings. Specifically, community-based service delivery, enhanced by peer-led support, can significantly reduce barriers to testing and prevention services for diverse populations.

The expertise gained within HIV and STI services primarily attended by LGBTQIA+ communities and key populations can be used to address unmet needs among other individuals usually not identified as key populations, but who are at substantial risk for HIV and STIs.

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Social Science, PROs

P 143 LILA'S VIRTUAL HELP DESK: GIVING VOICE AND EMPOWERING PEOPLE WITH HIV THROUGH REMOTE SUPPORT

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Background: LILA ONLUS (Italian League for Fighting AIDS) has been operating in Italy since 1987, supporting people with HIV (PWH) and working in prevention. In the past year (October 2023–September 2024), the NGO was reached by over 10,000 people via phone, social media, and email. More than 2,400 people took a rapid HIV test at LILA's centers, with high website traffic. During this period, the NGO launched a new service dedicated to PWH: the Virtual Help Desk (Sportello Virtuale). Since November 2023, LILA volunteer counselors provide support via video call, offering emotional support, legal, welfare, and employment counseling, as well as guidance on services and HIV info. Peer group sessions were also available. The project continues with ViiV Healthcare's unconditional support.
Materials and Methods: The main goal of the project is to provide PWH new empowerment opportunities. The service is free and offers up to five individual remote sessions using common video call platforms. Users fill a short form to indicate topics for discussion, and a follow-up satisfaction form is provided. Two online support and discussion groups for people with HIV have been activated, with an average of four participants per session. They have been meeting once a month since May 2024. LILA promoted this service via social media and healthcare networks (GPs, family planning clinics, addiction services, social services, HIV clinics). In its first year, the service was available for an average of 21 hours per week, while in its second year, availability increased to 29 hours per week. The development of the project also had an impact on LILA staff: specific training sessions, meetings with legal experts, doctors, psychologists, dietitians, and methodological supervision sessions were organized.
Results: The preliminary data from the Virtual Desk activity report 81 consultations conducted with 43 PWH (28 in the first year and 15 in the second). About the first year of the service: 28 people sought support, the majority being Italian men. The users were mainly aged between 30 and 49, with a high level of education and stable employment, living in medium to large cities in northern and central Italy. The main topics addressed were: emotional and relational issues, welfare counseling, treatments and doctor-patient relationships, U=U, parenting, and legal matters. In the ongoing year, 33 sessions have been provided to 15 people.
Conclusions: The Virtual Help Desk supports PWH without local HIV NGOs. It also fosters self-awareness and empowerment. This initiative has enabled counselors to acquire new skills and strengthen collaborations between different LILA centers. Despite serving a limited number of people, the project provided an additional opportunity for PWH to connect with trained professionals and access a safe and non-judgmental space for support.

Social Science, PROs

P 144 MULTIFACTORIAL VULNERABILITY AND HIV: LOCAL RESPONSE TO HEALTH-CARE NEEDS OF KEY POPULATIONS

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Background: Contemporary healthcare systems must consider, among various factors, so-called “multifactorial vulnerabilities.” The World Health Organization (WHO) defines social determinants of health (SDH) as the circumstances in which people are born, live, and work. These are particularly relevant when primary factors (e.g., migrant background, disability, transgender identity, etc.) intersect with HIV infection (Ferreira et al., 2021).
Materials and Methods: Enhancing network collaboration between local socio-health services and third-sector organizations is crucial to address the needs of marginalized populations with multifactorial vulnerabilities.
A valid example of this is the N.A.V.I.G.A.R.e Project, administered by the Veneto Region, which involves a coordinated effort among public and private social stakeholders. This integrated approach includes various interventions: outreach actions, assistance for healthcare and legal needs, and ongoing “monitoring” activities.
Other initiatives include the Spolato CAD, which offers psychological support, sexual health counselling, and has established a peer-support group based on self-help principles for people living with HIV (PWH).
Moreover, the recently inaugurated Padova Checkpoint is a sexual health center offering testing and counselling services, as well as psychological support tailored specifically to new HIV diagnoses.
Finally, Anlaids Padova collaborates with the aforementioned organizations in the effort to prevent HIV and STDs. One of the services offered by this association is a helpline aimed at educating and redirecting callers to the appropriate services.
Results: In 2024, the N.A.V.I.G.A.R.e Project supported 44 individuals, resulting in 129 instances of health accompaniment, 1/3 of which involved the Infectious and Tropical Diseases Unit. These included the management of 4 new HIV cases, one of which was a result of a rapid oral test performed during Community-Based Voluntary Counselling and Testing (CBVCT); 31 follow-up visits and 8 new PrEP treatments. Furthermore, 36 people received psychological support, of which 33% identified as part of the LGBT+ community.
Regarding the sexual and psychological health services provided by the Spolato CAD, the total number of users was 57, distributed as follows: 16 participants in the AMA (self-help) group; 19 individuals who requested sexual health counselling, testing (CBVCT), and linkage to HIV healthcare services; and 22 individuals who received psychological support.
Conclusions: The mentioned experiences highlight the effectiveness of the integrated, multi-agency approach provided by community-based programs in connecting and retaining key populations in care. It is therefore crucial to promote and sustain collaboration between public institutions and private social organizations, ensuring that successful experiences are replicated rather than remaining isolated examples of best practice.

Social Science, PROs

P 145 NEW CHALLENGES IN THE LONG-TERM MANAGEMENT OF PEOPLE LIVING WITH HIV (PLWH): INTRODUCTION OF PATIENT-REPORTED OUTCOMES (PROS) INTO ROUTINE CLINICAL PRACTICE. A PILOT STUDY

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Background: As HIV disease has evolved from a life-threatening to a chronic condition, attention has shifted to the long-term health of PLWH. In this context, the use of PROs and Patient-Reported Outcome Measures (PROMs) becomes essential to understand patient' perceptions and improve understanding of their overall well-being.
Methods: A 15-month, single-center, real-life interventional study was conducted at the HIV/AIDS Section of Ferrara Hospital aiming to integrate PROs and PROMs as additional parameters for the assessment of clinical outcomes, alongside standard care tools. We wanted to evaluate their effectiveness in measuring treatment adherence, therapy satisfaction and perceived quality of life (including health status, sleep quality, and mood), as well as to explore potential correlations between these factors and patients' epidemiological/clinical characteristics and treatment regimens. To address these issues, we developed a specific questionnaire, drawing on previously validated instruments such as the HIV Treatment Satisfaction Questionnaire (HIVTSQs), the EuroQol-5 Dimension (EQ-5D), the Pittsburgh Sleep Quality Index (PSQI), and the Patient Health Questionnaire-9 (PHQ-9). The questionnaire was administered to PLWH attending the Center during their routine access for follow-up laboratory tests.
Results: 176 PLWH were enrolled (table1), 97.7% of whom with HIV undetectable viral load. 86.9% reported good treatment adherence and 90.9% expressed sufficient satisfaction. About quality of life (personal care, mobility, ability to carry out usual activities), only mild deficits were reported, mainly among patients with non-HIV-related comorbidities. Symptoms of anxiety or depression were perceived by 39.9% of participants, with 27.5% presenting subthreshold depression and 15.9% meeting criteria for clinically significant depression. Additionally, 71.6% described health status as suboptimal, while 40.3% reported poor sleep quality, confirming the higher prevalence of these issues among PLWH compared to the general population. Statistical analysis (Stata) showed a positive association between age and therapy satisfaction, undetectable viremia and good health status, Italian nationality and absence of depression (Figures 1-2-3).
Conclusions: The use of PROMs enables early identification and management of depression, poor sleep quality and other issues, potentially improving HIV-related outcomes. In our study, PROs analysis provided precise information that determined specific diagnostic and therapeutic interventions. These findings further support the utility of PROs in the clinical and therapeutic management of PLWH. It also highlights the importance of considering quality of life as a key health indicator, particularly since viral suppression is easily achieved in adherent patients. Despite their relevance in both public health and clinical settings, PROs and PROMs have not yet been fully integrated into routine HIV care management.

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Social Science, PROs

P 146 PATIENT-REPORTED OUTCOMES (PROS) IN PEOPLE LIVING WITH HIV TREATED WITH LONG-ACTING INJECTABLE ANTIRETROVIRAL THERAPY (LAI-ART)

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Background: The implementation of LAI-ART could be a game-changer for the quality of life of people living with HIV (PLWH) in clinical trials. Patient-reported outcomes (PROs) represent a fundamental tool to explore this aspect. This study aims to assess the level of satisfaction with LAI-ART in a cohort of PLWH.
Methods: This monocentric prospective study enrolled PLWH switching to bimonthly cabotegravir (CAB) and rilpivirine (RPV) LAI-ART at the Infectious and Tropical Diseases Clinic of ASST Spedali Civili, Brescia (January 2023–December 2024). PROs were assessed via EQ-5D (Quality of Life and Health Status Scale), HIV-TSQs (Antiretroviral Therapy Satisfaction Scale), and RS (Resilience Scale) before the initiation of LAI-ART (T0) and after 7 (T7) and 13 months (T13).
Results: We included 65 individuals, 53 (81.53%) men, with a mean age of 46.6 years (SD 11.08). At the time of the analysis, all subjects completed the baseline PROs collection, 61 completed T7 (one discontinued LAI ART due to worsening of depressive symptoms), and 37 had completed T13 (one discontinued due to injection site reaction). At T0, EQ-5D mean scores were very high (Fig.1a), ranging from 1 to 1.3 in all measured items, with a mean perception of health status of 85.73 out of 100. HIVTSQs (Fig.1b) showed the lowest scores in the items related to the compatibility of ART with their lifestyle (mean 5.25 out of 6) and to their willingness to continue the current ART (5.08 out of 6). In RS (Fig.1c), we observed very high baseline mean scores, above 5.5 in all measured items.
Regarding HIVTSQs, we observed increased scores in all items at both follow-up visits, with therapy satisfaction reaching 5.9 out of 6 at T13. Side effects showed a mean score of 5.67 out of 6 at T7 and 5.8 out of T13. The most significant improvement over time was shown in the commitment required, convenience, flexibility, and adaptation of therapy to lifestyle. Most participants were content with continuing LAI-ART (mean score 5.94 out of 6 at T7, 5.97 out of 6 at T13) and would recommend it (6 out of 6 at T7, 5.97 out of 6 at T13). EQ-5D scores in quality of life remained high through the follow-up. The perceived health status had a modest improvement at T7 (mean score 87.39 out of 100) and a subsequent deterioration to values slightly lower than baseline at T13 (85.14 out of 100). The RS remained consistent over time with minimal variability. However, interest in the surrounding world progressively increased, while energy for performing daily activities, after an initial improvement at T7, declined at T13.
Conclusions: Quality of life, resilience and treatment satisfaction significantly increased and remained high months after the initiation of LAI-ART. Our findings highlight the role of PROs in evaluating patients' satisfaction, especially to understand the impact of a new paradigm in therapies, such as LAI-ART, and to improve clinical practice with the aim of creating patient-tailored care pathways.

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Social Science, PROs

P 147 PEOPLE LIVING WITH HIV IN TREATMENT WITH LONG-ACTING THERAPY: WHAT CHANGES IN TERMS OF STIGMA?

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Background: Despite advances in the development of antiretroviral therapy (ART), several challenges are associated with current treatment involving daily, lifelong oral pills (i.e., stigma concerns, daily reminders of HIV status, medical problems). Long-acting injectable (LA) ART allows reduced dosing frequencies, minimizing the impact of forgetfulness and high pill burden. Despite this, few studies have yet addressed the psycho-social aspects associated with this new regimen.
The present longitudinal study, which is part of a larger project, aimed to investigate perceived satisfaction and stigma in people living with HIV (PLWH) switching from oral ART to LA-ART.
Material and Methods: A total of 48 PLWH were recruited from the Infectious diseases Unit, Amedeo di Savoia Hospital, Turin. The study was proposed to PLWH who had been identified by the infectious disease physician as eligible for LA injection therapy since the time of approval by the Hospital Ethics Committee (reference number 0030555). Participation in the project was voluntary after signing informed consent.
PLWH were asked to complete questionnaires via an online survey during the first administration of LA therapy (T0) and during the fourth administration, five months later (T1).
In this study, the data collected included socio-demographic, clinical information and two psychosocial variables: stigma and satisfaction with the change of therapy.
Results: The sample consisted of 48 PLWH (45 male, 2 female and 1 non-binary) with an average age of 48.4 (9.1), who had been diagnosed with HIV for 14.09 years (7.9) and had been on ART for 6.75 years (5.6). Paired t-tests showed significant differences between the T0 and T1 evaluations on the total score of HIV Treatment Satisfaction Questionnaire (HIVTSQ) (t(47)=-2,925, p=.005) and "personalized stigma" subscale of the HIV Stigma Scale (HIVSS) (t(47)=-2,047, p=.046). No other statistically significant differences were found.
Conclusions: The results showed an increased level of satisfaction with switching from oral to long-acting treatment. Although PLWH expressed this satisfaction, they also appeared to have increased levels of personalized stigma. Personalized stigma refers to the consequences that the person perceives in terms of others knowing that he or she has HIV, such as the feeling that people may avoid him or her because of this, and the subsequent regret of telling others.
Finally, our data suggest that a change of therapy may be satisfactory from a medical point of view, but that it may cause unpleasant emotional experiences, especially in the early stages, which require psychological intervention.
Therefore, attention must be paid not only to social stigma, but also and above all to the personalized stigma of the person living with HIV, which appears to be a weakening and self-sabotaging element in terms of quality of life.

Social Science, PROs

P 148 PREP IS AN OBSTACLE RACE

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Background: In 2024, LILA Cagliari ODV (Voluntary Association Member of the Italian League for the Fight Against AIDS) launched a campaign on PrEP. The utter goal was to raise awareness with the Sardinian Regional Authorities and incentivise pre-exposure prophylaxis, mainly by removing the fees associated to STI testing, which are currently borne by users.
In Sardinia, there is no dedicated PrEP centre, and individuals are currently obliged to make multiple visits to various hospitals in order to undergo the STI screenings required by the protocol and obtain the therapy, all at their own expense. This is an obstacle which undermines prevention efforts and the widespread use of PrEP.
LILA Cagliari has formally requested on multiple occasions the Sardinian Regional Administration to address this issue and make PrEP truly accessible, also by counteracting the misuse of therapies purchased online.
This communication campaign was created to further draw the attention of policymakers and initiate concrete discussions with healthcare representatives.
Materials and Methods: To convey the message, the campaign featured a graphic depicting an athlete running a hurdles race, with the hurdle in the foreground being represented by the STI testing fees which effectively hinder access to PrEP (Figure 1).
The campaign included large 6x3 metre billboard posters displayed on the streets of Cagliari, advertisements in local newspapers, and TV spots on local channels.
In addition to traditional media, web activities and digital media were also put in place. Social media, online publications, and the web TV platforms involved in the campaign maximized the communication channels, encouraging users to interact with and share the message.
One of the large 6x3 metre billboard posters was placed directly in front of the offices of Sardinian Regional Health Department, serving as a reminder of the requests made by LILA Cagliari to the Sardinian Regional Administration.
Results: We believe we have achieved our goals by bringing attention to the need for PrEP to be truly accessible.
The campaign was presented in various contexts during World AIDS Day (Wad), widely shared on major social networks (Facebook, Twitter, Threads, Instagram and Telegram), and reposted on dozens of online publications across the web.
Conclusions: The message proved to be very effective and immediate, engaging many potential PrEP users who, for economic reasons, are unable to access it.
The numerous feedback responses from these users allowed us to collect a significant number of reports, which will be brought to the attention of the Sardinian Regional Health Department.

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Social Science, PROs

P 149 PROMOTING HEALTH THROUGH MOVEMENT: FIT-WALKING AS AN INTERVENTION TO REDUCE CARDIOVASCULAR AND METABOLIC RISK IN PEOPLE LIVING WITH HIV/AIDS IN TURIN

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Background: People living with HIV/AIDS (PLWHA) have a higher risk of developing cardiovascular and metabolic diseases compared to the general population. It is estimated that 40% to 50% of PLWHA living in high-income countries and on ART are overweight, while 13% to 18% are obese. Among the strategies to reduce cardio-cerebrovascular and metabolic risk is the adoption of an appropriate physical exercise routine, such as fit-walking.
Materials and Methods: Eleven PLWHA aged >18 years (mean age 49.9) with good virological control were enrolled from the Infectious and Tropical Diseases Unit I. Of these, 5 (45.5%) were men and 6 (54.5%) were women. All participants underwent a sports medical examination at the Sports Medicine Unit and were deemed fit to practice fit-walking, which took place in a public park. The program consisted of 10 weekly one-hour sessions, led by two corporate fit-walking leaders from the Clinical Nutrition Unit.
Results: 7 (64%) participants attended at least five sessions. No dropouts occurred during the program.
There was no statistically significant difference in BMI between T0 (mean 32.2 kg/m²) and T1 (mean 32.0 kg/m²) after 10 weeks, although BMI at T1 was lower than at T0. Waist circumference at T1 (mean 105.6 cm) was significantly reduced compared to T0 (mean 106.6 cm) (p=0.02).
Sleep quality was assessed using the Pittsburgh Sleep Quality Index (good sleep quality: score <5; poor sleep quality: score >5) in 9 participants (2 refused to complete the questionnaire) at both T0 and T1. 5 participants (55.5%) reported good sleep quality at both T0 and T1; 3 (33%) reported poor sleep quality at both T0 and T1; 1 (11%) had good sleep quality at T0 but poor sleep quality at T1.
Among the 11 participants, 6 (54.5%) completed two walking time measurements on a 760m circular track approximately four weeks apart; of these, 5 (83.3%) improved their personal time.
A satisfaction questionnaire was administered: of the 8 respondents, 5 (62.5%) stated they would highly recommend the course to others. Additionally, 6 (75%) participants started brisk walking for at least 20 minutes at least once a week.
Conclusions: No dropouts were recorded during the training program, and 64% of participants attended at least five sessions. Moreover, 75% of participants incorporated physical activity into their lifestyle. This, along with the significant reduction in waist circumference, represents an important initial result. Further project cycles should be implemented to collect more data, confirming the feasibility of fit-walking and its impact on anthropometric and cardiometabolic parameters in PLWHA.

Social Science, PROs

P 150 PSYCHOLOGICAL OUTCOMES AND LEARNING LOSS IN STUDENTS AFTER THE COVID-19 PANDEMIC: FINDINGS FROM EUCARE'S SCHOOL STUDIES

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Background: The COVID-19 pandemic highlighted the need for evidence-based strategies to support the school mission during health crises. The Lolli-Methode (LM) is a saliva PCR test well accepted by children aged 3 to 18, performed in pool by class twice a week, followed, if positive, by individual saliva PCR tests for the full class. We conducted an international cluster randomised controlled trial to assess the efficacy of the LM as a school surveillance tool and to investigate students' psychological symptoms and learning loss linked to school closures and other preventive measures, in collaboration with INVALSI.

Methods: We used the Strengths and Difficulties Questionnaire to measure psychological symptoms - Total Difficulties (TD), Emotional Problems (EP), Conduct Problems (CP), Hyperactivity (HY), and Peer Relationship Problems (PRP) - in students from kindergarten to high school in Italy, Portugal, and Mexico. Students' attitudes toward preventive measures were assessed via ad-hoc questionnaires. Data were collected at multiple time-points from November 2022 to March 2024. For Italian students, INVALSI provided performance data for Math and Italian for the school years 2018/19, 2020/21, 2021/22, 2022/23. We investigated associations among factors with linear mixed models and explored causal relationships with mediation analysis.

Results: We enrolled 23 schools in Italy, Portugal and Mexico, collecting 685 psychological questionnaires from students of all grades.

Abnormal EP were observed in 17.4% of secondary students, with highest levels in high school ($p<0.01$). EP were higher in girls in middle and high school (interaction $p=0.03$ and $p<0.001$, respectively), and for those reporting negative social distancing experiences ($p<0.001$).

PRP increased with age ($p<0.001$) and for recent experiences of distant learning ($p=0.02$). TD were associated with negative social distancing experiences ($p<0.001$). Girls reported worse experiences with distant learning, leading to greater TD than boys (Natural Indirect Effect: $p=0.03$, Fig. 1).

In Italy, Math and Italian performances declined during the pandemic compared to pre-pandemic levels, with greater learning loss for students from low socio-economic backgrounds ($p=0.05$, Fig. 2) and whose mothers had low educational levels ($p=0.01$, Fig. 3).

More students than teachers reported negative emotions regarding the preventive measures adopted in schools. Post-intervention data from Italy on the use of the LM suggest that the tool was well-received by both students and teachers.

Conclusions: Pandemic-related measures significantly affected students' mental health, with distant learning being particularly detrimental. Learning loss was influenced by socio-economic status and low maternal education. These findings underscore the need to prioritize students' mental health and address educational inequalities in post-pandemic recovery.

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Social Science, PROs

P 151 SCHOOL INTERVENTION FOR STIS PREVENTION 2024-2025

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Background: Associazione Solidarietà AIDS (ASA) is a community-based organization focusing on care for people living with HIV, HIV and STI prevention and awareness since 1985. It is crucial prevention efforts address adolescents, and schools are the venue of choice for reaching a broad audience. Therefore, ASA has a programme for providing sexual education in schools, focusing on HIV and STIs. The programme aims to engage students in a constructive dialogue about sexuality in a mature and informed way.

Methods: Between November and December 2024, the programme provided sexual education sessions in three secondary schools with different addresses (high schools, professional and technical schools) in Milano, addressing students aged between 14 and 18. More than 450 adolescents attended the sessions, designed to provide them with a comprehensive understanding of HIV and STIs. Each two-hour session was moderated by a psychologist and a person living with HIV. Sessions covered a number of STI-related topics, including routes of transmission, symptoms, diagnosis, prevention strategies, and available treatments. Sessions incorporated multimedia materials and personal stories providing firsthand experience of living with HIV and addressing the problems of stigma and discrimination. Starting this year, students were also offered the opportunity to submit anonymous questions online after the session and read the answers on ASA Instagram profile. To assess the impact of the programme, pre- and post-session questionnaires were proposed, along with a satisfaction survey. Descriptive statistics were used for analysis.

Results: Out of more than 450 students reached, 361 completed the pre-session questionnaire, while 300 completed the post-session questionnaire. The satisfaction survey received 245 responses. The analysis revealed a 16% improvement in correct answers on HIV and STIs (fig. #1). The satisfaction survey provided positive results, with 87% of respondents expressing satisfaction with the programme (fig. #2). However, many requested additional information (89%) and suggested dedicating additional time for questions (90%), highlighting areas for potential improvement. Anonymous questions answered on Instagram were viewed by 275 participants overall.

Conclusions: These results highlight the success of this programme. Personal stories of people living with HIV, complemented by audiovisual materials and interactive sessions, effectively engaged students and helped reduce HIV and STI-related stigma. Topics such as PrEP and U=U had a significant impact on participants. The programme is expected to continue for the second semester of the 2024-25 school year, with nine sessions, f for four classes each, already scheduled across three schools.

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Social Science, PROs

P 152 SEXUALIZED DRUG USE AND CHEMSEX: EXPLORING THE LINK BETWEEN ADDICTION, SEXUAL RISK, AND PSYCHOLOGICAL WELL-BEING AMONG MSM IN MODENA, ITALY

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Introduction: Sexualized Drug Use (SDU) involves using drugs before or during sex to enhance experiences, while chemsex specifically includes substances like GHB/GBL, ketamine, mephedrone, or methamphetamine. Both practices are common among men who have sex with men (MSM) and linked to increased sexual risk behaviors and mental health challenges. This study examines the prevalence of SDU, chemsex, and alcohol-influenced sex among MSM in Modena, Italy, and their associations with sexual health outcomes and psychological well-being.
Materials and Methods: An online survey was conducted between September 2024 and February 2025 via dating apps (Grindr and Romeo). Participants provided data on demographics, substance use (SDU, chemsex, alcohol), sexual behaviors, STI history, and psychological well-being (life satisfaction, sexual satisfaction, anxiety/depression, sexual self-efficacy). Descriptive, univariate, and multivariable logistic regression analyses were performed to identify substance use correlates.
Results: A total of 197 cisgender MSM responded to the survey, mostly were Caucasian, 87.3% identified as gay. Over half (52%) had a university/higher education, and 69.5% were single. Among participants, 16(8.1%) reported being HIV-positive, and 57(28.9%) were on HIV pre-exposure prophylaxis (PrEP). Approximately 20% reported having six or more sexual partners in the past month, with 42.1% engaging in condomless sex. Forty-nine participants (24.9%) reported at least a STI (primarily chlamydia) in the past six months.
Eighty-seven participants (44.2%) reported using substances before or during sex, categorized into 3 groups: those engaging in chemsex (27), those using only alcohol (12), and those using substances other than chemsex (48, Table 1). The most commonly used substances were cocaine (25.3%), ecstasy, and poppers (both 20.7%, Figure 1).
Univariate analysis revealed that substance users were significantly more likely to be on PrEP (P<0.001), have six or more sexual partners (P<0.001), and report lower life satisfaction, sexual satisfaction (both P<0.001), and sexual self-efficacy (P=0.002, Table 2). Multivariable analysis confirmed independent associations between substance use and being on PrEP (P=0.002), having six or more sexual partners (P=0.001), and lower life and sexual satisfaction (P=0.001 and P<0.001, respectively, Table 3).
Chemsex users differed significantly only in having six or more partners compared to other SDU users. (Table 4).
Conclusions: This study highlights the high prevalence of substances use during sexual activity among MSM in Modena. PrEP users appear to be more likely to engage in these practices, which are also associated with a higher number of sexual partners. Additionally, substance users reported lower life and sexual satisfaction. Tailored interventions are needed to reduce sexual health risks, particularly for PrEP users, and to improve psychological well-being among substance users.

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Social Science, PROs

P 153 STREETHAART PROJECT: ART AS A TOOL TO CHALLENGE STIGMA AND PROMOTE WELL-BEING AMONG PEOPLE LIVING WITH HIV

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HIV is not only a medical condition but also a deeply emotional and social issue that can hinder the spread of positive messages and weaken social cohesion. Based on this premise, the Street Haart project, led by Antinoo Arcigay Napoli, utilized art as both an expressive medium and a tool to combat stigma. Through skill-building and self-awareness, the initiative aimed to enhance the quality of life of People Living with HIV (PLWH) and foster collective well-being.

The project, funded by the Gilead Community Award in 2018, engaged a diverse community, including PLWH artists, inmates from Poggioreale prison, and students from the Giorgio De Chirico High School of Arts and Human Sciences in Torre Annunziata. The activities resulted in the creation of a large-scale mural inside the prison and the production of collaborative artworks. These pieces were later exhibited in a public showcase at Palazzo Venezia in Naples, offering a visual narrative of personal and collective experiences related to HIV. Themes ranged from risk behaviors and diagnosis to treatment adherence and stigma, ultimately conveying the hope for a future without HIV.

Feedback from participants and visitors highlighted the project's positive impact on social awareness, demonstrating how art can serve as a powerful tool for connection and transformation across different communities. Notably, PLWH were able to participate primarily as artists, inviting friends and family without necessarily having to disclose their status. The broad and diverse participation - including both contributors and the exhibition audience - allowed for an exploration of HIV-related issues from multiple perspectives, fostering a deeper understanding, the acquisition of new skills, and the exchange of ideas that can inspire social change.

With the goal of establishing art as a form of social prescribing in the non-medical treatment of PLWH, a selection of the most representative artworks will be presented. These works, accompanied by images and reflective commentary, aim to stimulate discussion and awareness among healthcare professionals. Additionally, new ideas are emerging within the Cotugno Hospital on how to further integrate art as a medium for conveying essential health information and awareness messages.

Figure

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Social Science, PROs

P 154 THE IMPACT OF AWARENESS-RAISING AND SCREENING INITIATIVES ON THE MIGRANT POPULATION LIVING IN BERGAMO

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Background: According to the COA, in 2023, 36.9% of new HIV diagnoses concern the migrant population. The incidence among foreigners increased from 12 per 100,000 in 2019 to 15 per 100,000 in 2023. In Italy, the rate of foreigners is about 9% (11% in Bergamo).
Bergamo FTC network has implemented specific actions for migrants to raise awareness, improve access to testing and facilitate linkage to care through various projects financed by pharmaceutical companies. Antibody tests for HIV, HCV and syphilis have been proposed, and the HBsAg test has been added since 2025.
Material and Methods: During testing, data were collected using the Cobatest questionnaire. To overcome language barriers, material was created in various languages and cultural mediators and social workers were involved. The population data came from ISTAT.
Results: Relating the number of tests carried out by foreigners to the total foreign population in Bergamo, we obtain an impact index of 1.3%; compared to the Italian, the index is 0.6%.
The analysis of the 7551 questionnaires collected (11/2021-02/2025) shows that the foreign population represents 21% of the people tested by Bergamo FTCI and that, over time, the share of foreigners has remained significant between 16 and 20% with an increase to 55.5% in the first months of 2025 due to the 'Test in The City' project.
52% of those tested defined themselves as male, 46.2% as female and 1.8% as trans, 32% are <24 years old, i.e. 17.4% of the total young population (FIGURE 1).
Only 19% of the foreign population (compared to 45.5% of Italians) took the test at the city checkpoint: 81% did the test during dedicated territorial events or in contexts close to vulnerable populations. In particular, about 44% of the total took the test at CPIAs (Provincial Centres for Adult Education), the rest at high schools and at university sites, or in low-threshold services (FIGURE 2).
With regard to risk behaviour, 37.5% stated that they had not used a condom during their last sexual intercourse but of these, only 17% claimed to have been tested because of a risk they had taken (vs. 27% in italian people (FIGURE 3).
No significant differences emerged in relation to the incidence of overall reactivity (around 1%), although the incidence of HIV was more than double (0.76%) that of the total population tested (0.31%), and significant data emerged from the recent offer of the HBsAg test with an incidence of around 4.65% in the tests carried out to date.
Conclusions: Data demonstrates the importance of promoting actions that increase health awareness and offer screening opportunities to the foreign population residing in Italy by approaching their places of life and in proximity contexts.
Finally, it must be stressed that in order to be able to continue with these actions to guarantee the right to personal health and promote public health, it is essential that the work of the third sector be recognised on an ongoing basis and supported by structural funds.

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Social Science, PROs

P 155 THE NEED AND FREQUENCY OF STI TESTING DEPENDS ON THE LIFESTYLE OF THE PEOPLE ON PREP. DATA FROM THE PREP POINT PLUS (PPP) IN BOLOGNA

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Background: According to the current national guidelines, people on PrEP are tested quarterly for HIV and the main STIs. Once fully operational, also our PrEP users come to our PrEP Point for visits every 3 months and respond to a clinical/behavioral questionnaire. Quarterly screening for chlamydia and gonorrhea is currently the subject of scientific debate. Several clinicians are considering whether it would be more appropriate to extend the PCR for CT/NG to six months.

Materials and methods: We extracted the behavioral data of our PrEP users from January 1st to December 31st 2024 from our database.

Results: Sample characteristics: In a group of 192 users on PrEP, 94% are white cisgender males, MSM, with a high level of education (70% with a degree). The group does not report cardiovascular, renal or bone diseases. 74% of the sample does not take medications continuously, apart from PrEP, there is a 7.7% who take anxiolytics/mood stabilizers. Risk exposure: in the last 3 months almost 70% of the sample reports sexual practices with several partners; 43% had group sex, almost 20% practice anal fisting and 7% exchange sex toys.

Condoms are never or less than half the time by 78.8% of the sample.

Almost 90% of the sample looks for sexual partners via app, sex is mostly consumed in private homes (89%) as well as saunas and sex clubs (32%).

Chemsex, i.e. the use of synthetic substances during sexual intercourse, is practiced by 23.6% of the sample (slightly decreasing compared to the previous year). The most used substances are: GHB/GBL 92.7%, mephedrone 75.6%, cocaine 39%, ketamine 16%.

Relatively “new” substances such as crystal meth or MDPV seem to be preceded by a “bad reputation” whereby many users would stay away from them. Despite this premise, respectively 12.3% and 15.7% of the sample have used them at least once.

Perception of PrEP

Over 85% of the sample benefits from PrEP and 97% consider it effective.

In the given framework, in 2024 we performed: 596 molecular tests for CT/NG (combo) of which 48 positives for NG and 41 for CT.

In 2024, 85.6% of respondents were not diagnosed with any STI between one visit and another at the PPP, a growing figure compared to previous years (see tab. 1).

For users who were diagnosed with STIs between visits to the PrEP Point, the values are relatively low and apparently decreasing compared to the previous year (see tab. 2).

Conclusions: Our PPP group is certainly selected as high risk and it is likely that a radical change in the guidelines on STI testing in people on PrEP, that does not take people's lifestyles into account.

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Social Science, PROs

P 156 THERAPEUTICAL GROUP FOR CHEMSEX ADDICTION

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Our association has been the first to offer group therapy for chemsex addiction aimed to face the ever growing problem of problematic chemsex and addiction inside the MSM community. Our groups are held by a professional psychotherapist and a peer.

Over the many years of experience and cooperation with public services (SerD) and MD we have identified some recurrent elements in the structure of personality of MSM that experience problematic chemsex (among others: internalized homophobia, self loathing, loneliness, non affective sexuality). We have identified different approaches aimed at freeing the participants from stigma and self-blame by focusing on the cultural and social origins go some of these problems, which can be shared by the whole group, and to possible individual, subjective declinations, which can be rooted in the individual history of each participant.
Over the past two years all of the participants where addicted to MDPV (Metilenediossipirovaleron), while in 2024 a growing number of requests came from people with addiction to other substances such as Mephedrone who used to be considered only as recreational drugs and therefore less dangerous and addictive.

The structure of the group is the same as the well known “mono symptomatic therapeutical group” used commonly for other addictions such as eating disorders, gambling or alcoholism and other psychological troubles.
The sharing of experiences and attributions of meaning to the use of substances, and to one's own specific experience is one important step that helps participants to feel empowered and creates authentic interpersonal relationships. Thought the interpretations of the different experiences and affections participants are accompanied to create a new, more positive representation of themselves and diminish the sense of self loathing ad guilt.

The setting within an established and historical organization in the Milan MSM scene, helped create a friendly environment that helps participants talk freely, without fear of being judged or stigmatised.
The synergy between professional figure and a member of the MSM community (although not technically a peer, for he is not a former chemsex user) has turned out to be fundamental to bridge potential cultural gap between users and therapist. in some cases psychopharmacological support is necessary, it is therefore important that each organization structures itself with one or more psychiatrists informed on this specific addiction, and to built a net of relation with the public services.

STIs

P 157 DOXYCYCLINE VS PENICILLIN FOR LATE LATENT SYPHILIS: COMPARATIVE ANALYSIS OF EFFICACY DATA

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Background: Late latent syphilis is routinely treated with intramuscular benzathine penicillin, but in cases of patients with penicillin allergy or where penicillin is unavaible, doxycycline should be used as an alternative. However, comparative evidence data between these two regimens remains limited.
Methods: An analysis was conducted based on data from randomised controlled trial and an observational study, including a total of 351 patients with latent syphilis, all of whom were living with HIV. Relative risk (RR) of serologic response and treatment failure and number needed to treat (NNT) were calculated. A meta-analysis was conducted using a fixed-effects model, and heterogeneity was assessed using I^2 statistics.
Results: Penicillin had a trend towards greater efficacy with 83-94% vs 79-94% rate of serologic response to doxycycline (RR=1.01; 95% CI: 0.92–1.10, NNT 234). The difference was not statistically significant. A meta-analysis, based on three studies, yielded an odds ratio (OR) of 1.07 (95% CI: 0.32–3.56), showing no significant difference between the two treatments. The heterogeneity test indicated an I^2 of 0%, suggesting minimal variability between studies and a consistent trend across datasets.
Conclusions: Doxycycline was as effective as penicillin in the treatment of late latent syphilis, with a trend towards reduced serologic response and more frequent adverse effects, though these findings were not statistically significant. Given the fact that few studies are available, further investigations with larger samples and prolonged follow-up are needed to confirm the current findings.

STIs

P 158 DYNAMICS OF SYPHILIS AMONG HIV+: PREVALENCE, INCIDENCE AND SEROLOGICAL RESULTS IN 1669 PLWH, 2021-23, "D. COTUGNO" HOSPITAL, NAPLES

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Background: Syphilis is on the rise worldwide, posing a significant public health concern, especially among key populations such as men who have sex with men (MSM). People living with HIV (PLWH) are at higher risk of acquiring syphilis due to shared risk factors. Moreover, in PLWH, syphilis serology often follows an atypical pattern, with a slower decline in VDRL titers even after appropriate treatment, which may complicate diagnosis and monitoring.

To estimate the burden and dynamics of syphilis, we analyzed data from PLWH followed at Cotugno Hospital, Naples, between 2021 and 2023.

Material and Methods: All PLWH followed in two different Medical Divisions at "D. Cotugno" Hospital, Naples, were included in the study. Data were derived from the electronic database (DB) used for clinical care of PLWH. All available data from January 2021 to December 2023 were included. According to international guidelines, we defined a new syphilis infection as either VDRL seroconversion (previously negative → now positive) or a 4-fold (2-dilution) VDRL increase in a previously positive patient. We defined a typical treatment response as a 4-fold (2-dilution) VDRL decline within 12 months (24 months for late syphilis).

Results: We included 1,669 PLWH with at least one follow-up visit during the study period. The main characteristics of the population were: males 72.6%; Italian 90%; mean and median age 46.8 and 47.5 years; viral load less than 50 copies/mL 82%; CD4 count mean and median 651 and 609; HBsAg+ 6.2%; HCV+ 8.9%.

Among them, 1,424 were tested at least once for syphilis, and 209 tested VDRL positive at least once. Among these, 161 were already positive at first control during the observation period; consequently, their full serological dynamics could not be assessed. During the same period, 48 new cases occurred. Overall syphilis prevalence was 14.6%, while the incidence, calculated among new cases only, was 1.4 per 100 person-years (95% CI: 1.03 – 1.83 per 100 person-years).

Detailed treatment data were available for 120 patients only: various types of penicillin were used in 95% of cases, doxycycline in the remaining. Serological dynamics after treatment were evaluated in these patients only: in 42 patients (35%), the serological response was atypical, with a lack of a 4-fold VDRL decline within 12 months and long-term persistence of high VDRL titers.

Conclusions: Our findings confirm a significant burden of syphilis among PLWH. Treatment data are likely biased, as penicillin—being more commonly prescribed and administered in hospitals—was more frequently recorded in DB, while doxycycline, often prescribed for home therapy via telephone consultations, may have been underreported. Independently by the therapy, our data confirm that a substantial proportion of PLWH show an atypical serological response even after correct treatment. This highlights the need for closer serological monitoring in this population to optimize treatment outcomes.

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P 159 DYNAMICS OF VACCINE-PREVENTABLE ANAL HPV GENOTYPES IN INDIVIDUALS SCREENED FOR HPV: A RETROSPECTIVE OBSERVATIONAL STUDY

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Introduction: Persistent infection with Human Papillomavirus (HPV) is a leading cause of anal intraepithelial neoplasia and anal cancer. The concurrent presence of multiple HPV genotypes is common, particularly among people with HIV (PWH) and men who have sex with men (MSM). However, the impact of multiple infections on HPV persistence and anal abnormalities remains unclear. This study aimed to evaluate the persistence of vaccine-preventable anal HPV types in individuals with single and multiple infections.

Methods: This retrospective study included individuals who underwent HPV screening (t0) at the Infectious Diseases Department, ASST Fatebenefratelli Sacco, Milan with an available follow-up 12 months after t0 (t1). Cytobrush samples were collected using ThinPrep™ (Hologic), and HPV DNA was detected using the HPV28 Detection assay (Seegene). HPV presence was correlated to biological sex, age, HIV status, cytological abnormalities, and vaccination history.

Results: Among 155 participants with available t1 follow-up, 95% (148/155) were assigned male at birth, with a median age of 47 (IQR: 38–54) years, and 89% were PLWH. At t0, 26% (40/155) had received HPV vaccination, and 43% (67/155) had normal cytology. Anal abnormalities were detected in 57% (88/155) of participants, including LSIL (32%), ASC (19%), and HSIL (6%). HPV prevalence was as follows: HPV16 (37%), HPV18 (17%), HPV31 (18%), HPV33 (17%), HPV45 (10%), HPV52 (12%), HPV58 (30%), HPV6 (21%), and HPV11 (10%). Single HPV infections were detected in 45% (70/155) of participants, while 55% (85/155) had multiple genotype infections.

Individuals with single infections were 93% (65/70) male, had a median age of 46 (37–53) years, and 89% (62/70) were PLWH. Vaccination rate was 30% (21/70) and anal abnormalities were found in 46% (32/70). In contrast, individuals with multiple infections were 98% (83/85) male, had a median age of 48 (39–55) years, and 89% (76/85) were PLWH, with a lower vaccination rate (22%, 19/85, p = 0.356) and higher prevalence of anal abnormalities (66%, 56/85, p = 0.015). At t1, complete clearance was observed in 24% (17/70) of individuals with single infections, compared to only 7% (6/85) in those with multiple infections (p = 0.005). Progression to anal abnormalities occurred in 24% (9/38) of individuals with single infections and 31% (9/29) of those with multiple infections (p = 0.583). However, regression of anal abnormalities was significantly higher in the single infection group (53%, 17/32) compared to the multiple infection group (30%, 17/56) (p = 0.043).

Conclusion: Our findings show that multiple HPV genotype infections are associated with a higher prevalence of anal abnormalities and a lower viral clearance suggesting a potential negative impact of genotype interactions on disease resolution.

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P 160 HPV AND STIS SCREENING IN OUTPATIENT CLINIC. THE MULTIDISCIPLINARY EXPERIENCE IN AOUP-PISA (PRELIMINARY DATA)

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Since 2015, an integrated program for screening, counseling, and treating those at risk of HPV-related cancers has been in place. From 2015 to 2025, 804 individuals were evaluated (259 females and 545 males), with an average age of 42. 7 years. The program aims to find the prevalence of high-risk and low-risk HPV genotypes and STIs in relation to HIV status. A total of 1780 samples were collected, including anal PAP tests and biopsies. Among the 804 patients, 212 were HIV positive, and 544 were HIV negative. STIs were found in 32. 9% of subjects and 39% of patients screened had at least one STI.

Cytological alterations in anal scraping were found in 16. 2% of 804 samples, showing changes like Ascus, LSIL, and HSIL. HPV was detected in 75. 6% of the samples, with 53. 2% showing high-risk (HR) types and 14.5% showing low-risk (LR) types. There were no detectable HPV in 207 samples. In HPV-HR samples, the most common types were HPV16, HPV53, and HPV18, while HPV6 was more common in benign lesions. HR strains were more frequent in subjects with both HPV and HIV compared to those with only HPV. The HPV test showed high sensitivity and an 80% negative predictive value for LR and HR genotypes, even with negative cytology. In histological analysis, 284 precancerous lesions were identified among subjects, and benign condylomas were present in many samples. Additionally, higher rates of U. urealyticum were noted in groups with detectable HPV. To date, 464 subjects have completed three doses of HPV9 vaccination, while 59 subjects have started it; follow-up will provide data on vaccination's efficacy in preventing local recurrences.

HPV testing effectively identifies LR and HR genotypes for anal cancer risk. U. urealyticum is more prevalent in HPV-positive patients. There's a need to enhance screening in HIV-positive patients with a focus on new diagnostic and therapeutic approaches and the potential use of vaccination as adjuvant therapy.

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P 161 IMPACT OF GENOTYPIC SUBSTITUTIONS ON TREATMENT FAILURE FOR MYCOPLASMA GENITALIUM INFECTION

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Background: Mycoplasma genitalium (MG) management can be challenging due to increasing resistance rates over time to both standard treatments with macrolides and quinolones. Aim of this study is to describe possible factors associated with MG treatment failure, with a focus on detected genotypic substitutions.
Material and Methods: Retrospective monocentric observational study, including all individuals tested positive for MG by NAAT from at least one among urine sample, pharyngeal, anal or cervical swab in our clinic between October 2022 and September 2024. Demographic, behavioural, clinical data and genotypic substitutions associated with antimicrobial resistance were registered. Tests of cure were performed to assess microbiological success. Descriptive statistics and nonparametric tests were used to describe study population and subgroups, while bivariate regression analysis described risk factors for treatment failure.
Results: 207 individuals were included: their main features are described in Table 1. Median bacterial load expressed in threshold cycle (Ct) was higher among symptomatic infections (30.8 (26.6-32.9) vs 33.7 (32.2-37.7)) (p=0.015). Overall, microbiological cure after antibiotic treatment happened for 174 (84.1%) individuals: success rate was 71.8% for azithromycin and 89.3% for moxifloxacin, while 60.9% of infections with confirmed both azithromycin and moxifloxacin genotypic resistance responded to therapy. Alternative therapeutic regimen showed often unsatisfactory efficacy among double-resistant MG: when used, moxifloxacin+doxycycline combination therapy and pristinamycin showed a microbiological cure rate of 20% (1 over 5) and 66.7% (2 over 3), respectively. At an adjusted bivariate regression analysis (Figure 1), G248T (OR 23.0, 95%CI 5.7-92.9, p<0.001) and G259A (OR 66.3, 95%CI 10.4-423.2, p<0.001) substitutions were strongly associated with moxifloxacin failure, while A2058G (OR 20.5, 95% CI 1.8-232.6, p=0.015) and A2059G could significantly lead to failure with azithromycin (OR 7.5, 95%CI 1.1-51.9, p=0.042). No impact on outcome was seen for bacterial load and exposure to doxycycline for both azithromycin and moxifloxacin treatment. Considering infections driven by MG resistant to both azithromycin and moxifloxacin, no impact on outcome was seen considering mutations detected, prescribed antibiotic treatment and bacterial load.
Conclusions: This study showed a high rate of MG antimicrobial resistance-associated genotypic substitutions, even if often responding to standard antibiotic treatment, suggesting a dubious impact of these mutations on outcome: only G248T and G259A for moxifloxacin, A2058G and A2059G for azithromycin were associated with treatment failure, and their overall prevalence was not so high. Higher bacterial load seemed to be associated with symptomatic infections, but with no impact on therapy efficacy.

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P 162 INVESTIGATION OF ADDITIONAL RISK FACTORS TO PRIORITIZE ANAL CANCER SCREENING IN MSM LIVING WITH HIV

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Background: Screening guidelines for the prevention of squamous cell carcinoma of the anus (SCCA) have been released in 2024 by the U.S. Department of Health and Human Services as well as by the International Anal Neoplasia Society (IANS). Screening is suggested for specific high risk populations, such as men who have sex with men (MSM) living with HIV (LWH). Age and anal high risk HPV (HR-HPV) infection represent major risk factors and screening for SCCA is suggested in MSM LWH >35 years. Baseline screening is conducted through anal cytology and/or anal HPV test with subsequent referral for high resolution anoscopy or periodic follow-up depending on the results of baseline evaluation.
Access to baseline SCCA screening and to HRA is limited. Defining additional risk factors could help prioritize individuals with the highest likelihood of precancerous lesions.
Material and Methods: In the present retrospective analysis, we enrolled 71 MSM LWH >35 years at their first SCCA screening. All participants underwent anal cytology and high-risk HPV (HR-HPV) test with HPV16 genotyping. Referral to HRA followed the IANS guidelines indications.
Variables included in the analysis were: age, anal HR-HPV infection, body mass index (BMI), current CD4 and CD8 count, CD4/CD8 ratio, smoking habit and HPV vaccination status.
Years lived with HIV and CD4 nadir were included, although data were available only for 35 individuals.
Data were compared between participants with histological diagnosis of high grade dysplasia (high grade squamous intraepithelial lesion, HSIL) and participants with no dysplasia or histological diagnosis of low grade dysplasia (low grade squamous intraepithelial lesion, LSIL).
Continuous variables are reported as median value.
Results: All participants were on antiretroviral therapy with undetectable HIV RNA since at least 5 years. 41 participants received histologic diagnosis of HSIL, 21 showed histologic LSIL and 9 had no evidence of dysplasia (cytology or histology).
HR-HPV other than HPV16 as well as HPV16 were more frequent in participants with HSIL, respectively 93% vs 50% (p=0.01) and 49% vs 7% (p=0.01). Current CD4 count was lower in participants with HSIL in respect to those with no dysplasia or LSIL (736±312 vs 884±306 cells/mL; p=0.05).
No differences were observed regarding age (46 vs. 51; p=0.26), BMI (24.4 vs 24.1; p=0.76), current CD8 count (810 cells/mL vs 792 cells/mL, p=0.80), current CD4/CD8 ratio (1.0 vs 1.05; p=0.12), years lived with HIV (20 vs 16; p=0.37), CD4 nadir (350 vs 400; p=0.59). Smoking was observed in 47% of participants with HSIL and 27% with LSIL or no dysplasia (p=0.37). 53% of participants with HSIL and 33% with LSIL or no dysplasia received vaccination (p=0.11), catch-up in all cases.
Conclusions: Aside from age, anal HR-HPV infection and result of anal cytology, evaluation of current CD4 count could help prioritize SCCA screening in MSM LWH, especially in settings where access to screening is limited.

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P 163 MORE TESTING, MORE STDS? THE PARADOX OF FOLLOW-UP IN PEOPLE ON PREP

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Background: Pre-exposure prophylaxis (PrEP) has revolutionized HIV prevention but has been associated with increased incidence of sexually transmitted diseases (STDs). This has been attributed to decreased condom use; however, new evidence shows that frequent clinical monitoring can affect the number of diagnoses.
Methods: Our Centre dataset of 318 participants on PrEP was subjected to analysis, the objective being to determine the correlation between age, risk factors, follow-up time, and MST development. The tests were done with statistical tests, regression analyses, and machine learning with the focus laid on follow-up time's influence on probability of MST diagnosis.
Results: The sample included a total of 318 subjects, mostly men, with a median age of 39 years and a median follow-up time of 2.6 years.
Syphilis was the most frequent STD with an incidence of 27% at presentation, followed by rectal Chlamydia trachomatis, which was present in approximately 3% of the patients. The mean time to the first STD was 2 years.
The variable analysis showed that follow-up time was the strongest predictor, having a predictive importance of 61.7%, followed by age (32.6%), while self-reported risk factors, such as sexual orientation (3.1%) or sex work (0.7%), had considerably less impact on the likelihood of contracting an STD. The results showed that the patients with the lowest STI risk were usually those with short follow-up and older age.
Conclusions: The correlation between the number of tests performed and the number of diagnoses gives rise to the question of whether long-term follow-up may be more of a diagnostic bias than an actual risk factor. The analysis indicated that the association of follow-up duration with STD diagnosis was extremely small (r=0.02), which means that a longer period of follow-up does not necessarily equal increased risk. While age as a factor seems to present, the gap between the not diagnosed and diagnosed groups of MST was small, with a median age gap of just 2 years (37 vs. 39). This observation suggests the possibility of other unmeasured variables exerting a more substantial influence on the outcome.
Our data show that follow-up time is the main predictor of MST diagnosis, more than age and traditional risk factors. This finding suggests that the higher incidence of STDs observed in this population may be, at least in part, an artefact of test frequency rather than a genuine increase in risk. If this hypothesis is validated, it would have significant implications for the clinical management of PrEP, emphasising the necessity to optimise screening protocols to ensure the early detection of clinically significant infections while circumventing the potential consequences of antibiotic overuse.

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P 164 OUTCOMES OF ANAL HIGH GRADE DYSPLASIA TREATMENT IN MSM LIVING WITH HIV AND MSM LIVING WITHOUT HIV

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Background: Incidence of squamous cell carcinoma of the anus (SCCA) is particularly high among men who have sex with men (MSM). MSM living with HIV (LWH) show an higher risk than MSM not living with HIV (NLH). Anal high grade squamous intraepithelial lesions (HSIL) are the precursors of SCCA. Treating HSIL reduces the risk of SCCA. Current guidelines do not give suggestions on follow-up after treatment of anal HSIL. Data comparing outcome of treatment between MSM LWH and MSM NLH are important to define post-treatment follow-up and could inform future guidelines update.

Material and Methods: We retrospectively analyzed follow-up data from 104 MSM (79 LWH and 35 NLH) after their first treatment of histology proven anal HSIL. Treatments were performed with electrocautery or infrared coagulation.

The evaluated post-treatment variables were: total number of treatments needed to fully ablate baseline HSIL, recurrence rate and time to recurrence of treated HSIL, onset of metachronous HSIL during follow-up and time to diagnosis of metachronous HSIL.

Age, BMI, smoking habit, HPV vaccination and number of HSIL were evaluated as baseline risk factors for recurrence or onset of metachronous lesions during follow-up.

Continuous variables are reported as median value.

Results: Median age was 45±9 in participants LWH and 40±11 in individuals NLH (p=0.02). All participants LWH were on antiretroviral therapy with undetectable HIV RNA. No differences were observed between participants LWH and NLH regarding BMI (23.9±2.2 vs 23.0±2.6; p=0.08), smoking habit (smokers 48% vs 29%; p=0.35), vaccination rate (51% vs 57%, catch-up in all cases; p=0.55). Median number of HSIL lesions at baseline was 2±0.9 in individuals LWH and 2±0.8 in participants NLH (p=0.21).

Total duration of follow-up after the first treatment was 24±11 months in MSM LWH and 18±8 in MSM NLH (p=0.22). Total number of treatments needed to ablate baseline HSIL was 2±1.0 and 2±0.5, respectively (p=0.16).

HSIL recurrence was similar between the two groups (33% in MSM LWH and 33% in MSM NLH; p=0.96). Number of recurrent lesions (1±0.6 vs 1±0.5; p=0.80) and months to recurrence (12±5.4 vs 12±6.4; p=0.90) were similar between the two groups. Recurrence was more frequent among MSM LWH with >1 HSIL at baseline (OR 0.18; p=0.05) and MSM NLH with HPV16 infection (OR 29.56; p=0.02).

Diagnosis of metachronous HSIL during follow-up occurred in 38% of individuals LWH and 29% of NLH (p=0.42). Number of metachronous HSIL (1±0.9 vs 1±0.5; p=0.93) and months to onset of metachronous HSIL (12±5.0 vs 9 ±11.7; p=0.88) were similar between the two groups. Metachronous lesions were more frequently observed among MSM LWH with a single baseline HSIL (OR 5.17; p=0.18).

Conclusions: Direct ablation of anal HSIL is equally effective in populations with different risk of SCCA.

Periodic follow-up is crucial for SCCA prevention since recurrence of HSIL as well as onset of metachronous lesions are frequent after primary treatment.

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P 165 PREVALENCE OF SYPHILIS AMONG PEOPLE LIVING WITH HIV (PLWH), PRE-EXPOSURE PROPHYLAXIS (PREP) USERS AND INDIVIDUALS SCREENED FOR SEXUALLY TRANSMITTED DISEASE (STD) ATTENDING FERRARA HIV/AIDS SECTION. A COMPARATIVE OBSERVATIONAL STUDY

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Background: According to available data, seroprevalence of syphilis among PLWH is high and has recently re-emerged, highlighting the frequent occurence of HIV-syphilis coinfection.
Material and Methods: An observational, monocentric study was conducted at the HIV/AIDS Section of the Infectious Diseases Unit of Ferrara Hospital, from June 2023 to May 2024. The aim was to evaluate the overall prevalence of Treponema Pallidum (TP) infection among PLWH attending the Center and to asses new diagnosis or reinfections at HIV diagnosis time and study period. This prevalence was also compared among PLWH, PrEP users, and people screened for STD attending the Center. The study included 542 PLWH tested for syphilis (anti-TP antibody screening) during scheduled laboratory follow-up, 87 PrEP users and 203 people screened for STD; sex, age at enrollment, nationality, sexual history and laboratory investigations of all syphilis cases were considered (Tables 1/2/3).
Results: The seroprevalence of syphilis at HIV diagnosis among PLWH was 8.5%, of whom 97.8% males, 97.8% Italians, 65.2% aged 35–59 years, 28.3% over 60 years, 23.9% with homosexual/bisexual history and 19.6% with heterosexual history. During the observational period, the seroprevalence was 18.8%, 95.1% males, 88.2% Italians, aged 35–59 years (55.9%), or over 60 years (36,3%). 22,6% tested positive for syphilis during the study period were negative at HIV diagnosis: 30,4% of them received treatment. Among PrEP users, prevalence at the start of PrEP was 21.8%, 94.7% males, 89.5% Italians, 47.4% aged 21-34 years, 47.4% aged 35-59 years. During the evaluation period only 37 PrEP users were screened; the seroprevalence was 27%, 50% males and Italians, 50% aged 21-34 years, 50% aged 35-59 years. Among individuals screened for STD, the seroprevalence was 9.9%, 85% males, 60% Italians, 45% aged 21-34 years. Subgroup analysis showed that overall prevalence of syphilis among men who have sex with men with HIV was significantly higher than among heterosexuals. Comparing the data at HIV diagnosis and during the study period in PLWH, an increase in the overall prevalence of syphilis over the years was evident. The rate of syphilis infection remained significantly higher among men, Italians, with a slight increase in prevalence among people over 60 years. We observed the same increase in TP infection among PrEP users. However, the prevalence among individuals screened for STD was lower. When new or reactivated syphilis was identified during the study period, due to new antibody TP detection or variations in rapid plasma reagin (RPR) value, treatment was administered. Patients with history of prior treatment or no change in RPR titers were not treated according to current guidelines.
Conclusions: Results confirm a high prevalence of syphilis in PLWH population and justify integrating routinary syphilis screening in HIV care and behavioral risk reduction counselling among high-risk individuals.

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P 166 SCABIES: NOT JUST A NEGLECTED DISEASE, BUT A PUBLIC HEALTH CONCERN AMONG KEY POPULATIONS

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Background: Scabies, caused by Sarcoptes scabiei var. hominis, is a widespread parasitic skin infestation affecting an estimated 400 million people globally each year. Traditionally associated with household and institutional outbreaks, scabies is now increasingly recognized as a sexually transmitted infection (STI), particularly among men who have sex with men (MSM). The aim of this study was to describe the evolving epidemiological pattern in order to reconsider scabies within the broader framework of STI surveillance and prevention.
Methods: A retrospective observational study was conducted at the Infectious Disease Outpatient Clinic of Fondazione Policlinico Gemelli in Rome. Clinical, demographic, and laboratory data were collected from patients diagnosed with scabies at the time of diagnoses, between January 2024 and January 2025.
Results: Seventeen cases of scabies were identified, all among MSM, with a median age of 39 years (IQR 32-51). The majority (12, 83.3%) were people living with HIV (PLWH), while the remaining 5 (16.7%) were individuals undergoing follow-up for oral PrEP with TDF/FTC. Notably, all patients reported engaging in unprotected sexual intercourses with multiple male partners in the days leading up to diagnosis and had a documented history of at least one prior STI. None of the PLWH had a history of AIDS-defining conditions, and all had CD4 counts above 200 cells/mmc at the time of scabies diagnosis. Among the PLWH, 5 had an HIV-RNA value above 50 copies/mL at the time of scabies diagnosis, of which 2 had levels exceeding 1000 copies/mL. No statistically significant differences were observed between PLWH and PrEP users at the time of scabies diagnosis.
Population characteristics are summarized in Tab.1.
Conclusions: Our findings highlight the growing recognition of scabies as a significant STI, particularly within high-risk populations. Given its potential to spread within sexually active MSM populations, targeted screening strategies should be considered in STI clinics. The absence of significant differences between PLWH and PrEP users further supports the notion that sexual behavior, rather than immune status, is the primary factor driving transmission dynamics. The presence of HIV-RNA in some PLWH at scabies diagnosis highlights its relevance as an STI and raises concerns about HIV transmission in high-risk sexual networks. These findings advocate for a paradigm shift in how scabies is perceived, calling for its integration into sexual health programs and STI prevention efforts.

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STIs

P 167 SEXUALLY TRANSMITTED INFECTIONS, CONDOM USE AND SEXUAL BEHAVIORS IN WOMEN: THE WOMANIST EXPERIENCE IN AN ITALIAN REFERENCE CENTER

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Background: Worldwide, sexually transmitted infections (STIs) are a major public health issue. In women, STIs are frequently asymptomatic and can lead to several complications such as infertility, ectopic pregnancy and PID. Women are a neglected category for early diagnosis and treatment for STIs for behavioral and socio-cultural reasons. Nowadays, hormonal contraception and female empowerment could promote a change in women sexual habits. In Italy, women get tested systematically for STIs only during pregnancy and there is no proper prevention. In 2024, we founded the WomanIST clinic at Legnano General Hospital, close to the Metropolitan city of Milan, to solve this gap. We perform a complete STIs screening with serological test for HIV, HCV and syphilis together with vaginal and endocervical swabs to perform NAAT for C. trachomatis, N. gonorrohoeae and urogenital mycoplasma in a discrete space. Moreover, we designed a specific questionnaire to investigate sexual behaviors of all patients attending the clinic.
Materials and Methods: We made a descriptive analysis focused on sexual behaviors of women who got tested in WomanIST clinic through the questionnaire.
Results: From January 2024 to February 2025, 128 patients answered the questionnaire. We selected only patients who were female at birth. The average age was 30 y.o., mostly caucasic. We analyzed education level and sexual orientation. Only 53 were vaccinated for HPV and 22% declared a previous STI. Regarding sexual behaviors, the average age of the first sexual intercourse was 17, 49% of patients did not regularly use condom during sex and 37 had more than one sexual partner/month; 51 used a hormonal contraceptive method, and 48% took an emergency contraception, at least once. All detailed variables are shown in Table 1. Fisher test demonstrated an association between a low education level and a higher number of previous STIs (p 0.04). No statistically relevant association was detected between previous STIs and inconsistent use of condom (p 0.89), inconsistent use of condom plus use of hormonal contraceptives (p 0.11) or use of hormonal contraceptives alone (p 0.82).
Conclusions: The analysis of WomanIST data had shown a high behavioral risk, an inconsistent use of condom and a weak prevention for STIs in our female population. A higher educational level seems to be relevant in STI prevention. New strategies are needed to screen STIs in women to avoid severe complications, including an adequate clinical evaluation to be closer to feminine needs without any stigma.

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Vaccines

P 168 A RAPID FLUOROMETRIC APPROACH FOR EVALUATING ADCC ACTIVITY AGAINST DIFFERENT FORMS OF HIV-1 ENV PROTEIN

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Background: Antibody-dependent cell-mediated cytotoxicity (ADCC) plays a critical role in the immune defense against HIV-1 infection and is crucial for the effectiveness of therapeutic antibodies targeting HIV-infected cells. Optimizing experimental protocols for rapid and reproducible results is essential for evaluating the ADCC activity of monoclonal antibodies (mAb) and sera against various Env forms. Insights into how these antibodies induce ADCC can help optimize their design and lead to more effective HIV therapies and vaccines.
Methods: We adapted a rapid fluorometric antibody-dependent cellular cytotoxicity assay (RFADCC) to evaluate the breadth and functionality of anti-Env antibodies by measuring their ADCC activity against various Env forms. Peripheral blood mononuclear cells (PBMCs) from healthy donors were used as effectors, while CEM NKr CCR5+ cells, pulsed with different Env proteins and opsonized with specific polyclonal and monoclonal antibodies, were used as target cells.
Results: Target cells were pulsed with monomeric and trimeric Env proteins (both cleaved and uncleaved) from clades A, B, and C. The study tested the mAb 17b, a polyclonal rabbit serum targeting trimeric ΔV2Env (TV1), and sera from people living with HIV (PLWH). Optimal experimental conditions were determined by selecting the appropriate antigen types, concentrations, and effector/target ratios. To extend and confirm the data, both monomeric (gp120) and trimeric (gp140) forms of various Env (tier 1a clade B SF162, tier 2 clade A BG505, and tier 2 clade C CNE8), were evaluated. The mAb 17b induced ADCC against target cells pulsed with gp120 but not trimeric Env proteins. In contrast, the rabbit serum mediated ADCC against both monomeric and trimeric proteins across all clades and tiers tested. Additionally, sera from PLWH naïve to antiretroviral therapy (ISS OBS-T003 trial, ClinicalTrials.gov NCT01029548) effectively mediated ADCC against cells pulsed with tier 1 and 2 trimeric Env.
Conclusions: The RFADCC assay is a reliable, fast, cost-effective, and sensitive method for assessing ADCC. Its high reproducibility, ease of use, and quick setup make it an ideal tool for evaluating antibody functionality from large biobanks, such as those used in clinical studies. Additionally, it allows for the simultaneous detection of ADCC activity against multiple targets and offers valuable insights into the functional properties of HIV-specific mAbs in high-throughput screening assays. Although it needs confirmation with infected target cells, this assay may represent a powerful tool for advancing antibody evaluation and supporting the development of HIV vaccines and antibody-based therapies.
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Vaccines

P 169 COMPARISON OF STI BURDEN AND ITS PREDICTORS IN PEOPLE DIAGNOSED WITH MPOX OR VACCINATED WITH MVA-BN

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Background: The 2022 mpox outbreak primarily affected individuals at high risk for sexually transmitted infections (STI), but the linkage between mpox and STIs remains unclear. This study examined STI prevalence, incidence, and risk factors among mpox cases (mpoxC) and MVA-BN vaccinated (VAC) individuals in a large hospital in Rome.
Methods: MpoxC and VAC were followed from baseline (mpox diagnosis or MVA-BN primary cycle) to December 31, 2024, in two observational studies with prespecified time points. Blood samples for testing HIV, HCV, syphilis and swabs for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) were analyzed.
Group characteristics were compared using Fisher's exact test, Wilcoxon rank sum test and Pearson's Chi-squared test. Cox proportional hazard model was employed to identify factors associated with STI risk. Incidence rates (IR) are presented per 100 person-years.
Results: The study included 95 mpoxC and 1,307 VAC, predominantly male at birth.
MpoxC were more likely MSM (94% vs. 91%; p<0.001), had fewer PrEP users (16% vs. 45%; p<0.001), but had more sexual partners (>10: 27% vs. 21%; p=0.031). (Tab1)
The baseline prevalence of HIV, HCV, and syphilis was higher in mpoxC vs. VAC (58% vs. 44%, p=0.023; 4% vs. 0.7%, p=0.07; 70% vs. 50%, p=0.003).
PLWH with detectable viral load were more prevalent in mpoxC (51% vs. 6%). (Tab1)
IR were higher in mpoxC for HIV (2.85; 95%CI 0.07-15.9 vs. 0.75; 0.2-1.92, p=0.27), HCV (3.4; 0.41-12.28 vs. 0.56; 0.15-1.44, p=0.07) and syphilis (32.74; 14.97-62.15 vs. 14.16; 10.92-18.04, p=0.04).
Conversely, CT and NG prevalence was lower in mpoxC (4.8% vs. 7.8%; p=0.76 and 7.1% vs. 9.3%, p=0.79), with similar IR between groups (13.75 6.29-26.1 vs. 15.34 12.13-19.15, p=0.87 for CT and 14.04 6.42-26.66 vs. 12.79 9.85-16.33; p=0.71 for NG). (Fig 1-2)
MpoxC had a higher overall STI risk than VAC (44.87; 28.44-67.32 vs. 24.47; 21-28.36, p=0.01). (Fig3)
At multivariable analysis, PrEP use was associated with higher STI risk (aHR: 3.61, p < 0.001), while older age reduced risk (aHR: 0.97, p=0.001).
Mpox diagnosis alone was not a significant predictor (aHR: 0.79, p=0.6).
Conclusions: Mpox cases faced a higher STI burden, especially syphilis and HIV. The strong association between mpox and uncontrolled HIV infection highlights the need for targeted interventions, including improved HIV care engagement and viral suppression strategies. The higher prevalence of STIs among PrEP users suggests that behavioral factors may contribute to STI transmission; however, this finding could also reflect increased STI screening rates among PrEP users, leading to higher detection rates rather than an actual increase in infections.
These results emphasize the importance of integrated sexual health programs, incorporating routine STI screening, behavioral counseling, and harm reduction strategies, especially for high-risk populations such as MSM and PLWH.

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Vaccines

P 170 CURRENT ADHERENCE AND VACCINE HESITANCY TO HERPES ZOSTER VACCINATION IN NORTHERN ITALY: A CUMULATIVE TREND ANALYSIS AT AN HIV CLINICAL CENTER IN TURIN

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Background: The SAGE group (WHO) recommends developing institutional systems and organizational skills at the local level to identify, monitor, and proactively address vaccine hesitancy. International and national guidelines recommend implementing Herpes Zoster vaccinations in PLWHA. Among the consequences of Herpes Zoster infection, in addition to postherpetic neuralgia, recent studies have demonstrated a strong relationship between this infection and an inflammatory mechanism at the arterial vascular level, leading to an increased risk of cardiovascular and cerebrovascular events. The adjuvanted recombinant vaccine (HZric) has been approved for use in immunocompromised individuals and those with chronic diseases since September 2021 in our region. The aim of our study is to assess the trend of adherence and vaccine hesitancy (ritardo nell'adesione o come rifiuto della vaccinazione, nonostante la disponibilità di servizi vaccinali) to HZric vaccination in our population.

Materials and Methods: We included 1201 PLWHA. Mean age (years) 52.88; 999 (83.2%) individuals were Italian while 202 (16.8%) were foreigners (we included in our study only foreigners permanently in care); 934 (77.8%) male and 306 (22.2%) female subjects at birth; risk of HIV transmission: MSM 538 (44.8%), ETX 426 (35.7%), TD 211 (17.5%), vertical 12 (0.9%) and parenteral 6 (0.5%) (missing data 8 – 0.6%). We have access to the SIRVA, the Piemonte Regional Informative System of Vaccination, to monitor adherence to vaccinations from September 2021 to 15/3/2025.

Results: Of the 1,201 PLWHA analyzed, 672 (55.9%) received at least one dose of HZric during the observed period. Specifically, in 2021, 91 (7.5%) PLWHA were vaccinated; in 2022, 341 (28.4%); in 2023, 126 (10.5%); in 2024, 103 (8.6%); and in the first months of 2025, 11 (0.9%). For a detailed analysis of the cumulative trend, please refer to the attached graphs (Figure 1 and Figure 2).

Conclusions: Although the HZric vaccine was launched at a time marked by skepticism surrounding the SARS-CoV -2 vaccination, the adherence to vaccination in our population is good, despite still facing some issues with vaccine hesitancy. In accordance with the recommendations of the SAGE group, at our center, we have started offering the HZric vaccine during follow-up visits for patients showing vaccine hesitancy to increase convenience. The next step is to institutionalize the vaccination service with dedicated spaces and hours.

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Vaccines

P 171 EVALUATING THE LONG-TERM ANTIBODY RESPONSE OF MVA-BN IN PEOPLE LIVING WITH HIV (PLWH): A TWO-YEAR MONOCENTRIC FOLLOW-UP STUDY

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Background: Mpox has been reclassified as a Public Health Emergency of International Concern, highlighting the urgent need for effective vaccination strategies. People living with HIV (PLWH) may have an altered immune response, raising concerns about the efficacy of vaccines such as MVA-BN, which has shown promise in the general population. We conducted this study to evaluate the antibody response to the MVA-BN vaccine in PLWH, aiming to assess its effectiveness in this vulnerable group.
Methods: From August 2022 to November 2024, serum samples were collected from PLWH attending our outpatient clinic for routine analysis and who were vaccinated with the MVA-BN vaccine. IgG against mpox were measured on cryopreserved serum samples by ELISA. No significant cross-reactivity or interference between anti-mpox IgG and analogues was reported. The MPXV-specific IgG levels were determined at several time points: immediately prior to vaccination (T0), immediately following the vaccine completion (within 6 months, T1), at 12 months (T2), and 24 months after immunization (T3). We used an adjusted linear mixed model for repeated measures to evaluate the effects of vaccination on the IgG levels over time.
Results: A total of 64 PLWH were assessed at all predefined time points. Characteristics of the participants are summarized in Table1. In the unadjusted analysis, no statistically significant differences in antibody levels were observed between time points. However, following adjustment for potential confounders – namely, age, zenith of HIV-RNA, nadir of CD4 cells – the mixed effects model revealed an upward trend in antibody levels only at T1 compared to T0 (p=0.004). This suggests a slight increase in the immune response immediately after vaccination, which both at T2 and T3 reverted to levels comparable to T0. Notably, one participant with a constant trend over time, exhibited an exponential increase in IgG levels at T3. Upo further interview, the participant reported a single vesicular lesion in the oral cavity, several days prior to the T3 blood sample collection.
Conclusions: The findings suggest that MVA-BN can elicit only a moderate and not prolonged immune response in PLWH. However, the significant antibody peak observed in one participant, despite the presence of very mild symptoms, highlights the potential for MVA-BN, in the case of overlapping natural infection, to provide robust hybrid protection even in this vulnerable population. Further research is needed to assess the role of cellular immunity.

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Vaccines

P 172 EVALUATION OF VIROLOGIC REBOUNDS IN PEOPLE LIVING WITH HIV (PLWH) AFTER RECEIVING MVA-BN VACCINATION FOR MPOX

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Background: The Mpox vaccination with modified vaccinia Ankara-Bavarian Nordic (MVA-BN) has emerged as a critical intervention for preventing disease spread. However, its potential impact on HIV viral load dynamics in people living with HIV (PLWH) remains unclear. This study aims to evaluate whether MVA-BN vaccination is associated with the occurrence of virological rebound [(VR), viral blips (VB) or virologic failure (VF)] in PLWH within 6 months following vaccination.

Methods: We enrolled all PLWH who were vaccinated with MVA-BN and had maintained stable virological suppression (target non detectable, TND) for at least 12 months prior to vaccination. Participants were required to be on the same antiretroviral therapy for at least 6 months, have at least 200 CD4+ cells/mmc at the time of vaccination, and have at least one determination of HIV-RNA within 6 months after completing the vaccination cycle. VB were defined as a single determination of HIV-RNA > 50 cp/mL followed by a determination < 50 cp/mL, while VF was defined as a single determination > 1000 cp/mL or at least two consecutive measurements > 50 cp/mL. Time to VR was estimated using Kaplan-Meier analysis, and a Cox regression analysis was conducted to evaluate the factors associated with the occurrence of VR.

Results: A total of 74 PLWH, all male, met the inclusion criteria and were enrolled. The clinical and demographic characteristics of the population are summarized in Table 1. We observed 8 VB [incidence rate 1.93 per 100 patient-months of follow-up (PMFU), 95%CI 0.59 – 3.27], with all events exceeding 100 copies/mL, and 1 VF (incidence rate 0.24 per 100 PMFU, 95% CI 0.00 – 0.71) with 7410 copies/mL. Previous low-level viremia (LLV, defined as at least 2 consecutive measurements > 50 cp/mL and < 200 cp/mL) occurring between 3 and 1 year before vaccination, independently predicted VR after vaccination in a multivariate regression analysis (aHR = 13.8; 95%CI 2.2 – 88.0; p = 0.005). For all events, adherence issues were excluded, and all participants returned to a TND status at the subsequent determination without any modifications to their therapeutic regimen.

Conclusions: Although rare, the occurrence of VR following MVA-BN vaccination in PLWH suggests the need for careful monitoring of HIV-RNA levels after vaccination, especially in individuals with a history of viral load fluctuations. Further research is needed to elucidate the underlying mechanisms and assess the clinical and epidemiological implications.

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Vaccines

P 173 HEPATITIS B VACCINE RESPONSE IN PEOPLE LIVING WITH HIV AND WITH ISOLATED ANTI-HBC SEROLOGICAL PROFILE: A RETROSPECTIVE STUDY

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Background: Globally, 8% to 10% of people living with HIV (PLWH) are also infected with chronic HBV. An isolated hepatitis B core antibody (IAHBc) profile, characterized by a positive anti-HBc with negative HBsAg and anti-HBs, is found in 14% to 44% of PLWH and in up to 31% of those coinfected with HIV and hepatitis C virus (HCV). This study aims to assess the antibody response (AR) after vaccination, defined by an HBsAb result of ≥10 mIU/mL, and the associated factors, in a selected group of PLWH with an IAHBc serological profile.
Material and Methods: This retrospective study analysed data from PLWH who attended the outpatient clinic at Policlinico San Martino Hospital, between 2016 and 2025. The focus was on individuals with an IAHBc profile who received at least one dose of HBV vaccine. Clinical data included CD4 counts before HBV vaccination and HCV coinfection status. CD4 counts were analysed both as continuous and dichotomized variables at 350 cells/μL according to literature (CD4 350: 0=≤350, 1=>350). Age was similarly analysed both continuously and dichotomized at the mean value.
Results: Of the 926 PLWH subjects attending the outpatient clinic, 24 were included in the analysis. HBV DNA testing was available and negative in 20 subjects (83.3%). The study population had a mean age of 62.25 (SD 4.9) and a predominance of males (83.3%). HCVAb were detected in 19 subjects, representing the 79.2%. HBVAb serology was assessed in two groups (fig.1-2): in the first group (8 subjects), it was assessed at least one month after the single recall dose; in the second group (14 subjects), after a full vaccination cycle (3 doses).
In the first group, 50% achieved an AR, 25% did not achieved an AR and thus completed the full vaccination cycle, 25% were lost to follow-up. Among those who completed the cycle, none achieved an immunological response (IR). In the second group, 42.9% achieved an IR, 42.9% did not respond, and 12.5% were lost to follow-up. Of the 6 non-responders, 4 received a second complete vaccination cycle and 2 of them achieved an IR. Fisher's exact test showed no significant association between age and protective antibody levels (p=0.266) after one cycle. However, a non-significant trend was observed, with 75% of participants above the mean age having protective titres, compared to 33.3% in participants below the mean age. Spearman's correlation revealed no significant association between pre-vaccination CD4 counts and post-single recall dose antibody titres (rho=-0.1670, p=0.6823). The same analysis showed a strong association when considering the antibody titre after one complete cycle (rho = 0.55, p = 0.053).
Conclusions: This study found variable antibody responses to HBV vaccination in PLWH with an IAHBc profile. Age and CD4 counts showed no significant impact, although a trend toward better responses in older individuals was noted. However larger samples are needed to better understand factors influencing vaccine efficacy.

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Vaccines

P 174 MULTI-CYTOKINE ASSESSMENT OF T-CELL RESPONSES TO VARICELLA ZOSTER VIRUS GLYCOPROTEIN E AFTER VACCINATION WITH A RECOMBINANT ADJUVANTED SUBUNIT VACCINE IN PATIENTS WITH MULTIPLE SCLEROSIS ON IMMUNE MODULATING TREATMENTS

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Background: The reactivation of varicella-zoster virus (VZV) causes herpes zoster (HZ). T-cell–mediated immunity (CMI) is fundamental to prevent HZ. Age and immunomodulating drugs can impair VZV-specific CMI and contribute to VZV reactivation. An adjuvanted recombinant subunit vaccine(HZ/su) is recommended to prevent HZ in adults>50 years and immunocompromised individuals>18 years. This study aimed to explore VZV-specific CMI with a multi-cytokine approach, in people living with multiple sclerosis(PwMS) on immune modulating treatments after HZ/su vaccination.

Material and Methods: PwMS on active follow-up were enrolled in the study. Two doses of HZ/su were administered 2 months apart (T0 and T1 respectively), with a follow-up visit 1 month after the second dose (T2). T-cell responses were assessed at T0, and T2 with an in-house multi-Cytokine Release Assay (mCyRA), consisting of heparin whole blood stimulation with VZV gE peptide libraries (JPT). Each test included negative(NC) and positive control. Cytokine production was assessed with the LEGENDplex HU Th Cytokine Panel (Biolegend). Data are shown as median and interquartile range [IQR]. Before-After analysis was performed using the Wilcoxon test. Differences among groups were assessed using the Kruskal-Wallis test.

Results: 43 PwMS (29 females) were enrolled. Median age was 55 years[43-59]. All patients were on either first- or second-line treatments for MS at the time of vaccination. Treatments were distributed as follows: First line (interferon (IFN)-beta, glatiramer acetate, dimethilfumarate):19/43, 44%; natalizumab: 6/43, 14%; anti-CD20: 9/43, 21%; fingolimod 9/43, 21%. On overall, in PwMS a statistically significant increase of VZV gE specific cytokine production was observed for interleukin (IL)-2, -4, -5, -6, -10, -13, -17A, IFN-y and tumor necrosis factor (TNF)-a, after vaccination with HZ/su. No significant increase was observed for IL-9, IL-17F, IL-22(Figure 1A). An effective cytokine response was defined as a 4-fold increase in its production comparing T2 to T0. Consequently, we could assess the number of cytokine effective responses for each subject. After stratifying PwMS according to treatments, those on fingolimod showed a lower number of cytokine effective responses compared to those on first line treatments, natalizumab or anti-CD20 (1[1-0]vs4[5-2]vs3[5-1]vs3[4-2]) respectively, Kruskal-Wallis p=0.019)(Figure 1B). Finally, 7/49 PwMS(14%) were CMI non responder(no 4-fold increase for any of the 12 cytokines) and 4/7(57%) were on fingolimod.

Conclusions: VZV gE CyRA can represent a sensitive and specific tool to characterize CMI after HZ/su vaccination, providing also an assessment of the quality and polyfunctionality of the response. Fingolimod appears to globally impair cytokine production by circulating VZV gE-specific T-lymphocytes. These aspects highlight the importance of assessing VZV-specific CMI after HZ/su vaccination, in patients receiving immune modulating treatments.

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Vaccines

P 175 THE IMPACT OF VACCINATION ON PRESENTATION AND CLINICAL OUTCOMES IN PATIENTS HOSPITALIZED FOR COVID-19 PNEUMONIA IN A LOMBARDY TERTIARY CARE CENTER

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Introduction: The COVID-19 pandemic challenged healthcare systems and prompted global vaccination programs. These efforts significantly reduced illness severity, hospitalization, and death rates while helping control virus spread. Our study compared clinical and laboratory features, as well as outcomes, between fully vaccinated and unvaccinated patients during the fourth COVID-19 wave in a tertiary care setting.

Materials and Methods: In this retrospective, monocentric study, we analysed data of patients hospitalized with confirmed COVID-19 pneumonia during the fourth wave (01/10/2021-31/03/2022). Patients were categorized according to vaccination status: fully vaccinated (3 doses), unvaccinated and partially vaccinated, with the latter being excluded from further analysis. We compared demographic characteristics, comorbidities, laboratory findings, treatment regimens and clinical outcomes—including the incidence of pulmonary thromboembolism/deep vein thrombosis (PTE/DVT), the need for invasive mechanical ventilation (IMV), and in-hospital mortality—between the unvaccinated and fully vaccinated patients. Pearson correlation analysis assessed the relationship between inflammatory biomarkers and mortality. Cox regression analysis was conducted to evaluate the impact of age and comorbidities on mortality in both groups.

Results: Of the 398 patients, 102 fully vaccinated and 168 unvaccinated patients were considered. The vaccinated group was significantly older (median age 81.5 vs. 68 years; $p < 0.001$) and exhibited a higher burden of comorbidities, particularly cardiovascular and nephrological diseases, immunodeficiencies, and cancer ($p < 0.001$). Laboratory analysis revealed that vaccinated patients had higher leukocyte counts and CRP values, whereas unvaccinated patients showed higher ferritin and LDH levels.

However, stronger and more significant correlations with mortality were found in the unvaccinated group for CRP, ferritin, and neutrophil/lymphocyte ratio, suggesting a more pronounced inflammatory response and greater impact on mortality. Despite a higher clinical risk profile, the vaccinated group had a markedly lower incidence of PTE/DVT and a reduced need for IMV. No statistically significant difference in overall in-hospital mortality was observed between vaccinated and unvaccinated patients. However, in Cox regression model, cardiovascular diseases, diabetes mellitus and especially chronic kidney disease were found to have a strong and statistically significant association with mortality regardless of vaccination status. Age showed a trend toward an increased risk of death, although this did not reach statistical significance.

Discussion: Vaccination led to fewer complications and lower inflammatory burden, although it didn't impact overall mortality—apparently driven primarily by preexisting conditions. Tailored strategies for high-risk patients remain essential.

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Virology and Pharmacology

P 176 EVALUATION OF AD4SEQ HIV-1 WHOLE GENOME FOR DRUG RESISTANCE TESTING

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Background: The identification of resistance associated mutations (RAMs) in people with HIV (PWH) still plays an important role for clinical management and treatment optimization. Pol gene has traditionally been the region of interest for this purpose, but as new drug classes, such as Entry and Capsid Inhibitors, are being approved for treatment, there is a growing need to explore new regions of the viral genome. This is now possible due to the widespread adoption of viral whole-genome sequencing (WGS). This study aims to evaluate the overall performance and ability to detect pol RAMs of the AD4SEQ HIV-1 Whole Genome kit (Arrow Diagnostics),, compared to the targeted pol AD4SEQ HIV-1 Solution v2 kit (Arrow Diagnostics), validated for diagnostic use.
Material and Methods: HIV RNA samples, having heterogeneous viral load and subtypes, as reported in Tab. 1 and Fig. 1, were selected from those genotyped with the v2 kit. Libraries were prepared with AD4SEQ HIV-1 Whole Genome kit, following manufacturer's instructions and sequenced on iSeq100 (Illumina). FASTQ files were analyzed both using SmartVir software (SmartSeq) and our in-house pipeline. A 10% threshold consensus sequence was set for pol RAMs assessment, based on the HIV Drug Resisting Database (Stanford University).
Results: Coverage analysis of 47 sequenced samples, showed a Mean Read Depth (MRD) of 3228 (IQR: 2792–4362), and Mean Coverage at 100x was 85.5% (IQR: 85.75–93.75) (Fig. 2). Analysis of coverage for all HIV genes by stratification for HIV RNA viral load showed that gag and pol consistently achieved at least 95% coverage across all RNA levels, whereas other genes had lower coverage, particularly at log10 2 and 3. Comprehensive results are shown in Tab. 1 and Fig. 2. HIV RAMs detection was also evaluated in comparison with the routine POL (v2) method. Among all 2698 identified mutations (Major, Accessories and Other mutations, as defined by Stanford HIV Database), 2341 were concordant between methods, all RAMs included (100% concordance). Conversely, POL (v2) uniquely detected 215 mutations (including 16 accessory mutations), whereas WGS identified 124 unique mutations (including 2 accessory mutations). Further evaluation will be conducted to explain this discrepancy.
Conclusions: Sequencing the entire genome of HIV offers several important advantages, like the opportunity of studying resistance to new drug classes, as well viral evolution and epidemiology. The high concordance (100% for RAMs) observed between WGS, and the routine pol-based method confirms the reliability of this new approach for drug resistance testing. However, optimization of sequencing protocols and bioinformatics pipelines is needed to improve coverage uniformity, particularly for regions like env and accessory genes, which remains challenging in samples with low HIV RNA levels. Further analysis will evaluate HIV RAMs at 5% and 20% thresholds respectively.
Figure 1
Figure 2
Figure 3
Table 1

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P 177 EXPLORING THE RELATIONSHIP BETWEEN HIV-DNA LOAD AND ARCHIVED ANTIRETROVIRAL DRUG RESISTANCE IN TREATED INDIVIDUALS WITH SUPPRESSED OR LOW-LEVEL VIREMIA

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Background: Given that most treated HIV-1 infected individuals have suppressed or low-level viremia, HIV-DNA quantification and sequencing deserve attention as tools to evaluate the viral reservoir. Our aim was to assess whether HIV-1 DNA levels were associated with the extent and type of archived resistance in individuals with suppressed/low-level viremia.

Methods: Total HIV-1 DNA quantification (Real-time PCR, ELITe InGenius) and genotypic resistance testing by next-generation sequencing (NGS-GRT, Illumina Miseq) were performed using whole-blood samples from 62 participants with suppressed (≤50 cps/mL) or low-level (51-200 cps/mL) viremia. PR/RT/IN HIV-1 DNA sequences were analysed at 5%, 10%, and 20% (Sanger-like) frequency thresholds (HIVdb ver 9.8). Major resistance-associated mutations (MRM) were evaluated and compared with any available historical GRT (hGRT). Participants were stratified based on the population median HIV-1 DNA load, and viro-immunological parameters, archived resistance, and APOBEC hypermutation (HM) signals were compared between the two groups.

Results: At GRT, 90.3% of PWH had been suppressed for a median time of 6 (2-10) years and 9.7% had LLV. Most of them (64.5%) received INSTI-based regimens (50% BIC/DTG; 14.5 % RAL). Median (IQR) HIV-1 DNA levels were 3.0 (2.8-3.4) log10 cps/10^6 CD4 cells. APOBEC HM signals were detected in 41.9%, 24.2%, and 16.1% participants at NGS thresholds 5%, 10%, and 20%, respectively. At 5% only, HM signals increased markedly at HIV-1 DNA levels ≥3 log10 cps/10^6 CD4 cells (Fig. 1A). At 5%, MRM were observed in 45% of participants. The proportion decreased slightly at the 10% threshold, while reducing to 27.4% at 20%. INSTI MRM were mostly detected at 5%. Only INSTI MRM was more often detected in the HIV-1 DNA ≥3.0 log10 cps/10^6 CD4 stratum while no differences were observed for the other MRM classes (Fig. 1B). HIV-1 DNA testing detected >50% of h-GRT MRM, while it revealed clinically relevant MRM in a subset of individuals without h-GRT (Table). INSTI-related MRM were primarily detected as APOBEC-context mutations. Specifically, the G140R mutation was found either as a minority variant or at Sanger-like threshold setting (Table). Nadir CD4 count, zenith viremia, subtype, duration of virological suppression, CD4 count was not found to differ by HIV-1 DNA stratum.

Conclusion: In treated individuals with suppressed/low-level viremia, HIV-1 DNA levels ≥3 log10 cps/10^6 CD4 cells are associated with APOBEC HM signals in minority variants. Our findings confirm that NGS HIV-1 DNA testing can be useful for assessing resistance in individuals lacking h-GRT. INSTI MRM were mostly detected as APOBEC-context mutations, with negligible clinical impact. Archived resistance testing requires careful interpretation to avoid overestimating resistance.

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P 178 HIV-1 WHOLE GENOME SEQUENCING: COMPARATIVE ANALYSIS OF ILLUMINA AND NANOPORE TECHNOLOGIES

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Background: Whole-genome sequencing (WGS) is a key tool for studying HIV-1 diversity, evolution, and epidemiology, especially as new drug classes emerge. The two main technologies, Illumina short-read and Oxford Nanopore (ONT) long-read sequencing, offer complementary advantages: Illumina's high accuracy (<1% error) enables reliable variant detection, while ONT's long reads improve haplotype resolution, essential for quasispecies analysis. However, despite improvements, ONT still has ~5% error rate, particularly in homopolymeric regions, which affects variant calling accuracy. This study evaluates WGS libraries obtained with AD4SEQ HIV-1 Whole Genome kit (Arrow Diagnostics) and sequenced on both technologies.

Material and Methods: Viral RNA was extracted using the ELITech InGenius® system. Illumina libraries were sequenced on iSeq100, while RT-PCR amplicons (~2600 bp) were processed with the Native Barcoding Kit 24 V14 (SQK-NBD114.24) and sequenced on MinION Mk1b for 19h. Illumina FASTQ reads were analyzed using Smartvir (Smartseq) and an in-house pipeline, while ONT reads were processed with MinKnow and the EPI2ME pipeline. A 10% threshold consensus was obtained, focusing RAMs comparison initially on gag and pol, as they are easily analyzed on HIV Drug Resistance Database (Stanford University).

Results: Out of 24 samples, 2 were excluded due to library failure. The overall WGS coverage was similar for both methods as well as stratification for HIV-RNA levels (Fig.1), except that ONT showed higher sample variability on low viral loads (Tab.1). Subtype-based analysis showed that subtype B had a mean WGS coverage of 83% for Illumina and ONT. Recombinant subtypes (CRF) exhibited the lowest coverage, with 57% (IQR: 45.0–69.0%) in Illumina and 66% (IQR: 48.8–82.1%) in ONT (Fig. 2). Gene-level analysis showed that at low viral loads (log 2-3), Illumina performed better in vif, tat, vpr and vpu, while ONT had superior coverage in nef; gag and pol were comparable. At higher viral loads, ONT showed better coverage for all accessory genes (Fig.3). As per RAMs detection in pol, both technologies showed 100% concordance. In gag, 76% of mutations were detected by both platforms, 16% were found exclusively with ONT and 7% only with Illumina. Further investigations are ongoing.

Conclusions: These findings indicate that for pol RAM's evaluation both technologies provide good results. As per coverage performance, Illumina ensures more stable sequencing for low viral loads, important for clinical samples, while Nanopore benefits from higher template availability, achieving superior coverage in high-viral-load samples. However, bioinformatics analysis parameters must also be carefully considered. While 99.9% accuracy is typical for Illumina (Q30), ONT operates around 90–95% accuracy (Q10), requiring additional filtering and error correction. Bioinformatics settings significantly impact sequencing outcomes and need to be further analyzed to refine analytical strategies.

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P 179 HIV-DNA ANALYSIS IN PLWH WITH A COMPLEX TREATMENT HISTORY: CORRELATION WITH IMMUNOLOGICAL AND VIROLOGICAL PARAMETERS

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Background: For this study we aimed to investigate a population of people living with HIV (PLWH) with a complex therapeutic history in order to find a relationship between the clinical and immuno-virological parameters and the levels of total HIV-DNA.

Material and Methods: During outpatient visits a peripheral blood sample was collected. After plasma separation, HIV-RNA levels were measured using the Alinity m HIV-1 assay, peripheral blood mononuclear cells (PBMCs) were then isolated for HIV-DNA quantification. DNA extraction was performed using the QIAamp® Blood Mini Kit and the nucleic acid was subsequently quantified using the Qubit dsDNA HS Assay on a Qubit 4.0 fluorometer. HIV-DNA levels were determined using the Generic HIV-DNA Cell assay. Clinical and immunological data were retrieved from medical records.

Results: A total of 57 PLWH were enrolled. Median age (IQR) was 61 (58–65) years, 33.3% were female, and 66.7% were male, all on combined antiretroviral therapy (cART). The median time since HIV diagnosis was 31 (24–37) years, the median time since ART initiation was 26 (20–31) years, and the median time since virological suppression was 16 (9–23) years. HCV and HBV co-infections were present in 16 and 2 patients, respectively.

Forty percent of the patients were on INSTI-based treatment, 12.3% on NNRTI, 7.0% on PI, and 40.4% underwent salvage therapy. Median CD4 count was 706.0 (49.0–934.0), median CD8 count was 804.0 (628.0–1024.0), and the median CD4/CD8 ratio was 0.9 (0.7–1.1).

The population was stratified according to HIV-RNA levels: undetectable (56.1%), detectable (<20 copies/mL, 26.3%), and quantifiable (>20 copies/mL, 17.5%). The median HIV-DNA level was 1253.4 (625.1–2451.5) copies/10^6 cells.

A higher HIV-DNA level was observed in PLWH with quantifiable HIV-RNA compared to both the undetectable and detectable groups (p=0.028 and p=0.029, respectively). Furthermore, when stratified by the received treatment, patients undergoing PI-based therapy had higher HIV-DNA levels than those on INSTI-based regimens. Finally, in multivariable logistic regression analysis, the only variable associated with HIV-DNA levels was the CD4/CD8 ratio <1 (aOR=7.24, 95% CI: 1.17–44.61, p=0.033).

Conclusions: The obtained results suggest the presence of a relationship between HIV- DNA levels, the degree of suppression of viral replication and the extent of immunological recovery. The persistent viral replication, although of low intensity, is still able to sustain and replenish the reservoir potentially explaining the high levels of HIV-DNA detected. Additionally, although the median CD4 count reached normal values, the CD4/CD8 ratio indicates a still impaired immune system that may still affect the ability to fully control viral replication, even when reaching virological suppression. In conclusion, our findings highlight the complexity of our population treatment history that may have influenced the observed virological and immunological outcomes.

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P 180 IN VITRO CHARACTERIZATION OF PEPTIDOMIMETIC PROTEOLYSIS TARGETING CHIMERA (PROTAC) AS A DEGRADER OF 3-CHYMOTRYPSIN-LIKE PROTEASE (MPRO/3CLPRO) AGAINST SARS-COV-2

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Background: The main protease of SARS-CoV-2 (Mpro/3CLpro) is a key target for antiviral development, essential for viral maturation and replication. Effective drugs such as nirmatrelvir/ritonavir have some limitations due to drug interactions and frequent dosing. To address these issues, more selective, less toxic, and better-tolerated drugs are needed. A chemoinformatic analysis identified a new class of peptidomimetic 3CLpro degraders and screened 250 in-house compounds which led to FT235, as potential degrader with micromolar range activity. This study aims to further characterize this compound, focusing on its in vitro antiviral activity.

Material and Methods: SARS-CoV-2 3CLPro inhibition (60 nM) was assessed via a fluorescence-based enzyme assay using the Hilyte Fluor-488-ESATLQSGLRKAK-(QXL-520)-NH_2 substrate. IC_{50} values were determined from dose-response curves (1 nM–1 mM). Protein degradation in a cellular context was analyzed by immunoblotting in HeLa cells stably expressing C-terminal HA-tagged 3CLPro via lentiviral transduction. Antiviral activity and cytotoxicity were evaluated in VERO E6 cells infected with SARS-CoV-2 B.1 or BA.5 using the Cell Viability Assay, with or without the P-gp inhibitor (CP100356, 0.5 µM). Viability was measured with CellTiter-Glo 2.0 (Promega) and detected by GloMax® Discover Reader. IC_{50} values were obtained via nonlinear dose-response analysis (GraphPad Prism 9.5.1), normalized to 0% (infected) and 100% (uninfected) controls. FT235 was tested in triplicate in at least two independent experiments.

Results: The fluorimetric enzyme inhibition assay confirmed FT235's inhibitory activity against SARS-CoV-2 3CLPro, with an IC_{50} of 21.2 ± 5.8 µM. Immunoblotting in HeLa cells expressing SARS-CoV-2 3CLPro revealed a reduction in protein levels following treatment, suggesting a degradation effect. The Cytotoxicity assays demonstrated that FT235 exhibited no significant cellular toxicity at concentrations below 200 µM (CC_{50}= 202.5 µM with CP100356; CC_{50}= 206.1 µM without). Analysis of antiviral activity against SARS-CoV-2 variants revealed differential susceptibility between the two tested strains (B.1 and BA.5). In the in vitro antiviral assays against the ancestral SARS-CoV-2 B.1 variant, the compound exhibited an IC_{50} of 77.52 ± 0.018 µM in the presence of the P-gp inhibitor. In the absence of the efflux pump inhibitor, the IC_{50} increased to 188.0 ± 0.048 µM, suggesting an involvement of the efflux system. Conversely, the antiviral efficacy of FT235 against the Omicron BA.5 variant was markedly reduced, with an IC_{50} of 322.9 ± 0.079 µM in the presence of the P-gp inhibitor and 1,984 ± 0.450 µM in its absence.

Conclusions: Preliminary data indicate that FT235 has moderate antiviral activity against SARS-CoV-2, laying the groundwork for optimizing peptidomimetics. These findings support further studies on this class of compounds, including their evaluation in combination with other antiviral molecules.

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P 181 INJECTION SITE PAIN AND CABOTEGRAVIR/RILPIVIRINE TROUGH PLASMA CONCENTRATION IN PEOPLE WITH HIV

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Background: Among people with HIV (PWH) on antiretroviral therapy (ART) with long acting (LA) cabotegravir (CAB) and rilpivirine (RPV), injection site reactions (ISRs) are frequent and typically transient, mild to moderate in severity, and decreasing in frequency over time, with pain being the most frequent symptom. This study aims to evaluate the correlation between pain as ISR and trough plasma drug concentrations among PWH on LA ART with CAB/RPV.

Materials and Methods: In this prospective cohort study of PWH with stable undetectable viremia, 150 participants were enrolled in LA ART at the Infectious Diseases Unit of San Raffaele Scientific Institute, Milan, Italy, between July 2022 and July 2024 (SCohoLART study; NCT05663580). People were divided in two groups based on presence (100) or absence (50) of pain as ISR defined as a visual analog scale (VAS) >7, VAS >3 with associated systemic symptoms/fever, or duration of pain >7 days. Plasma concentrations of CAB and RPV after 1 year of LA ART were assessed using Liquid ChromatographyTandem Mass Spectrometry (LC-MS/MS). Mann-Whitney test and Spearman correlation coefficient for numerical variables were used to define the correlation between CAB/RPV plasma concentration and pain/no pain group. Mann-Whitney test and Chi-squared test for categorical variables were used to evaluate differences between the two groups and other numerical/categorical predictors

Results: Overall, 133 were male (88.7%), with a median age of 51 years (interquartile range, IQR 40;58) (Table 1). CAB median concentration was 1101ng/ml (IQR 758;1652) in pain group and 1161ng/ml (IQR 898;1733) in no-pain, respectively. RPV median concentration was 67ng/ml (IQR 55;92) in pain group and 68ng/ml (IQR 54;85) in no-pain, respectively. No significant differences in both CAB and RPV concentrations were found between pain/no-pain group. Among numerical predictors, time on ART in years was significantly correlated to pain (p=0.047). All other categorical variables were independent. Female gender was significantly associated with CAB concentrations exceeding the threshold (p=0.002) (Table 2). For CAB, baseline hemoglobin levels differed significantly between participants above and below the 664 ng/mL threshold (p<0.05). CAB concentrations were also significantly associated with concurrent HCV infection (p=0.025) (Figure 1). For RPV, significant differences were found in baseline PLT, AST, and neutrophil count (p<0.05). Participants above the 50 ng/mL RPV threshold showed differences in nadir CD4 count, virological suppression duration, ART years, HIV diagnosis years, and baseline glucose levels (p<0.05) (Figure 2).

Conclusions: In our cohort, no significant correlation was identified between both CAB and RPV concentrations and pain as injection site reaction among PWH on LA ART. Remarkably, female gender represented a correlated factor with higher CAB concentration levels. Additionally, duration on ART in years was significantly correlated to pain.

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Grand Round Clinical Cases

CC 1 SYPHILIS MALIGNA RUPIA: AN ATYPICAL PRESENTATION OF "THE GREAT PRETENDER"

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Background: Malignant syphilis is a rare vasculitic presentation of secondary syphilis, mostly seen in immunocompromised individuals although several reports in immune competent persons have been published.
Case presentation: In July 2021 a man who have sex with men aged 38 attended our HIV clinic for the first time. His infection was diagnosed in UK in 2013, but he did not deliver any medical note from his previous physicians. He referred of having performed HIV test for fever, weight loss, and the presence of dark, hard skin lesions that disappeared once he started antiretroviral treatment with FTC/TDF/EFV. A presumptive diagnosis of Kaposi Sarcoma was made, and he was classified as a CDC C stage.
At the first evaluation in our clinic he showed undetectable HIV RNA, CD4 count of 781 cell/mmc, and a positive low-titre serological test for syphilis (RPR 2), but he stated of having been recently treated with benzathine benzylpenicillin before leaving London. He switched to 3TC/DTG maintaining a good immune-virologic control.
During the following years he showed good adherence to the antiretroviral treatment; he was a heavy smoker with alcohol abuse but denied chemsex practices. He acquired in 2022 an asymptomatic Chlamydia trachomatis infection, and in July 2023 he presented a typical secondary syphilis skin rash. The infection was confirmed with a high serologic titre (RPR 512), and he underwent treatment with 2.4 MU benzathine benzylpenicillin. Clinical resolution was fast, while serologic response appeared slow (at the last evaluation in November 2024 RPR was 16).
At the end of January 2025, he presented fever, general malaise, and well-demarcated plaques with thick, lamellate, and adherent crusts on the surface on his trunk, arms and right leg (Figure 1, panel A). He did not complain itch or pain, but he stated that the lesions looked like what he had in 2013 showing also the scars of the previous episode (panel B).
An immune-mediated vasculitis was suspected, and a dermatologic evaluation was prescribed. Syphilis serology was repeated and RPR showed an increase to 256. Patient declined skin biopsy, but a diagnosis of malignant syphilis rupia was made, and he underwent prompt treatment with 2.4 MU benzathine benzylpenicillin weekly for 3 weeks. He was pre-medicated with prednisone to avoid Jarisch-Herxheimer (JH) reaction. Before the end of antibiotic treatment, skin lesions improved significantly (panels C-D), while constitutional symptoms disappeared after 10 days.
Discussion: Classic diagnostic criteria rely on comparable gross and microscopic morphology, high serologic titre, JH reaction, and dramatic response to antibiotic therapy. There is no consensus about treatment, but most literature recommends a benzathine benzylpenicillin course for 3 weeks and JH prophylaxis with high dosage steroid.
Malignant syphilis should be considered in presence of atypical skin lesions in individuals at high risk of sexually transmitted infections.

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Grand Round Clinical Cases

CC 2 A PML FIGHTER: TWO-YEAR FOLLOW-UP OF A VIRO-IMMUNOLOGICALLY SUPPRESSED 29-YEAR-OLD MAN LIVING WITH HIV AND ACTIVE PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY RECEIVING JC VIRUS-SPECIFIC T-CELL THERAPY AND HUMAN RECOMBINANT INTERLEUKIN 7

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Background: Progressive Multifocal Leukoencephalopathy (PML) is a severe demyelinating disease caused by JC polyomavirus (JCV), affecting immunodeficient individuals. Currently, there is no specific treatment, and immune reconstitution, such as initiating antiretroviral therapy (ART) in people with HIV, is the only effective approach. This report describes a man with HIV infection with stable virological suppression at PML diagnosis, who has non-progressing, yet active PML nearly two years after combined therapy with human recombinant interleukin 7 (hrIL-7) and JC virus-specific T lymphocytes (VST).

Case Presentation: The patient is a 29-year-old male with perinatally acquired HIV infection. He was exposed to various ART regimens without significant issues until 2020, when he stopped ART. At the last control on ART, viral load (VL) was 91 copies/mL and CD4+ was 756 cell/μL. Twenty months after ART withdrawal (VL 31100 cp/mL, CD4 + 128 cell/μL), he developed a clinical-neurological picture suggestive of PML, though JCV-DNA resulted negative in CSF and cryptococcal meningitis was diagnosed. After specific treatment for cryptococcosis and ART reintroduction, he improved clinically with residual right leg hyposthenia. In late 2022, left hemiparesis and worsening walking difficulties developed. In March 2023, investigations showed undetectable HIV-RNA, 525 CD4+ cells/μL, hyperintense T2/FLAIR lesions in the left parieto-temporal-occipital cortex on MRI, and CSF JCV-DNA of 14000 copies/mL, indicating a PML relapse. In May 2023, he started compassionate treatment with hrIL-7 (weekly for 4 weeks) and JCV-VST (every 4 weeks for 19 doses), without adverse events. Clinically, left hemiparesis improved significantly, with a modified Rankin scale (mRS) score from 3 to 2 at the latest observation in February 2025. MRI showed decreased PML lesion size with persistent contrast enhancement (Figure 1). CSF JCV-DNA ranged between 2470 and 14500 cp/mL, initially decreasing after VST donor change at week 16. HIV VL remained undetectable, with transient CD4+ increase after rhIL-7 (Figure 2). Full JCV-DNA sequencing revealed a change in viral mutations: a 100% 123-133 amino acid deletion in the baseline virus, replaced by a new variant with a 100% S269F mutation after 5 months of VST.

Conclusions: Despite hrIL-7 and VST therapy, and a full immuno-virological response to ART, the patient did not virologically recover from PML, though partial clinical and radiological improvement was observed. In the absence of a natural immune response, this innovative approach may have positively impacted the disease's clinical and radiological progression. This case highlights the complexity of PML, particularly with VST administration.

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Grand Round Clinical Cases

CC 3 PHARMACOKINETIC PARADOX IN HIV MANAGEMENT: WHEN LOW PLASMA LEVELS DEFY VIROLOGICAL LOGIC IN THE ERA OF LONG-ACTING ART

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Background: Despite the availability of highly effective oral antiretroviral therapy (ART), a subset of people living with HIV (PLWH) fails to achieve virological suppression despite full genotypic susceptibility. This case highlights the impact of severe inflammatory bowel disease (IBD) on ART absorption and the unexpected pharmacokinetic profile of long-acting (LA) injectable therapy.

Case Presentation: A 54-year-old Italian male was diagnosed with HIV in 2019 as a late presenter with wasting syndrome (HIV-RNA 729,236 cp/mL, CD4 79/mmc). Genotypic resistance testing (GRT) showed full susceptibility to all ART classes. His medical history includes two episodes of syphilis and a diagnosis of monkeypox. He started DRV/c/TAF/FTC but was also diagnosed with diverticular disease and later severe IBD, leading to recurrent hospitalizations. Persistent HIV viremia (>86 cp/mL) was likely due to malabsorption. Infliximab was started but discontinued due to recurrent pneumonia, and vedolizumab was introduced in August 2024. Notably, vedolizumab has been studied as a potential therapy for HIV due to its action on the $\alpha_4\beta_7$ integrin, which is implicated in gut-associated viral reservoirs and immune response regulation.

Due to persistent fever, weight loss, and bloody diarrhea despite treatment, the patient underwent colonic and rectal resection with ileostomy in December 2024. After surgery, systemic inflammation decreased, but ART absorption concerns remained, necessitating an alternative approach.

In October 2024, he started long-acting cabotegravir (CAB) and rilpivirine (RPV). Therapeutic drug monitoring (TDM) at weeks 2, 4, and 6 revealed low CAB (573–911 ng/mL; cut-off 1120 ng/mL) and RPV (16.35–31.80 ng/mL; cut-off 32 ng/mL) levels. Despite these suboptimal values, HIV-RNA remained <50 cp/mL, with a transient 58 cp/mL blip in January 2025, followed by consistent suppression <20 cp/mL. The patient's clinical condition improved, with resolution of chronic diarrhea and stabilization of nutritional status.

Discussion and Conclusions: This case underscores the complex relationship between drug absorption, systemic inflammation, and ART pharmacokinetics. The paradox of virological suppression despite low CAB/RPV levels questions conventional pharmacokinetic thresholds. Altered gut permeability, immune activation, and possible drug depot effects at the injection site may explain this dissociation. Furthermore, this case suggests that long-acting ART can provide effective treatment even in patients with severe gastrointestinal pathology, potentially bypassing the limitations of oral absorption.

These findings highlight the need to reconsider TDM cut-offs in special populations and reinforce the role of long-acting therapy in patients with impaired drug absorption. Future studies should explore alternative biomarkers and individualized dosing strategies to optimize ART in complex clinical scenarios. Personalized therapeutic approaches may further refine treatment strategies, ensuring long-term success in challenging patient populations.

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HIV e STI

CC 4 A CASE OF SECONDARY CEREBROSPINAL FLUID HIV ESCAPE IN A PATIENT ON LONG-ACTING CABOTEGRAVIR/RILPIVIRINE. A CASE OF SECONDARY CEREBROSPINAL FLUID HIV ESCAPE IN A PATIENT ON LONG-ACTING CABOTEGRAVIR/RILPIVIRINE

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Background: The introduction of long-acting Cabotegravir and Rilpivirine (LA CAB/RPV) led to significant improvement in the quality of life of people with HIV (PWH). A LATTE-2 sub-study showed a cerebrospinal fluid (CSF) HIV-1 RNA <50 cp/ml in all participants, with drug concentrations exceeding the in vitro EC50 for wild-type HIV -1. We present the case of a PWH on LA CAB/RPV who presented with a secondary CSF escape during neurosyphilis.

Case presentation: The patient is a male PWH in his fifties that had been living with HIV for 15 years. At diagnosis, he had CD4 T cell 482/mm3, no evidence of HIV RAMs: he started a NNRTI- based regimen. In the following years, he did not develop any co-morbidities and maintained the virological suppression. In February 2023 he switched to LA CAB/RPV. In 2016 he was treated with intramuscular Penicillin G for primary syphilis with normalization of serum VDRL. He underwent to annual routine screening for Treponema reinfection, which resulted positive in august 2024, with a VDRL of 1:128. He was completely asymptomatic, without no CNS involvement. A lumbar puncture was performed and CSF examination revealed non-reactive VDRL, elevated protein concentration (51.8 mg/dl), and pleocytosis (WBC 0.066 109/l, L 96.9%). The neuroinflammatory markers were also positive, with a IgG index of 1.2, a Reiber index of 39.1%, and the presence of oligoclonal bands. CSF HIV-RNA was 156 cp/ml but amplification for resistance testing was not possible. Patient was treated with intravenous ceftriaxone 2g daily for 14 days for possible neurosyphilis. Four months later a control LP was performed. The CSF examination showed no pleocytosis (WBC 0.004/l, L 75%) and proteins and neuromarkers in the normal range: CSF HIV-RNA was undetectable.

Discussion: This case suggests considering the risk of secondary CSF escape in patients with ongoing inflammatory conditions, such as neurosyphilis: this is the first reported case of CSF escape with LA CAB/RPV but resistance was not observed and the treatment of syphilis led to HIV viral load suppression.

HIV e STI

CC 5 A PECULIAR CASE OF PERSISTENT CPK ELEVATION IN A NEWLY ACUTELY DIAGNOSED PERSON WITH HIV

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Background: The coexistence of common and rare conditions in a single person may be a diagnostic and management challenges. We herein report the case of a young gentleman who was diagnosed with an acute HIV infection and experienced persistently elevated serum levels of creatine phosphokinase enzymes, with a clinical history of myalgias and exercise intolerance.
Clinical Presentation: A 24-year-old gentleman was diagnosed with an acute HIV infection in April 2023 (HIV-RNA>10.000.000 copies/ml, CD4+ T cell count 417 cell/L), and a same day ART was started (DRV/C+TAF/FTC +DTG) due to ongoing unprotected sex and high risk of transmission, and switched to DTG/3TC once undetectable, 6 weeks after. After 5 months, he was hospitalized with fever, fatigue, severe headache, and acute renal failure (creatinine 500 umol/L). CPK peaked >22,000 mg/dl. He denied chemsex/drug use and mentioned having started the gym a few days before. HIV-RNA was undetectable, CSF was unremarkable. cART was temporally stopped. The tests gradually returned to normal, and this person was discharged. After 20 days, cART was restarted, as well as physical activity. Due to relapse of symptoms, the patient was then readmitted to the ward and, after extensive intravenous hydration, CPK and transaminases showed a progressive decrease. Test for antimyositis antibodies, low titer ANA, and ENA were negative. A complete microbiological work-up was negative, too. With the suspect of a drug-related myositis (data on myopathies under integrase inhibitors have been reported) muscle MRI, muscle biopsy, genetic analyses, hair analysis were performed. He tested positive for cocaine and amphetamines. Muscle biopsy showed type 1 fiber atrophy. The muscle MRI was unremarkable. In January 2025, the results of the genetic analyses showed type VII glycogenosis with a homozygous pathogenic variant in the PFKM gene (c.238-3A>G, ACMG class 4) and heterozygous variants in TTN (12559C>T, p.Gln4187Ter - ACMG class 3) and AGL genes.
Discussion: This case shows us the diagnostic complexity that a rare metabolic syndrome can represent, a complexity that is exacerbated by the coexisting acute HIV infection, the need of use medications (antiretrovirals), and drug use. This peculiar case allows us to highlight the importance of considering rare metabolic disorders as differential diagnosis, which can pose significant diagnostic challenges by mimicking other systemic diseases or drug-related adverse effects.

HIV e STI

CC 6 A RARE CASE OF WELLS SYNDROME DIAGNOSIS IN HUMAN IMMUNODEFICIENCY VIRUS INFECTION

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Background: Wells syndrome is a rare dermatologic condition characterized by the sudden onset of multiple edematous lesions, usually with a patch-like pattern, covered in vesicles or bullae combined with dysesthesia (itching and/or burning). The lesions typically appear on the trunk or the extremities and evolve over approximately 10 days in indurated plaques which disappear after 4 to 6 weeks without leaving permanent skin sequelae. Although only a limited number of cases have been reported in literature, this dermatosis is known for its recurrent nature. Peripheral blood hypereosinophilia is a common finding.
The etiology and physiopathology of the disease remain unknown but some triggering factors have been identified, including viral, parasitic, fungal and bacterial infections, hematologic malignancies, hypereosinophilic syndromes.
From an histopathological perspective, the characteristic, although not pathognomonic, “flame-figures”, resulting from the disintegration of eosinophilic granules, are usually documented.
Case presentation: A 54 year-old male with HIV infection developed several erythematous-edematous papules on the trunk, upper back and the scalp accompanied by severe itching. Laboratory exams revealed both relative and absolute hypereosinophilia.
TABLE A: One month prior to the cutaneous manifestation, an HIV infection diagnosis had been made (viral load of 1.870.886 copies/mL, CD4 count of 38/mL, 3%, ratio CD4/CD8 of 0.04). A drug-resistance test identified a wild type virus. HLA-B serotype analysis resulted positive for HLA-B*5701.
At the diagnosis, the patient presented several AIDS-defining conditions (CDC C3) including a bilateral P. jirovecii interstitial pneumonia and HIV-related cutaneous and visceral Kaposi’s sarcoma. For all these conditions he underwent several antimicrobial treatments and chemotherapy.
The patient’s viral load steadily decreased to 200 copies/ml and the CD4 count has slowly increased but remained under 200/mmc.
Antiretroviral therapy was initiated with a two-NRTIs backbone (FTC/TDF), and a second-generation INSTI (DTG) regimen. A switch to FTC/TAF/BIC was performed due to an increase in serum creatinine and in suspicion of an allergic etiology for the cutaneous lesions.
Due to the persistence of the dermatological condition, a biopsy was performed.
The histological examination revealed several features consistent with Wells syndrome, including flame figures.
Corticosteroid therapy was initiated and the patient is currently undergoing a gradual tapering down and no new lesions have occurred.
TABLE B
Conclusions: A very limited number of Wells syndrome cases have been described in the literature in people living with HIV and usually presented clinical features resembling acute cellulitis, very dissimilar to our patient presentation.
It is still uncertain whether the recent HIV diagnosis alone can play a decisive role in the development of Wells syndrome.

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HIV e STI

CC 7 ACUTE CHOLESTATIC HEPATITIS AS THE PRESENTING MANIFESTATION OF SYPHILIS IN AN HIV-INFECTED PATIENT

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Background: Most cases of acute/chronic hepatitis in people living with HIV (PLWH) are caused by HCV or HBV, due to the shared transmission mode, but also drug toxicity, alcohol consumption, MAFLD can be at the basis of liver disease. If these are excluded, the etiological diagnosis can be challenging and several rarer causes should be investigated.

Case presentation: 57 years old MSM, diagnosed with HIV infection and regularly followed at our centre since 2020. The patient was treated with FTC/TAF/BIC, obtaining virological suppression and optimal immunological recovery (CD4 742/mmc, CD4:CD8 ratio 0,95). In December 2024, the patients complained fatigue and itching in the absence of a visible skin rash. Physical examination revealed scleral jaundice. Blood tests showed an acute cholestatic hepatitis (AST /ALT 144/349 U/L, total bilirubin 3.6 mg/dL of which direct 3.5 mg/dL, ALP 563 U/L, gGt 803 U/L, bile acids >180 umol/L). Several microbiological investigations were performed to investigate the cause of liver involvement. HbsAg, HBsAb, HBcAb and total antibodies against HCV, HBV DNA, HCV RNA, serologies for HEV, CMV, EBV and Toxoplasma were negative. Dosage of ceruloplasmin, alpha1antitrypsin, iron profile and hepatic autoimmunity were normal. HAV serology showed a previous vaccination. A screening for STI was also performed showing VDRL 1:32, TPHA 1:10240, while multiplex PCR on urine and anal swab was negative. An abdominal ultrasound examination did not detect any pathological liver changes, biliary tract was not dilated.

A diagnosis of secondary syphilis with liver involvement was made. The patient reported previous unprotected sex intercourses but no clinical manifestations suggestive of primary syphilis.

Treatment with benzylpenicillin 2,400,000 IU IM weekly for three weeks was started with gradual resolution of symptoms and improvement of liver function.

Discussion and Conclusions: PLWH are usually considered to be at higher risk for STIs, and atypical clinical manifestations of these infections should be taken into consideration. Syphilis presenting only with liver involvement and without other classical primary or secondary manifestations, could be an example. For these reasons, this case report is a reminder of the importance of maintaining a high clinical suspicion on STI in this population. Regular follow-up and screening for STIs even in the absence of suggestive symptoms should remain a cornerstone of infectious diseases clinical practice.

HIV e STI

CC 8 ACUTE POLYRADICULONEURITIS IN ADVANCED HIV: A CASE OF IMMUNE DYSREGULATION FOLLOWING ART DISCONTINUATION

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Background: Neurological complications in HIV can result from infections, autoimmune mechanisms, or chronic inflammation. Acute inflammatory demyelinating polyradiculoneuropathy (AIDP), the classic form of Guillain-Barré syndrome (GBS), is rare in patients with low CD4 counts but can occur due to immune dysregulation. In advanced HIV, other neuropathies like chronic inflammatory demyelinating polyneuropathy (CIDP) and HIV-associated distal symmetric polyneuropathy (DSP-HIV) must be excluded.

Case presentation: A 69-year-old man with HIV since 2000, under follow-up in Brazil, presented with progressive weakness and lower limb dysfunction after stopping antiretroviral therapy (DRV/r + DTG) three months prior. He had asthenia, anorexia, and dyspnoea, with mild HIV-related thrombocytopenia. His CD4 count was 67/mm³, and HIV RNA was 489,892 copies/mL. Neurological examination showed lower limb paresis, right upper limb weakness, hypoesthesia, absent reflexes, and weakened bicipital reflex. CT of the brain and spine showed prior fractures but no acute lesions. Lumbar puncture revealed elevated protein (331 mg/dL) and lymphocytic pleocytosis (196 cells/mm³). Nerve conduction studies confirmed acute demyelinating polyradiculoneuropathy, and MRI showed areas consistent with posterior reversible encephalopathy syndrome (PRES). Serum beta-glucan was positive, while cerebrospinal fluid (CSF) HIV RNA was 68,955 copies/mL. PCR tests for JC virus, CMV, EBV, and Mycobacterium tuberculosis were negative. A diagnosis of AIDP was made, and treatment with intravenous immunoglobulins (0.4 g/kg/day for five days) followed by high dose steroid therapy led to partial muscle strength recovery. ART with DRV/c/FTC/TAF was restarted, reducing HIV RNA to 80 copies/mL. Follow-up showed improvement in upper limb strength, but lower limb paresis persisted. A second lumbar puncture suggested CIDP progressio. As a result, treatment with corticosteroids was continued to manage the evolving condition and neurological follow-up was planned. The patient was transferred to a rehabilitation facility after partial recovery of motor function. At the last check-up, he is able to move both lower limbs, except for weakness in the left foot. He reports that he has started walking with assistance.

Discussion e/o Conclusions: This case highlights the complexity of managing AIDP in advanced HIV, requiring careful differential diagnosis. The patient's CSF showed evolving albuminocytologic dissociation, suggesting a shift from AIDP to CIDP, with HIV RNA indicating immune dysregulation. At the last check-up, despite some recovery in lower limbs, persistent weakness and CIDP progression underline the importance of long-term neurological follow-up and individualized treatment.

HIV e STI

CC 9 ATYPICAL DERMATOLOGICAL MANIFESTATIONS IN ADVANCED HIV: DIAGNOSTIC CHALLENGES AND CLINICAL CONSIDERATIONS

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Background: The diagnostic approach in cases of AIDS is particularly challenging due to the overlap of skin manifestations from a variety of conditions. Infectious diseases like mpox, syphilis, atypical mycobacterial, pyoderma, histoplasmosis, and cryptococcosis, as well as non-infectious conditions like neoplastic lesions, sarcoidosis and drug reactions, can present with similar dermatological features.

Case Presentation: We present the case of a 60-year-old Caucasian male with a one-month history of intermittent fever, dry cough, mild mental confusion, dizziness and headache with the recent onset of disseminated multiform skin lesions. The patient had a known history of HIV infection, diagnosed in 2011, characterized by irregular follow-up and poor adherence to ART regimen (dolutegravir/abacavir/lamivudine), with the last visit occurring in 2022. His medical history also included occult HBV infection, a previous episode of herpes zoster (2006), and latent syphilis (2012) previously treated with further negative RPR.

On physical examination, the patient exhibited widespread, red-brownish, non-pruritic, disseminated multiform skin lesions (nodular, annular, vesicular and pustular), distributed across all body (Figure 1a). Non genital lesions were evidenced. Nasopharyngeal and skin swabs were negative for mpox. Blood tests were negative for cryptococcal antigen, while RPR titer was 1:32. Dermatological evaluation and skin biopsy revealed a dense mixed inflammatory infiltrate and a positive immunohistochemical staining for Treponema pallidum (Figure 2a, b), confirming the diagnosis of secondary syphilis in the context of poorly controlled HIV infection. Despite neurosyphilis and cryptococcal meningitis were excluded after lumbar puncture, treatment with IV penicillin G was promptly started and prolonged for 14 days, due to the persistence of neurological symptoms. After one week of treatment, the fever resolved, and skin lesions improved. To monitor the progression of the dermatological condition and ensure re-engagement in follow-up care, a visit was scheduled two months later, revealing further improvement of the skin lesions, with only residual maculae still visible (Figure 1b).

Conclusions: Syphilis presents with a broad spectrum of cutaneous manifestations, with up to four overlapping patterns, complicating diagnosis. Therefore, syphilis should be considered in the differential diagnosis of any recent, widespread, symmetric eruption. A comprehensive medical history, including travel, animal contact, and current therapies, along with a thorough skin examination, is essential for early detection. Given the rising incidence of syphilis -at its highest since the 1950s- and the notable increase in congenital syphilis cases, as reported by the CDC, it is crucial to remain vigilant in identifying this condition across diverse patient populations.

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HIV e STI

CC 10 BENEFICIAL SWITCH TO LONG-ACTING INJECTABLE CAB/RPV FOR A WOMAN LIVING WITH HIV STRUGGLING WITH DAILY ORAL MEDICATION ADHERENCE: A CASE REPORT

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Background: Adherence to treatment is a key element of staying healthy while living with HIV. Individuals who experience adherence issues with daily oral ART should be provided with support measures aimed at overcoming the barriers enhancing the risk of disengagement from care. Long-acting ART seems to have the potential to increase the chances of virologic suppression among selected PLH who are struggling with pill fatigue.
Case presentation: In May 2018, a 20-week-pregnant Nigerian woman living with HIV, came to our attention. She had been diagnosed with HIV infection during pregnancy screening tests. She started a DTG/ABC/3TC cART that took during all pregnancy and delivered with a C-section a HIV-negative baby. From the beginning, the patient showed a refusal to accept the diagnosis, which resulted in a lack of adherence to the therapy. Both the patient and her child were lost to follow-up. When she came back to our attention in March 2023, we found out that, as she delivered, she stopped taking the cART and, since she breastfed, the baby had contracted HIV infection. Mother and daughter had been followed at another center and, while the child was on antiretroviral treatment with suppressed viremia, the mother, after taking cART during a second pregnancy, had suspended it again. The patient reported that she was aware of the importance of taking cART and for this reason she administered it daily to her daughter, but reported that a psychological block prevented her from taking it. After HIV drug resistance genotyping identified no mutations (see Figure 1), the patient restarted cART with DTG/ABC/3TC with rapid achievement of virologic suppression. In the final months of pregnancy, the patient persistently requested an alternative regimen to oral cART. Postpartum, we agreed that if she continued oral cART regularly with maintenance of virologic suppression, we would consider a switch to long-acting injectable CAB/RPV. The long-acting therapeutic strategy has maximized adherence since then, allowing a sustained virologic suppression (see Table 1) and contributing to an improved life quality.
Discussion/Conclusions: When appropriate, to switch ART to meet patients in need, sharing the decision-making process, has the potential to be a beneficial approach. In this case, the patient had poor adherence to therapy due to a psychological block in taking it, while she had excellent adherence to the outpatient follow-up. Switching to injectable regimens, once virological suppression has been achieved and maintained, can be a winning strategy for PLH with problems taking oral therapy.

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HIV e STI

CC 11 BREAKTHROUGH HIV INFECTION IN A PRE-EXPOSURE PROPHYLAXIS (PREP) USER: THE ROLE OF THE SIGNAL-TO-CUTOFF (S/CO) RATIO IN EARLY DIAGNOSIS

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Introduction: Pre-exposure prophylaxis (PrEP) is an effective strategy for preventing HIV infection. In 2023, more than 3.5 million people worldwide received PrEP at least once. Studies estimate that its effectiveness reaches 99% when taken daily and 96% when taken at least four days a week. Despite its high efficacy, breakthrough HIV infections in PrEP users remain a rare occurrence. Few cases have been reported, attributed to a lack of adherence, exposure to drug-resistant viral strains or undetected acute HIV infection at the time of PrEP enrollment. Timely detection of these infections remains a challenge, and the signal-to-cutoff (S/CO) ratio is emerging as a potentially useful tool for identifying early seroconversion. This case report highlights its role in facilitating early diagnosis and treatment initiation.

Case description: We present the case of a 41-year-old man who has sex with men (MSM) and reported engaging in chemsex. Over the past year, he had been diagnosed with multiple sexually transmitted infections (STIs), including secondary syphilis, gonococcal urethritis and HBV infection. He initiated on-demand PrEP in 2022 with reported full adherence. In March 2023, he tested negative for HIV during routine screening. At a routine follow-up in June 2023, he reported the recent onset of bilateral inguinal lymphadenopathy and laboratory tests showed a positive HIV-1/2 antigen/antibody (Ag/Ab) test with an S/CO ratio of 3.5 and an indeterminate Western blot (gp120 +/-, gp41 +/-, p31 -, p24 -, P17 -, gp105 -, gp36 -). A few days later, the HIV test was repeated due to the initial indeterminate result. It confirmed a positive HIV-1/2 Ag/Ab test (S/CO ratio 2.2), a negative Western blot and an HIV RNA test detecting 4,290 copies/ml. Given these conflicting findings and the patient's risk factors, a shared decision-making process led to the initiation of rapid antiretroviral therapy (ART) with bictegravir/tenofovir alafenamide/emtricitabine (BIC/TAF/FTC), resulting in prompt immunovirological control. The subsequent HIV test showed an HIV-1/2 Ag/Ab positive result (S/CO ratio 3.8); however, unlike the previous test, HIV RNA was undetectable. HIV genotyping was not performed due to the non-amplifiability of the samples.

Conclusions: An increasing number of people newly diagnosed with HIV report previous use of PrEP. In our experience the progressive increase in the S/CO ratio discordant and virological findings raised suspicion of an evolving infection and guided to repeat HIV-RNA every week. These findings open the debate on the need to define both effective tools and the optimal sampling kinetics for identifying early seroconversion.

HIV e STI

CC 12 BREAKTHROUGH MONKEYPOX INFECTION IN A FULLY VACCINATED INDIVIDUAL: A CASE REPORT AND CLINICAL INSIGHTS

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Background: Monkeypox is a zoonotic disease caused by the Monkeypox virus, related to Variola and Vaccinia. It spreads through direct contact with infectious lesions, bodily fluids, and respiratory droplets. Since early 2022, an international outbreak has affected primarily MSM individuals. Despite the administration of the Imvanex/Jynneos vaccine, there have been reports of breakthrough infections. These cases usually present with milder symptoms.
Case Presentation: This case involves a 39-year-old male who has sex with men (MSM) presenting to our outpatient clinic in January 2025. The patient reported the onset of pharyngitis, low-grade fever, and the progressive development of vesicular-pustular lesions on the tongue, chin, upper lip, and scrotum (Figure 1) starting one week prior to his visit. These lesions were initially misdiagnosed as impetigo by a dermatologist. He had received two doses of Imvanex/Jynneos vaccine in November and December 2022. The patient disclosed that his most recent sexual encounter, which involved oral-genital contact without barrier protection, occurred ten days prior with a partner that subsequently developed similar vesicular lesions on the right hand and face.
Laboratory tests using PCR on urine, blood, and vesicles confirmed the presence of the Monkeypox virus (West African lineage). Additionally, Ureaplasma urealyticum was detected in the urine. Despite the mucocutaneous lesions, the disease showed limited progression, with no significant systemic involvement or new lesion formation following the initial outbreak. The patient was treated with doxycycline 100 mg twice daily for seven days for the Ureaplasma infection and received post-exposure prophylaxis with benzathine penicillin G due to exposure to a syphilis-positive partner. The lesions progressed through the expected healing stages without complications, which may indicate an attenuated course due to prior vaccination.
Discussion: This case exemplifies a breakthrough monkeypox infection in an individual who was fully vaccinated, underscoring the necessity for ongoing vigilance. Although the Imvanex/Jynneos vaccine does not confer complete immunity, its role in reducing disease severity is significant. The lack of lesion dissemination and severe systemic involvement indicates a protective, albeit partial, effect, which warrants further investigation into the vaccine's efficacy in real-world settings.
Conclusion: Breakthrough monkeypox infections highlight the need for ongoing clinical awareness, even among vaccinated individuals. Early differential diagnosis is crucial, especially in MSM populations with STI co-infections, and vaccination may limit disease severity. Further research is needed to improve immunization strategies and understand breakthrough infections in high-risk groups.

Attach: https://www.icar2025.it/upload/clinicalCaseAttach/Attach_CliCase_39.jpg

HIV e STI

CC 13 CMV RETINITIS IN HIV PATIENT WITH GOOD COMPLIANCE TO ART: CASE REPORT

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Background: We describe a case of a 54-year-old woman diagnosed HIV positive in 2023. Her CD4 were 12 cell/uL, and HIV RNA was 1.985.810 cp/ml. She was hospitalized due to Pneumocystis jiroveci pneumonia, esophageal candidosis, CMV blood reactivation with positive CMV-PCR results in cerebrospinal fluid and bronchoalveolar lavage. She had no neurological symptoms although the MRI showed signs of ventriculitis, fundus examination was normal. The patient was treated with trimethoprim-sulfamethoxazole, azytromicin, ganciclovir switched to valganciclovir, bictegravir-emtricitabine-tenofovir alafenamide. After 4 months of ART, HIV RNA was < 40 cp and after 9 months CD4 count was >100/mmc.

Case presentation: In January 2025 the patient reported scotomas in the right eye and decreased vision. A fundus examination of the right eye revealed a large area of retinal necrosis and large area of ischemia, diffuse hemorrhages; the left eye was normal. The ophthalmologist diagnosed necrotizing retinitis, leading to a diagnostic paracentesis and hospitalization for further diagnostic workup. At this time CMV DNA level in blood samples were negative, HIV-RNA VL < 40 cp/ml and CD4 count was 186/mmc. Intravenous ganciclovir was started, CMV in the paracentesis fluid was 271.684 cp/ml; Toxoplasma gondii, HSV, and VZV molecular tests, were all negative. The patient was discharged with a prescription of valganciclovir and steroid therapy, as ophthalmological indication.
Following her discharge, the patient was evaluated at the infectious Disease and Ophthalmology clinic:, where a partial recovery of vision in the right eye was observed (from 3/10 to 5/10). She then received photocoagulation laser therapy. A fundus examination showed some improvement after 3 weeks of therapy, however, there were still areas of retinal necrosis and considerable ischemia present. Currently, ophthalmological follow-up is ongoing.

Discussion and Conclusion: Before the availability of potent ART, CMV retinitis was among the most common complication of AIDS. However, following the introduction of ART the incidence of CMV retinitis significantly decreased (1).
In this case we have a patient who already experienced a CMV-related organ disease at the time of her HIV diagnosis and was successfully treated. Subsequently, the patients received ART along wiht CMV prophylaxis with valganciclovir, which was discontinued when CD4+ > 100 cells/microl, which many studies showed to be a safe immunological cutoff value to avoid relapses (2). Furthermore, CMV relapses in patients who failed ART appear to be more common in those with CD4 count decreased to less than 50 cells/mm3. In this case, the patient experienced a relapse of CMV organ disease despite her CD4+ lymphocyte counts being above the threshold. It can be speculated that the central nervous system may have acted as an anatomical reservoir for CMV in a patient who had previously demonstrated positive CSF viremia at the time of presentation.

HIV e STI

CC 14 DISSEMINATED CRYPTOCOCCOSIS IN AN HIV-POSITIVE PATIENT: A CASE REPORT HIGHLIGHTING DIAGNOSTIC CHALLENGES AND THERAPEUTIC APPROACHES

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Background: Cryptococcosis is a severe fungal infection, particularly insidious in immunocompromised patients. This clinical case presents a 54-year-old man with AIDS-stage HIV who developed disseminated cryptococcosis, initially undiagnosed, highlighting the importance of vigilant surveillance in patients with advanced immunodeficiency.
Case Presentation: The patient, with a history of HIV (CDC stage B3), exhibited signs of clinical deterioration, including acute confusion and vision loss. During the initial hospitalization (January-February 2024), blood tests revealed elevated troponin levels and a positive antigen test for SARS-CoV-2. Chest CT scans indicated signs of pneumonia and pulmonary inflammation, initially treated with remdesivir and dexamethasone. Serological tests demonstrated severe immunosuppression (HIV-RNA 136,000 copies/ml, CD4+ 3/uL). Bronchoalveolar lavage (BAL) revealed multiple infections (CMV, EBV, Aspergillus, HSV1, Toxoplasma). Brain CT suggested the presence of cerebral toxoplasmosis, confirmed by subsequent examinations.
The second hospitalization (March-June 2024) was characterized by visual obscuration and disorientation. Despite initial clinical improvement, the patient exhibited signs of neurological deterioration and developed apparent ulcerated sebaceous hyperplastic skin lesions. An antigen test (on blood and cerebrospinal fluid) confirmed the presence of Cryptococcus neoformans, establishing a diagnosis of cryptococcal meningitis.
Therapeutic Approach: Following an induction phase with amphotericin B, the patient was discharged on maintenance therapy with Biktarvy, trimethoprim/sulfamethoxazole, and fluconazole. General conditions improved, but complications such as neutropenia and acute renal failure emerged.
Discussion: Cryptococcosis, initially confined to the lungs, evolved into meningitis, a common manifestation in patients with CD4+ counts <100. Sebaceous hyperplasias may be interpreted as signs of disseminated cryptococcosis, underscoring the necessity for careful monitoring and antigen testing in blood and cerebrospinal fluid, as antigenemia may precede the clinical presentation of meningitis. This case emphasizes the importance of early diagnosis and timely treatment in cryptococcal infection to improve outcomes in immunocompromised patients. The management of comorbidities and iatrogenic complications remains crucial for long-term clinical recovery.

HIV e STI

CC 15 DOLUTEGRAVIR/LAMIVUDINE COMBINATION THERAPY IN AN ANTIRETROVIRAL-NAIVE PREGNANT WOMAN LIVING WITH HIV. TIME TO ACT?

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Background: Clinical trials and real-life studies have shown the efficacy of a dolutegravir/lamivudine regimen both as initial treatment for a few antiretroviral-naive people living with HIV (PLWH) or as therapy for experienced patients with undetectable viral load and without known HIV drug resistance mutations.However the prescription rate for this regimen in daily clinical practice is lower than expected. Current guidelines on treatment of pregnant women living with HIV state that in naïve pregnant women antiretroviral therapy must be initiate as soon as possible,even without waiting drug-resistance test's results, However, two-drug antiretroviral regimens,like dolutegravir plus lamivudine, are not recommended in antiretroviral therapy-naive pregnant women because there are not data about their efficacy in pregnancy.

Case Presentation: We report the case of a pregnant woman living with HIV and naive to antiretroviral therapy, whom we treated with dolutegravir/lamivudine. She was at 24 weeks of gestation and arrived in Italy from Nigeria. Serology for HIV was positive, CD4+ cell count was 41/µL (6.2%) and HIV-RNA level was 25,100 copies/mL. The woman's weight was 76 Kg and her BMI was 25.2. While waiting for the results of drug-resistance testing, we started a dolutegravir/lamivudine combination regimen, co-trimoxazole (three times weekly, as prophylaxis against Pneumocystis jirovecii) and folic acid. Serology for hepatitis B was negative and drug-resistance testing detected no resistance mutations. After one month of antiretroviral therapy, the CD4+ cell count rose to 107/µL (11.7%), HIV_RNA was <20 copies/mL.Serum glucose and lipids levels (within normal limits at baseline) were unchanged one and three months after starting treatment, while the woman's body weight increased to 79 Kg (BMI 27.34) at the end of pregnancy. At the time of her vaginal delivery in .January 2024, HIV-RNA was still <20 copies/mL.A 2-week zidovudine regimen was started for newborn to reduce the risk of perinatal transmission of HIV .At the end of antiretroviral prophylaxis baby was in good clinicla conditions and without HIV infection.

Discussion and Conclusions: Real-world efficacy and safety of a dolutegravir/lamivudine regimen in ART-naïve adults were demonstrated in a number of clinical studies. However, a systematic literature review of real-world studies on this combination in women found no report on outcomes related to weight, effectiveness and birth outcomes in pregnancy. The implementation of a dolutegravir/lamivudine regimen in naive patients could be associated with a significantly longer time between first visit and treatment initiation, due to the need to asess HBV serostatus and test for resistance mutations but, its use would case fewer side-effects and lower discontinuation rates.We think that dolutegravir/lamivudine regimen could be tested, in a multi center Italian randomized trial,in pregnant naive-antiretroviral women.

HIV e STI

CC 16 HPV-RELATED ANAL SQUAMOUS CELL CARCINOMA IN MSM- HIV PATIENT: A CASE REPORT

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HPV is the most common STI worldwide. PLWH have an increased risk for HIV-HPV coinfection with a major prevalence in men who have sex with men and higher incidence in HPV-related cancers. HIV-positive men are about 1.4 times more likely to be HPV positive than HIV-negative men.
Despite the availability of ART, the incidence of several HPV-related cancers is higher in PLWH and the burden of persistent HPV-related disease has become a significant concern in an aging PLWH. Sexual contact represents the main mode for transmission of both HIV and HPV. Despite molecular interactions in coinfection are not fully understood, several mechanisms have been proposed. HIV proteins Tat,Vpr and Rev participate in HPV pathogenesis and increase the risk of HPV-associated cancers. Immunosuppressive status, led by decreasing CD4+ lymphocytes count and altered CD8+ lymphocyte activity, reduces the clearance of HPV. HPV-16 clearance is 1.6 times higher in HIV negative MSM compared to HIV-positive MSM. Anal cancer, which represents 2% of all intestinal mucosal malignant tumors, is 19 times more common in PLWH than in the general population. HPV-16 accounts for 85% of total squamous cell carcinoma of the anus.
We present a case of a 67-year-old HIV-positive patient with an anal squamous cell carcinoma, linked to HPV infection.
The patient has been living with HIV since 1985. His clinical history is significant for progressive multifocal leukoencephalopathy which led to hemiplegia of the left face, arm and leg. Additionally, the patient has bilateral visual field deficits, bilateral uveitis, right optic atrophy and a history of esophageal candidiasis.
The patient is classified as CDC C3. Despite multiple therapeutic changes due to poor adherence to ART, the patient is currently on a combination therapy DRV/c and RAL with viral suppression.
The patient is not vaccinated against HPV.
The patient presented with anemia and anal bleeding lesion. Physical examination revealed an ulcerated and indurated mass. An incision biopsy was performed with histological evidence of poorly differentiated squamous cell carcinoma (SCC), classified as G 2-3.The histological diagnosis was consistent with an HPV-associated anal SCC.
Molecular analysis of the tissue was positive for high-risk oncogenic HPV genotype 16, a well-known etiological factor in the development of anal cancer, particularly in immunocompromised individuals such as those living with HIV.
Oncological team did not recommend active systemic therapy but only palliative radiotherapy.
The lack of HPV vaccination in this patient may have contributed to the development of anal cancer, emphasizing the importance of vaccination, especially in PLWH.
This case underscores the importance of recognizing HPV as a major oncogenic risk in PLWH and highlights the need for vigilant screening and early intervention. A multidisciplinary approach is essential for optimizing treatment outcomes and providing comprehensive care for PLWH.

HIV e STI

CC 17 IMPACT OF HIV-1 INTEGRASI N155H AND K156N MUTATION IN A CLINICAL ISOLATE

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Background: The most frequent mutations in patients treated with RAL involve one of the three major mutations: Y143H/R/C, Q148H/R/K and N155H1. DTG is effective against viruses resistant to RAL, with changes involving the N155 and Y143 residues, but is less effective against Q148 viruses2.

Case report: We present a case of a 62-year-old caucasian male diagnosed in 2008 with a HIV subtype B. At baseline CD4 184 cells/uL (9%); HIV-RNA 367000 copie/mL. According to CDC, Atlanta classification, he had category A3 disease. His risk factor for HIV infection was MSM. At baseline genotypic analysis of integrase was tested in RNA and did not document any mutations against INSTIs. In 2008 he started ART with ATV/r+TDF/FTC with undetectable HIV RNA. From February 2019 to April 2024 he switched to INSTIs regimen with RAL/TAF/FTC with a stable undetectable HIV RNA. In April 2024 viral load becomes detectable in plasma at 890 copies/ml and 1290 copies/ml in second determination. Drug resistance mutations were examined in the integrase gene by sequence analysis. Genotypic analysis at month 62 with raltegravir, revealed the development of primary resistance mutation N155H. The following accessory INSTI-resistance mutations were found: K156N, E11D, S17T, S119P, T122I, T124S, V151I end I220V.

Discussion: Consecutive RT and PR genotyping results of other mutations from the RT and PR genes imply the evolution of the initial virus strain, rather than reinfection with a new virus strain. N155H mutation is associated with the highest level of reduced susceptibility or virologic response to RAL and EVG and reduce CAB susceptibility or virologic response and contribute to reduced susceptibility in combination with other INSTI resistance mutations3. In combination with other INSTI-associated DRMs, it reduces susceptibility to DTG and CAB and possibly BIC4. Currently, specific DTG resistance pathways have not yet been clearly identified, but the VIKING trials show that DTG is efficient against most of the viral strains resistant to RAL and EVG, particularly regarding the N155H mutation, but confers slight resistance when the Q148 residue is associated with secondary mutations5-6. Hightower et al. in one study show that DTG harbored slower dissociation rates on mutated in DNA complexes harboring the N155H mutation compared to raltegravir7. In the literature several studies show that the N155H mutation confers some resistance to DTG that increases consistently when the K211R/E212T and K156N mutations are added. In literature, some studies have shown that K156N could play an important role in the selection of a virus resistant to dolutegravir5-6-8-9. In view of these data, the patient was treated with a PI-based regimen with stable virologic response for 9 months.

Conclusions: Would be important to carefully explore the presence of this mutation in patients in whom RAL therapy is failing in order to evaluate its involvement in Second-Generation INSTIs resistance.

HIV e STI

CC 18 INVASIVE INFECTION CAUSED BY TALAROMYCES MARNEFFEI IN A PATIENT WITH HIV INFECTION: A CASE REPORT

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Background: Talaromyces marneffei is a dimorphic fungus which is endemic in several areas of Asia, such as Southeast Asia. It can cause disseminated infections particularly in immunocompromised patients, including patients with HIV and low CD4 count. Clinical manifestations are very different and include fever, weight loss, lymphadenopathy, hepatomegaly, splenomegaly, skin lesions, cough, abdominal pain and neurological manifestations. Diagnosis can be difficult as the fungus grows slowly (from 4 days to a few weeks). If infection is diagnosed or at least suspected, antifungal therapy should be started as soon as possible as untreated infection has a high mortality rate. The antifungal therapy of choice is liposomal amphotericin B for 2 weeks followed by itraconazole for 10 weeks. In HIV patients, after completion of 12 weeks, therapy with itraconazole should be continued until CD4 count is permanently ≥100 cells/microL for a minimum of 6 months.

Case Presentation: We present the case of a 53-year-old Italian patient who recently returned from Thailand where he had lived for 5 years. The patient was already known to have HIV infection and was previously followed at another hospital, but he was no longer taking antiretroviral therapy as he had self-suspended it for some time. On admission, the patient presented febrile and cachectic. Blood tests showed leukopenia with lymphopenia (total CD4 54 cells/microL) and anaemia requiring transfusion support; HIV RNA on blood was positive with 84000 cp/ml. Empirical antibiotic therapy with piperacillin/tazobactam was initially administered, with no clinical response. A CT scan of the chest and abdomen was performed, showing small (5-6 mm) bilateral lung nodules, mild hepatomegaly and diffuse lymphadenopathies, particularly in the abdomen. An MRI of the brain showed diffuse atrophy in the absence of other lesions. For further examination, a lumbar puncture was performed, which showed slight hypoglycorrhachia (41 mg/dl), elevated protein concentration (125 mg/dl) and HIV RNA positivity (3700 cp/ml); the other findings were within limits. Blood cultures came back positive for Talaromyces marneffei nine days after collection and so antifungal therapy with liposomal amphotericin B 3 mg/kg/day IV was initiated with progressive clinical improvement. Meanwhile, anti-retroviral therapy with ABC/3TC/DTG had also been started. Antifungal therapy was continued for 2 weeks with a subsequent switch to itraconazole 200 mg twice a day per os for other 10 weeks. Afterward, the indication given was to continue therapy as secondary prophylaxis with itraconazole 200 mg/day per os; however, the patient again self-suspended both antiretroviral and antifungal therapy.

Conclusions: The diagnosis of invasive Talaromyces marneffei infection can be insidious. Nevertheless, it should be considered in immunocompromised patients who have travelled to Asia, as early diagnosis is crucial to reduce infection-related morbidity and mortality.

HIV e STI

CC 19 LENACAPAVIR AS RESCUE THERAPY IN A CASE OF MULTIDRUG-RESISTANT HIV-1 INFECTION AND PREVIOUS VIROLOGICAL FAILURE WITH DIFFERENT ANTIRETROVIRAL REGIMENS

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Background: HIV remains a global public health challenge despite significant advances in antiretroviral therapy (ART). Highly Treatment-Experienced (HTE) people living with HIV (PLWH), defined as those who have failed multiple ART regimens and limited treatment options due to drug resistance mutations and/or drug intolerance , represent a particularly vulnerable subset of individuals. HTE individuals have two or fewer classes of antiretroviral drugs available and a reduced number of drugs that can be used within each class, thus representing a group of PLWH at high risk of virological failure (VF), clinical progression and worsening the prognosis.
Case description: We present the case of a 63-year-old man diagnosed with B3 HIV-1 infection since 1989 and several comorbidities (HCV-related liver cirrhosis with sustained virological response, diabetes mellitus, hypertensive heart disease, localized bladder cancer, benign prostatic hypertrophy, COPD, lipodystrophy, dyslipidemia). Despite being on ART with adequate adherence, he experienced recurrent VF due to the development of resistance to multiple drug classes, so that over the years, he had been switched between twenty-one different ART regimens, each of which failed to gain virological suppression (VS).
While he was taking ART regimen containing fostemsavir-lamivudine-doravirine without achieving VS, resistance test revealed an extensive profile of mutations: high-level resistance to most of first-line NRTI, NNRTI, PI, INSTI and intermediate resistance to etravirine (ETR) and tenofovir (TDF) only [Fig.1]. So, in May 2024 he started a salvage therapy regimen consisting of lenacapavir (LEN), TDF and ETR. A reduction in viral load was observed after just one month, with HIV RNA levels undetectable. In addition, at subsequent follow-up, a slight recovery of immune function and normalization of some inflammation indices were observed [Tab.1].
Discussion: LEN is a novel long-acting capsid inhibitor that interferes with the viral replication process by inhibiting the viral capsid, approved for the treatment of HIV-1 infection in combination with other antiretroviral drugs in HTE adults with multidrug-resistant (MDR) virus in whom their current ART is failing due to resistance, intolerance or safety considerations . This case highlights the importance of tailoring treatment regimens to specific resistance profiles and the need for continuous monitoring of drug resistance in the management of MDR HIV-1 infections. Despite the intermediate susceptibility of both TDF and ETR in this case, the regimen was highly effective, as LEN, through its unique mechanisms of action, demonstrates strong antiviral activity. LEN represents a promising approach to overcome resistance challenges and achieve VS, providing a model for the treatment of HTE cases moving forward.

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HIV e STI

CC 20 OPPORTUNISTIC SEXUALLY TRANSMITTED INFECTION IN AN IMMUNOCOMPROMISED PATIENT WITH CROHN'S DISEASE TREATED WITH ADALIMUMAB: A CASE REPORT

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Background: Crohn's disease is a chronic inflammatory bowel syndrome requiring immunosuppressive therapies such as adalimumab, a TNF-α inhibitor. While adalimumab effectively controls disease activity, it predisposes patients to opportunistic infections, including sexually transmitted infections (STIs). Given the prevalence of Crohn's disease in young adults, sexually transmitted infection screening should be considered in patients undergoing immunosuppressive therapy.

Actinomyces species are gram-positive bacteria known to be causative of chronic infections in different sites of human body. Actinomyces turicensis has been identified as a commensal organism in the female genital tract and may serve as a reservoir. Although its pathogenic role in female genital tract infections and pelvic inflammatory disease is documented, its involvement in male urethritis remains poorly characterized and may be underdiagnosed, particularly in immunocompromised hosts.

Case Presentation: A 31 y.o. male, MSW, with ileocecal Crohn's disease, undergoing to adalimumab 40 mg fortnightly since 2018, came to medical attention with oral herpetic mucositis in January 2024 and adalimumab was readily suspended. After successful resolution of mucositis with valacyclovir, the patient reported new-onset dysuria, urethral discharge and burning sensation: STIs screening revealed a positive urethral swab for Actinomyces turicensis, M. genitalium and C. trachomatis. Actinomyces turicensis has limited documentation as a pathogen in male urethritis, but some cases of severe anogenital infections were reported in literature. Meanwhile his asyntomatic partner tested positive for endocervical-pharyngeal and rectal C. trachomatis, but Actinomyces turicensis and M. genitalium were not detected. Both the patient and his partner began doxycycline 100 mg twice daily with different duration: 30 days and 7 days respectively, tailoring the therapy on the specific infection and, finally, we assisted to patient's symptoms resolution.

Discussion: This case highlights the importance of considering both common and uncommon pathogens as STIs in immunocompromised patients. While M. genitalium and C. trachomatis role in STI is well established, the identification of Actinomyces turicensis raises questions about the role of opportunistic pathogens in male urethritis and their complications. The decision to start the treatment required careful considerations: according to the need to reintroduce adalimumab therapy as soon as possible, one-month doxycycline regimen was chosen. Despite the lack of therapeutic guidelines, the therapy was set considering the treatment of other actinomyces infections and the slow proliferation of these bacterias. This approach aimed to mitigate the risk of untreated infection while balancing potential adverse effects and the development of antibiotic resistance. We cannot forget anymore opportunistic STIs as potential side effects of immunosuppressive therapy.

HIV e STI

CC 21 PML-IRIS: MORE SHADOWS THAN LIGHTS—AN ONGOING CHALLENGE. CASE REPORT OF PML-IRIS IN AN HIV PATIENT AND CONSIDERATIONS ON POSSIBLE DIAGNOSTIC AND THERAPEUTIC STRATEGIES

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Background: Progressive multifocal leukoencephalopathy (PML) is a severe demyelinating disease caused by JC Polyomavirus (JCV) reactivation in immunocompromised patients, particularly those with advanced HIV. Initiation of antiretroviral therapy (ART) in these patients can trigger immune reconstitution inflammatory syndrome (PML-IRIS), characterized by worsening neurological symptoms due to an immune response against infected glial cells. Treatment primarily involves corticosteroids to control inflammation and ART for viral suppression, yet outcomes remain poor with high disability and mortality rates. New potential therapeutic strategiesy include immune checkpoint inhibitors (e.g., Pembrolizumab), recombinant IL-7, CAR-T therapy, and CCR5 agonists (e.g., Maraviroc). However, their efficacy is still under investigation. This report presents a case of PML-IRIS in an advanced-stage HIV patient, discussing diagnostic and therapeutic challenges.

Case Report: A 58-year-old HIV-positive man was transferred to our center following esophageal candidiasis, interstitial pneumonia, and physical deterioration. His HIV test was positive with 17,100 copies/mL viremia, CD4+ count of 78/mL, and a CD4+/CD8+ ratio of 0.23 (CDC C3). CT and MRI scans suggested PML, confirmed by cerebrospinal fluid (CSF) analysis detecting 1,051 copies/mL of JCV-DNA. ART (DTG/ABC/3TC) was initiated, and resistance testing showed no mutations. Initial improvement allowed discharge, but he was readmitted a month later following a loss of consciousness. A second lumbar puncture showed increased CSF JCV-DNA (2,500 copies/mL); plasma HIV viremia was 2,190 copies/mL. MRI confirmed stable PML lesions but revealed internal carotid artery occlusion. Two months later he deteriorated showing severe weakness, incontinence, and cognitive decline. CSF JCV-DNA rose to 2,677 copies/mL, while HIV viremia decreased (121 copies/mL) with CD4+ cells count of 406/mL. MRI indicated worsening PML. High-dose corticosteroids were started for suspected PML-IRIS. Pembrolizumab off-label was administered and all the procedures for CAR-T therapy were initiated, but 10 days after, the patient died due to central respiratory failure.

Conclusion: Despite promising emerging therapies, treatment of PML-IRIS remains controversial. Some interventions, like Maraviroc, show potential in preventing IRIS in iatrogenic PML, but their role in established PML-IRIS remains off-label due to the lack of randomized clinical trials. Pembrolizumab and CAR-T therapy pose risks of exacerbated inflammation, increasing neurological damage, autoimmunity, cytokine release syndrome, and opportunistic infections. Our case highlights the need for early neurological monitoring in HIV patients. PML-IRIS onset after ART initiation was the key driver of deterioration. We propose systematic lumbar punctures in all HIV CDC C3 patients, periodic neuroimaging post-ART initiation, and early therapeutic intervention to mitigate disease progression. Establishing national referral centers could optimize long-term management of PML patients.

HIV e STI

CC 22 PULMONARY NOCARDIOSIS IN AN AIDS-PRESENTER PATIENT: DIAGNOSTIC AND TREATMENT CHALLENGES

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Background: Nocardia spp. are gram-positive, mildly acid-fast bacilli belonging to the aerobic actinomycetes group. Nocardia spp. can cause various clinical syndromes in immunocompromised patients, with pulmonary nocardiosis accounting for up to 70% of all cases. Pulmonary nocardiosis diagnosing is challenging due to its clinical presentation which mimics other respiratory infections like M. tuberculosis, its non-specific CT findings, and the need for prolonged culture incubation. Additionally, no consensus currently exists on its optimal management.
Case presentation: A male patient in his fifty presented to our Emergency Department with persistent fever unresponsive to amoxicillin/clavulanate, asthenia, productive cough with chest pain, and a 15 kg weight loss over the past month. His previous medical history was unremarkable. Blood tests showed leukocytosis (WBC 15,550/mm³, PMN 88%), high inflammatory markers (CRP 289 mg/L), and anemia (Hb 9.6 g/dL). A chest X-ray and subsequent CT scan revealed a large right upper lobe consolidation with intralobular ground-glass opacities, associated with mediastinal lymphadenopathy (Figure 1). Empirical ceftriaxone and azithromycin were initiated, and the patient was admitted to the Infectious Diseases unit.
HIV test requested at admission was positive (CD4+ 52/mm³, CD4/CD8 ratio 0.09, HIV RNA 180,000 copies/mL). The patient started treatment with Biktarvy and cotrimoxazole prophylaxis.
Two days after admission, he underwent fibro-bronchoscopy with BAL and EBUS of mediastinal lymph node. Cultures for bacteria and fungi, microscopy for AFB, and M. tuberculosis PCR were negative on BAL. Urinary antigen tests for Legionella and S. pneumoniae, respiratory panel, P. jirovecii PCR, cryptococcal and galactomannan antigen tests, and QFTB were all negative. Plasma CMV-DNA was 355 U/mL (fundus oculi was negative). Ten days later, thoracic lymph node histology revealed the presence of Gram-positive filamentous elements suggestive of Nocardia spp and PCR for Nocardia spp DNA tested positive, while atypical mycobacterial PCR was negative. Meropenem was delivered for 14 days, combined with full-dose cotrimoxazole, with fever resolution and radiological improvement (Figure 2). After discharge, lymph node aspirate culture was positive for M. avium, for which no immediate treatment was started. After 4 weeks of treatment with full-dose cotrimoxazole, the patient developed a severe cutaneous allergic reaction, which led to the discontinuation of therapy. Standard culture testing and mycobacterial culture did not show positivity for Nocardia spp, precluding the selection of a targeted therapy. Therefore, therapy with linezolid 600 mg BID was initiated with weekly TDM monitoring, currently ongoing, together with atovaquone prophylaxis.
Discussion: Nocardiosis' management is characterized by several challenges: difficulties in confirming the diagnosis, empiric drug selection, tolerability of first line regimens.

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HIV e STI

CC 23 RELAPSE OF EXCEPTIONAL WEIGHT GAIN WITH CAB+RPV IN FORMER TREATMENT WITH SECOND GENERATION INTEGRASE STRAND TRANSFER INHIBITORS

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Background: Antiretroviral therapy (ART) with integrase strand transfer inhibitors (INSTIs) is widely used due to their efficacy and safety. Recent studies have shown an association between this drug class and significant weight gain. The mechanisms behind this phenomenon are still under investigation and may involve various determinants, including host-related factors such as altered fat distribution, insulin resistance, and changes in lifestyle. In the era of ART optimization, these factors might have to be taken into account, leading to closer monitoring and individualized management strategies for people living with HIV undergoing INSTI-based therapy.
Case presentation: We present the case of a 35-years-old french MSM diagnosed with HIV infection in 2013 during hospitalization for asthenia, myalgia, and a neurological syndrome of undetermined etiology (which regressed over a few weeks), with evidence of acute seroconversion. During hospitalization, CD4+ count was reported as >400/mmc. Upon diagnosis, first-line antiretroviral therapy with RAL + FTC/TDF was initiated. Around 2021, a proactive switch to BIC/FTC/TAF was made, followed by a switch to DOR/3TC/TDF after approximately 9 months due to weight gain, with reported stabilization of weight to 90 kilograms (BMI?). In February 2024, a regimen proactive switch to intramuscular administration of cabotegravir (CAB) + rilpivirine (RPV) was made (after 30 days of oral bridge), due to patient request; injections were well-tolerated, with only mild gluteal pain reported. Weight increased from 90 to 105 kg over the year following the switch to CAB+RPV, with no significant lifestyle changes reported in term of diet and physical activity. The patient reported increased sense of hunger. In September 2024, a thorough metabolic assessment was performed, including genetic testing, abdominal ultrasound, and FibroScan. The evaluation allowed for diagnosis of mild hepatic steatosis of likely metabolic origin, with no elevation in transaminases or significant hepatic fibrosis in grade I obesity. PNPLA3 heterozygosis indicated an intermediate risk for progressive metabolic liver disease, with LDL cholesterol not at target for the risk class (desired LDLc < 100 mg/dL). No cardiovascular abnormalities were detected. Statin therapy was deferred, and lifestyle modifications, including a careful diet and physical activity, were recommended. On January 10, 2025, in light of ongoing weight gain, a proactive switch to Delstrigo (DOR/3TC/TDF) was made. The patient is awaiting a new metabolic assessment.
Conclusion: This case highlights an aspect of the emerging issue of weight gain associated with INSTIs in HIV treatment, as two very different second-generation INSTI regimens were discontinued due to weight gain due to patient request, hampering optimization and hinting to class intolerance. Detailed metabolic studies are needed to identify factors associated to exeptional weight gain in response to INSTIs.

HIV e STI

CC 24 SUCCESSFUL IMPLEMENTATION OF LONG-ACTING ANTIRETROVIRAL THERAPY IN A HEAVILY TREATMENT-EXPERIENCED PATIENT WITH VERTICAL HIV INFECTION

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Background: Heavily Treatment-Experienced (HTE) People Living with HIV (PLHIV) who develop drug resistance face challenges in maintaining virological suppression and immune recovery. The introduction of Long-Acting Antiretroviral Therapy (LA-ART), such as lenacapavir and ibalizumab, offers a new opportunity to achieve and maintain virological undetectability. We present the case of a 29-year-old woman with vertically transmitted HIV-1 infection, severe immunodepression, opportunistic infections, and numerous treatment failures.

Case Presentation: The woman was diagnosed with HIV-1 at the age of 2 months, and throughout childhood, she suffered from recurrent opportunistic infections, leading to multiple hospitalizations. Over the years, she was exposed to various ART regimens with suboptimal adherence, resulting in progressive virological failure and the accumulation of extensive major resistance-associated mutations across multiple ARV classes. In 2022, due to resistance to non-nucleoside reverse transcriptase inhibitors (NNRTIs), a long-acting cabotegravir/rilpivirine regimen with the addition of darunavir/cobicistat was started. However, due to the patient's unwillingness to adhere to oral therapy, the nonadherence led to resistance to integrase inhibitors (INSTIs) and resulted in LA therapy failure and discontinuation. With psychological support, the patient understood the need for a new therapeutic strategy, including drugs with different mechanisms of action. Consequently, a compassionate-use program for lenacapavir was approved, allowing for a salvage regimen with fostemsavir, darunavir/cobicistat, and tenofovir alafenamide/emtricitabine. Furthermore, to optimize the Background Regimen (OBR), intravenous ibalizumab was added, despite the logistical challenges of administering it every 14 days in a day-hospital setting. Following discharge, a Directly Observed Therapy (DOT) program was implemented to support treatment compliance via video calls, with the patient being supervised by trained healthcare personnel. At the six-month follow-up, the patient showed significant clinical and virological improvement. No drug-related adverse events were reported, and the patient demonstrated increased adherence to treatment and achieved complete virological suppression in 2023.

Discussion and Conclusions: This case illustrates the efficacy of long-acting therapy as a strategy for achieving virological suppression and immune recovery in a patient with limited options. Further research is needed to explore the role of novel antiretroviral agents in optimizing treatment outcomes for multidrug-resistant HIV and to identify strategies for improving adherence in HTE PLHIV. This case highlights the importance of individualized and personalized treatment approaches that integrate new-generation antiretrovirals for patients with limited therapeutic options.

HIV e STI

CC 25 SWITCH FROM IBALIZUMAB TO LENACAPAVIR IN A RESCUE REGIMEN FOR AN MDR HIV PATIENT

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Background: Advances in antiretroviral therapy have improved efficacy,but some patients show multidrug resistances(MDR).The guidelines in this case suggest using new generation drugs together to those with residual efficacy.Ibalizumab(IBA)is a new monoclonal antibody that blocks the CD4 cell receptor.Lenacapavir(LEN)is a new viral capsid inhibitor,which represents a new therapeutic target.

Methods: Our clinical case concerns an MDR HIV patient with multiple mutations.A rescue therapy was set up combining drugs with low level resistance(Etravirine+Tenofovir/Emtricitabine+Dolutegravir)and IBA.At that time,HIV-RNA resulted 37.800 copies/ml and CD4+ were 147 cells/μL.Ibalizumab was administered intravenously in April 2022,first as monotherapy with a loading dose of 2000 mg,then after 7 days an 800 mg dose associated with residual effective drugs.Subsequently,this dose was repeated every 15 days.After 12 months,to optimize adherence and improve the patient's quality of life,IBA was replaced by LEN,with a more comfortable long-acting dosage.The drug was administered first orally,then subcutaneously,once every 6 months.

Results: This rescue strategy showed viro-immunological efficacy.After 7 days,IBA alone had already reduced the HIV viral load by 2 logs.Then,after combining other drugs with residual efficacy,viral suppression was achieved in only one month.After 12 months CD4 count improved from 147 to 245 cells/μL.There were no adverse events except hypertension after ibalizumab infusions.During the follow-up we also noticed a progressive reduction in the detectability of viral mutations in the reservoir.HIV-DNA genotyping test in fact no longer showed viral mutations that were evident before this rescue regimen.After 12 months of treatment,the patient voluntarily discontinued IBA,without losing viro-immunological efficacy.After 1 month,LEN was added to the regimen replacing IBA.LEN allowed to keep efficacy optimizing adherence,being administered subcutaneously every 6 months.It showed good efficacy and tolerability.After other 12 months of treatment,viro-immunological efficacy was maintained with CD4+ 277 cells/μL, HIV-RNA undetectable and stable pressure on HIV-DNA in terms of reduced detectability of previous viral mutations (Fig.1,Tab.A).

Conclusions: Our case report shows that IBA was effective in a rescue regimen,obtaining virological suppression and an immunological recovery,never previously obtained by the patient.The efficacy was also highlighted in the reservoir with a progressive reduction of HIV-DNA demonstrated by the impossibility of detecting initial previous mutations.The overall safety profile was good,despite hypertension following infusions.The subsequent switch to LEN maintained the viro-immunological efficacy and stable pressure on HIV-DNA,showing good tolerability and better long acting posology.This case report shows efficacy of LEN in switch strategy in a rescue regimen and in this context there are no data in the literature.

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HIV e STI

CC 26 THE CHALLENGE OF LEISHMANIASIS IN IMMUNOLOGICAL NON RESPONDERS AMONG PEOPLE LIVING WITH HIV

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Background: Although leishmaniasis is not included in the CDC's definition of AIDS, it is gaining clinical significance as an opportunistic infection in people living with HIV (PLWH). The clinical presentation of leishmaniasis may be nonspecific and therapeutic failures and relapses are common, presenting significant diagnostic and treatment challenges.

Case Description: We report the case of a 39-year-old male from the Dominican Republic, diagnosed with C3 HIV-1 infection and classified as an immunological non-responder (INR) due to persistently low CD4+T-cell counts (<350 cells/μL) despite antiretroviral therapy (ART) with bictegravir/emtricitabine/tenofovir alafenamide. He developed both visceral leishmaniasis first and cutaneous leishmaniasis later, failing to respond to the standard treatment with liposomal amphotericin B. His clinical symptoms included pancytopenia, splenomegaly and confluent subcutaneous nodules, which progressed to a leonine facies with hyperesthesia [Fig. 1]. Diagnostic workup excluded Mycobacterium species and lymphoma, confirming leishmania infantum infection through positive serology (titer 1:2560), microscopic examination and histological findings from a skin biopsy, which revealed marked histiocytic dermal infiltration. During one of several hospitalizations due to relapse episodes, he was treated with liposomal amphotericin B (3 mg/kg daily) for 21 days, resulting in significant improvement of the nodules. However, due to his low CD4 count (70 cells/mm³), he required maintenance therapy with liposomal amphotericin B every 2–4 weeks. Despite this, the cutaneous lesions worsened and his kidney function and pancytopenia deteriorated. Due to continued failure to restore CD4+ T-cell counts, his treatment was modified, including miltefosine and GM-CSF immunotherapy.

Discussion: Visceral leishmaniasis in immunocompromised hosts is a serious opportunistic infection. While amphotericin B is effective in immunocompetent individuals, relapses are common in immunosuppressed hosts. The most important prognostic factor for response to therapy and relapse rate is the degree of immunosuppression: a CD4 cell count below 100 cells/ml and no increase in CD4 at follow-up are the main risk factors for disease relapse. HIV-induced immunological abnormalities such as selective depletion of CD4+T cells, impaired Th1 cytokine production and macrophage dysfunction, contribute to poor response to therapy and high relapse rates. On the other hand, bone marrow infiltration, pancytopenia and chronic immune activation due to leishmaniasis hinder immune recovery and long-term remission.

This case underscores the importance of multidrug combination therapy and long-term maintenance treatment in severely immunosuppressed individuals with leishmaniasis. It also highlights the dramatic challenges and complexities in managing this disease, as therapy is often complicated by high rates of toxicity and low cure rates with guideline-recommended regimens.

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HIV e STI

CC 27 THE POTENTIAL BENEFITS OF NEW PRE-EXPOSURE PROPHYLAXIS (PREP) REGIMENS: A CLINICAL CASE FROM THE PAST

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Since its introduction, more than 11000 people started pre-exposure prophylaxis (PrEP) in Italy. The injectable PrEP regimen with Cabotegravir (CAB) was approved by European Medicines Agency in 2023, but it has only arrived in a limited number of Italian centers at the end of 2024.

We present the case of a 30-year-old Italian male, a MSM who engages in both receptive and insertive sexual intercourse without condoms, with his stable and occasional partners, approximately 800 throughout his sexual life, according to him. He regularly practices chemsex on weekends and had syphilis once and several infections from Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT).

In June 2023, he visited the PrEP clinic at Policlinico Tor Vergata, and after testing negative for HIV a month later, he began daily PrEP with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) with good adherence and no side effects. He did not alter his sexual practices and experienced two episodes of proctitis: one by NG and the other by CT.

In May 2024, he reached out to our clinic reporting that the previous weekend he had participated in a chemsex chill-out and had not used PrEP or condoms. We decided to start post-exposure prophylaxis (PEP) with raltegravir (RAL) and TDF/FTC for 28 days. In the ER, he was provided with only one box of RAL and was advised to return 14 days later for the second box and blood tests to evaluate toxicity.

After ten days he was assessed by phone, reporting no side effects and no missed pills. Although he remembered his next appointment, he did not show up; a week later, he emailed us stating that he had developed high fever, oral ulcers and diarrhea starting the day before the appointment. He continued TDF/FTC without RAL, so we advised him to stop the medication and come to the clinic for swabs for CT and NG, which returned negative, as well as HIV viremia testing. However, he never returned to complete the blood tests and stopped responding to phone calls and emails, becoming lost to follow-up.

Even though oral PrEP is effective when taken regularly, it is not the best option for everyone. In this specific case, the new injectable regimen, if available, could have prevented the loss to follow-up of a user with hundreds of sexual partners and a possible new HIV infection.

CAB-PrEP could be particularly helpful for individuals struggling with adherence or for sex workers who cannot always carry their pills with them, but its administration may be challenging in some centers due to a lack of proper capacities, insufficient staff or difficulties in obtaining the drug.

Moreover, this case highlights the need for expanding community-based PrEP, as some users may feel more comfortable discussing their concerns with a peer rather than with a doctor.

Since oral PrEP does not represent the right regimen for everyone, the same should be considered for CAB-PrEP. However, having more options could be beneficial in situations like the one we described.

HIV e STI

CC 28 VIROLOGICAL FAILURE AFTER TWO YEARS OF CABOTEGRAVIR + RILPIVIRINE LONG-ACTING TREATMENT: CASE REPORT

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Background: Cabotegravir + rilpivirine injectable long-acting (LA) therapy is an innovative switch strategy in virologically suppressed people living with HIV (PLWH). Some risk factors (BMI>30 kg/m², A1-A6 subtype, RPV resistance in historical genotype) could be predictive of virologic failure (VF), which can be associated with integrase inhibitors resistance. We report a case of VF after 2 years of LA treatment in a PLWH.

Case presentation: PG is a 59-year-old MSM, AIDS presenter in 2006 with diagnosis of cryptococcal meningitis. No significant medical history, except syphilis treated with benzylpenicillin in 2018 and no chronic therapy were reported. LPV/r+ABC/3TC was started in 2006: viral suppression with immunological recovery was rapidly achieved. In 2010 EFV/TFD/FTC was set and in 2014 he switched to RPV/TDF/FTC. Over the years he has always been fully compliant to ART and follow-up visits. In April 2023 he asked to switch to LA because he preferred injections over daily oral intake, so evaluation of risk factors was assessed: BMI was 27,66 kg/m², CD4 T cell count was 667 cell/mm³, HIV-RNA was steadily undetectable, historical genotype showed no RPV resistance. Switch to LA was performed. Initially viro-immunological check was done every 2 months showing a sustained virological suppression and a stable CD4 T cell count. No serious adverse event was reported. After one year we decided to switch to routinary follow-up every 6 months. In October 2024 his HIV-RNA was 353.352 cp/ml, CD4 T cell count was 469/mm³. He was immediately called for an unscheduled visit: he reported low-grade fever and asthenia in the last month but denied weight loss. He didn't miss any scheduled injection. Drug-drug interactions were carefully ruled out. VF in LA was confirmed, so we suggested to switch to BIC/FTC/TAF. In counselling we also asked for change in lifestyle: actually, he admitted an increase in physical exercise, especially in weightlifting activities, since June. After oral switch to BIC/FTC/TAF, HIV-RNA decreased with stable undetectability (last FU visit 4 months after switch). The genotypic resistance test is reported below (Table 1)

Conclusions: Although he had no risk factors for VF, we consider that physical activity could have played a key role: vascular supply of the muscle favors release from the drug depot, so higher blood flow in the muscle could have led to increased CAB+RPV uptake. LA plasma concentrations could have been affected by abnormal faster absorption. Presence of NNRTI mutations (K101P, E138K) discouraged us to restart RPV/TAF/FTC. Q148R is the most common INSTI-associated mutation in VF in LA which provides low level resistance to BIC: nevertheless, viral suppression was achieved with BIC/FTC/TAF. Currently little is known about risk factors leading to VF, so collecting more data in the rarest VF in PLWH with no risk factors could help us to identify borderline situations worthy of a closer clinical check.

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Viral infections in the immunocompromised host

CC 29 A CASE OF ATYPICAL PNEUMONIA

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Background: Mucormycosis is a rare but severe disease with high mortality, caused by Mucorales fungi. Main risk factors include uncontrolled diabetes, severe trauma, and prolonged glucocorticoid use. The incidence has increased with SARS-CoV-2, especially in India. Treatment combines radical surgery and systemic antifungals, primarily liposomal amphotericin B, followed by azoles, with an average duration of about 6 months.
Clinical Case: The patient is a 55-year-old woman from Romania, residing in Italy since 2004, with type II diabetes mellitus. On August 28, 2024, she was referred to the ER for glycemic decompensation. Tests showed a blood glucose level of 362 mg/dL, neutrophilic leukocytosis, and increased inflammatory markers. Abdominal ultrasound revealed right hydronephrosis and a renal abscess (52x42 mm), confirmed by CT. Empirical antibiotic therapy was initiated, later modified. Due to worsening inflammatory markers, she was transferred to the Infectious Diseases department on September 2, 2024. Upon arrival, she was cachectic, eupneic, and febrile. Antibiotic therapy was modified. On September 6, a percutaneous drainage of the abscess isolated an ESBL-resistant Escherichia coli. Subsequent ultrasound checks showed resolution of the abscess. On September 7, a CT scan revealed necrotizing pneumonia in the lower right lobe. Due to high bleeding risk, bronchoscopy with bronchoalveolar lavage (BAL) was not performed, and a four-drug antitubercular therapy was introduced, along with ceftaroline and meropenem. Due to worsening respiratory exchanges, a radiological check documented an extension of the pulmonary inflammatory picture with a lobar artery aneurysm and segmental pulmonary thromboembolism. A multidisciplinary evaluation indicated the need for right pneumonectomy to reduce recurrence and improve clinical outcome. The postoperative course showed improvement in respiratory function. Antibiotic therapy was discontinued on October 3. Intraoperative cultures on lung biopsy were negative for bacteria and mycobacteria. The patient was discharged home on October 9, 2024, in good condition. At outpatient checks, she had no fever or significant symptoms. Pathological anatomy of the removed lung showed fungal spread in the lymphovascular spaces, indicative of mucormycosis. Post-hospitalization blood tests showed normalization of leukocytosis and CRP. Given the improvement in well-being and blood tests, a watchful waiting approach with close monitoring was adopted.
Conclusions: Given the strong association between mucormycosis and uncontrolled diabetes mellitus, we focused on this clinical case. It presents peculiarities both at onset and in its overall course. Radical surgical therapy contributed to the favorable evolution of the patient's clinical and laboratory picture. Today, the patient shows no respiratory symptoms or recurrence of the inflammatory picture, with marked improvement in inflammatory markers.

Viral infections in the immunocompromised host

CC 30 A CASE OF VARICELLA ZOSTER VIRUS (VZV) ENCEPHALITIS IN A YOUNG IMMUNE-COMPETENT WOMAN AFTER MRNA COVID-19 VACCINE

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Background: Since the introduction of SARS-CoV-2 vaccines, there has been a notable increase in VZV reactivations following the administration of mRNA COVID-19 vaccines. The majority of these cases were dermatological and primarily affected older or immunocompromised individuals, typically after the first or second dose. In this report, we present a case of VZV encephalitis occurring after the third dose of the mRNA COVID-19 vaccine in a young, immunocompetent woman, with no skin involvement.

Case description: A 23-year-old woman with no significant medical history presented to the emergency department with headache and nausea, which began the day after receiving her third dose of the BNT162b2 COVID-19 vaccine, administered 4 days earlier. After being discharged, she returned the following day with psychomotor agitation and fever. No skin or mucosal lesions were noted.

An EEG revealed brief episodes of recurrent slow activity in the anterior regions of both hemispheres. A CT brain scan (figure 1) showed possible thalamic heterogeneity on the left side. A lumbar puncture revealed monocyte pleocytosis, normal glucose levels, and elevated protein levels in the cerebrospinal fluid (CSF). PCR testing of the CSF confirmed the presence of VZV DNA. The patient was admitted to the Infectious Diseases Unit and started on intravenous acyclovir 750 mg three times a day for 21 days, leading to a full recovery.

Two days after admission, a brain MRI was performed, revealing enlarged perivascular spaces in the subcortical white matter of the frontal gyrus, the superior frontal gyrus on the left side, and at the vertex (figure 2).

Discussion: In our case, the timing of VZV reactivation suggests a potential link to the administration of the mRNA COVID-19 vaccine booster. Interestingly, contrary to what is typically reported in the literature, the patient was both young and immunocompetent. Additionally, most documented cases involve dermatological manifestations, with central nervous system (CNS) involvement being rare.

From a pathogenic perspective, it is possible that the shift in CD8+ naïve T cell production following the vaccine could lead to a temporary reduction in VZV-specific CD8+ T cell production and activity, resulting in a loss of control over the latent infection and an increased risk of reactivation. Another potential explanation is that the interaction of the mRNA vaccine with Toll-like receptors (TLRs) may impair their ability to recognize VZV, thereby contributing to its reactivation.

This case report should serve as a reminder that atypical and severe VZV reactivation following mRNA COVID-19 vaccination should be considered and ruled out, even in young, immunocompetent patients.

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Viral infections in the immunocompromised host

CC 31 FULMINANT HEPATITIS DUE TO ENTEROVIRUS SYSTEMIC INFECTION IN A PEDIATRIC PATIENT

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Introduction: Enteroviruses (EV) are non-enveloped, single-stranded RNA viruses belonging to the Picornaviridae family, which includes poliovirus, coxsackievirus, echovirus, and other EV genotypes. While EV infections are common in children and often present with mild symptoms, certain strains can cause severe complications such as meningoencephalitis, myocarditis, and, more rarely, acute liver failure (ALF). PALF is a rare but severe condition with a high mortality rate and frequent need for liver transplantation. In 30% to 60% of cases, the underlying cause remains unknown.

Case Report: A nearly four-year-old child presented with high fever and progressive clinical deterioration. Initial laboratory findings showed leukocytosis (24,000/μL) and mild hypertransaminasemia (ALT 140 IU/L, AST 193 IU/L), along with positive IgM for Epstein-Barr virus (EBV), indicating acute EBV infection. Two days after admission, the child developed jaundice, marked hypertransaminasemia (ALT 7,026 IU/L, AST 12,450 IU/L), hyperbilirubinemia (4.31 mg/dL), and coagulopathy with an INR of 2.65, progressing to fulminant hepatic failure. The clinical course worsened with increased ammonia levels (131.6 μg/dL), altered mental status, and further coagulation impairment (INR 4.96).

Molecular testing identified enterovirus RNA in the blood (30,476 copies/mL), cerebrospinal fluid (4,240 copies/mL), stool, and nasopharyngeal swab, while EBV DNA levels were low (182,980 copies/mL). The child received supportive care, including antibiotics, acyclovir, N-acetylcysteine, arginine, fresh frozen plasma, and prothrombin complex concentrate. Therapeutic plasma exchange (TPE) and continuous veno-venous hemofiltration (CVVH) were initiated, leading to gradual clinical and biochemical improvement.

Discussion: Enterovirus-induced fulminant hepatitis is exceptionally rare in pediatric patients. While EV infections are typically self-limiting, they can occasionally cause severe complications, particularly in immunocompromised individuals or in the presence of co-infections. In this case, the co-infection with EBV may have contributed to immune dysregulation and worsened liver injury. Although EBV DNA levels were low, the presence of EBV-specific IgM suggests recent infection, which may have created a permissive environment for EV-induced liver damage.

The successful outcome was likely due to early diagnosis and timely initiation of extracorporeal therapies. Early consideration of TPE and CVVH was critical in preventing irreversible multi-organ failure.

This case underscores the importance of early diagnosis and molecular diagnostics in identifying rare causes of PALF. The successful use of combined TPE and CVVH highlights the potential benefit of extracorporeal therapies in severe cases of pediatric fulminant hepatitis. Further research is needed to better understand the mechanisms of EV-induced liver injury and to develop targeted treatment strategies.

Viral infections in the immunocompromised host

CC 32 HHV-6 DNA IN CEREBROSPINAL FLUID OF HIV PATIENTS WITH UNRECOGNIZED NON-HODGKIN CEREBRAL LYMPHOMA: TRUE ENCEPHALITIS OR A DIAGNOSTIC RED HERRING? A CASE REPORT

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Background: Human herpesvirus-6(HHV6)infection is common in childhood and is responsible for roseola infantum. HHV6 can cause encephalitis in children and,less frequently,in adults.Primary HHV6 infection may be complicated by neurologic sequelae including encephalitis,acute encephalopathy with biphasic seizure syndrome,or demyelinating disease,regardless of age.In adults,HHV6 encephalitis can occur in both primary infection and in reactivation.Studies showed that adults might be seropositive for HHV6,without presenting any risk of active viral infection,known as chromosomally integrated HHV6 DNA(ciHHV6)individuals. In presence of HHV6 DNA in cerebrospinal fluid(CSF), accurate differential diagnosis between HHV6 encephalitis and presence of viral DNA in CSF of ciHHV6 individuals must be performed to avoid misdiagnosis.We report a case of a PLHV in whom the onset of neurological symptoms had been attributed to HHV6 encephalitis,but which later turned out to be the onset symptoms of a cerebral lymphoma.

Case report: A 38-yrs male PLHV followed at Outpatients Clinic of IRCCS Policlinico S.Matteo showed up to emergency department complaining about sudden onset of right hemiface hypoesthesia,lagophthalmos and deviation of oral rim.He received diagnosis of Bell's palsy and started a steroid therapy.He was in treatment with dolutegravir/lamivudine with HIV-RNA undetectable,974 cells/mmc CD4.Due to worsening of neurological symptoms during following wks he came back to ER where rachicentesis was performed.Analysis on CSF were negative except for detection of 1480cp/ml of HHV6DNA so antiviral therapy with ganciclovir 5mg/kg bid was started.During following dys the pt didn’t show any clinical improvement;HHV6 DNA research in blood documented a viral load of 221400000 cp/ml.However,given the detection of HHV6-DNA in CSF and blood showing CSF/blood ratio<1 investigation of viral DNA on hair bulb was conducted,and it showed 212428cp\100.000cell.The presence of chromosomally integrated HHV6 was confirmed,excluding related HHV6 encephalitis.Another rachicentesis was performed,together with flow cytometric analysis of the CSF,leading to a diagnosis of Lymphoma Non Hodgkin typeB CD10+ CD20+ with Myc rearrangement and leptomeningeal localization.BOM,chest-abdomenCT and PET resulted negative.BrainMRI showed focal enhancement of III,VI,VII cranial nerves.After 3cycles of immune-chemoterapy he achieved a complete remission.

Conclusions: Although HHV6 infection could be complicated by neurological sequelae including encephalitis,acute encephalopathy with biphasic seizures sd,or demyelinating disease,the presence of HHV6 DNA in CSF alone isn’t sufficient to diagnose HHV6 encephalitis.Even if germ-line inheritance of HHV6 occur in about 1% of population,it’s important to be careful in interpreting results of PCR testing.The CSF/blood replication ratio<1 must give an idea about presence of ciHHBV6 and encourage to seek alternative diagnosis.

Viral infections in the immunocompromised host

CC 33 ONSET OF KAPOSI SARCOMA IN A PLWH WITH UNDETECTABLE HIV-RNA AND HIGH CD4+ COUNT: A RARE BUT POSSIBLE EVENT

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Background: Kaposi Sarcoma (KS) is an AIDS defining condition, but still occurs among PLWH also with immune restoration, mainly as persistent-recurring form in spite of ART. We present the case of a KS diagnosis in an undetectable and immunologically-recovered PLWH.

Case Presentation: The patient was 52 yo Italian MSM with HIV infection diagnosed abroad in 2016 during a stomatitis episode, in CDC stage B1 (seborrhoeic dermatitis), CD4-nadir of 535 cells and baseline HIV-RNA viral load of 229790 cp/ml, wild type HIV on GRT. He had a previously treated syphilis, dyslipidaemia and dysthyroidism. He started ART firstly with EFV/FTC/TDF, and since 2019 with DTG/3TC with full virological response and CD4 recovery (CD4+ 686 cells/mcl with CD4/CD8 of 0.48 at that time).

He refers onset of brown skin lesions at legs in October 2023, without mentioning it to the doctor. At that time CD4+ count was 731 cells and HIV-RNA undetectable. After some months he was diagnosed as vasculitis by a dermatologist and stated a local therapy, with slow but progressive extension of the lesions (Fig. 1). A skin biopsy revealed dermic not ulcerated KS, with intense HHV-8 cells positivity at immunohistochemistry; HHV8-DNA vas detected in peripheral blood. A full-body CT scan and endoscopies of GI tract revealed no other disease localization. ART was switched in BIC/FTC/TAF. After 2 months many new skin lesions appeared and were again biopsied, confirming the diagnosis. At that time CD4+ was 929 cells (25%) and HIV-RNA undetectable, with CD4/CD8 of 0.7. Considering the quick onset of copious lesions with high cumulative extension (Fig. 2), chemotherapy with liposomal doxorubicin was proposed by oncologist and recently started. Latest blood test showed a CD4/CD8 of 0.5. After the first chemotherapy administration skin lesions became smaller and dryer, but the patient experienced oral mucositis (WHO 2-3), nausea, chest pain, fatigue.

Discussion and Conclusions: Few case series of KS occurring or recurring in aviremic PLWH despite full immune recovery have recently enhanced this emerging and difficult-to treat condition. They are mainly indolent and mucocutaneous but a validated prognostic-specific staging in this field is lacking. Thus, indolent skin lesions may be aesthetically unacceptable and perceived as stigmatizing. Therapeutic approach can be local or systemic chemotherapy with high toxicity; PD-Checkpoints inhibitor may play a role in the future. Pathogenesis may reside in loss of specific anti-HHV-8 response, and data shows that CD8 hyperlymphocytosis and low CD4/CD8 correlates with increased KS risk in undetectable PLWH, suggesting a role of persistent immune activation. This may favour a triple vs dual therapy, but there are no evidence of risk rates associated with different ART, included PI-based. Multicenter cohorts collecting aviremic PLWH with KS are needed to verify extent and evolution of this emerging condition.

Ref. Palich R et al, Cancers (Basel). 2021.

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Viral infections in the immunocompromised host

CC 34 SAFETY AND LONG-TERM IMMUNOLOGICAL AND VIROLOGICAL OUTCOMES OF LENACAPAVIR PLUS FOSTEMSAVIR-BASED OBR IN THE TREATMENT OF A CASE OF MDR HIV INFECTION

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Managing multidrug-resistant (MDR) HIV in treatment-experienced individuals still poses significant challenges due to limited therapeutic options. A promising approach is the use of lenacapavir (LEN), a novel long-acting HIV capsid inhibitor, combined with an optimized backbone regimen(OBR). However, research exploring these specific combinations remains relatively limited.

The patient, a 55-year-old cisgender woman diagnosed with HIV in the early 1990s, had a long history of ART with inconsistent adherence and resistance to all major drug classes. Despite multiple ART regimens over decades, she never achieved sustained virologic suppression or immune recovery, leading to uncontrolled HIV-1 infection (CDC '93 category C3, subtype B, tropism CXCR4) and bacterial sepsis at the time of referral.

Her treatment history included regimens such as AZT +/- SQV, LPV/r + AZT/3TC, LPV/r + TDF + ddT, TDF/FTC + DRV + RAL, DRV/c + RAL, DRV/c/FTC/TAF +/- DTG, FTR + DRV/r + TAF, and TDF/FTC/DOR + double-dose DTG. A detailed timeline of her history of ART regimens is provided in Table 1A. Besides, serial genotypic resistance tests revealed extensive resistance mutations, leaving few therapeutic options (Table 1B). In March 2024, she was started on a complex regimen combining LEN with DRV/r 600 mg bid, DTG 50 mg bid, FTR 600 mg bid, and TAF/FTC 200/10 mg qd. LEN was chosen due to its novel mechanism of action and full expected activity, while DRV/r and DTG were included for their residual susceptibility and ability to strengthen the regimen; TAF/FTC was retained to leverage the crippling effect of the M184V mutation on viral replication.

The regimen was well-tolerated, with only mild injection-site reactions (erythema and induration) following first LEN administration and the onset of a transient subcutaneous nodule after second injection, which resolved without sequelae. Viral load declined rapidly, dropping from 193,156 cp/mL to 34 cp/mL within three months, and remained suppressed (<200 cp/mL) at 52 weeks (Figure 1). However, transient viral blips occurred during episodes of CMV reactivation, which impaired oral drug absorption and temporarily increased HIV-RNA levels (e.g.,1,001 cp/mL in June 2024)(Fig.1). These blips highlighted the impact of concurrent infections on HIV control.

Immunologically, the patient experienced significant recovery, with CD4 counts increasing from 10 to 843 cells/μL (Fig.1), %CD4 raising from 5 to 31%, and the CD4/CD8 ratio improving from 0.04 to 0.9 by 52 weeks.

This case underscores LEN-based regimens 's potential to achieve rapid and sustained virologic suppression in HTE individuals with MDR HIV, even in the context of prior adherence challenges and extensive resistance. It also emphasizes the importance of addressing comorbid conditions, such as CMV, to optimize management. The successful outcome demonstrates the crucial role of innovative therapies like lenacapavir in transforming the treatment landscape for complex HIV cases.

Attach: https://www.icar2025.it/upload/clinicalCaseAttach/Attach_CliCase_30.jpg

Viral infections in the immunocompromised host

CC 35 THE COMPLEXITIES OF TREATING VISCERAL LEISHMANIASIS IN VULNERABLE IMMUNOCOMPROMISED PATIENTS

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Background: Leishmaniasis poses a significant health threat to immunocompromised individuals, particularly those living with HIV/AIDS or undergoing immunosuppressive therapy, as they are at a heightened risk of developing severe forms of the disease (1). Despite this, research on managing visceral leishmaniasis (VL) in immunocompromised patients without HIV remains scarce.

Case(s) description: We report five cases of visceral leishmaniasis (VL) in immunocompromised patients admitted to the Lazzaro Spallanzani National Institute for Infectious Diseases between January 2023 and January 2025 (Table 1). Three patients had mieloma multiple, one patient had thymoma and Good's syndrome and one patient lung adenocarcinoma. All patients presented with fever, anemia, and bone marrow aspirates (BMA) revealed amastigotes. BMA and peripheral blood PCR for Leishmania infantum were positive. Treatment with liposomal amphotericin B (LAB) was administered for five consecutive days, followed by weekly doses for a total of ten. Three out of four patients received monthly secondary chemoprophylaxis with LAB. Patient 1 had three relapses, each treated with LAMB for induction and monthly maintenance, with miltefosine added for the last relapse. The patient is now disease-free for 10 months. Patient 2 experienced one relapse, treated with LAMB induction and ongoing monthly maintenance. Patient 3 had two relapses after discontinuing monthly prophylaxis and is currently receiving treatment. Patient 4 has remained relapse-free for 6 months, and, finally, patient 5 had one relapse. PCR for Leishmania was negative in all patients during treatment.

Discussion: Visceral leishmaniasis in immunocompromised patients, particularly those without HIV infection, poses unique challenges due to the absence of standardized treatment guidelines. This gap underscores the need for standardized treatment protocols tailored to this patient group. Our case series highlights the importance of adopting individualized therapeutic approaches. Although liposomal amphotericin B and secondary prophylaxis were employed, frequent relapses emphasized the need for ongoing research to optimize treatment strategies. The successful resolution of refractory cases through combination therapy indicates the need for standardized treatment protocols tailored to this patient group.

Attach: https://www.icar2025.it/upload/clinicalCaseAttach/Attach_CliCase_32.JPG

Viral infections in the immunocompromised host

CC 36 VENTRICULITIS IN AIDS-PRESENTER PATIENT: DIAGNOSTIC DILEMMA BETWEEN TOXOPLASMOSIS AND MILIARY TUBERCULOSIS

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Background: Toxoplasmic ventriculitis in AIDS is often associated with other conditions, such as Herpes Zoster Virus (VZV) and Tuberculosis (TB). VZV infection of the central nervous system is common in HIV individuals and should be considered in ventriculitis cases. HIV increases the risk of developing active TB.
Case presentation: A 64-year-old woman with severe deterioration of her general condition presented to the emergency department due to rapid neuro-cognitive decline. She was admitted to the intensive care unit, where she was diagnosed with HIV. Following viro-immunological tests (CD4+ lymphocyte count and HIV-RNA at 39,000 copies/ml), a diagnosis of AIDS was confirmed. A chest X-ray showed bilateral reduced parenchymal transparency with pseudonodular opacities, suggesting miliary pneumonia. A CT scan revealed tri-ventricular hydrocephalus with trans-ependymal resorption, indicative of meningoencephalitis. A ventriculostomy was placed. The clinical, radiological and cerebrospinal fluid (CSF) findings (notable hyperprotidorrachia and hypoglycorrhachia) strongly suggested neuro-TB and miliary TB in an HIV-positive patient with severe immunosuppression. Despite an indeterminate Quantiferon test, the radiological findings, low CD4 count, and the patient's critical condition led to the decision to begin anti-TB therapy for suspected miliary tuberculosis. This was done pending further microbiological results and, in any case, before starting anti-HIV therapy (cART), as recommended by the EASC Guidelines. Following the isolation of Toxoplasma gondii from the CSF, cerebral toxoplasmosis was onfirmed, and trimethoprim/sulfamethoxazole was administered and antituberculosis therapy was therefore interrupted. After two months of hospitalization, the patient showed significant neurological and immunovirological improvement.
Discussion and conclusions: This case emphatizes the importance of considering a broad differential diagnosis in HIV patients with ventriculitis, including Toxoplasma gondii, VZV, and TB. HIV testing should be performed in all patients with nonspecific neurological symptoms. Cerebral toxoplasmosis should be considered in AIDS patients with neurological symptoms, even without abscesses. Diagnosing latent tuberculosis infection (LTBI) is crucial for preventing further spread. HIV does not affect the Quantiferon response in active TB, but it can influence uncertain results in LTBI. HIV individuals often present with atypical TB, including sputum smear-negative and extrapulmonary cases. The absence of a T-lymphocytic response can result in miliary TB, complicating diagnosis and treatment. A treatment based on clinical suspicion, even if apparently risky, could represent an advantageous choice for critically ill patients awaiting microbiological diagnostic clarifications. This underlines the value of an "ex juvantibus" diagnostic approach in the management of complex AIDS-related clinical manifestations.

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