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# Abstract Supplement

HIV Glasgow - Virtual
5–8 October 2020




Volume 23, Supplement 7, October 2020

WILEY

# Abstract Supplement
# HIV Glasgow - Virtual
# 5–8 October 2020

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SPEAKER ABSTRACTS

# Keynote and Lock Lectures

## KL1

### HIV and Obesity

A Carr

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Obesity/overweight is common in the general population and results in an increased risk of death and multiple morbidities. Weight gain has been noted in more HIV-infected adults over the last three years. This presentation will summarise some basic epidemiology of obesity, and focus predominantly on its relationship to antiretroviral therapy. The existing data suggest that some, if not all, integrase inhibitors are associated with weight gain, as is tenofovir alafenamide, whereas tenofovir disoproxil fumarate and efavirenz may inhibit weight gain. Some weight gain in adults initiating antiretroviral therapy is due to a 'return-to-health' or a 'return-to-societal norm', with substantially less weight gain in patients switching antiretroviral therapy or initiating HIV pre-exposure prophylaxis. The weight gain appears to be modest for most patients, but outliers exist, with weight gain more likely in women and in those of Black race. There are minimal data on any underlying mechanism(s); possibilities include increased appetite, reduce physical activity, or greater ability of adipose tissue to store lipid. Multiple unknowns remain, including preventative and treatment strategies, reversibility, outcomes beyond two years of antiretroviral therapy and whether three (rather than one) antiretroviral drug classes can all affect body weight. Answers will only come from well-designed randomised trials that keep in mind lessons learned from the evaluation of other HIV-related comorbidities, in particular HIV lipodystrophy.

## KL2

### COVID-19: Where Are We Now and What Next?

K Lacombe

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The SARS-CoV2 infection responsible for Covid-19 has hit the world mostly unprepared for a massive pandemic due to a new coronavirus with widely diverse clinical phenotypes, ranging from completely asymptomatic expression to septic shock with rapid death. Because there is no cross-immunity with other coronaviruses, and barriers to virus dissemination have not been optimal at the beginning of the viral spread, the pandemic has rapidly overflowed health systems. Covid-19 has soon represented a global issue, addressing the clinical research effort but also challenging societies in their response to the threat to the most at-risk populations (including the elderly, obese and those with cardiovascular or pulmonary chronic conditions). In this plenary talk, we will share some basics in virology and pathophysiology, in order to better understand the features of viral transmission and how to prevent it, as well as the clinical characteristics of Covid-19. We will then review what we know and do not know about therapeutics (repurposed drugs including antivirals and corticosteroids) as well as management decisions adapted to the clinical status (anticoagulation, oxygen therapy) and proven to have significantly decreased the burden of death. Finally, we will discuss the impact of Covid-19 on hospital organisation as well as on ambulatory medicine. The Covid-19 pandemic symbolises the necessity to anticipate the emergence of new pathogens in an era where globalisation and climate change may cause considerable disruption to the course of the world.

## KL3

### PrEP in Practice

J Molina

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PrEP is an effective prevention method to reduce the risk of HIV acquisition and has been recommended by WHO since 2015 as an additional prevention method when HIV-incidence is 3% or greater. PreP when used in addition to wide scale HIV testing and immediate treatment, has the potential to contain the HIV/AIDS epidemic. PrEP should be proposed to all sexually active adults and adolescents taking into consideration past but also future risk of HIV acquisition. Such populations include non-condom using MSM, transgender individuals, and heterosexual men and women in groups with a high HIV incidence. Before starting PrEP a negative HIV antigen/antibody assay should be obtained, ideally within seven days of PrEP start. If there is a clinical suspicion of acute HIV infection, HIV RNA testing should be performed and PrEP initiation deferred. Additional testing include serum creatinine, tests for hepatitis (A, B and C), and bacterial STIs (*N. gonorrhoea*, *C. trachomatis* and syphilis). Daily TDF/emtricitabine (one pill every day) is the recommended PrEP regimen for all populations. For MSM there are two alternatives: on demand TDF/emtricitabine (or 2-1-1) or daily TAF/FTC in case TDF is contraindicated (eGFR < 60 mL/mn or osteoporosis). Other PrEP regimen will likely be approved in the near future. The first prescription should be written for one month, and individuals seen one month later to assess PrEP tolerability, adherence and to repeat HIV testing to rule out acute infection at the time of PrEP initiation. Next visits are planned every three months to assess PrEP safety, adherence to the regimen, and to allow early diagnosis of STIs, assess mental health issues and chemsex use. Should an HIV test return positive during follow-up, after excluding a false-positive result in a well-adherent individual, a fully suppressive ART regimen should be started, pending the results of a genotypic resistance test. Upscaling PrEP implementation will need involvement and support from the community, user-friendly access to PrEP services including teleheath, the use of generic drugs, and task shifting.

## LL1

### Lock Lecture: Managing costs while delivering state-of-the-art HIV care

R Walensky

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The 2020 Lock Lecture will focus on the data related to costs and cost-effectiveness of antiretroviral therapy, pre-exposure prophylaxis and generic regimens in the US and in Europe. We will review the influence of costs in treatment guidelines and how different costs across countries may relate to overall rates of HIV virologic suppression and PrEP

access. We will describe the methods of cost-effectiveness, review related ART, PrEP and generic cost-effectiveness studies and discuss how the results of these studies have been used to motivate policy.

# HIV and Obesity

## O111

### Fat distribution and density in people living with HIV with ≥5% weight gain

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**Background:** We assessed ectopic fat quantity and density in virally suppressed ART-experienced PLWH who had weight gain (WG) after switching to INSTI-based ART (INSTI-s) versus remaining INSTI-naive (INSTI-n) on stable ART.
**Materials and methods:** In an observational cohort study from 2007 to 2019 at Modena HIV Metabolic Clinic, PLWH were grouped as INSTI-s versus INSTI-n and matched for sex, age, first visit BMI and follow-up duration. Significant WG was defined as an increase of ≥5% weight from first visit over follow-up. Body composition (BC) was assessed at first visit and at last evaluation. In the INSTI-s group, the first visit was prior to switch. DXA assessed weight, total lean and fat mass. Computed tomography assessed visceral (VAT), subcutaneous (SAT) and epicardial (EAT) adipose tissue area and density (VAT-d, SAT-d and EAT-d), liver-to-spleen density ratio (L/S) and psoas muscle density (P-d).
**Results:** A total of 418 PLWH (71% male), mean age 50 (±8) years with median HIV duration of 17.4 years (IQR 12.3 to 22.6) were analysed at first visit and after four years (±2.2). INSTI-s switched to DTG in 68 (32%), RAL in 131 (62%) and ELV/c in 11 (6%) cases. INSTI-n were on PI in 96 (46%) and on NNRTI in 105 (51%) cases. At the first visit, BC measurements were similar in INSTI-s and INSTI-n groups (all $p > 0.05$). At follow-up, the mean change in body weight (1.6 vs 2.4 kg, $p = 0.3$) and the prevalence of WG (24.6% vs 27%, $p = 0.66$) were similar for INSTI-n versus INSTI-s. Among weight gainers only, the change in BMI and absolute weight was greater in the INSTI-s versus INSTI-n group (11.8 kg vs 9.4 kg, $p = 0.02$). The VAT increase over the interval was similar in both groups. The VAT-d decreased in the INSTI-s group, suggests a change in fat quality. Other changes in BC were not observed (Table 1).
**Conclusions:** Over a 4-year interval, PLWH with ≥5% WG INSTI-s had a greater gain in BMI compared to those who remained INSTI-naïve, but there were no differences in the changes in ectopic fat depots. The differences in VAT density associated with INSTI require further studies.

## O112

### Weight gain plateaus at 24-months follow-up for ART-experienced patients that switched to dolutegravir in a Nigerian early adopter cohort

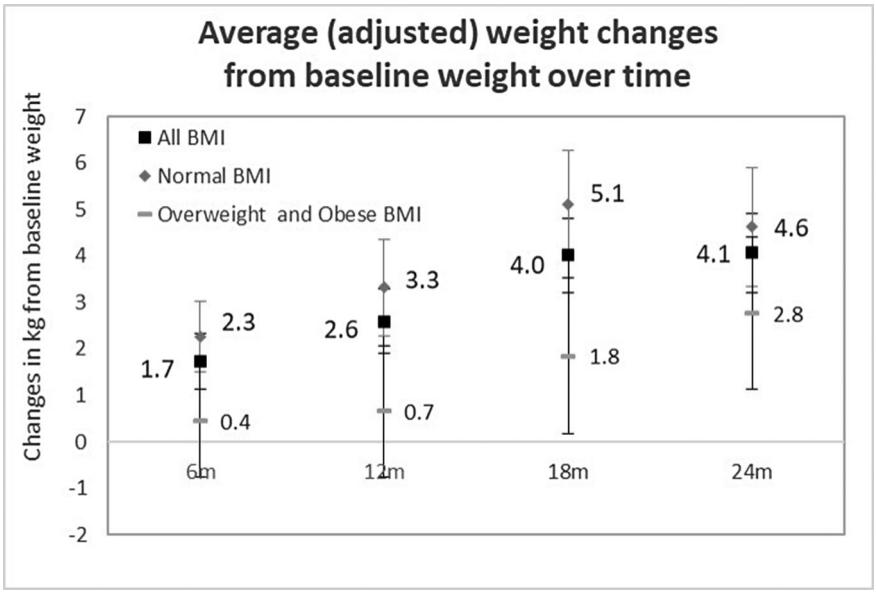
J Campbell[1]; O Abudiore[2]; I Amamilo[2]; J Harwell[3]; C Middlecote[4]; J Conroy[5]; W Eigege[2]; N Otubu[2]; J Jiboye[2]; L Anomnachi[2]; F Lufadeju[2]; C Amole[6]; O Wiwa[2]; O Agbaji[7]; D Anweh[8] and S Akanmu[9]

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**Background:** Weight gain has been associated with integrase inhibitor class of drugs including the widely adopted dolutegravir (DTG). A pilot study in Nigeria found an increase in appetite was a prominent self-reported side-effect. This analysis assessed weight and body mass index (BMI) changes for the same cohort at 24-months follow-up (24 m).
**Materials and methods:** ART-experienced adult patients with an intolerance to NNRTIs switched to TDF/3TC/DTG (TLD) starting July 2017 at three pilot sites in Nigeria. Study subjects who completed 24 months on TLD by end of March 2020 were included in the analysis. We analyzed weight and BMI changes at 6-month intervals up to

**Abstract O111-Table 1. Fat distribution and density of both INSTI-n and INSTI-s PLWH who experienced weight gain over a follow-up**

| PLWH with WG only at follow-up | INSTI-n, n = 51 | INSTI-s, n = 57 | *p* | INSTI-n, DELTA change n = 51 | INSTI-s, DELTA change n = 57 | *p* |
|---|---|---|---|---|---|---|
| Follow-up, years, mean (± SD) | 4 (±1.1) | 4.5 (±2.5) | 0.35 | 4 (±1.1) | 4.5 (±2.5) | 0.35 |
| BMI kg/m², mean (± SD) | 25 (±4.2) | 25.4 (±3.9) | 0.5 | 1.9 (±0.32) | 2.47 (±0.3) | 0.006 |
| Obesity (%) | 11.8% | 14% | 0.95 | +1.45% | +2.52% | 0.22 |
| VAT, cm², mean (± SD) | 165.7 (±81.2) | 166.1 (±77.4) | 0.82 | 36 (±15.8) | 51.1 (±14.4) | 0.18 |
| SAT, cm², mean (± SD) | 194.9 (±112.4) | 205.8 (±106.8) | 0.5 | 45.5 (±13.8) | 61.3 (±12.6) | 0.06 |
| EAT, cm², mean (± SD) | 133.6 (± 49) | 132.5 (±62.2) | 0.5 | 9.8 (±9.6) | 12.7 (±6.14) | 0.16 |
| VAT-d, HU, mean (±SD) | −89.8 (±28) | −94 (±.6.9) | 0.8 | −2(±2) | −5.8 (±1.9) | <0.001 |
| SAT-d, HU, mean (±SD) | −100.4 (±4.9) | −97.6 (±27.8) | 0.56 | −3.7 (±2.3) | −4.15 (±2.1) | 0.22 |
| EAT-d, HU, mean (±SD) | −81.9 (±4.9) | −81.9 (±5.4) | 0.48 | −1.1 (±2.4) | −3.4 (±1.8) | 0.96 |
| Liver to spleen ratio, mean (± SD) | 1.2 (±0.2) | 1.2 (±0.2) | 0.9 | −0.04 (±0.06) | −0.15 (±0.06) | 0.62 |
| Psoas-d, HU, mean (±SD) | 53.8 (±5.7) | 53.9 (±5.7) | 0.77 | 1.4 (±1.6) | 3.6 (±1.9) | 0.64 |
| Total lean, kg, mean (± SD) | 48. (±9.8) | 47.2 (±9) | 0.89 | −0.6 (±0.7) | 0.5 (±1.1) | 0.37 |
| Total fat, kg, mean (±SD) | 20.1 (±8.6) | 19.5 (±6.4) | 0.9 | 5.5 (±0.9) | 6.2 (±1.7) | 0.3 |




**Abstract O112-Figure 1. Average (adjusted) weight changes from baseline weight over time. Square: all BMI. Diamond: normal BMI. Dash: overweight and obese BMI.**

24 months from time of switch, using generalized estimated equations adjusted for facility clustering, age, and gender.

**Results:** Two hundred and seventy-one subjects were enrolled in the original study; of these, 206 were ART experienced and had weight and BMI data at baseline and at least one other time point. Sixty-four percent were female, median age 47, 62% had a normal baseline BMI and median weight of 62 kg and 95% were virally suppressed time of switch (n = 130). For all BMI categories combined and those with normal baseline BMI, weights increased at 6, 12, and 18 m and then plateaued at 24 m ($p < 0.01$). There was no interaction of weight gains with gender or age at 24 m. Patients with overweight or obese baseline BMI continued to gain weight over time with a 2.8 kg increase at 24 m ($p < 0.01$). At 24 m, of those subjects with normal baseline BMI, 35% had weight gain of 10% or more, and 34% had increased in BMI category to overweight; there was 4% treatment-emergent obesity (Figure 1).

**Conclusions:** Supplementing previous weight increase findings, we found evidence to support a plateauing of weight increases in most patients at 24 m. However, patients with above-normal baseline BMI were also starting to exhibit weight gains. This study was not originally designed to measure weight changes and does not compare normal weight gains in the general population. These real-world findings show that weight gains should be monitored in patients on TLD and patients and clinicians should work to mitigate weight gains along with other risk factors especially in the first two years on TLD.

# Ageing, Paediatrics and Cancer

## O121

### HIV and ageing

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In the last decades, HIV-infected population has significantly aged in high-income countries. Two main reasons explain the growing number of older PLWH: 1) the increased rate of new HIV cases in older individuals and 2) the access to an effective antiretroviral therapy, with the consequent improvement of the patients' life expectancy. Other factors, however, have also contributed such as the use of less toxic antiretroviral drugs and the better care and treatment of common coinfections and cardiovascular risk factors. In addition to the increasing incidence of PLWH aged 50 years or older, there is much evidence that HIV-infected population experience an accentuated aging process compared with general population. As a result, older HIV-infected persons exhibit an excess burden of co-morbid conditions and a higher risk of polypharmacy, frailty and other age-related conditions. Older adults typically present a chronic low-grade inflammatory phenotype (inflammaging); in older PLWH, however, these levels are higher due to additional factors commonly associated with HIV infection [cytomegalovirus (CMV) and hepatitis coinfections, traditional risk factors, ART toxicities, microbial translocation, residual HIV replication. . .], which could be the reason of the higher prevalence of comorbidities. The fact that both HIV and some ART drugs can affect the hallmarks of aging could also play a role to explain the accentuated aging. In addition, there are also data that support that the process is also accelerated, a premature onset, although this is still a controversial topic.

## O122

### What is new in HIV paediatrics?

H Lyall

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PMTCT of HIV is highly effective, infected children having declined from 400 000 in 2000 to 160 000 in 2018. However, we missed the WHO target of 40 000 infant infections for 2018 and half that for 2020, and we do not yet know the potentially negative effect of the pandemic on PMTCT services this year. For HIV infected infants, mortality remains high, diagnosis frequently delayed, and few achieve viral suppression in the first year of life. Recent studies have demonstrated that a point of care HIV PCR diagnosis in the first weeks of life can make a significant difference to this cascade. Access to modern combination ARVs remains an issue, with lack of appropriate dosing and formulations. This year sees the approval of a 5 mg dolutegravir tablet (dispersible) for use down to four weeks of age (3 kgs), but only seven years after approval for adults. The availability of this integrase inhibitor for infants will harmonise dosing for all ages, and provides a palatable and robust option where full viral suppression remains difficult to achieve on PI/NNRTI regimes in infants. Currently, children aged

<6 years (<25 kgs) do not have access to fixed dose combinations, but pharmacokinetic modelling suggests that the FDC "Biktarvy" may be considered down to two years of age. The paradigms of rapid drug development used for antivirals during the pandemic were applied to all ages simultaneously, and this must be considered for future HIV drug development. Worldwide, there are now over 15 million HIV exposed uninfected children (HEUs), recent studies show that they have an increased risk of infections, developmental delays, stunting, and other issues. The future for HEUs should be not just HIV free, but also with every opportunity to thrive, studies are underway to better understand influences on their outcomes.

# O123

## Cancer screening and treatment in HIV

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People living with HIV (PLWHIV) have an increased risk of developing cancer and cancers have become the leading cause of death among this population in France [1]. The advent of the highly active antiretroviral therapies (HAART) has led to a significant decrease in the incidence of AIDS-related cancers (Non-Hodgkin Lymphoma (NHL), Kaposi's disease and cervical cancer) [2]. However, there is currently a resurgence of Kaposi's disease among PLWHIV on HAART despite suppressed HIV viremia [3] and the relative risk for PLWHIV of developing NHL remains 10 times higher [4]. Regarding non-AIDS-related cancers, some associated with oncogenic viruses (anal cancer, Hodgkin's lymphoma, hepatocarcinoma and head and neck carcinoma) or not (lung cancer and melanoma) are much more frequent among PLWHIV [5-8]. Thus, specific organised cancer screening campaigns should be offered to this population such as annual clinical skin examination and proctological exam [9] without ignoring screening tests for general population (in France: breast, cervical and colorectal cancers). High performance of HAART on suppressing HIV replication has led to massive improvement in survival and prevention of comorbidity and the international recommendations are now to start antiretroviral therapies as soon as possible [10]. Regarding the management of PLWHIV with cancer, it is increasingly accepted that the same oncologic treatments should be offered to this population (with rare exceptions). However, drug interactions between HAART and oncologic treatments can lead to serious unwanted effects or to a reduction in the therapeutic effects, therefore they require expertise [11] and a close monitoring, especially in immunotherapy [12]. Furthermore, PLWHIV remained even on HAART more exposed to infections and specific prophylaxis should be considered during their cancer treatment course [9;13]. Although HIV-positive serology remains an exclusion criterion for many cancer clinical trials, therapeutic innovation should be offered to PLWHIV by broadening inclusion criteria and conducting specific trials.

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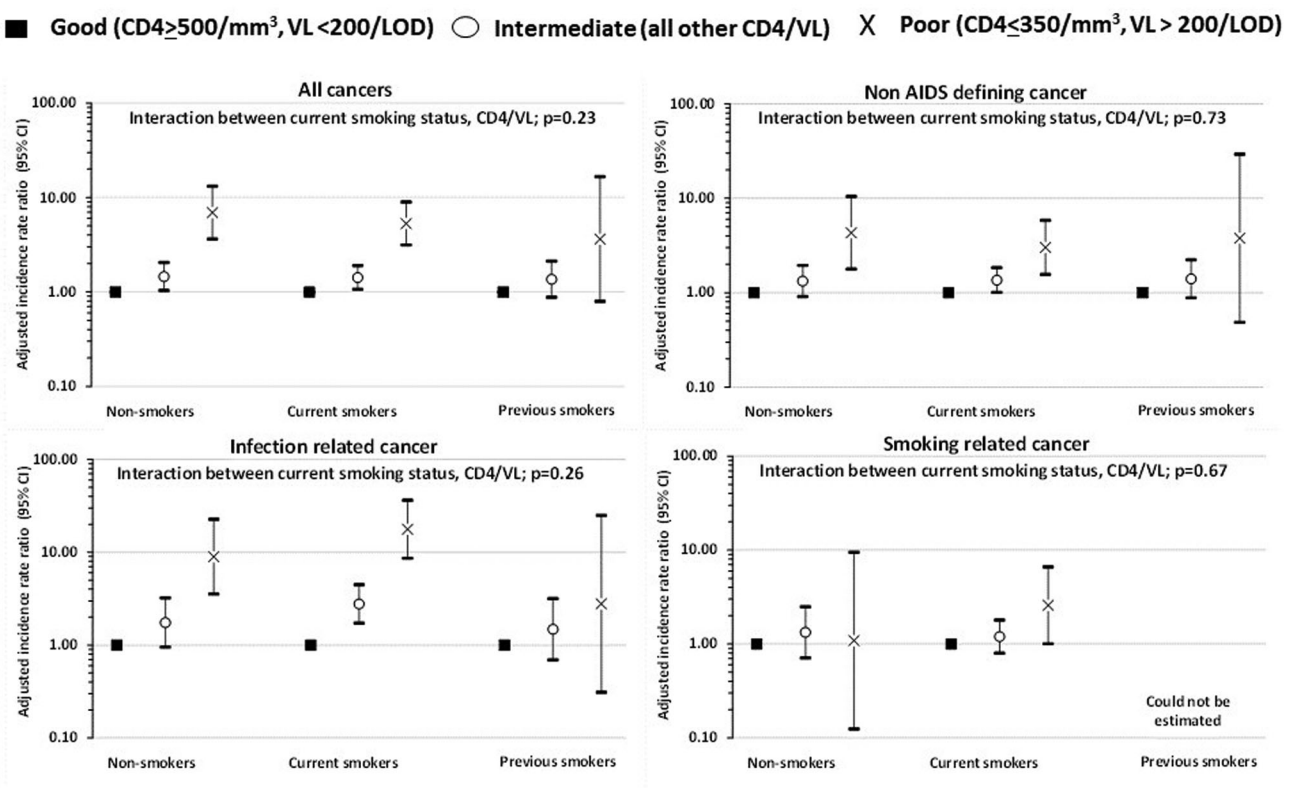
# O124

## The relationship between smoking, CD4, viral load and cancer risk in HIV-positive adults

A Mocroft

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**Background:** Smoking and other risk factors for cancer are highly prevalent in PLHIV. It is unknown if there is an interaction between CD4 count and viral load (VL) and smoking, increasing the vulnerability of PLHIV to carcinogenic smoking effects.
**Material and methods:** Adults enrolled in RESPOND with information on baseline and follow-up smoking status were included. Smoking status was classified as never, ex-smoker and current smoker. CD4/VL outcomes were classified as 'good' (CD4 > 500/mm$^3$ and VL < 200 copies/mL), 'poor' (CD4 < 350/mm$^3$ and VL > 200) and 'intermediate' (all other CD4/VL combinations). Poisson regression investigated the interaction between current CD4/VL, current smoking status and all cancers, non-AIDS defining cancers (NADC), smoking-related cancers (SRC) and infection-related cancers (IRC). Models were adjusted for a range of baseline confounders (Figure 1).
**Results:** Of 19 964 persons included, 14 741 (73.8%) were male, 8209 (41.1%) were never smokers, 8930 (44.7%) current and 2825 (14.2%) ex-smokers at baseline. CD4/VL outcomes at baseline were poor for 707 (3.5%), intermediate for 9102 (45.6%) and good for 10 155 (50.9%). There were 520 cancers in 513 persons during 75 615 person-years of follow-up (PYFU; median 3.5 [IQR 2.0 to 6.2] years per person); incidence rate (IR) 6.8/1000 PYFU (95% CI 6.2 to 7.4); 441 NADC (IR 5.8; 5.3 to 6.4), 207 SRC (IR 2.7; 2.4 to 3.1) and 188 IRC (IR 2.5; 2.1 to 2.8). Compared to never smokers, after adjustment current smokers had an increased incidence of all cancer (adjusted incidence rate ratio 1.44; 1.17 to 1.79), NADC (1.65; 1.30 to 2.08), SRC (2.20; 1.53 to 3.17) and IRC (1.39; 0.98 to 1.97). Compared to persons with currently good CD4/VL outcomes, those with poor outcomes had a significantly increased incidence of all cancer (5.70; 95% CI 3.89 to 8.35), NADC (3.54; 2.14 to 5.85), SRC (2.08; 0.89 to 4.85) and IRC (11.59; 6.77 to 19.84). There was no strong evidence that the association between smoking and cancer or subtypes of cancer differed depending on the CD4/VL strata (Figure 1).
**Conclusions:** In the large RESPOND cohort both smoking and poor CD4/VL outcomes predicted increased cancer rates, but without evidence of an interaction suggesting the impact from smoking on cancer risk in PLHIV is similar regardless of HIV viraemia or CD4 count.




***Adjusted for (all at baseline) gender, ethnicity, HIV risk group, hepatitis B and C status, antiretroviral status (naïve, experienced with VL < 200/LOD and experienced, VL >200/LOD), BMI, hypertension, diabetes, AIDS, prior cardiovascular disease, non-AIDS defining cancer, end stage liver disease, fractures, time HIV positive, nadir CD4, baseline date and age**

**Abstract O124-Figure 1. Adjusted* incidence rate ratio of cancer, stratified by current CD4/VL and smoking status.**

# Biological, Clinical and Ethical Imperatives for Involving Diverse Women in Clinical Trials

## O211

### Biological, clinical and ethical imperatives for involving diverse women in clinical trials

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The HIV field is not the only one in medicine which has historically had an underrepresentation of women in clinical trials of new pharmaceutical agents and interventions. Appropriate enrolment of women in clinical trials and sex-specific analysis of the data is critical when decisions on dosing, safety and efficacy of therapeutic agents are being made. Historically safety concerns have been cited as a primary reason but there are a number of reasons why women are excluded. Instead of simply excluding pregnant, lactating and women of childbearing potential as well as transgender women from participation in early phase research, risk can be mitigated by responsible research practices. Attention to sex and gender in biomedical, health and clinical research is important to identify sex differences including in the response of medications relative to safety and efficacy and to ensure prompt access for women to new medicines and interventions. This panel of experts will explore the need, barriers and facilitators to increasing the inclusive participation of women in clinical trials.

# The Role of Gender in Important Health Considerations in HIV

## O221

### 90:90:90—Are the differences between women and men changing?

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We live in an era of effective treatment for HIV which, for many who can access treatment, will result in a normal life expectancy. Gender-

related factors can, however, influence treatment outcomes, management decisions and the overall long-term wellbeing of people living with HIV. The Women Against Viruses in Europe (WAVE) Working Group was established by the European AIDS Clinical Society in 2017 to address this health disparity and to promote the health and wellbeing of all women living with HIV. WAVE organises workshops and seminars to improve education, guidelines and share knowledge on the complexities of optimising the healthcare of women with HIV. Cis and transgender women remain disadvantaged with respect to access, engagement and retention. In addition to comprehensive management of their HIV therapy women require support with management of comorbid conditions, life events such as conception, pregnancy, hormone therapy/transitioning and menopause as well as psychosocial support for mental health, partner violence and poverty. Menopause, in particular, is significantly undermanaged in women and even more so in women with HIV despite a significant increase in the risk of cardiovascular events and deterioration of bone health faced by many postmenopausal women living with HIV. Sessions at the HIV Glasgow 2020 Congress will broach the topics of menopause and gender disparity outcomes in women living with HIV through case presentation, short plenaries and discussion led by experts in the field. The listed team of WAVE contributors will bring the prominence deserved to the topics to be discussed.

# Tuberculosis Transmission and Clinical Care

## O232

### Catching bacilli in flight: direct sampling of tuberculosis aerosols

R Wood

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**History:** Attempts to demonstrate M.tb in aerosols from tuberculosis (TB) cases span more than 100 years. In 1917 Chauseé reported 20% of guinea pigs became infected when directly exposed to coughs from selected TB cases. In 1959 Riley showed that exhausted air from a TB ward could remotely infect guinea pigs and estimated 13% of patients were infectious. In 2012 Fennelly was able to culture M.tb organisms from the coughs of 28% of sputum-positive TB cases [1].
**Particle production:** Particles are produced in the peripheral lung spaces when collapsed airways open during inspiration, from airflow passing through the large airways and from the upper oropharyngeal structures. The combination of particles from these lung structures are exhaled in a warm moist plume at a variety of velocities up to 40 metres per second during a strong cough. Particle size determines airborne survival and the deposition within the target respiratory tract. The median particle size produced by most respiratory activities is 0.5–2.0 micrometre diameter range capable of deposition in the peripheral lung.
**Capture and detection:** At cough-exhaled velocity, air is incompressible presenting technical collector challenges. Therefore, an aerodynamic high-flow collector was developed to fully capture high-speed coughs into a small volume of fluid. Coupled with a sensitive salvatochromic fluorescent detection probe, metabolically active M.tb organisms were visualised in a microscope slide grid of nanolitre-sized cells.
**Results:** Metabolically active M.tb organisms were detected in 100% of sputum smear-positive patients (n=30) and 90% (21 of 23) of sputum-negative TB suspects. During early four-drug TB therapy M.tb organism numbers declined at 2 weeks ($p<0.04$) and 2 months ($p<0.004$).
**Conclusions:** Direct capture of exhaled aerosols combined with sensitive detection enabled isolation and identification of metabolically active M.tb in a wider spectrum of TB disease than identified by sputum-based, culture plate or historical guinea pig studies.

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# HIV Care in the COVID-19 Era: A Community Perspective

## O241

### HIV care in the COVID-19 era: a community perspective

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The HIV Glasgow 2020 community session "HIV care in the COVID-19 era" reviewed lessons learned so far and ways to improve community and healthcare services preparedness to respond to the needs of people living with or affected by HIV over the coming months. According to community reports, healthcare providers sought alternative ways to engage with patients via remote consultation, prioritising urgency, and proactive outreach. Yet, many people were not being contacted, especially for co-infections, comorbidities, opioid substitution therapy, and PrEP [1]. The community also reports that remote/online services may not be a suitable replacement for everyone [2]. Testing for HIV, other STIs and infections were early victims of COVID-19, and in many cases limited to emergencies in health care settings, and reduced or suspended at community level [3]. As a response, other modes of testing for HIV such as self-testing, posting testing kits to homes, or availability via vending machines, were reportedly available. Further data are required to gauge the impact on linkage to care. One residual effect of the crisis may be changes in testing and care delivery models, and for the future it will be essential to engage with service users to ensure these are person-centred and rights-based. Internationally, coronavirus laws and responses are being weaponised against the most marginalised within society, as is the case with HIV criminalisation laws [4]. Such responses, based on fear and panic, rather than science and proportionality, exacerbate, perpetuate, and highlight existing inequalities [5]. They may well result in damaging residual post 'crisis' barriers to achieving universal access to healthcare. Many community organisations and health care providers found alternative ways of providing consultations and access to treatment, testing and prevention and responding to emerging needs. These have to an extent bridged the gap between pre-COVID and COVID worlds with new or expanded use of digital tools, increasing self-testing accessibility and further focusing on psycho-social support and information about access to HIV care. However, online services have limitations for some. Community services are essential and should be recognised and funded as such in national COVID-19 responses. Funding must be flexible to encompass innovative interventions.

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## O242

### STI and HIV testing to break the chain of infection: local innovation in the midst of COVID-19

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**Background:** The national lockdown in March 2020 for COVID-19 resulted in the cessation of asymptomatic screening, and as a large network of sexual health clinics in North West England, this left many patients untested. However, as we came out of lockdown, it presented a unique opportunity to test high-risk individuals at a time when their sexual risk-taking behaviour was likely to be at its lowest and when they were at the end of infection window periods, thus breaking the chain of infection.
**Methods:** A significant proportion of our cohort come under the BHIVA HIV testing guidance [1]; therefore, before the lockdown measures were relaxed, we identified 1413 patients considered at particularly high risk. These patients were sent a text inviting them to do a home test kit (HTK), including a dried blood spot for HIV.
**Results:** From 1413 texts sent, 324 (22.9%) responded and requested testing. Of these 324, we have received 209 (64.5%) HTKs back to date. These were predominantly White British (71.8%), male (95.2%) and MSM (92.3%), with a median age of 31 (range 18 to 61). 71.3% had not tested for over three months at the time of their HTK. New STIs were identified in 38 (18.2%) patients, including one new HIV diagnosis. Of the 115 who requested kits, but have not returned them, 48.5% had testing in the three months preceding the text, in keeping with BHIVA guidance, which may explain the lower return rate; our usual HTK return rate is around 70%.
**Conclusions:** COVID-19 has had a negative impact on STI and HIV testing; however, in such unusual times a cheap targeted intervention such as this was effective in detecting a significant number of infections. This local intervention complemented national HIV testing campaigns [2] with the additional benefit of full STI screening and local linkage into care. As a service, we will review the utility of sending three-monthly reminder texts to patients at higher risk. Our intention is to approach those who did not respond, to help us better understand what strategies and measures we can put in place to support them to test.

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# The Role of Gender in Important Health Considerations in HIV

## O311

### Key questions in WLWHIV and ageing: menopause and frailty in clinical practice

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We live in an era of effective treatment for HIV which, for many who can access treatment, will result in a normal life expectancy. Gender-related factors can, however, influence treatment outcomes, management decisions and the overall long-term wellbeing of people living with HIV. The Women Against Viruses in Europe (WAVE) Working Group was established by the European AIDS Clinical Society in 2017 to address this health disparity and to promote the health and wellbeing of all women living with HIV. WAVE organises workshops and seminars to improve education, guidelines and share knowledge on the complexities of optimising the healthcare of women with HIV. Cis and transgender women remain disadvantaged with respect to access, engagement and retention. In addition to comprehensive management of their HIV therapy women require support with management of comorbid conditions, life events such as conception, pregnancy, hormone therapy/transitioning and menopause as well as psychosocial support for mental health, partner violence and poverty. Menopause, in particular, is significantly undermanaged in women and even more so in women with HIV despite a significant increase in the risk of cardiovascular events and deterioration of bone health faced by many postmenopausal women living with HIV. Sessions at the HIV Glasgow 2020 Congress will broach the topics of menopause and gender disparity outcomes in women living with HIV through case presentation, short plenaries and discussion led by experts in the field. The listed team of WAVE contributors will bring the prominence deserved to the topics to be discussed.

# HIV and Resistance

## O321

### Do we need to worry about ART drug resistance anymore?

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Antiretroviral therapy (ART) has strongly improved over the last decade and has resulted in high proportions of virologically suppressed individuals in many populations. This has led to decreasing numbers of AIDS-related morbidity and mortality in many countries. Nevertheless, there is a dichotomous development in respect to HIV drug resistance. In resource rich settings (RRS) the emergence of acquired (ADR) but also of transmitted/pretreatment (TDR/PDR) drug resistance has strongly decreased. In resource limited settings (RLS) however, where—until recently—mostly non-nucleoside reverse transcription inhibitor (NNRTI) based treatments were used for initial therapy, prevalence of ADR and PDR has been increasing and in some places are very high and have exceeded the WHO threshold. If this

worrying increase in ADR and PDR against NNRTI and also to some extent nucleos(t)ide RTI is not halted, it could jeopardize benefits achieved in resource limited settings (RLS) and could result in imported resistant viruses in RRS. A change in treatment strategy to integrase inhibitor (InSTI) based treatment regimens as initial but also for switch and in treatment failing individuals is a valid option to decrease ADR and PDR at least for some time. If this switch to InSTI based therapies, however, will not be accompanied by improved monitoring strategies including plasma RNA and resistance testing, success of such changes may only turn out to be of transient nature. To lay the ground for an evaluation of these issues I will discuss in this talk the benefits of HIV drug resistance testing for (i) individualized ART considering the fact that ART needs to be taken lifelong, (ii) for special populations, (iii) for surveillance of TDR/PDR and ADR also in the light of migration and (iv) for molecular epidemiology and timing of infection for informing public health.

## O322

### Integrase-based first-line HIV antiretroviral treatment in the Mediterranean Resistance (MeditRes) HIV collaboration

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**Background and objective:** Integrase strand-transfer inhibitor (INSTI)-based regimens are preferred regimens for first-line antiretroviral therapy in Europe. Our objective has been to study the prevalence of transmitted drug resistance to the INSTIs and the NRTI backbone in newly diagnosed patients that are naïve to ART.
**Patients and methods:** MeditRes HIV is a consortium that includes ART-naïve people living with HIV that have been newly diagnosed in France, Greece, Italy, Portugal and Spain during the years 2018 and 2019. Reverse transcriptase (RT) and integrase were sequenced following standard methodologies in use at the participating centres. To evaluate the prevalence of surveillance drug resistance mutations (SDRM) we used the Calibrated Population Resistance (CPR) tools for integrase and RT available at Stanford HIV website. To evaluate clinically relevant transmitted resistance, we used the Stanford HIVdb algorithm v8.9-1.
**Results:** Overall, we included 1844 patients with integrase and RT data available. At diagnosis, 79% were men, 72% of them were men that have sex with men, median age was 40 (IQR 30 to 54) years and median viral load was 104 000 (IQR 22 409 to 415 000) copies/mL; 47.2% of patients were infected by HIV-1 non-B subtypes. In particular, the most prevalent non-B subtypes were: CRF02_AG (20.0%), A (6.2%), C (4.6%), F (4.6%) and CRF01_AE (1.7%). The prevalence of INSTI SDRMs was 0.22% (T66I, n = 1; T66A, n = 1; E138T, n = 1; and R263K, n = 1). The prevalence of NRTI SDRMs was 3.6% (M184V, n = 16, 0.86%; K65R, n = 2, 0.1%; any STAMs, n = 45, 2.44%). Clinically relevant resistance, defined as any resistance level for Stanford interpretation ≥3, was 2.45% for INSTIs (0.05% to dolutegravir and bictegravir; 2.4% to raltegravir; 2.4% to elvitegravir), and 1.68% to the components of the NRTI backbones (0.76% to TDF/TAF; 1.46% to abacavir; 0.97% to lamivudine/emtricitabine).
**Conclusions:** Here we describe the most recent data on transmitted drug resistance to integrase-based first-line regimens in Mediterranean Europe. Given the low prevalence of clinically relevant resistance to second-generation INSTIs and to first-line NRTIs, in the years 2018 and 2019 it is very unlikely that a newly diagnosed patient in MeditRes countries would present with baseline resistance to a first-line regimen based on second-generation INSTIs.

## O323

### Impact of multi-drug resistance on mortality: a multi-cohort Italian study

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**Background:** In the past decades, HIV+ patients harbouring multidrug resistant (MDR) virus seemed to have an increased mortality, but recent data considering the new ART scenario are lacking.
**Methods:** The analysis included data of HIV+ patients of a retrospective multi-cohort study (Icona Foundation cohort, ARCA database and anonymous databases of Italian clinical centres). In order to account for variation in the frequency of genotype resistance test (GRT) across cohorts, both Stanford GSS v8.9 and previous history of virological failure on specific drugs (VFscore) were combined to estimate the rate of loss of drugs as future options. At each month, NRTI class was considered active if GSS and/or VFscore ≥2; NNRTI, PI, MVC, T20 if GSS and/or VFscore ≥1; and INSTI if GSS and/or VFscore ≥1.5. MDR at each month of follow-up was defined as currently having ≤2 active drug classes among drugs available for use. Poisson analysis

**Abstract O323-Table 1. Rates, crude and adjusted relative rates (95% CI) of death (a) and of composite endpoint of AIDS diagnosis/death (b) from fitting a Poisson regression model in overall population and after stratification by calendar period**

| a) | Rates of death | | | Relative rates | | | |
|---|---|---|---|---|---|---|---|
| | Deaths | PYFU | Rates per 100 PYFU (95% CI) | Unadjusted | | Adjusted[a] | |
| Current calendar period | | | | | | | |
| 1996 to 2007 | 572 | 70666 | 0.81 (0.75, 0.88) | 1.00 | | 1.00 | |
| 2008+ | 760 | 147220 | 0.52 (0.48, 0.55) | 0.64. (0.57, 0.71) | <.001 | 0.57 (0.48, 0.68) | <.001 |
| 1996 to 2007 | | | | | | | |
| MDR | | | | | | | |
| No | 442 | 55698 | 0.79 (0.72, 0.87) | 1 | | 1 | |
| Yes | 130 | 14968 | 0.87 (0.73, 1.03) | 1.09 (0.90, 1.33) | 0.366 | 1.62 (1.24, 2.12) | <.001 |
| 2008 to 2019 | | | | | | | |
| MDR | | | | | | | |
| No | 756 | 146965 | 0.51 (0.48, 0.55) | 1 | | 1 | |
| Yes | 4 | 255 | 1.57 (0.59, 4.18) | 3.05 (1.14, 8.15) | 0.026 | 2.43 (0.60, 9.80) | 0.213 |

| b) | Rates of composite outcome of AIDS/death | | | Relative rates | | | |
|---|---|---|---|---|---|---|---|
| | AIDS/deaths | PYFU | Rates per 100 PYFU (95% CI) | Unadjusted | | Adjusted[b] | |
| Current calendar period | | | | | | | |
| 1996 to 2007 | 393 | 62535 | 0.63 (0.57, 0.69) | 1 | | 1 | |
| 2008+ | 584 | 109139 | 0.54 (0.49, 0.58) | 0.85 (0.75, 0.97) | 0.014 | 0.87 (0.72, 1.06) | 0.169 |
| 1996 to 2007 | | | | | | | |
| MDR | | | | | | | |
| No | 304 | 49109 | 0.62 (0.55, 0.69) | 1 | | 1 | |
| Yes | 89 | 13426 | 0.66 (0.54, 0.82) | 1.07 (0.85, 1.36) | 0.570 | 1.39 (1.00, 1.92) | 0.051 |
| 2008+ | | | | | | | |
| MDR | | | | | | | |
| No | 580 | 108950 | 0.53 (0.49, 0.58) | 1 | | 1 | |
| Yes | 4 | 190 | 2.11 (0.79, 5.62) | 3.97 (1.48, 10.60) | 0.006 | 3.24 (1.03, 10.17) | 0.044 |

[a]Adjusted for age, gender, nationality, mode of HIV transmission, HBV/HCV coinfection status, AIDS diagnosis, CD4 and HIV/RNA- at enrolment and year of enrolment;
[b]adjusted for age, gender, nationality, mode of HIV transmission, HBV/HCV coinfection status, CD4 and HIV-RNA at enrolment and year of enrolment.

was used for crude and adjusted relative rates (aRR) for death and for a composite endpoint of AIDS or death.
**Results:** Of 31 445 patients, 5954 (19%) were MDR. Median age was 38 (IQR 32 to 46), year of enrolment/diagnosis 2008 (2003 to 2013), calendar year of MDR 2003 (1999 to 2005). One thousand, three hundred and thirty-two deaths were observed over 217 886 person-year-follow-up (PYFU): 134 among MDR patients (IR 0.88 per 100 PYFU, 95% CI 0.74 to 1.04), 1198 among no-MDR (IR 0.59, 95% CI 0.56 to 0.63). MDR patients globally had a higher rate of death after the adjustment for potential confounders (aRR 1.67, CI 1.31 to 2.13). A lower RR of death was observed after 2008 (aRR 0.57, CI 0.48 to 0.68) in comparison with 1996 to 2007 period. Both in 1996 to 2007 and in ≥2008 calendar period, MDR patients had a higher aRR of death (aRR 1.62, CI 1.24 to 2.12, $p < 0.001$ and 2.43, CI 0.60 to 9.80, $p = 0.213$, respectively) versus no-MDR (Table 1a). In 25 084 patients evaluated for the composite endpoint AIDS/death, 5257 (21%) were MDR. MDR patients globally had a higher rate of AIDS or death (aRR 1.24, CI 0.93 to 1.67), confirmed also in the two calendar periods: 1.39 (CI 1.00 to 1.92) in 1996 to 2007 aRR and 3.24 (CI 1.03 to 10.17) after 2008 (Table 1b).
**Conclusions:** This retrospective study showed that despite a statistically significant decrease in mortality in HIV+ patients over time, those harbouring MDR are still burdened with higher disease progression and mortality.

## O324

### Lenacapavir resistance analysis in a phase Ib clinical proof-of-concept study

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**Background:** Lenacapavir (LEN, GS-6207) is a first-in-class subcutaneous (SC) long-acting inhibitor of HIV-1 capsid function, which can be administered every six months. *In vitro* resistance selections with LEN have identified seven mutations in HIV-1 capsid protein (CA) associated with reduced susceptibility to LEN, most with significantly reduced fitness. We conducted a phase Ib proof-of-concept study in which PLWH received a single SC injection of LEN 20, 50, 150, 450, or 750 mg. LEN demonstrated potent antiviral activity with up to 2.3 log10 decline in HIV-1 RNA after nine days of monotherapy. Here we describe the resistance analyses for all participants.
**Materials and methods:** Study 4072 is a double-blind, placebo-controlled, dose-ranging, randomized (3:1; n = 8/group) study in PLWH who were capsid inhibitor naive. Resistance analyses were performed for all participants prior to study entry and at the end of monotherapy using genotypic and phenotypic Gag-Pro assays (Monogram Biosciences) and next-generation sequencing (NGS; Seq-IT). Samples were

evaluated for the emergence of CA mutations and/or change in phenotypic susceptibility to LEN.
**Results:** Thirty-nine PLWH enrolled in the study, 29 receiving LEN and 10 receiving placebo. All PLWH responded to LEN with no rebound. In the pre-treatment analysis, none had HIV-1 harboring resistance mutations to LEN, with all having wild-type (WT) phenotypic susceptibility to LEN. Post-monotherapy analyses revealed the emergence of CA mutation Q67H at Day 10 in two participants. One participant (20 mg group) had a Q67Q/H mixture detected both by population and NGS analysis, and another participant (50 mg group) had a Q67H mutation, detected only by the NGS analysis. No other substitutions were observed in the CA protein.
**Conclusions:** Overall, emergence of resistance to LEN was rare and only occurred well below exposures expected to be achieved in PhII/III studies, with the emergence of a single mutation *Q67H*. Notably, previous *in vitro* characterization identified that Q67H mutation had the least impact on fitness and susceptibility to LEN, which may explain its emergence at lower LEN exposures. These results support further evaluation of LEN as a long-acting antiretroviral agent in PLWH.

# New Perspectives on ART

## O411
### Two-drug regimens
P Cahn

Juan Fernandez Hospital and Huésped Foundation, and Buenos Aires University Medical School, Buenos Aires, Argentina

Paddle study, a small pilot study, opened the route for the use of 3TC-DTG demonstrating that the combination is effective. This was followed for another single arm study (the ACTG5353) that also proved the potency of this combination, later the GEMINI 1&2 studies confirmed in two randomised controlled trials the non-inferior efficacy of DTG/3TC against a 3-drug antiretroviral regimen in treatment-naïve individuals. Today, DTG/3TC has gained a place as treatment for ARV-naïve individuals in several international clinical guidelines, with the limitation of rolling out the presence of chronic hepatitis B and pre-existent resistance to lamivudine. In treatment-experienced patients with virological suppression of at least six months, without evidence of previous failure, two INSTI-based combinations have been successfully tested in well-powered randomised clinical trials. The SWORD studies showed non-inferiority of switching to a combination of dolutegravir and rilpivirine, compared to the ongoing ARV triple-drug therapy. The TANGO studies showed non-inferiority of dolutegravir plus lamivudine, compared to the ongoing TAF-based triple therapy. The SALSA studies (still recruiting participants) are designed similar to TANGO, but excluding patients suppressed on a TAF-based regimen. Long-acting IM cabotegravir in combination with IM rilpivirine showed similar results when compared to standard of care triple therapy (LATTE studies). Previously other studies testing the efficacy and safety of PI-based dual therapy showed similar results in naïve patients (GARDEL, ANDES), as well as in virologically suppressed participants (OLE, DUAL-GESIDA). Therefore, it looks like that two-drug INSTI or PI-based regimens are here to stay. Remaining issues like its use in pregnant women, TB-coinfected patients, children and individuals harbouring a virus with the M184V/I mutation deserve further investigation.

## O412
### Long acting injectables for ART
M Boffito

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Long-acting injectable antiretroviral drugs present a remarkable milestone in treatment options for people living with HIV. They may improve adherence to therapy and extend opportunities for therapeutic or prophylactic interventions to a variety of patient populations. Recent advances in the development of long-acting injectable antiretroviral agents will be discussed and different pharmacological aspects of these agents discussed to increase knowledge and confidence in prescribing injectable long acting drugs. Nanoformulations of rilpivirine and cabotegravir, which are at the very late stages of clinical development, will be the focus of the presentation, followed by newer agents, which will be approved in the near future.

## O413
### Novel ART compounds
C Orkin

Queen Mary University of London and Barts Health NHS Trust, London, UK

How does the antiretroviral therapy (ART) pipeline differ in 2020 from 2019? What will the future of HIV therapy look like? The diversity of the HIV pipeline is ever-expanding. A plethora of novel compounds are being developed to inhibit almost every conceivable step in the HIV life-cycle. In this plenary talk consideration will first be given to what the need is for these novel compounds and discuss who is in the greatest need of them. The author will review the clinical data presented in 2020 on the most advanced novel compounds in the pipeline such as islatravir and lenacapavir and explore the mode of delivery, frequency and possible partner compounds for these drugs. There will then be a review of the planned clinical development programme for these and other drugs in earlier phase development. Finally, I will consider issues of equitable access to novel ART and cultural sensitivity when developing drugs and offering clinical trials. As science advances, new questions of social justice evolve around when, where, how and to whom we offer these drugs. These must be considered in parallel with drug development to ensure that people with HIV remain at the heart of all we do.

## O414
### Safety and efficacy of cabotegravir + rilpivirine long-acting with and without oral lead-in: FLAIR Week 124 results
R D'Amico[1]; C Orkin[2]; E Bernal Morell[3]; D Tan[4]; H Katner[5]; Y Singh[6]; H Stellbrink[7]; E Belonosova[8]; R DeMoor[9]; S Griffith[1]; S Thiagarajah[9]; R Van Solingen-Ristea[10]; H Crauwels[10]; S Ford[11]; P Patel[1]; A Cutrell[1]; K Smith[1]; K Vandermeulen[10]; D Margolis[1]; M St. Clair[1] and W Spreen[1]

[1]ViiV Healthcare, Research Triangle, NC, USA. [2]Queen Mary University of London and Barts Health NHS Trust, London, UK. [3]Hospital General Universitario Reina Sofía, Murcia, Spain. [4]St. Michael's Hospital, Division of Infectious Diseases, Toronto, Canada. [5]Mercer University Medical School, Macon, GA, USA. [6]Desmond Tutu HIV Foundation, Cape Town, South Africa. [7]ICH Study Center, Hamburg, Germany. [8]Orel Regional Center for AIDS, Orel, Russian Federation. [9]GlaxoSmithKline, London, UK. [10]Janssen Research and Development, Beerse, Belgium. [11]GlaxoSmithKline, Research Triangle, NC, USA

**Background:** FLAIR (NCT02938520), a phase III, randomised, open-label study, established noninferiority of switching virologically sup-

pressed participants from daily oral dolutegravir/abacavir/lamivudine (CAR) to monthly cabotegravir (CAB) + rilpivirine (RPV) long-acting (LA) following a CAB+RPV oral lead-in (OLI) over a 2-year period. Herein, we report results from the extension phase focussing on the efficacy, safety and tolerability of switching CAR arm participants to LA therapy with or without OLI.

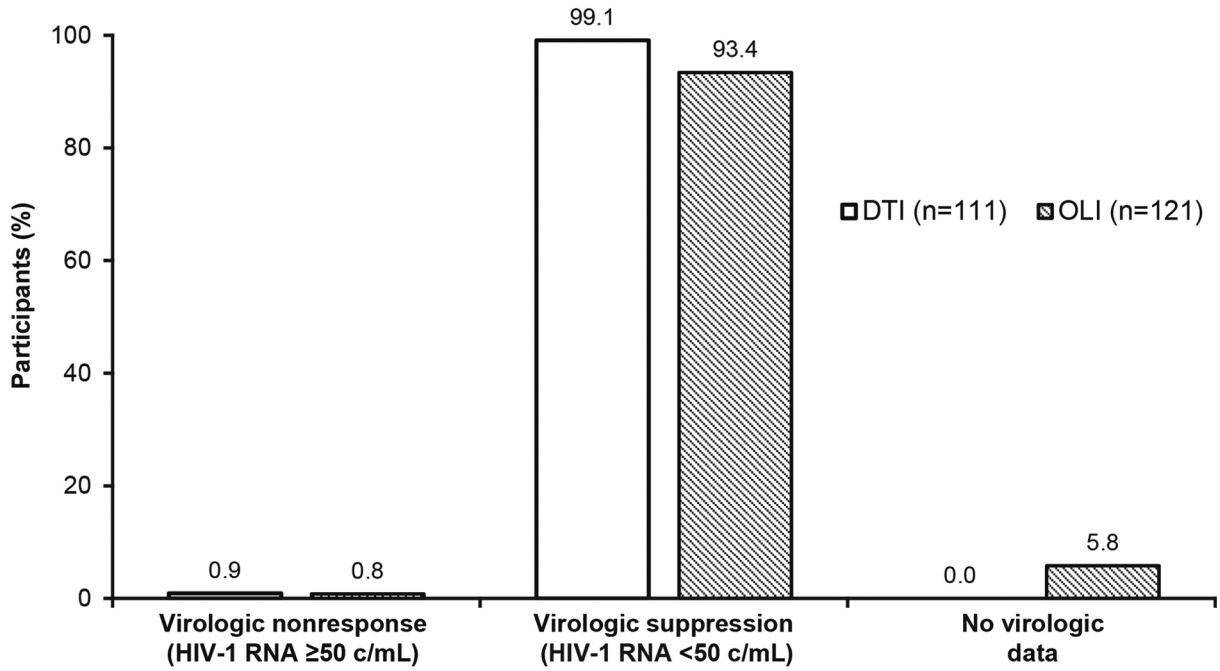
**Materials and methods:** ART-naive participants achieving virological suppression (HIV-1 RNA < 50 copies/mL) with CAR during the 20-week induction phase were randomised (1:1) to either continue CAR or switch to LA (283 per arm). Participants randomised to LA therapy received an OLI of CAB+RPV once daily for ≥4 weeks before receiving monthly injectable CAB+RPV LA. At Week (W) 100, CAR arm participants could elect to switch to LA therapy (Extension Switch population), either directly (Direct to Inject [DTI] arm) or with a 4-week OLI (OLI arm), or withdraw. Endpoints assessed at W124 for the Extension Switch population included plasma HIV-1 RNA ≥ 50 copies/mL and <50 copies/mL, confirmed virological failure (CVF; two consecutive HIV-1 RNA ≥ 200 copies/mL), safety and tolerability.

**Results:** In total, 111 and 121 CAR arm participants transitioned to CAB+RPV LA, entering the DTI or OLI arms, respectively. At W124, one participant (<1%) in each arm had HIV-1 RNA ≥ 50 copies/mL (Table 1; Figure 1). Further, 99% and 93% of participants in the DTI and OLI arms maintained virological suppression (HIV-1 RNA < 50 copies/mL), respectively. One participant in the DTI arm developed CVF at W112. Adverse events (AEs) leading to withdrawal were infrequent. There was one Grade 4 drug-related AE in the DTI arm (mixed cellularity Hodgkin's lymphoma). The number of participants experiencing serious AEs was comparable between arms. Overall, CAB+RPV LA was well tolerated; injection site reactions were the most common AE, with most classified as mild/moderate in severity.

**Abstract O414-Table 1. Key outcomes at Week 124 data analysis**

| Outcome, n (%) Extension Switch population | DTI arm n = 111 | OLI arm n = 121 |
|---|---|---|
| HIV-1 RNA < 50 copies/mL at W124[a] | 110 (99.1) | 113 (93.4) |
| HIV-1 RNA ≥ 50 copies/mL at W124[a] | 1 (0.9) | 1 (0.8) |
| Data in window not <50 copies/mL | 0 | 1 (0.8)[b] |
| Discontinued due to lack of efficacy | 1 (0.9) | 0 |
| Discontinued due to other reasons while not suppressed | 0 | 0 |
| No virological data in W124 window | 0 | 7 (5.8) |
| Discontinued study due to AE or death | 0 | 2 (1.7)[c] |
| Discontinued study for other reasons | 0 | 5 (4.1)[d] |
| Number of injections | 2314 | 2128 |
| Number of ISR events | 576 | 338 |
| Grade 1 events - mild | 478 | 271 |
| Grade 2 events - moderate | 97 | 62 |
| Grade 3 events - severe | 1 | 5 |
| ISR duration ≤7 days | 516 | 290 |
| Median ISR duration, days | 3 | 3 |
| Withdrawals due to ISRs | 0 | 1 (0.8) |
| Incidence of skin and subcutaneous tissue disorders (dermatological AEs) | 19 (17.1)[e] | 10 (8.3) |
| Maximum Grade 3 or 4 AEs | 5 (4.5) | 9 (7.4) |
| Maximum Grade 3 or 4 AEs excluding ISRs | 4 (3.6) | 5 (4.1) |
| Maximum drug-related Grade 3 or 4 AEs excluding ISRs | 1 (0.9) | 0 |
| Maximum Grade 3 or 4 emergent chemistry toxicities | 13 (11.7) | 5 (4.1) |
| Serious AEs | 4 (3.6) | 5 (4.1) |
| Mean change (range) from extension baseline[f] in ALT, IU/L | −1.1 (−157, 80) | 1.1 (−37, 45) |
| Mean change (range) from extension baseline[f] in AST, IU/L | −0.3 (−257, 308) | −0.7 (−124, 84) |
| Mean change (range) from extension baseline[f] in bilirubin, μmol/L | 1.5 (−14, 24) | 1.0 (−8, 14) |
| Liver monitoring/stopping events | 0 | 0 |

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ISR, injection site reaction.
[a]Per FDA Snapshot algorithm;
[b]participant had HIV-1 RNA of 57 copies/mL;
[c]two discontinuations after OLI: one injection site pain, one increased weight;
[d]two discontinuations during OLI: one subject relocation, one pregnancy. Three discontinuations after OLI: one burden of procedures and intolerability of injections, one burden of travel, one use of prohibited medicine;
[e]includes one cyst and two herpes zoster, which were not coded to "skin and subcutaneous tissue disorders";
[f]W100.




**Abstract O414-Figure 1. FLAIR Week 124 Snapshot virological outcomes (Extension Switch population).**

**Conclusions:** Switching directly to LA therapy without OLI demonstrated similar safety and tolerability to treatment including OLI. Further, similar efficacy was observed across arms at W124. This suggests that CAB+RPV LA, with or without OLI, is a well-tolerated and effective maintenance therapy.

## O415

### Islatravir in combination with doravirine maintains HIV-1 viral suppression through 96 weeks

J Molina[1]; Y Yazdanpanah[2]; A Afani Saud[3]; C Bettacchi[4]; C Chahin Anania[5]; E DeJesus[6]; S Klopfer[7]; A Grandhi[7]; K Eves[7]; D Hepler[7]; M Robertson[7]; C Hwang[7]; G Hanna[7] and T Correll[7]

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**Background:** Islatravir (ISL, MK-8591) is the first nucleoside reverse transcriptase translocation inhibitor (NRTTI) in development for treatment and prevention of HIV-1. We present efficacy and safety data for ISL and doravirine (DOR) for treatment of HIV-1 through Week 96.
**Materials and methods:** Randomized, double-blind, dose-ranging trial participants initially received ISL (0.25, 0.75, or 2.25 mg) with DOR (100 mg) and lamivudine (3TC, 300 mg) or fixed-dose combination of DOR, 3TC, and tenofovir disoproxil fumarate (DOR/3TC/TDF) daily. Participants receiving ISL achieving HIV-1 RNA < 50 copies/mL at Week 20 or later stopped taking 3TC and continued to take assigned dose of ISL (still blinded) with DOR for minimum of 24 weeks. Once dose-selection occurred participants taking ISL transitioned to the selected dose of 0.75 mg. Efficacy endpoints at Week 96 included proportion of participants maintaining HIV-1 RNA < 50 copies/mL. Safety was assessed by adverse event (AE) reporting.
**Results:** One hundred and twenty-one participants received study drug and were included in analyses. All participants in the ISL groups transitioned to the selected dose of 0.75 mg between Weeks 60 and 72. At Week 96, 86.2% (25/29), 90.0% (27/30), 67.7% (21/31) of participants maintained HIV-1 RNA < 50 copies/mL in the 0.25, 0.75, and 2.25 mg ISL groups, with 81.1% (73/90) for ISL combined, as compared to 80.6% (25/31) with DOR/3TC/TDF. The numerically lower response rate for the 2.25 mg ISL group was largely driven by discontinuations through Week 48. After Week 48, two, two, and four participants discontinued treatment in the 0.25, 0.75, and 2.25 mg ISL groups and one additional participant in the DOR/3TC/TDF group. One participant discontinued with PDVF between Weeks 48 and 96; this participant was in the 2.25 mg ISL group and met failure criteria at Week 72 with an HIV-1 RNA level of 79 copies/mL (confirmed at 70 copies/mL). A higher rate of drug-related AEs was reported for DOR/3TC/TDF (22.6%) participants compared with ISL (combined 7.8%). No additional discontinuations due to drug-related AEs occurred after Week 48. Among the 90 participants taking ISL, no specific drug-related AE (at both system organ class or preferred term level) occurred in more than 5% of participants.
**Conclusions:** ISL+DOR demonstrated efficacy in maintaining viral suppression and was well tolerated through Week 96. The 0.75 mg dose of ISL will be used for further clinical development.

## O416

### Single doses of MK-8507, a novel HIV-1 NNRTI, reduced HIV viral load for at least a week

W Ankrom[1]; D Schuermann[2]; D Jackson Rudd[3]; A Schaeffer[1]; I De Lepeleire[4]; E Friedman[5]; M Robberechts[4]; S Zhang[6]; C Keicher[2]; J Hofmann[7]; A Stoch[5] and M Iwamoto[5]

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**Background:** MK-8507 is a novel, potent NNRTI with a high *in vitro* barrier to resistance in clinical development as a once-weekly oral

treatment for HIV-1 infection. This study evaluated the antiviral efficacy, pharmacokinetics (PK), and safety/tolerability of single doses of 40, 80, and 600 mg MK-8507 over 7 to 14 days in HIV-1 infected participants in a proof of concept study.
**Materials and methods:** This was a phase Ib open-label study in which HIV-1 infected, antiretroviral-naïve adult males (22 to 56 years) received a single oral dose of 40, 80, or 600 mg MK-8507. Blood was collected at prespecified timepoints for viral load testing and PK through 14 days (N = 3 at 600 mg) or seven days (N = 6 at 40 mg, N = 6 at 80 mg, and N = 3 at 600 mg) postdose.
**Results:** Single doses of MK-8507 resulted in a robust reduction in viral load at seven days, comparable to other NNRTIs dosed daily for seven days. At seven days postdose, a mean (95% CI) viral load reduction of 1.22 (1.52 to 0.91) log10 copies/mL at 40 mg, 1.50 (1.80 to 1.19) log10 copies/mL at 80 mg, and 1.53 (1.84 to 1.23) log10 copies/mL at 600 mg were observed. PK was similar to that observed in uninfected participants, with mean concentrations at seven days postdose of 78.1, 214, and 1400 nM at the 40, 80, and 600 mg doses, respectively. Beginning at Day 10 following a 600 mg dose, one participant experienced viral recrudescence with F227C, a NNRTI-associated resistant variant. All doses were generally well tolerated; the most common adverse experiences were nasopharyngitis and headache. One participant experienced the serious adverse event of diffuse large B cell lymphoma which was not considered related to study drug. Following completion of sampling, participants were advised to initiate non-NNRTI, standard-of-care antiretroviral therapy.
**Conclusions:** MK-8507 reduced HIV viral loads for a week following single doses as low as 40 mg. The antiviral potency and human PK are conducive to once-weekly administration as part of combination antiretroviral therapy.

# HIV, ART and COVID-19: Interplay and Interactions

## O421

### HIV, ART and COVID-19: interplay and interactions

C Sabin[1]; L Waters[2]; A Sparrowhawk[3]; A Owen[4] and M Çevik[5]

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This session, organised by the British HIV Association (BHIVA), will cover some of the key issues related to COVID-19 and HIV, an area that has been rife with misinformation. The actions which BHIVA has undertaken since the start of COVID-19 to provide information to people with HIV, and their specialist and non-specialist care providers, will be summarised, including contingency plans for HIV care, critical care guidelines and advice about COVID-19 risk. The impact of COVID-19 on the community of people living with HIV will be presented through a summary of results from key community surveys. Since the start of the pandemic there have been claims related to antiretrovirals for treatment and prevention of COVID-19 and, thanks to social media, rapid propagation of tenuous *in silico* findings presented as true efficacy. The session will therefore describe the levels of evidence for drug activity, from computational methods through to phase 3 human trials, and the current evidence for antiretrovirals in the management of COVID-19. Much has been learned about SARS-CoV-2 transmission dynamics, pathogenesis and host immune responses since the start of the pandemic so we will collate current knowledge including where and how HIV may have an impact. We will cover vaccine development to date, and how HIV may impact vaccine response. Finally this session will include the oral abstract presentation of outcomes in individuals hospitalised in the UK with COVID-19 from ISARIC, an international consortium; this presentation will describe the impact of HIV on mortality. A summary of future plans by BHIVA to gather the evidence to inform future management of COVID-19 in people with HIV will close the session.

## O422

### Outcomes of COVID-19 related hospitalisation among people with HIV in the ISARIC WHO Clinical Characterisation Protocol (UK): a prospective observational study

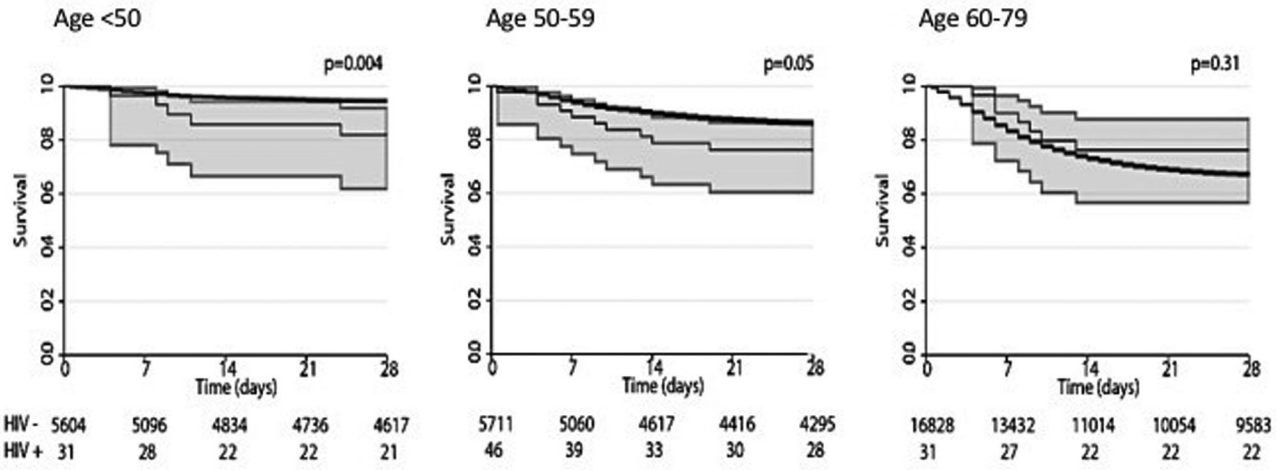
A Geretti[1]; A Stockdale[1]; S Kelly[1]; G Villa[2]; L Turtle[1]; M Semple[3] and C Sabin[4]

[1]University of Liverpool, Institute of Infection, Liverpool, UK. [2]Brighton & Sussex Medical School, Global Health and Infection, Brighton, UK. [3]University of Liverpool, Institute of Translational Medicine, Liverpool, UK. [4]University College London, Institute for Global Health, London, UK

**Background:** There is conflicting evidence about the influence of HIV on the outcomes of COVID-19. We compared the admission characteristics and outcomes of PWH and people without HIV who were hospitalised with COVID-19 from 17 January 2020 to 4 June 2020 at 208 centres in the UK [1].
**Materials and methods:** We analysed data from ISARIC WHO CCP [2]. Participants were hospitalised adults (≥18 years) with laboratory confirmed or highly likely COVID-19; those with definite hospital-acquired COVID-19 were excluded. The primary endpoint was Day 28 mortality; patients were followed from admission/symptom onset to date of death, with follow-up right-censored on transfer to another hospital or at Day 28 for those discharged earlier or who remained in hospital. Analyses used Kaplan-Meier methods and Cox regression to describe the association with HIV status after adjustment for: age, sex, ethnicity, indeterminate/probable hospital acquisition of COVID-19, date and presence/absence of 10 comorbidities. We additionally included adjustment for disease severity on admission as defined by hypoxia/oxygen requirement.
**Results:** Among 47 539 patients, 115 (0.24%) had confirmed HIV-positive status, typically (103/115, 89.6%) with a record of being on antiretroviral therapy. At admission, compared to those without HIV, PWH were younger (median 55 vs 74 years; $p < 0.001$), had a higher prevalence of obesity and moderate/severe liver disease, higher lymphocyte counts and C-reactive protein, and more systemic symptoms. There were no differences in respiratory rate, oxygen requirement or prevalence of chest infiltrates. The cumulative incidence of Day 28 mortality was 25.2% in PWH versus 32.1% in the comparator group ($p = 0.12$); however, stratification for age revealed a higher mortality in PWH (Figure 1), which was confirmed in adjusted analyses (adjusted hazard ratio [aHR] 1.49, 95% confidence interval 0.99 to 2.25; $p = 0.06$). Following additional adjustment for disease severity at admission, the mortality risk in PWH was higher than in the comparator group (aHR 1.63 [1.07 to 2.48]; $p = 0.02$). Among PWH, those who died were slightly older and had a higher prevalence of diabetes with complications and obesity than those remaining alive, with no differences in sex, ethnicity, smoking or other comorbidities.
**Conclusions:** In this UK cohort, HIV-positive status was associated with a 63% increased risk of Day 28 mortality following a COVID-19 related hospitalisation.

### References

1. Presented on behalf of the ISARIC4C Investigators, and on behalf of the CHASE Study Group [also including: Muge Cevik (University of St Andrews), Simon Collins (HIV I-Base, London), Daniel Bradshaw, Alison Brown,




**Abstract O422-Figure 1. Kaplan-Meier analysis of cumulative mortality stratified by age group among people with HIV (grey line with 95% confidence interval) and people without HIV (black line) who were hospitalised with COVID-19. *p*-values represent log-rank tests.**

Nicky Connor, Valerie Delpech, Tamyo Mbisa (Public Health England), Saye Khoo (University of Liverpool), Chloe Orkin (Barts Health, London), and Laura Waters (Mortimer Market Centre, London)].
2. International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC). WHO Clinical Characterisation Protocol (CCP) [Internet]. [cited 2020 Jul 17]. Available from: https://isaric4c.net/ Accessed 17 August 2020.

# Cure Update

## O431

### Progress towards developing an effective cure of HIV infection

S Deeks

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Antiretroviral therapy (ART) must be administered for life. This requirement poses challenges for many individuals and health care systems. Identifying strategies that can fully eradicate HIV (a 'cure') or achieve durable post-ART control (a 'remission') is now a global priority. Over the past few years, the field has made significant progress in identifying how the virus persists during effective ART. Multiple therapeutic strategies are now being developed, including those that seek to induce virus production and cell death ('shock and kill'), cause permanent silencing ('block and lock') or achieve a state of immunologic control similar to that in exceptional controllers and post-treatment controllers. Most strategies now being tested aim to enhance immune control of the virus, but there is growing consensus the most promise may lie with gene therapies. Although progress in the clinic has been limited, several strategies have demonstrated promise in the non-human primate model. Recent therapeutic advances will be summarised, and the future directions of HIV cure research described.

## O432

### HBV cure

M Maini

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HIV and HBV infection have shared routes of transmission, with approximately 10% of HIV positive patients worldwide being co-infected with HBV. These two chronic infections also share the hallmark of immune dysregulation and a number of other hurdles that need to be overcome in order to develop eradication strategies [1]. This presentation will discuss the dual barriers to cure in HBV infection: persistent episomal and integrated HBV DNA and an exhausted immune response. It will overview the different novel antiviral drug classes in development for HBV cure and will then focus on the major categories of immunomodulatory approaches being considered to rev-up, release, restore or replace the failed immune response. The presentation will highlight the striking number of immunomodulatory approaches being developed in parallel for HBV and HIV functional cure.

### Reference

1. Maini MK, Peppa D. Shared immunotherapeutic approaches in HIV and hepatitis B virus: combine and conquer. Curr Opin HIV AIDS. 2020;15 (3):157-64.

# Emerging Topics in HIV and COVID-19

## O441

### Switching to DTG/3TC fixed-dose combination (FDC) is non-inferior to continuing a TAF-based regimen (TBR) in maintaining virologic suppression through 96 weeks (TANGO study)

J van Wyk[1]; F Ajana[2]; F Bisshop[3]; S De Wit[4]; O Osiyemi[5]; J Portilla[6]; J Routy[7]; C Wyen[8]; M Ait-Khaled[9]; M Nascimento[9]; K Pappa[10]; R Wang[11]; J Wright[12]; B Wynne[10]; M Aboud[1] and K Smith[10]

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**Background:** DTG/3TC two-drug regimen (2DR) was non-inferior to a TAF-based 3/4DR through the Week 48 primary endpoint in TANGO. Here we present Week 96 secondary endpoint analyses.

**Materials and methods:** TANGO, a randomized, open-label, non-inferiority phase III study evaluates the efficacy and safety of switching to once-daily DTG/3TC in HIV-1-infected, virologically suppressed (>6 months, no prior virologic failure, no major NRTI or INSTI resistance) adults versus remaining on a TBR, over 148 weeks. Participants were randomized 1:1, stratified by baseline third agent class: PI, NNRTI, INSTI. Week 96 analysis assessed non-inferiority with a 4% non-inferiority margin for Snapshot virologic failure (VF) and 8% for virologic success (VS; FDA Snapshot algorithm, intention-to-treat–exposed [ITT-E] population).
**Results:** Seven hundred and forty-one randomized/exposed participants (DTG/3TC: 369; TBR: 372). For Snapshot VF, switching to DTG/3TC was non-inferior to continuing TBR at Week 96 in the ITT-E analysis: 0.3% versus 1.1%; adjusted difference: −0.8% (95% CI −2.0%, 0.4%) and superior to TBR in the per-protocol analysis: 0% versus 1.1%; adjusted difference: −1.1% (95% CI −2.3%, −0.0%); $p = 0.044$ (two-sided). Snapshot VS was high in both arms and demonstrated non-inferiority (Table 1). Forty-four participants (5.9%) had missing data in the Week 96 window due to COVID-19 impact. Zero participants on DTG/3TC and three (<1%) on TBR met protocol-defined VF with no resistance observed at failure. Overall adverse event (AE) rates were similar between arms, with more drug-related AEs in the DTG/3TC arm (Table 1). TC, LDL-cholesterol, and triglycerides improved significantly with DTG/3TC while HDL-cholesterol (HDL-C) changes significantly favored TBR, with no difference in TC/HDL-C ratio between arms. Decreases in GFR by cystatin C were observed with a significantly lower decrease in the DTG/3TC arm; proximal tubular function marker changes were small and similar across arms.

**Abstract O441-Table 1. Efficacy and key safety results for the ITT-E and safety population**

| Week 96 study outcome by Snapshot analysis (ITT-E population), n (%) | DTG/3TC (N = 369) | TBR (N = 372) |
|---|---|---|
| HIV-1 RNA ≥ 50 copies/mL (Snapshot virologic failure) | 1 (0.3) | 4 (1.1) |
| HIV-1 RNA < 50 copies/mL (Snapshot virologic success)[a] | 317 (85.9) | 294 (79.0) |
| No virologic data in Week 96 window | 51 (13.8) | 74 (19.9) |
| Week 96 virologic success for efficacy evaluable population,[b] n (%) | (N = 353) | (N = 344) |
| HIV-1 RNA < 50 copies/mL (Snapshot virologic success) | 317 (89.8) | 294 (85.5) |
| Key safety results (safety population), n (%) | (N = 369) | (N = 371)[c] |
| Any AEs | 324 (87.8) | 325 (87.6) |
| AEs or death leading to withdrawal | 21 (5.7) | 4 (1.1) |
| Drug-related Grade 2 to 5 AEs[d] | 21 (5.7) | 7 (1.9) |
| Serious adverse events | 42 (11.4) | 35 (9.4) |

[a]Snapshot virologic success adjusted difference in (DTG/3TC) − TBR: 6.8% (95% CI 1.4%, 12.3%). Estimates and confidence intervals were based on a stratified analysis using Cochran-Mantel-Haenszel weights adjusting for baseline third agent class;
[b]sensitivity analysis excluding 16 and 28 participants in the DTG/3TC and TBR arms, respectively, because of no Week 96 HIV-1 RNA data due to COVID-19 pandemic impact. Snapshot virologic success adjusted difference in (DTG/3TC) − TBR: 4.3% (95% CI −0.6%, 9.2%);
[c]one participant was excluded due to receiving a TDF-based regimen instead of a TAF-based regimen;
[d]two deaths (one homicide and one unknown reason) both unrelated to treatment occurred in the DTG/3TC arm.

**Conclusions:** At Week 96, switching to DTG/3TC FDC was non-inferior to continuing a TAF-based 3/4DR in maintaining virologic suppression in HIV-1-infected ART-experienced adults. The safety profile of DTG/3TC FDC was consistent with the DTG and 3TC respective labels. DTG/3TC 2DR offers a robust switch option with durable efficacy, good safety and tolerability, and a high barrier to resistance with zero protocol-defined VF through 96 weeks.

## O442

### A combination of viral and participant factors influence virologic outcome to long-acting cabotegravir and rilpivirine: multivariable and baseline factor analyses across ATLAS, FLAIR, and ATLAS-2M phase III studies

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**Background:** Phase III studies demonstrated the efficacy and safety of long-acting (LA) HIV treatment with cabotegravir (CAB) and rilpivirine (RPV) dosed every four weeks (Q4W) in ATLAS and FLAIR, and every eight weeks (Q8W) in ATLAS-2M, with a virologic failure rate of ~1% across studies. Post-hoc analyses explored potential factors associated with virologic outcome at Week 48.
**Materials and methods:** Data from 1039 HIV-infected adults naïve to CAB+RPV were pooled in a multivariable analysis to examine the influence of baseline viral, participant factors and dosing regimen, and post-baseline plasma drug-concentrations on confirmed virologic failure (CVF) using regression modeling with a variable selection procedure. Retained baseline factors were then further evaluated to understand contribution to CVF when present alone or in combination.
**Results:** 94.3% (980/1039) of participants on Q4W and Q8W dosing maintained virologic suppression through Week 48, with only 1.25% (13/1039) having CVF. Four covariates were significantly associated ($p < 0.05$ for each adjusted odds ratio) with increased risk of CVF: RPV resistance mutations at baseline, A6/A1 HIV-1 subtype, BMI (associated with CAB pharmacokinetics), and Week 8 RPV concentration. There was a high correlation between A6/A1 and L74I, but only one (1/57, 1.75% [95% CI 0.04 to 9.4]) participant with L74I alone had CVF, consistent with the overall population rate. Other variables (e.g. Q4W or Q8W dosing, female at birth, other viral subtypes) had no significant association. Participants with no or one significant baseline

factor had high virologic success rates (94.8% and 96.0%, respectively, for 0 or 1 factor). The combination of two or more factors was uncommon in the study populations (3.37%; 35/1039), with 71.4% (25/35) maintaining HIV-1 suppression <50 copies/mL by FDA Snapshot algorithm (Table 1).

**Abstract O442-Table 1. Week 48 outcomes by presence of key baseline factors of RPV RAM, subtype A6/A1, BMI ≥ 30 kg/m$^2$**

| Baseline factors (number) | Virologic successes[a] | Confirmed virologic failure (%)[b] |
|---|---|---|
| 0 | 694/732 (94.8) | 3/732 (0.41) |
| 1 | 261/272 (96.0) | 1/272 (0.37)[c] |
| ≥2 | 25/35 (71.4) | 9/35 (25.7)[d] |
| TOTAL | 980/1039 (94.3) | 13/1039 (1.25) |
| (95% confidence interval) | (92.74 to 95.65%) | (0.67 to 2.13%) |

[a]Based on the FDA Snapshot algorithm of HIV-1 RNA < 50 copies/mL;
[b]defined as two consecutive measurements of HIV-1 RNA > 200 copies/mL;
[c]positive predictive value (PPV) < 1%; negative predictive value (NPV) 98%; sensitivity 8%; specificity 74%;
[d]PPV 26%; NPV 99.6%; sensitivity 69%; specificity 97.5%.

**Conclusions:** CAB+RPV LA demonstrated high efficacy in phase III studies and was non-inferior to oral antiretroviral therapy for the maintenance of virologic suppression. No baseline factor alone was predictive of virologic failure. In the small number of participants with a combination of RPV resistance mutations, A6/A1 subtype or higher BMI, the risk of CVF modestly increased. These findings should be contextualized with the high overall success rate observed with both Q4W and Q8W regimens.

# O443

## Safety and immunogenicity of V114, a 15-valent pneumococcal conjugate vaccine, in adults infected with HIV: a phase III trial

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**Background:** HIV infection increases the risk of pneumococcal disease (PD). Sequential vaccination with PCV followed by 23-valent pneumococcal polysaccharide vaccine (PCV) (PPSV23) has been recommended for prevention of PD in HIV-infected individuals. V114 is an investigational 15-valent PCV and contains all serotypes in PCV13, plus serotypes 22F and 33F. This phase III trial evaluated the immunogenicity and safety of V114 or PCV13 followed eight weeks later by PPSV23 in HIV-infected adults.
**Materials and methods:** Eligible HIV-infected adults aged ≥18 years, pneumococcal vaccine naïve and receiving antiretroviral therapy were randomised 1:1 to receive either V114 or PCV13 followed by PPSV23 eight weeks later. Randomisation was stratified by CD4 + cell count. Serotype-specific opsonophagocytic activity (OPA) and immunoglobulin G (IgG) antibodies were measured immediately prior to V114/PCV13 and 30 days after each vaccination.
**Results:** Three hundred and two participants were randomised to receive V114 (n = 152) or PCV13 (n = 150). Of the participants, 78.8% were males; 72.2% were 18 to 49 years old; 98.7% had CD4 + T-cell count ≥200 cells/μL; and 51.7% had CD4 + T-cell count <500 cells/μL at screening in both intervention groups; 78.5% had undetectable HIV RNA. All vaccines were generally well tolerated, and safety profiles were generally comparable across vaccination groups. V114 and PCV13 induced OPA and IgG antibodies at 30 days post vaccination (Day 30) to all serotypes included in the respective vaccines. Thirty days following administration of PPSV23, V114 and PCV13 OPA and IgG antibody levels were generally comparable to those observed at Day 30 after V114/PCV13 administration for serotypes in the respective PCVs. Geometric mean fold rises, percentages of subjects with ≥4-fold-rise from baseline and reverse cumulative distribution curves for both OPA and IgG antibodies were consistent with an immune response that was generally comparable between V114 and PCV13 for shared serotypes.
**Conclusions:** In pneumococcal vaccine-naïve adults infected with HIV, V114 followed eight weeks later by PPSV23, as per recommendations aimed at prevention of PD in HIV-infected individuals, is generally well tolerated, and induces immune responses for all 15 pneumococcal serotypes as assessed by OPA geometric mean titers and IgG geometric mean concentrations at 30 days after V114 and after PPSV23 administration.

# O444

## SARS-CoV-2 infection in pregnancy and newborn in a Spanish multicentric cohort (GESNEO-COVID)

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**Background:** Knowledge about SARS-CoV-2 infection in pregnancy and newborn is scarce [1,2]. The objective of the study is to describe clinical and epidemiological characteristics of a cohort of women infected with SARS-CoV-2 during pregnancy and their newborns.
**Materials and methods:** Multicentre observational study of five hospitals of the GESNEO-COVID cohort, participants in RECLIP. Women with confirmed SARS-CoV-2 infection by PCR and/or serology during pregnancy, diagnosed and delivering during the period 15 March to 1 July 2020 were included. Epidemiological and clinical data were collected.
**Results:** There were two twin births so 74 mothers and 76 newborns were included. The median age of pregnant women was 33.5 (IQR 28.8 to 37.0) years; 52.7% were Spanish and 47.3% were foreigners (68.6% from Latin America). Almost 7% were diagnosed during the second quarter and 90.5% during the third quarter. More than half (67.6%) of pregnant women had symptoms, fever (56%) and cough (52%) the most frequent. 37.8% received treatment for COVID-19. One-third (35.1%) had pneumonia and three (11.5%) of them were admitted to the ICU, requiring invasive mechanical ventilation. All pneumonia was diagnosed during the first month of the study. Pregnant women with pneumonia had a higher proportion of Caesarean sections (61.5% vs 29.2%; $p = 0.014$) and premature newborns (42.3% vs 12.5%; $p = 0.009$) than those not having pneumonia. Globally, 40.5% of pregnant women had a Caesarean delivery (around 20% last year), the indication was severity of COVID-19 for 30% of them.

Overall prematurity was 23% (around 15% last year) and in C-sections by COVID-19, 77.8%. 19.7% of newborns required admission to intensive care with a median duration of 4 (IQR 1 to 13) days. 64.5% were breastfed. Nasopharyngeal PCR was performed at birth, being 100% negative (71/71), and at 15 days of life, being 1/42 positive (4.2%), assuming contagion in the family environment. A 20-days-old newborn died due to prematurity-related causes.
**Conclusions:** SARS-CoV-2 infection during pregnancy could cause COVID-19 pneumonia that would condition an alteration in the course of pregnancy. We find a high proportion of Caesarean sections and prematurity, being higher in pregnant women with pneumonia, which would worsen neonatal prognosis. There is no vertical transmission in our series but a case of horizontal transmission by intra-family contact was found.

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# POSTER ABSTRACTS

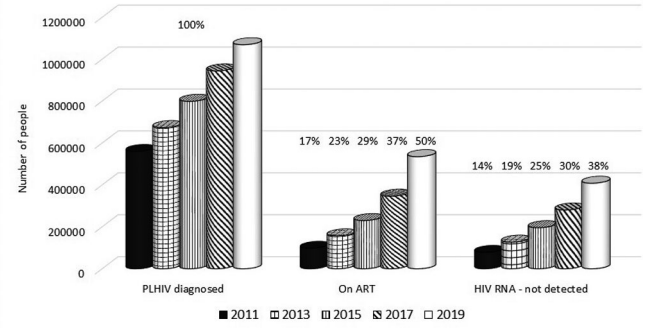
## ARV-based Prevention

### P001

### Progress in HIV cascade in Russia from 2011 to 2019

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**Background:** The cascade of HIV care is one of the main tools to assess the individual and public health benefits of ART and identify barriers of treatment as prevention concept realisation. We aimed to characterise changes in engagement of PLHIV in care in Russia.
**Methods:** We analysed the National AIDS/HIV statistic data collected by Rospotrebnadzor from 2011 to the end 2019 (Figure 1).
**Results:** More than 500 000 new HIV cases were registered in Russia from 2011 to 2019 and reached 1 068 839 PLHIV in the end 2019. Proportion of PLHIV who received ART from the total diagnosed PLHIV increased from 17% in 2011 to 50% in 2019 and the total number of PLHIV receiving ART has exceeded 500 000. Half of patients (51.8%) started ART with CD4 > 350 cells in 2018 compared to 35.5% of patients in 2016. There was satisfactory adherence to ART so viral suppression was not less than 78% in patients on ART during 2011 to 2018. And 76% of PLHIV receiving ART achieved HIV RNA below the detection level of test systems used in the reporting period in 2019. Only 17% of HIV diagnosed patients had viral suppression which is necessary to prevent viral transmission in 2011. In 2019, this proportion increased to 38%.




**Abstract P001-Figure 1. HIV cascade in Russia, 2011 to 2019 (percentage is from PLHIV diagnosed).**

**Conclusions:** During the nine years from 2011 to 2019 we noted the positive trends in the involvement of PLHIV in treatment despite the rapid increase of new HIV cases. Although the total number of PLHIV receiving ART in Russia is constantly growing, the percentage of ART coverage remains unsatisfactory due to the large number of newly diagnosed cases. Therefore, further improvement of HIV care cascade depends on the effectiveness of HIV prevention.

### P002

### Side effects of antiretroviral therapy and their association with adherence among postpartum Malawian women

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**Background:** With global implementation of test and treat strategies for the prevention of maternal to child transmission (PMTCT) of HIV, understanding barriers to ART adherence in postpartum women is important. We describe the prevalence of ART side effects (SEs) and their association with adherence and viral load in postpartum Malawian women.
**Materials and methods:** We conducted a cross-sectional analysis of women four to twenty-six weeks postpartum enrolled in the National Evaluation of Malawi's PMTCT Programme study (2014 to 2016); national guidelines at the time initiated pregnant/breastfeeding women on life-long ART (efavirenz, lamivudine and tenofovir). Semi-structured interviews collected socio-demographic data, self-reported ART adherence (suboptimal adherence ≥2 doses missed in the last 30 days) and SEs experienced (grouped by the Division of AIDS criteria [1]). Maternal venous samples determined plasma viral load (detectable ≥40 copies/mL). Multiple logistic regression explored the association of SEs with suboptimal adherence or detectable viral load.
**Results:** At enrolment, 493/561 (87.9%) were on ART, of whom 10.5% (n = 52) reported suboptimal adherence and 18.3% (n = 90) had a detectable viral load. Of 475 women with complete SE data, 38.1% (n = 181) reported at least one SE. Neurological (49.2%, n = 89) and psychiatric (48.6%, n = 88) SEs were the most commonly reported categories. Controlling for age, education and timing of ART

initiation, women who experienced any SE had twice the odds of suboptimal adherence compared to those who did not (aOR 2.06, 95% CI 1.12 to 3.76, $p = 0.019$). Suboptimal adherence was also higher in women who experienced neurological SEs (aOR 2.71, 95% CI 1.39 to 5.27, $p = 0.005$) and psychiatric SEs (aOR 2.16, 95% CI 1.11 to 4.19, $p = 0.028$). There was insufficient evidence for an association between any SE and detectable viral load (aOR 1.41, 95% CI 0.86 to 2.30, $p = 0.174$), controlling for maternal age, education, timing of ART initiation and number of antenatal care visits.
**Conclusions:** Neurological and psychiatric SEs are frequently reported by postpartum Malawian women on efavirenz-containing ART and are associated with suboptimal adherence. The findings contribute to ongoing discussions on offering dolutegravir as an option, and highlight the importance of recognising SEs in women on ART and intervening with appropriate counselling and care.

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## P003

### Maintaining medical care for PrEP users via home sampling during the COVID-19 shutdown in Switzerland: Checkpoint@home

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**Background:** Medical routine checks were not allowed during six weeks in 2020 in Switzerland because of the COVID-19 pandemic. As postponing HIV pre-exposure prophylaxis (PrEP) checks might put PrEP user on health risks, we performed a pilot study to test the feasibility of lab home sampling at the biggest PrEP clinic in Switzerland during that time before offering it to other clients.
**Material and methods:** We asked 30 participants of the SwissPrEPared study, if they either want to use home sampling or postpone their visit. Those who agreed received a kit for capillary blood self-sampling, swabs, a written instruction and an instruction video. Validation was performed with a questionnaire, including multiple-choice questions, five-point Likert scale and open questions. Lab results were discussed with the participants via phone. People with symptoms of a sexually transmitted infection were excluded and asked to come to the clinic. An interim analysis was performed after the first 12 results.
**Results:** Twenty-four of the 30 clients agreed to participate (80%). All were men who have sex with men. The median age was 46 years (range: 31 to 70). Two clients could not participate due to unexpected reasons. Of the 22 remaining participants, 20 filled out the questionnaire. Comprehensibility of the written instructions was rated as a 4.85/5 and 5/5 for the video. One client reported to be unsure, if he performed the swabs right. Two clients reported that they could not gain the blood sample as required and one client was unsure. The interim analysis showed that four of the 12 blood samples could not be fully analysed due to either haemolysis (2/4) or insufficient amount of blood in the tube (2/4). We could identify and solve the problems. All further samples could be fully analysed. Nineteen of 20 participants reported that they would use home sampling for further PrEP consultations (95%), 2/20 reported that they primarily want to use home sampling in future.
**Conclusions:** Home sampling was well accepted, the instructions were good to understand and the sampling operation was feasible for most of the participants. The programme helped to continue care for PrEP users during the COVID-19 shutdown and will help to prevent SARS-CoV-2 infections in the clinic in future.

## P004

### Disclosure of PrEP status and its association with online sexual networking among men who have sex with men in Hong Kong

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**Background:** Social media is a commonly used platform of MSM for seeking partners, which has been researched in relation to sexual risk behaviours. While pre-exposure prophylaxis (PrEP) has emerged as an option for HIV prevention, little is known as regards the impact of the identity of "PrEP users" on engagement in online sexual networking. This study aimed to understand the experience of communicating PrEP status by MSM in the context of online sexual partner networking.
**Materials and methods:** A qualitative study was conducted that included in-depth and semi-structured interviews performed on 20 Hong Kong-Chinese MSM, who have used PrEP between March and August 2019. The interviews were audio-recorded, transcribed and thematically analysed using a grounded theory approach.
**Results:** We identified three types of disclosure behaviours as regards PrEP: continuous disclosure through online profile; concealment after first-time disclosure through online profile; and offline disclosure with continuous concealment of online profile. The findings highlighted three main themes: (1) "PrEP as an additional partner selection criterion by social media members", (2) "PrEP users are seen to be more available for high-risk activities by social media members", and (3) "PrEP concealment online as a strategy of risk reduction". Some PrEP users regarded revealing PrEP status offline only, with the potential partner, and at the moment of sex negotiation, would be a safer means. Participants who persistently practiced condom use with casual partners, in particular, expressed challenges with encountering increased online requests for condomless anal intercourse, and a great need for alertness about consistent condom use to protect against other sexually transmitted infection.
**Conclusions:** In the MSM community, knowledge of the identity of "PrEP users" may influence the pattern of sexual networking. Future research on the perception of PrEP held by social media members is needed so that providers can better support PrEP users with the communication skills that are needed for safer sex negotiation.

## P005

### Cork University Hospital clinical audit: the management of pregnancies in HIV-positive women and the safety and efficacy of ART during pregnancy

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ART is used during pregnancy to decrease the incidence of mother-to-child transmission (MTCT) of HIV but its effects on the developing foetus have not been fully studied. The objective of this study was to evaluate the management of pregnancies in women with HIV by the Cork University Hospital (CUH) HIV Clinic and determine the safety and outcome of ART use in pregnancy, with a focus on the new antiretrovirals. A database of pregnancies managed by the CUH HIV Clinic and patient charts were used to collect data on pregnancies between 2009 and 2019. Commencement of ART, viral load at delivery and ART were recorded and compared to BHIVA guidelines for the management of HIV in pregnancies. Primary outcomes were MTCT, pregnancy outcome (live birth, stillbirth, miscarriage), gestational age at birth and birthweight, with adverse outcomes, preterm delivery and low birthweight analysed for associations with specific ART. One hundred and forty-eight pregnancies were recorded: 89.3% began ART before 24 weeks gestation, 78.8% had a nondetectable viral load at time of delivery, and 93% were on recommended or equivalent ART. The

MTCT rate was 0.8% (one in 131 live births). There were 131 live births (89.1%), 14 miscarriages (9.5%) and two stillbirths (1.4%). Of the 85 live births with recorded birthweight, nine had low birthweight, but only two had low birthweight for gestational age (1.5%, both on combination of Truvada+darunavir+ritonavir). There was no statistically significant association between any of the ART regimens and adverse pregnancy outcomes, low birthweight or preterm delivery. There were 17 pregnancies managed with new ARTs. There were four patients on Descovy, with one incidence of miscarriage, no stillbirths and one incidence of preterm delivery with low birthweight. There were five patients on Genvoya, with one incidence of stillbirth, no miscarriages and one preterm delivery. There were eight patients on Odefsey, with two incidences of miscarriage, no stillbirths and no preterm deliveries. The CUH HIV Clinic largely meets the BHIVA guidelines in their management of pregnancies in HIV-positive women. There were no specific ART regimens associated with adverse pregnancy outcomes, preterm delivery or low birthweight, which may be due to low sample size. The newer ARTs need further investigations on their use during pregnancy.

# Treatment Strategies: New Treatments and Targets

## P006

### Cabotegravir + rilpivirine long-acting as HIV-1 maintenance therapy: ATLAS Week 96 results

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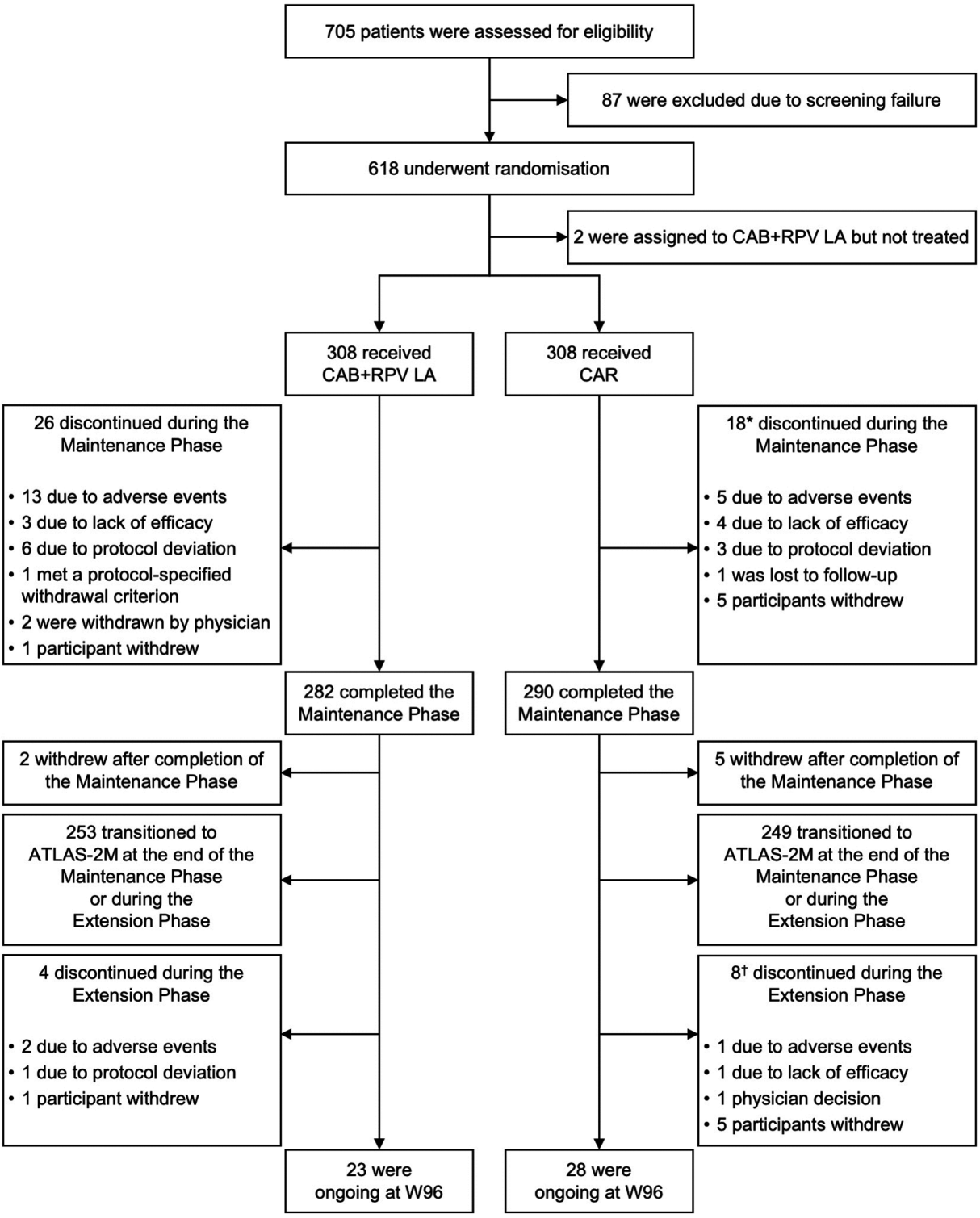
**Background:** Long-acting (LA) injectable therapies have the potential to address some challenges associated with daily oral ART, e.g. pill fatigue, drug/food interactions, stigma and sub-optimal adherence. ATLAS (NCT02951052) is a phase III, multicentre, open-label study. Week (W) 48 data demonstrated switching to monthly injectable cabotegravir (CAB) + rilpivirine (RPV) LA was noninferior to continuing three-drug daily oral ART for adults living with HIV-1 [1].

**Materials and methods:** Virologically suppressed ART-experienced participants were randomised (1:1) to continue current ART (CAR arm) or switch to LA therapy (LA arm) for a 52-week maintenance phase (MP) [1]. After completion, participants could withdraw, transition to

**Abstract P006-Table 1. Key outcomes**

| Outcome, n (%) intention-to-treat exposed and switch population | LA arm (Day 1 to W52) n = 308 | CAR arm (Day 1 to W52) n = 308 | LA arm (W52 to W96) n = 280[a] | Switch arm (W52 to W96) n = 174[b] |
|---|---|---|---|---|
| Present at W96 data analysis[c] | N/A | N/A | 23 | 29 |
| HIV-1 RNA ≥ 50 copies/mL at W96 data analysis | N/A | N/A | 0 | 1 |
| HIV-1 RNA < 50 copies/mL at W96 data analysis | N/A | N/A | 23 | 28 |
| Number of injections | 6978 | N/A | 1363 | 1264 |
| Number of ISR events | 1460 | N/A | 154 | 238 |
| Grade 1 ISR events—mild | 1156 | N/A | 134 | 184 |
| Grade 2 ISR events—moderate | 283 | N/A | 20 | 51 |
| Grade 3 ISR events—severe | 21 | N/A | 0 | 3 |
| ISR duration ≤7 days | 1288 | N/A | 113 | 199 |
| Number of participants discontinuing due to ISRs | 4 (1) | N/A | 0 | 1 (<1) |
| Overall AEs | 294 (95) | 220 (71) | 1[d] | 105 (60) |
| Maximum Grade 3 or 4 AEs | 35 (11) | 23 (7) | 2[d] | 7 (4) |
| Drug-related AEs | 255 (83) | 8 (3) | 0[d] | 79 (45) |
| Maximum Grade 3 or 4 drug-related AEs | 14 (5) | 1 (<1) | 0[d] | 4 (2) |
| AEs leading to withdrawal | 14 (5) | 5 (2) | 2[d,e] | 1 (<1)[f] |
| Drug-related AEs leading to withdrawal | 10 (3) | 1 (<1) | 1[d] | 1 (<1) |
| Serious AEs[g] | 13 (4) | 14 (5) | 2[d] | 2 (1) |

AE, adverse event; ISR, injection site reaction; LA, long-acting; W, week.
[a]Number of participants at W52 visit;
[b]all participants from the CAR arm who received ≥1 dose of cabotegravir/rilpivirine during the extension phase;
[c]W96 ± 4 weeks;
[d]number of new participants with AEs during the extension phase;
[e]includes acute hepatitis B and fear;
[f]injection site pain;
[g]no serious AEs were classified as related to cabotegravir/rilpivirine.




**Abstract P006-Figure 1. Participant disposition through Week (W) 96. *includes two participants that deviated from protocol/transitioned to ATLAS-2M prior to the completion of the maintenance phase. †one participant who discontinued at W92 was included in the W96 data analysis.**

ATLAS-2M (NCT03299049; investigating CAB+RPV LA dosed every eight weeks vs CAB+RPV LA dosed every four weeks) or enter an extension phase (EP). Participants entering the EP at W52 either continued LA therapy (LA arm) or switched from CAR to CAB+RPV LA (Switch arm). Endpoints assessed at W96 included: proportion of participants with plasma HIV-1 RNA < 50 copies/mL and ≥50 copies/mL, confirmed virological failure (CVF; two consecutive HIV-1 RNA ≥ 200 copies/mL), safety, tolerability and patient-reported outcomes.

**Results:** The majority of participants completing the MP transitioned to ATLAS-2M (88%, 502/572), leaving 52 in the ATLAS study for inclusion in the W96 data analysis (Figure 1). Of those 52 participants, 100% (23/23) and 97% (28/29) in the LA and Switch arms maintained

virological suppression at the W96 data analysis, respectively (Table 1). No participants in either arm had CVF during the EP. Safety and tolerability data for LA and Switch arm participants were comparable, and similar to data reported during the MP [1]. The most common drug-related adverse events were injection site reactions, which were generally mild/moderate in severity and of short duration (median duration, three days). All Switch arm participants responding to the questionnaire at W96 (100%, 27/27) preferred LA treatment to their previous daily oral regimen.

**Conclusions:** CAB+RPV LA maintained virological suppression in the majority of participants who entered the EP and were present at the W96 data analysis, with no CVFs or new safety signals identified. These longer-term efficacy and safety data, in addition to patient preference data, support the therapeutic potential of CAB+RPV LA treatment.

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## P007

### Multicenter, open-label, post-authorization safety study (PASS) of elsulfavirine (Elpida®) used in the first-line therapy for HIV-1 infected patients added to standard ART (NNRTI + two NRTIs)

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**Background:** VM1500A is a novel, potent non-nucleoside reverse transcriptase inhibitor with a unique clinical pharmacokinetic profile and broad-spectrum activity across HIV-1 variants. A 20 mg oral capsule formulation of elsulfavirine (ESV), pro-drug of VM1500A, was approved for marketing in Russia in 2017 for treatment of HIV-1 in combination with two nucleoside reverse transcriptase inhibitors as part of a standard ART regimen, under the brand name Elpida®. The safety and efficacy PASS study of Elpida was initiated in 19 clinical sites across Russia in 2018.

**Methods:** The study includes HIV-1 infected patients treated with 20 mg ESV daily as part of HAART. Efficacy endpoints including viral load, CD4 + T-cell count and drug resistance, and safety endpoints including clinical adverse events (AEs), serious adverse events (SAEs), ECG and laboratory data have been observed. The safety analysis included 1141 patients who enrolled no later than 48 weeks before the cut-off date, both treatment naïve and treatment experienced. The efficacy population included treatment-naïve patients who completed 48 weeks of treatment.

**Results:** Of 397 treatment-naïve patients 281 had a baseline viral load of $\leq 10^5$ copies/mL, and 116 patients had $>10^5$ copies/mL. A significant reduction in viral load was observed from Week 4 and it was sustained through the treatment. At Week 48, a total 87.4% of patients had an undetectable viral load. The average $CD^{4+}$ T-cell count increased from 447.5 to 655 copies/mL, independent of the baseline viral load. The treatment was well tolerated for the first 48 weeks. Most of the observed AEs were of mild/moderate severity. A total 12 (1.1%) patients reported SAEs, all deemed unrelated to treatment. A subgroup of 131 patients completed 96 weeks of treatment confirming sustained efficacy and devoid of safety issues.

**Conclusions:** The interim analysis of the study supports the previous safety and efficacy data for Elpida and encourages further treatment. The preliminary efficacy data shows a consistently high full viral suppression rate in patients with significant immunological efficacy. The safety and tolerability profile allows for high adherence and long-term treatment with ESV 20 mg as part of ART.

## P008

### Social, psychological, and treatment-related challenges of a new HIV diagnosis in old age

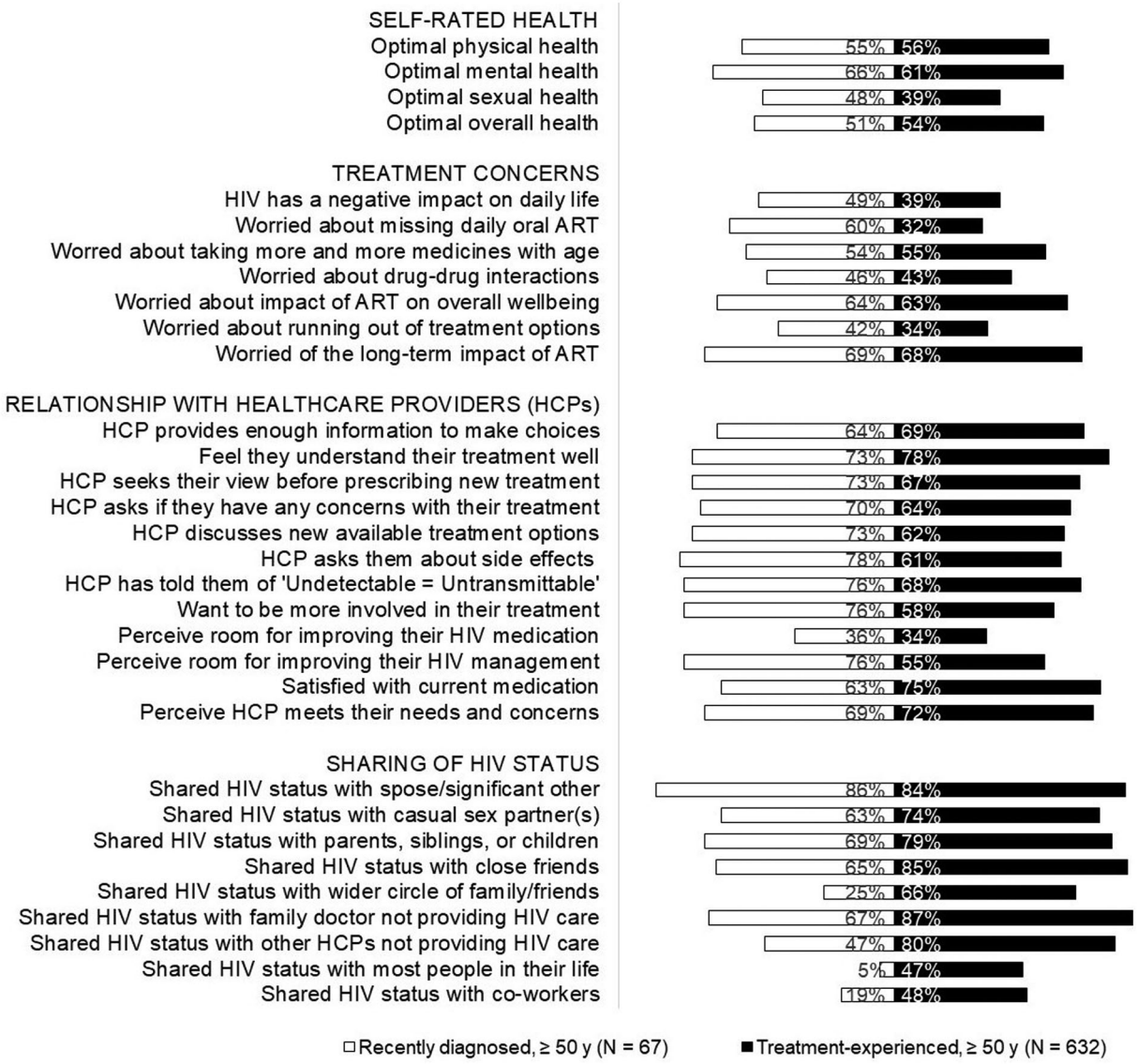
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**Background:** New HIV infections can occur at any age. We examined factors associated with recent HIV diagnosis among older adults and perceived treatment challenges.

**Materials and methods:** Data were from the 25-country 2019 Positive Perspectives study of PLHIV ≥ 18 years (n = 2389). Multivariable logistic regression explored correlates of recent (≤2 years) diagnosis among ≥50-year-olds (N = 699).

**Results:** Recent HIV diagnosis among older adults was unlikely to be through recreational drug use (aOR 0.13, 95% CI 0.02 to 0.97), but likely to be sexually contracted, especially among those with multiple sexual partners versus none (aOR 3.10, 95% CI 1.14 to 8.43). Odds of recent HIV diagnosis was higher among women versus MSM (aOR 3.88, 95% CI 2.01 to 7.48), employed versus nonemployed (aOR 2.81, 95% CI 1.56 to 5.05), and middle- versus high-income countries (aOR 1.87, 95% CI 1.01 to 3.48). Compared to newly diagnosed <50-year-olds, newly diagnosed ≥50-year-olds reported greater concerns that daily dosing increased chances of unwanted disclosure of HIV status (67.2% [45/67] vs 50.7% [244/481], $p = 0.012$); they also were more likely to withhold their HIV status for fear of exclusion (58.2% [39/67] vs 39.7% [191/481], $p = 0.004$), or being denied healthcare (31.3% [21/67] vs 20.2% [97/481], $p = 0.037$), but were less concerned about romantic discrimination (19.4% [13/67] vs 34.7% [167/481], $p = 0.012$). Newly diagnosed ≥50-year-olds were less open with their HIV status than treatment-experienced ≥50-year-olds (Figure 1). Non-HIV comorbidities were higher among newly diagnosed ≥50-year-olds (58.2% [39/67]) versus <50-year-olds (37.8% [182/481]), but lower versus treatment-experienced ≥50-year-olds (85.8%). Treatment satisfaction among newly diagnosed ≥50-year-olds (62.7% [42/67]) was similar to <50-year-olds (64.2% [309/481]), but lower versus treatment-experienced ≥50-year-olds (75.0% [474/632]). Compared to treatment-experienced ≥50-year-olds, newly diagnosed ≥50-year-olds reported higher percentages for perceived gaps with HIV management (76.1% [51/67] vs 54.6% [345/632]) and interest in greater involvement in care (76.1% [51/67] vs 58.1% [367/632]).




**Abstract P008-Figure 1. Self-reported treatment status, perceptions, and behaviors among people living with HIV aged ≥50 years, by duration of disease.**

**Conclusions:** Women had the highest likelihood of new HIV diagnosis among older adults. Unwillingness of newly diagnosed ≥50-year-olds to share HIV status with family/friends may constrict social support; unwillingness to share with healthcare providers may increase likelihood of fragmented care. Considering the unmet needs of newly diagnosed older adults when planning treatment and actively involving them may improve treatment satisfaction.

## P009

### HIV cure trials acceptability, representations and ethical issues among patients living with HIV: a qualitative study

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**Background:** Recently, new experimental HIV cure strategies based on stem-cell therapy have been investigated in cure-related clinical trials. These therapies generate many expectations, from patients and the scientific community, but raise some ethical concerns as well [1]. In light of these concerns, several researches investigated PLHIV motivations or reluctance to participate in such trials [2–4]. However, most of the time participants of these researches had little information about the course of a participation, the treatment itself and the consequences in terms of side effects. Our research aimed at exploring PLHIV representations of cure trials and understanding participation decision-making processes, using a standard (fictive) patient information letter (PIL).

**Materials and methods:** We conducted 15 semi-structured interviews organised in two parts: (1) an open discussion about cure trials in general and the "London" and the "Berlin" patients and (2) a discussion based on the fictive PIL. This letter was used to depict patients' decision-making process and "non-expert" theories about cure's functioning. Interviewees were French-speaking PLHIV aged over 18 years, recruited from Lausanne and Geneva HIV consultations. Interviews were analysed using thematic content analysis.

**Results:** Ten themes classified into three broad categories emerged from the analyses: (1) living with HIV, (2) ART's constraints and threat

of treatment interruption and (3) decision-making process leading to participating or not in the trial. Perception of personal vulnerabilities, personal experience with HIV, ART and side effects, trust in treating physicians, perceived or experienced stigmatisation, were key elements to understand PLHIV intention to participate.

**Conclusions:** With this study, we investigated connections between key factors involved in decision-making process concerning participation in a HIV cure trial. Results allowed to better understand participation's issues at both patients' and ethical levels. For example, participants who had been living with HIV for less than 5 years and expressing a strong fear of being stigmatised expressed higher levels of hope for a cure and were thus less reluctant to participate. Moreover, results stressed that interviewees held blurry perceptions, and sometimes misconceptions, about HIV researches, highlighting the ethical importance of considering these misconceptions when recruiting patients for HIV cure trials.

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# P010

## Efficacy and safety of dolutegravir in treatment-naive people living with HIV-1 stratified by age: meta-analysis of 48-week results from ARIA, FLAMINGO, SINGLE, and SPRING-2

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**Background:** Although data in treatment-experienced people living with HIV-1 (PLWH) aged ≥50 years have been described in the literature, the data are lacking in treatment-naive populations aged ≥50 years due to under-representation in clinical trials. We evaluated the efficacy and safety profile of the integrase strand transfer inhibitor (INSTI) dolutegravir (DTG) relative to comparator ART in PLWH naive to ART by age group from four phase III/IIIb clinical trials.

**Materials and methods:** This meta-analysis combined data from the ARIA, FLAMINGO, SINGLE, and SPRING-2 trials (ClinicalTrials.gov Identifiers: NCT01910402, NCT01449929, NCT01263015, and NCT01227824, respectively). PLWH in each trial were randomized 1:1 to receive either DTG or comparator treatment (atazanavir/ritonavir in ARIA, darunavir/ritonavir in FLAMINGO, efavirenz in SINGLE, and raltegravir in SPRING-2) in combination with two NRTIs through 48 weeks. Data were summarized by age group (<50 years, ≥50 to <65 years, and ≥65 years) and treatment (DTG and comparator group). Endpoints at Week 48 included proportion of participants with plasma HIV-1 RNA < 50 copies/mL (defined as virologic success; Snapshot algorithm), change from baseline in mean $CD^{4+}$ cell counts, and adverse events (AEs). Concomitant medications and comorbidities were analyzed.

**Results:** PLWH were divided into three age groups: <50 years (DTG, n = 1157; non-DTG, n = 1158), ≥50 to <65 years (DTG, n = 148; non-DTG, n = 148), and ≥65 years (DTG, n = 10; non-DTG, n = 13). Percentages of patients achieving virologic success at Week 48 were comparable for patients receiving DTG and non-DTG treatment (<50 years: 87% vs 81%; ≥50 to <65 years: 89% vs 85%; ≥65 years: 80% vs 62%). Across age strata, mean change from baseline in $CD^{4+}$ cell count was comparable in the DTG and non-DTG groups. Concomitant medication use and rate of comorbidities increased with age for DTG and non-DTG cohorts. For all age groups, drug-related AEs and AEs leading to withdrawal by Week 48 were comparable in the non-DTG and DTG groups.

**Conclusions:** Regardless of age, PLWH naive to ART and treated with DTG-based regimens achieved high rates of virologic success. Safety profiles were generally similar across age strata, and increased concomitant medication use and comorbidities were associated with increasing age.

# P011

## Comparability of 48-week efficacy and safety of cabotegravir + rilpivirine long-acting every 8 weeks to standard of care in suppressed HIV-1-infected patients

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**Background:** Switching to cabotegravir (CAB) + rilpivirine (RPV) long-acting (LA) administered every four weeks (Q4W) demonstrated non-inferiority in maintaining viral suppression versus continuing oral standard of care (SoC) in two pivotal phase III studies (Antiretroviral Therapy as Long-Acting Suppression [ATLAS; NCT02951052] and First Long-Acting Injectable Regimen [FLAIR; NCT02938520]). Furthermore, CAB+RPV LA given every eight weeks (Q8W) demonstrated noninferiority in maintaining viral suppression versus Q4W dosing in a phase IIIb study (ATLAS every two Months [ATLAS-2M; NCT03299049]). This analysis assesses comparability of CAB+RPV LA Q8W to SoC via an indirect comparison of these trials.

**Materials and methods:** CAB+RPV LA Q8W and SoC were indirectly compared through a generalisation of Bucher's methodology to calculate

**Abstract P011-Table 1. Results of the indirect comparison of CAB+RPV LA Q8W versus SoC at Week 48**

| Outcome (95% CI) | Relative risk | Risk difference, % | Odds ratio |
|---|---|---|---|
| Snapshot HIV-1 RNA ≥ 50 copies/mL | 1.10[a] (0.25, 4.90) | 0.2[a] (−2.2, 2.6) | 1.10[a] (0.24, 5.03) |
| Snapshot HIV-1 RNA < 50 copies/mL | 1.01[a] (0.95, 1.06) | 0.5[a] (−4.4, 5.3) | 1.04[a] (0.49, 2.22) |
| CD4 + cell change from baseline, cells/μl[b] | - | −5.1[a] (−40.0, 29.7) | - |
| No virological data | 0.95[a] (0.42, 2.15) | −0.7[a] (−4.9, 3.6) | 0.94[a] (0.40, 2.24) |
| Discontinuations due to AEs[c] | 1.48[a] (0.40, 5.46) | 0.5[a] (−2.5, 3.5) | 1.49[a] (0.39, 5.65) |
| Grade 3 or 4 non-ISR AEs | 1.68[a] (0.78, 3.61) | 3.3[a] (−1.3, 7.8) | 1.74[a] (0.77, 3.92) |

AE, adverse event; CAB, cabotegravir; ISR, injection site reaction; LA, long-acting; RPV, rilpivirine; SoC, standard of care, W, Week.
[a]p>0.1;
[b]mean difference;
[c]participants with no virological data at W48 who discontinued due to AEs.

relative risks, odds ratios and risk differences using CAB+RPV LA Q4W as a common comparator. Pooled data from ATLAS/FLAIR (SoC, n = 591; Q4W, n = 591) and the ATLAS-2M subgroup with no prior CAB+RPV exposure (Q8W, n = 327; Q4W, n = 327) were used to inform the analysis, given the similarity in baseline participant characteristics. Outcomes assessed at Week (W) 48 according to the FDA Snapshot algorithm were proportion of participants with plasma HIV-1 RNA ≥ 50 copies/mL and <50 copies/mL (virological suppression), those with no virological data and the number of discontinuations due to adverse events (AEs). Mean $CD^{4+}$ cell count change from baseline at W48 and the incidence of Grade 3 or 4 non–injection site reaction AEs during the maintenance phase were also assessed.
**Results:** No statistically significant difference was found for any outcome analysed for CAB+RPV LA Q8W versus SoC at W48 (Table 1). The proportion of participants on INSTI-based regimens at baseline was higher in the pooled ATLAS/FLAIR population (65%, 767/1182) versus the ATLAS-2M subgroup (42%, 277/654). Despite this imbalance, no significant difference in Snapshot HIV-1 RNA ≥ 50 copies/mL at W48 was found in a subgroup analysis by baseline treatment class in both ATLAS and ATLAS-2M, as well as in this indirect comparison.
**Conclusions:** CAB+RPV LA given Q8W demonstrated comparability in efficacy and safety to SoC consisting of guideline-recommended daily oral ART. These data support the therapeutic potential of CAB+RPV LA for people living with HIV-1 who seek alternative options to daily oral ART.

## P012

### Subgroup analysis of patient-reported outcomes among participants in two phase III clinical trials of long-acting cabotegravir and rilpivirine (ATLAS and FLAIR)

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**Background:** Patient-reported outcomes (PROs) in phase III clinical trials (ATLAS and FLAIR) of long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV) indicated higher levels of treatment satisfaction and acceptance versus daily oral ART in virologically suppressed participants. Subgroup analyses of PROs stratified by participant demographics and clinical characteristics are presented here.
**Materials and methods:** Multivariable analyses for baseline treatment satisfaction using the HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs), and treatment acceptance using the general acceptance domain of the Chronic Treatment Acceptance Questionnaire (ACCEPT) were conducted by region, sex, age, race/ethnicity, body mass index (BMI), Centers for Disease Control and Prevention (CDC) HIV stage, number of comorbidities, baseline third-agent ART class, prior single- or multi-tablet ART, and time on ART at study entry as covariates. Change from baseline for the above subgroups was estimated for Weeks 44 and 48. Factors influencing baseline (Week 5) acceptability of injection-site reactions (ISRs) with CAB+RPV LA were also explored.
**Results:** Baseline third-agent ART class, single- or multi-tablet ART, and time on ART were identified as significantly influencing baseline scores for both HIVTSQs and ACCEPT ($p < 0.05$), whereas race/ethnicity, CDC HIV stage, and number of comorbidities at baseline showed no impact. Participants with prior protease inhibitor–based regimens, multi-tablet regimens, or those with prior ART experience of 48 to 72 weeks reported the lowest levels of baseline treatment satisfaction and acceptance. Participants on integrase inhibitor–based regimens, single-tablet regimens, or who had prior ART experience of <24 weeks had the highest levels of baseline treatment satisfaction and acceptance. Improvements in treatment satisfaction and acceptance from baseline in all participants receiving CAB+RPV LA were greater than in those receiving ART at Weeks 44 and 48, regardless of baseline values. Overall initial acceptability of ISRs with CAB+RPV LA was high at Week 5, with women and participants with higher BMI being more accepting of pain and local reactions following initial injections with CAB+RPV LA versus men and those with lower BMI.
**Conclusions:** Participants receiving CAB+RPV LA showed significant increases from baseline in treatment satisfaction and acceptance at Week 48, regardless of key baseline demographics and clinical characteristics.

## P013

### Experience from a real-life cohort: outcome of 984 HIV infected patients treated with bictegravir/emtricitabine/tenofovir alafenamide in Hospital Clinic, Barcelona

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**Background:** The use of bictegravir/emtricitabine/tenofovir alafenamide (BIK) is mainly based on robust pivotal clinical trials [1,2]. However, data in real life are not widely available. In HIV Unit of Hospital Clínic in Barcelona we have a large cohort of BIK-treated patients.
**Methods:** This was an observational, retrospective, single-centre study. All antiretroviral-naïve (TN) and -experienced (TE) adult patients and starting BIK from 07/06/2018 to 04/06/2020 were included. We describe the demographic and HIV-related characteristics of the population. Effectiveness (HIV-RNA < 50 copies/mL, on-treatment (OT) (discontinuation/missing=excluded), modified intention-to-treat (mITT) (discontinuation=failure, missing=excluded) and ITT), tolerability and safety (drug-related (DR) adverse events (AEs) and DR serious AEs (DRSAEs)) were assessed during six and twelve months of follow-up.
**Results:** A total of 984 HIV-1 infected patients (157 TN [16%], 827 TE [84%]) were included. Median follow-up was 7.4 (4 to 10.5) months, with 67% and 17% patients reaching six and twelve months, respectively. Eighty-seven percent were male, median age 42 (34 to 51) years. Time since HIV diagnosis was 9 (3 to 16) years. Thirteen percent were HCV antibodies positive. Baseline $CD^{4+}$ was TN 293 (172 to 510) cells/$mm^3$ (30% <200 cells/$mm^3$) and TE 635 (446 to 853); baseline HIV-RNA was TN 61 500 (14 100 to 232 000) copies/mL (43% >100 000 copies/mL). Of those patients with available HIV-1 RNA data at Month 6 (n = 460) effectiveness was TN 82%–TE 94% by OT; TN 76%–TE 88% by mITT (n = 494); and TN 75%–TE 87% by ITT (n = 499). Of the patients with HIV-1 RNA ≥ 50 copies/mL was <200 copies/mL in 64% of them. Median CD4 cell count increased to 502/μl (Q1 to Q3: 295 to 764) in TN and to 694/μl (Q1 to Q3: 539 to 926) in TE patients at Month 6. Six hundred and sixteen (94%) patients persisted with BIK after six months; five (0.8%) were lost to follow-up and 34 (5.2%; five TN and 29 TE) discontinuing BIK prior to Month 6: due to DRAEs 24 (3.6%) (neuropsychiatric 11 (1.7%), gastrointestinal 8 (1.2%) (no DRSAEs), other AEs 4 (0.6%), virological failures 3 (0.4%) (no treatment-emerging resistance), interactions 2 (0.3%) and simplification 1 (0.1%)).
**Conclusions:** This observational cohort supports the high effectiveness (only 0.4% virological failure), tolerability and safety of BIK in clinical practice and demonstrates high persistence through six months.

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## P014

### Factors associated with interest in a long-acting HIV regimen: perspectives of people living with HIV and physicians in western Europe

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**Background:** Current ARTs require daily oral dosing—a challenge for some PLWHIV. Unmet needs associated with daily oral dosing include medical conditions interfering with oral administration, suboptimal adherence, confidentiality concerns and emotional wellbeing related to daily tablet requirements. With dosing every two months, long-acting cabotegravir and rilpivirine (CAB + RPV LA) is an innovative treatment for virally suppressed PLWHIV, proven to be as effective as daily oral ARTs. We assessed what percentage of PLWHIV and physicians would be interested in such a long-acting regimen (LAR), and why.

**Materials and methods:** Two web-based surveys were administered to 120 HIV physicians and 688 PLWHIV on ART from France, Germany, Italy and the UK during June–August 2019. A balanced description of a hypothetical LAR was provided including its efficacy, administration, possible side effects, patient-reported outcomes and affordability. PLWHIV interest in *trying* this LAR ("very"/"highly") and physicians' willingness to *offer* ("Definitely"/"Probably") in different situations, with perceived benefits and concerns, were assessed.

**Results:** Overall, 65.8% [453/688] of PLWHIV were interested in trying the new LAR, especially <50-year-olds (69.8% [338/484]) versus ≥50-year-olds (56.4% [115/204]) ($p$ = 0.001). PLWHIV with unmet needs felt LAR would help with strong medical needs (malabsorption and interfering gastrointestinal conditions, >90%), suboptimal adherence (80.5% [301/374]), confidentiality/privacy concerns (87.6% [458/523]) and emotional wellbeing related to daily tablet requirements (79.0% [240/304]). Of physicians, willingness to offer LAR varied situationally with high rates in settings of: strong medical need (dysphagia, 93.3% [112/120]; malabsorption, 91.6% [110/120]; interfering gastrointestinal issues, 90.0% [108/120]; CNS disorders, 87.5% [105/120]); suboptimal adherence (84.2% [101/120]); confidentiality/privacy concerns (hiding medications, 86.6% [104/120]) and convenience/lifestyle (84.2% [101/120]) (Figure 1). The most favoured LAR attributes were easier travel because of not having to carry pills (56.3% [387/688]) for PLWHIV and increased patient contact (54.2% [65/120]) for physicians. Perceived negative attributes were scheduling challenges (37.2% [256/688]) and resource constraints (57.5% [69/120]) for PLWHIV and physicians, respectively. Physicians estimated 25.7% (SD = 23.1%) of their patients would switch; higher estimates were reported by providers who were male, metropolitan-based and had fewer patients.

**Conclusions:** Both physicians and PLWHIV viewed LAR as addressing unmet needs. Alternative treatment routes, including LAR, may help improve treatment satisfaction, adherence and retention in care.

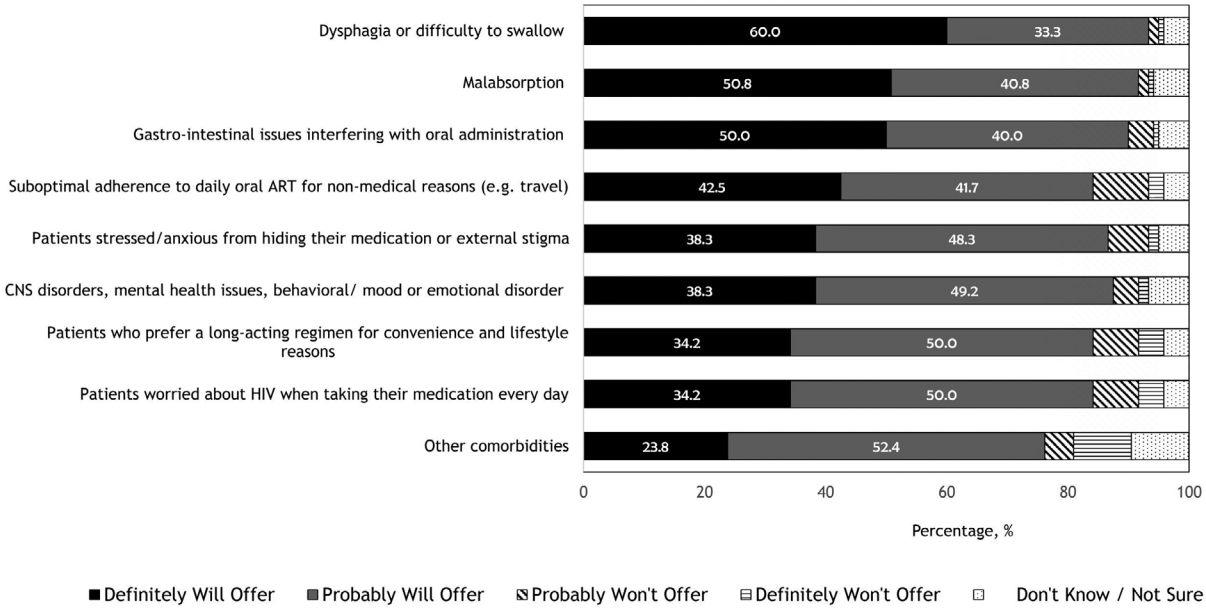
## P015

### Long-acting treatments: people's expectations and attending physicians' preparedness. Are we ready to manage it?

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**Figure 1. Degree of HIV physicians' willingness to offer long-acting HIV regimen for different medical or emotional challenges among their HIV+ patients**




**Abstract P014-Figure 1. Degree of HIV physicians' willingness to offer long-acting HIV regimen for different medical or emotional challenges among their HIV+ patients.**

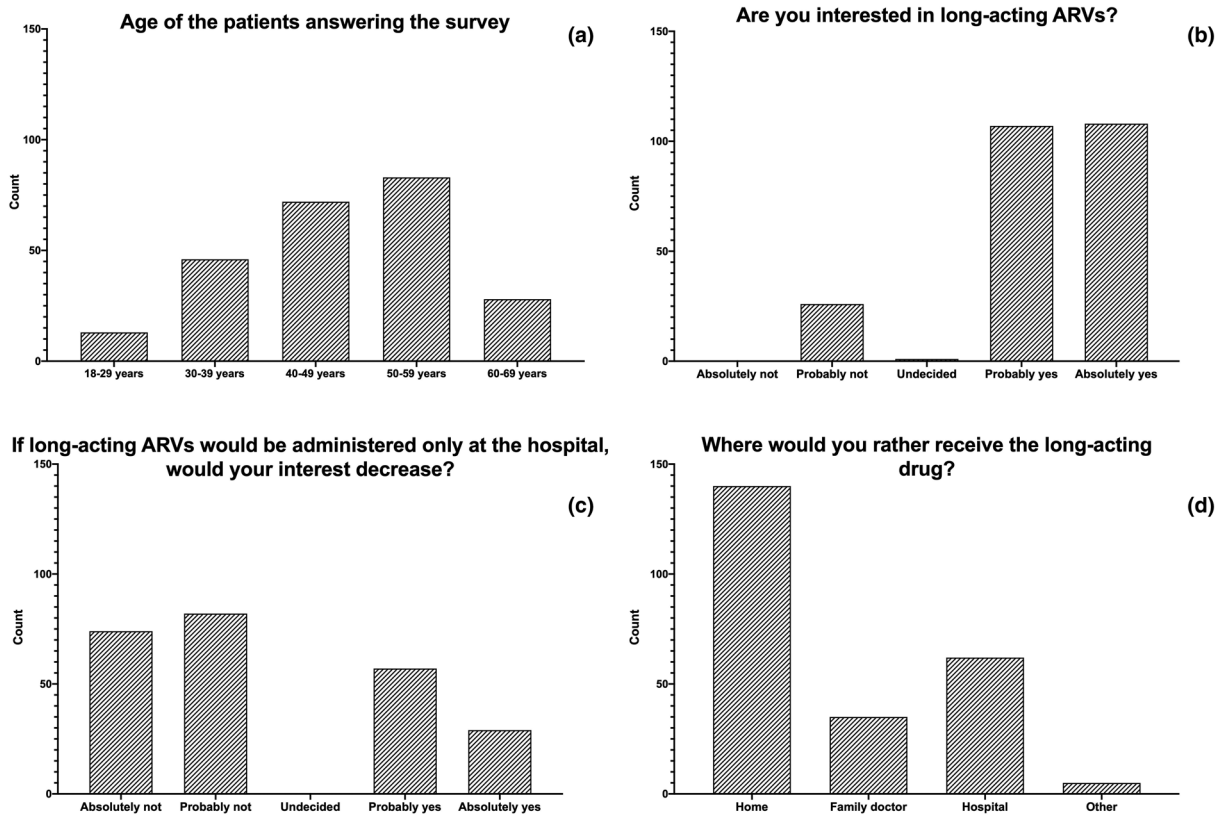
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**Background:** Available studies about long-acting drugs only evaluated patients' related outcomes. However, there is a need to know what the patients think about these revolutionary drugs. The aim of this multicentre cross-sectional study was to evaluate the expectations of the patients about long-acting antiretroviral agents and how they would like to receive them.

**Materials and methods:** We carried out an anonymous online survey through Google modules, asking HIV-positive people to judge their relationship with daily ART and to give their opinion about long-acting drugs. We also collected data about the age of the patients, the centre where they are followed, time passed since the diagnosis and their compliance.

**Results:** We collected data about 242 patients, 58 females (24.0%), 182 males (75.2%) and two transgenders (0.8%), with an age ranging from 18 to 69 years. The majority of the interviewed patients (81.8%) have a good relationship with ART; however, 33.6% of them considers daily ART an obligation and a restriction to their freedom. One hundred and forty-three patients (59.1%) knew about long-acting before this interview, and 215 patients (88.8%) are interested in these new drugs. Moreover, 156 patients (64.5%) states that their interest would not decrease even though the drugs would be administered only at HIV outpatient clinics, although the majority of the interviewed patients (57.9%) would rather receive the intramuscular injection at their home (Figure 1).

**Conclusions:** The data emerging from our survey reveal that around 90% of the patients are interested in changing their actual treatment with a long-acting one. Moreover, for the first time to our knowledge, a so high number of patients showed an enthusiastic response to the new opportunity to be treated directly at home. The introduction of these new drugs could be revolutionary and represent another step towards simplification.




**Abstract P015-Figure 1. (a) This figure shows the age distribution of the people answering our survey. It can be seen that the majority of the patients belongs to the 50 to 59 age range. (b) People living with HIV/AIDS (PLWHA) are largely interested in long-acting drugs. (c) Some people would lose their interest in long-acting agents if they would be available only at hospital HIV outpatient clinics. (d) The large majority of PLWHA would rather receive their injection at home.**

## P016

### What about me? The unmet needs of men who have sex with women and differences in HIV treatment experiences, perceptions, and behaviors by gender and sexual orientation in 25 countries

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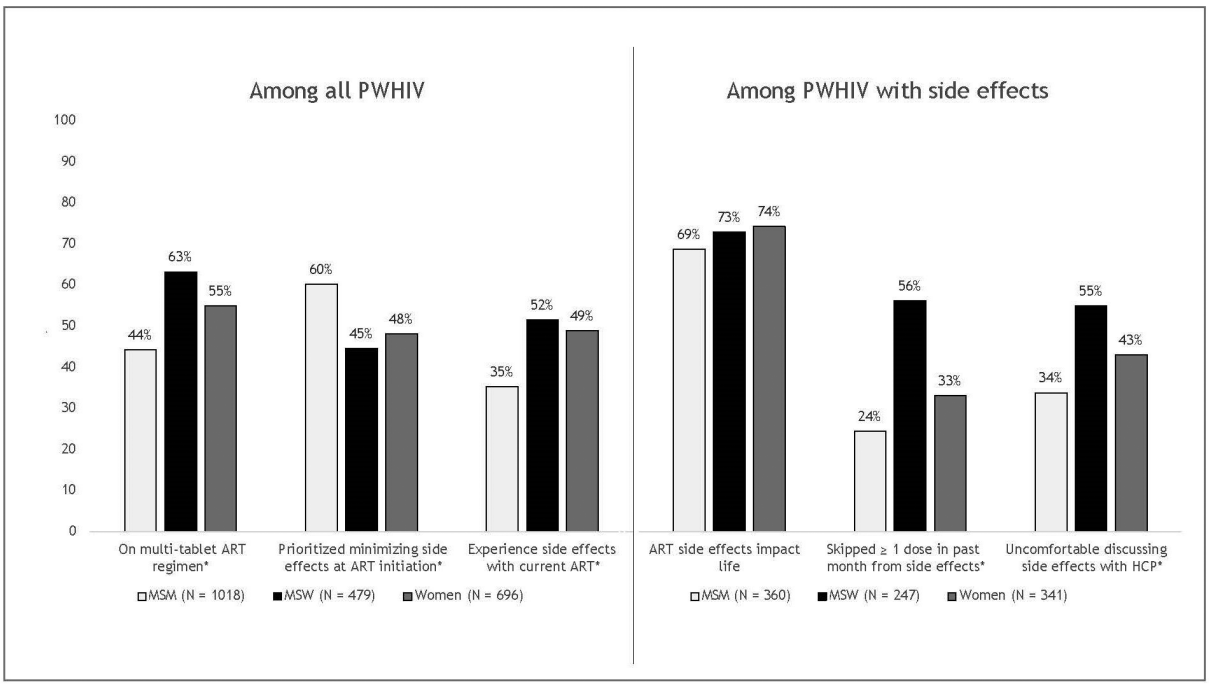
**Background:** Understanding differences in unmet needs and treatment preferences among MSM, men who have sex with women (MSW), and women is critical to tailor treatment. We investigated geographic distributions and differences in perceived health outcomes among MSM, MSW, and women with HIV.

**Materials and methods:** Two thousand, three hundred and eighty-nine adults with HIV in 25 countries completed a web-based survey in 2019 ('Positive Perspectives'). Classification of respondents as MSM (n = 1018), MSW (n = 479), or women (n = 696) was derived from two separate variables for self-classified gender and sexual orientation; HIV-related perceptions/behaviors were assessed. Data were summarized with percentages and compared using bivariate/multivariate techniques ($p < 0.05$).

**Results:** In high-income countries, median time from diagnosis was nine, four, and five years for MSM, MSW, and women, respectively, whereas it was 3, 6, and 6 years, respectively, in middle-income countries. MSM reported more favorable health outcomes than MSW or women, respectively, including lower rates of suboptimal adherence (15.5%, 38.8%, and 28.0%), viral non-suppression (10.9%, 43.2%, 37.1%), and suboptimal overall health (36.5%, 47.2%, and 46.2%, all $p < 0.05$). There were more differences between MSW and MSM, both in the number of health indicators, and the magnitude of disparity, than between MSW and women. MSW reported the lowest percentage of those who considered issues of ART side effects when starting treatment (44.7%) yet reported the highest prevalence of ART side effects (51.6%, Figure 1). Among those experiencing side effects, MSW were the most likely to miss ≥1 ART dose in the past month because of side effects (56.3% [139/247], vs women, 33.1% [113/341], and MSM, 24.4% [88/360], all $p < 0.001$). MSW were more likely to report polypharmacy (45.1%) than either MSM (38.5%, $p = 0.017$) or women (38.2%, $p = 0.020$), despite having the lowest prevalence of diagnosed non-HIV comorbidities (MSW = 46.1% vs MSM = 64.6%, or women = 56.7%, all $p < 0.001$). Of MSW, 87.9% reported barriers to discussing salient health issues with providers, versus MSM (59.0%) or women (72.7%) (all $p < 0.001$).

**Conclusions:** MSW reported a distinct set of treatment experiences that could negatively affect health outcomes. Comparatively, and especially relative to MSM, MSW had the greatest unmet needs. Acknowledging these differences when planning/administering care can help narrow disparities.

Asterisks (*) indicate overall differences at P< 0.05 based on $\chi^2$ tests. MSM=Men who have sex with men; MSW=Men who have sex with women; ART=Antiretroviral therapy; PWHIV=People with HIV




**Abstract P016-Figure 1. Characterization of the prevalence and nature of ART side effects as reported by MSM, MSW, and women with HIV.**

# Treatment Strategies: Target Populations

## P017

### Outcomes for women receiving long-acting cabotegravir + rilpivirine monthly and every two months: ATLAS-2M study Week 48 results

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**Background:** Cabotegravir (CAB) and rilpivirine (RPV) dosed IM every four weeks (Q4W) was noninferior to daily oral three-drug ART in phase III studies [1,2], CAB+RPV Q8W was noninferior to Q4W in the ATLAS-2M study [3]. We describe the efficacy, safety, and treatment satisfaction outcomes for women in ATLAS-2M.

**Materials and methods:** ATLAS-2M is a multicenter, open-label, phase IIIb noninferiority (NI) study of CAB+RPV maintenance therapy administered Q8W (600 mg CAB + 900 mg RPV) or Q4W (400 mg CAB + 600 mg RPV) to treatment-experienced, HIV-infected adults. Week 48 primary and secondary endpoints were the proportion with plasma HIV-1 RNA ≥ 50 copies/mL (Snapshot, ITT-exposed [ITTe], NI margin 4%) and HIV-1 RNA < 50 copies/mL (Snapshot, ITTe, NI margin 10%) respectively. Target recruitment for women was 25%. A subgroup analysis by sex at birth was planned.

**Results:** Two hundred and eighty women were randomized and treated with CAB+RPV Q8W (n = 137; 26%) or Q4W (n = 143; 27%); 56% white, median age 44 years; 53% CAB+RPV naive. Proportion with HIV-1 RNA ≥ 50 copies/mL was 3.6% (Q8W) and 0% (Q4W) and HIV-1 RNA < 50 copies/mL was 91% in both arms. Five women developed confirmed virologic failure (CVF), with none occurring after Week 24, 3/5 were subtype A/A1, 4/5 had archived NNRTI resistance associated mutations (RAMs). At CVF 4/5 had RPV and 3/5 INI RAMs, 2/5 and 3/5 developing emergent RPV and INI RAMs respectively. Plasma CAB+RPV concentrations were within the same range as for the overall study population. The safety profile among women was similar in both arms. Injection site reactions (ISRs) were mild-moderate (99%), three to four days median duration. Discontinuation for adverse events occurred in ≤4% (Q8W, n = 5; Q4W, n = 5); n = 4 due to ISRs. Women without prior CAB+RPV exposure reported increased treatment satisfaction; adjusted mean change from baseline (95% CI) in HIVSTQs; Q8W: 5.4 (3.76 to 7.04) and Q4W: 3.9 (2.26 to 5.47). In the Q8W arm, among women with prior CAB+RPV exposure: 88% (56/64) versus 8% (5/64) versus 2% (1/64) preferred Q8W, Q4W, and oral dosing respectively (Table 1).

**Abstract P017-Table 1. Data by gender**

| | CAB + RPV LA Q8W n (%) | | | CAB + RPV LA Q4W n (%) | | |
|---|---|---|---|---|---|---|
| | Women n = 137 (26) | Men n = 385 (74) | Total n = 522 | Women n = 143 (27) | Men n = 380 (73) | Total n = 523 |
| Median age, years (range) | 46 (23 to 69) | 40 (20 to 83) | | 44 (23 to 66) | 40 (19 to 75) | |
| Prior exposure to CAB + RPV (any) | 64 (47) | 131 (34) | 195 (37) | 68 (48) | 128 (34) | 196 (37) |
| None | 75 (53) | 254 (66) | 329 (63) | 75 (52) | 252 (66) | 327 (63) |
| 1 to 24 weeks | 27 (20) | 42 (11) | 69 (13) | 23 (16) | 45 (12) | 68 (13) |
| >24 weeks | 37 (27) | 89 (23) | 126 (24) | 45 (31) | 83 (22) | 128 (24) |
| BMI > 30 (kg/m$^2$) | 52 (38) | 61 (16) | 113 (22) | 42 (29) | 56 (15) | 98 (19) |
| White race | 78 (57) | 292 (76) | 370 (71) | 80 (56) | 313 (82) | 393 (75) |
| Region | | | | | | |
| W&C Europe & N America | 69 (50) | 292 (77) | 361 (69) | 75 (52) | 290 (76) | 365 (70) |
| E Europe & C Asia | 36 (26) | 33 (9) | 69 (13) | 30 (21) | 39 (10) | 69 (13) |
| S Africa | 25 (18) | 15 (4) | 40 (8) | 31 (22) | 11 (3) | 42 (8) |
| Latin America | 3 (2) | 19 (5) | 22 (4) | 4 (3) | 19 (5) | 23 (4) |
| HIV-1 RNA ≥ 50 copies/mL at W48[a] | 5 (3.6) | 4 (1.0) | 9 (1.7) | 0 (0) | 5 (1.3) | 5 (1.0) |
| HIV-1 RNA < 50 copies/mL at W48[a] | 125 (91) | 367 (95) | 492 (94) | 130 (91) | 359 (94) | 489 (93) |
| Adverse events (AE) | | | | | | |
| Adverse events (AEs) | 116 (85) | 357 (93) | 473 (91) | 125 (87) | 357 (94) | 482 (92) |
| Serious adverse events | 6 (4) | 21 (5) | 27 (5) | 6 (4) | 13 (3) | 19 (4) |
| Drug-related adverse events | 88 (64) | 312 (81) | 400 (77) | 97 (68) | 302 (79) | 399 (76) |
| AEs leading to withdrawal | 5 (4) | 7 (2) | 12 (2) | 5 (3) | 8 (2) | 13 (2) |
| Injection site reactions (ISRs) | | | | | | |
| Total number of injections | 2124 | 4191 | | 6246 | 11 520 | |
| Total number of ISRs | 477 | 809 | | 2030 | 2343 | |
| Rate of ISR per injection | 0.22 (22) | 0.19 (19) | | 0.32 (32) | 0.2 (20) | |
| Mean number per subject | 4 | 6 | | 5 | 6 | |

[a]As per FDA Snapshot algorithm.

**Conclusions:** CAB+RPV demonstrated high efficacy rates and was well tolerated with high satisfaction rates in women. These results support the therapeutic potential of CAB+RPV monthly or every two months in women.

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## P018

### Durable efficacy of dolutegravir (DTG) plus lamivudine (3TC) in antiretroviral treatment-naïve adults with HIV-1 infection: 3-year results from the GEMINI studies

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**Background:** Two-drug regimens (2DRs) have the potential to reduce cumulative drug exposure during life-long antiretroviral therapy in HIV-1 infected patients. In GEMINI-1 and GEMINI-2 (ClinicalTrials.gov: NCT02831673/NCT02831764), the efficacy of the 2DR of DTG + 3TC was non-inferior to DTG+ tenofovir/emtricitabine (TDF/FTC) at Weeks 48 and 96 in treatment-naïve adults.
**Materials and methods:** GEMINI-1&2 are identical double-blind, multicenter phase III studies. Participants with HIV-1 RNA ≤ 500 000 copies/mL at screening were randomized 1:1 (stratified by plasma HIV-1 RNA and $CD4^+$ cell count) to once-daily treatment with DTG + 3TC or DTG+TDF/FTC. The primary endpoint was the proportion of participants with plasma HIV-1 RNA < 50 copies/mL at Week 48 (Snapshot algorithm). We present efficacy and safety data from prespecified 144-week secondary analyses. Estimates and confidence intervals were based on a stratified analysis using Cochran-Mantel-Haenszel weights.
**Results:** Seven hundred and fourteen and 719 adults were randomized and treated in GEMINI-1&2, respectively. At baseline, 20% had HIV-1 RNA > 100 000 copies/mL, 8% had CD4 + <200 cells/$mm^3$. At Week 144, DTG + 3TC was non-inferior to DTG+TDF/FTC in both GEMINI-1&2 and in the pooled analysis (using a 10% non-inferiority margin) (Table 1). Response rates in participants with baseline HIV-1 RNA > 100 000 copies/mL were high and similar between arms. Consistent with Week 48 and 96 outcomes, response remained lower in DTG + 3TC participants with CD4 + <200 cells/$mm^3$. Across both studies, 12 participants on DTG + 3TC (one since Week 96) and nine on DTG+TDF/FTC (two since Week 96) met protocol-defined confirmed virologic withdrawal (CVW) criteria through Week 144; none had treatment-emergent integrase strand transfer inhibitor or NRTI resistance mutations. One non-CVW DTG + 3TC participant with reported non-adherence developed M184V (Week 132; HIV-1 RNA 61 927 copies/mL) and added R263R/K at Week 144 (135 copies/mL), conferring a 1.8-fold change in DTG susceptibility. Overall rates of AEs were similar, with low rates of withdrawals due to AEs in both arms. DTG + 3TC had a significantly lower rate of drug-related AEs than DTG+TDF/FTC (20% vs 27%; relative risk ratio 0.76; 95% CI 0.63 to 0.92). Post-baseline changes in markers of bone and renal function favored DTG + 3TC through Week 144.
**Conclusions:** DTG + 3TC remains non-inferior to DTG+TDF/FTC in treatment-naïve adults at Week 144. Both regimens were well tolerated. The results demonstrate durable efficacy and potency of DTG + 3TC, further supporting it as a first-line option for HIV treatment.

## P019

### Clinical significance of gp120 polymorphisms, temsavir IC50FC, and HIV-1 subtype in BRIGHTE

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**Background:** The ongoing phase III BRIGHTE study is evaluating fostemsavir (FTR), a first-in-class attachment inhibitor approved in combination with other antiretrovirals for heavily treatment-experienced adults with multidrug-resistant HIV-1 infection. FTR is a prodrug of temsavir (TMR). We present the impact of key baseline factors on short-term virologic outcome and durability of response to FTR in the randomized cohort (RC).
**Materials and methods:** RC participants, with 1 to 2 fully active antiretrovirals were randomized (3:1) to blinded FTR 600 mg (n = 203) or placebo (n = 69) twice daily (BID) plus failing regimen

**Abstract P018-Table 1. Proportion of participants with plasma HIV-1 RNA < 50 copies/mL at Week 144: Snapshot analysis—ITT-E population**

| | | GEMINI-1 | GEMINI-2 | Pooled |
|---|---|---|---|---|
| Snapshot responders | DTG + 3TC | 281/356 (79%) | 303/360 (84%) | 584/716 (82%) |
| | DTG+TDF/FTC | 296/358 (83%) | 303/359 (84%) | 599/717 (84%) |
| Adjusted difference (95% CI) | | −3.6 (−9.4, 2.1) | 0.0 (−5.3, 5.3) | −1.8 (−5.8, 2.1) |

**Abstract P019-Table 1. Virologic response to FTR at Day 8 of functional monotherapy and Week 96 by baseline factors in the randomized cohort**

| | Randomized cohort monotherapy[a] FTR 600 mg BID (N = 203) | | | Randomized cohort total FTR 600 mg BID + OBT (N = 272) | |
|---|---|---|---|---|---|
| | Median change in HIV-1 RNA from Day 1 to Day 8 log10 copies/mL (min, max)[b] | n | Virologic response >0.5 log10 copies/mL from Day 1 to Day 8 n (%) | n | HIV-1 RNA < 40 copies/mL at Week 96 n (%) |
| Baseline gp120 polymorphisms | | | | | |
| Sequenced | −0.92 (−2.70, 1.25) | 194 | 127 (65) | 263 | 160 (61) |
| No predefined polymorphisms of interest in gp120 | −1.03 (−2.70, 1.25) | 106 | 79 (75) | 141 | 87 (62) |
| With predefined polymorphisms of interest in gp120[c] | −0.65 (−2.17, 1.16) | 88 | 48 (55) | 122 | 73 (60) |
| S375H/I/M/N/T | −0.82 (−2.17, 1.16) | 64 | 38 (59) | 86 | 52 (60) |
| M426L | −0.36 (−1.92, 0.35) | 22 | 10 (45) | 32 | 18 (56) |
| M434I | −1.04 (−2.03, 1.16) | 9 | 5 (56) | 17 | 9 (53) |
| M475I | 0.47 (0.47, 0.47) | 1 | 0 | 3 | 3 (100) |
| Multiple predefined polymorphisms of interest in gp120 | −1.18 (−1.92, 1.16) | 8 | 5 (63) | 16 | 9 (64) |
| Baseline TMR IC50 FC category | | | | | |
| Phenotyped | −0.88 (−2.70, 1.25) | 194 | 126 (65) | 263 | 160 (61) |
| ≤0.5 | −1.02 (−2.11, 1.25) | 71 | 50 (70) | 93 | 50 (54) |
| >0.5 to 1 | −1.08 (−2.70, 0.24) | 27 | 21 (78) | 39 | 23 (59) |
| >1 to 10 | −0.89 (−2.46, 0.80) | 53 | 36 (68) | 63 | 44 (70) |
| >10 to 50 | −0.69 (−2.11, 1.16) | 19 | 9 (47) | 26 | 19 (73) |
| >50 to 100 | −0.61 (−1.14, −0.07) | 3 | 2 (67) | 8 | 5 (63) |
| >100 to 1000 | −0.18 (−2.17, 0.35) | 10 | 4 (40) | 16 | 7 (44) |
| >1000 to 5000 | −0.32 (−1.29, 0.47) | 7 | 3 (43) | 11 | 8 (73) |
| >5000 | −0.24 (−1.92, −0.01) | 4 | 1 (25) | 7 | 4 (57) |
| HIV-1 subtype at baseline | | | | | |
| All subtypes | −0.88 (−2.70, 1.25) | 203 | 134 (66) | 272 | 163 (60) |
| B | −0.92 (−2.70, 1.25) | 163 | 108 (66) | 216 | 125 (58) |
| F1 | −0.76 (−1.61, 0.28) | 14 | 9 (64) | 20 | 14 (70) |
| BF1 | −0.87 (−1.75, −0.01) | 10 | 7 (70) | 14 | 10 (71) |
| C | −0.82 (−2.02, 0.05) | 6 | 5 (83) | 9 | 4 (44) |
| A1 | −0.10 (−0.32, 0.13) | 2 | 0 | 2 | 1 (50) |
| AE | 0.47 (0.47, 0.47) | 1 | 0 | 2 | 1 (50) |
| Other[d] | −1.08 (−2.11, 1.16) | 7 | 5 (71) | 9 | 8 (89) |

BID, twice daily; FC, fold-change; FTR, fostemsavir; OBT, optimized background therapy; TMR, temsavir.
[a]FTR monotherapy refers to functional monotherapy where FTR is given on a background of failing antiretroviral therapy;
[b]does not include participants with missing Day 1 or Day 8 HIV-1 RNA values;
[c]predefined polymorphisms of interest in gp120 domain are S375H/I/M/N/T, M426L/P, M434I/K, M475I. No participants had M426P or M434K present at baseline;
[d]other includes (n): could not be analyzed/not reported (1); G (3); AG (1); recombinant virus/mixtures (4).

for eight days of functional monotherapy, followed by open-label FTR 600 mg BID plus optimized background therapy (OBT; n = 272). Impact of baseline factors gp120 polymorphisms, TMR IC50 fold-change (FC), and HIV-1 subtype on virologic outcome was evaluated.

**Results:** Overall, 46% (122/263) of evaluable RC participants had a relevant gp120 polymorphism present at baseline. Median change in HIV-1 RNA at Day 8 was lower among monotherapy participants with versus without baseline gp120 polymorphisms of interest (−0.65 vs −1.03 log10). However, 55% (48/88) of participants with baseline gp120 polymorphisms achieved viral load reduction >0.5 log10 at Day 8. Baseline TMR IC50FC from reference was observed over a broad range (0.05 to >5000-fold; median 0.99-fold), with 74% (195/263) and 87% (229/263) of evaluable participants with TMR IC50FC <10- and <100-fold, respectively. While monotherapy participants with TMR IC50FC >100-fold at baseline had a median change in HIV-1 RNA of <0.5 log10 at Day 8, this did not prevent a decline of >0.5 log10. In fact, 38% (8/21) of participants with baseline TMR IC50FC >100-fold achieved >0.5 log10 decline over this time. Majority of RC participants (79% [216/272]) had HIV-1 subtype B. Similar proportions of monotherapy participants with subtype B (66% [108/163]) versus non-B (65% [26/40]) achieved >0.5 log10 decline in HIV-1 RNA at Day 8 (Table 1).

**Conclusions:** In BRIGHTE, baseline gp120 polymorphisms of interest, TMR IC50FC, and HIV-1 subtype did not reliably predict virologic outcome at Day 8 of FTR functional monotherapy and did not impact durability of response (HIV-1 RNA < 40 copies/mL) to FTR+OBT through Week 96 among heavily treatment experienced RC participants.

# P020

## Feasibility, efficacy, and safety of using dolutegravir/lamivudine (DTG/3TC) as a first-line regimen in a test-and-treat setting for newly diagnosed PLWH: the STAT study

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**Background:** DTG/3TC is indicated for treatment-naive PLWH; however, concerns remain about use in a test-and-treat setting due to potential transmitted resistance and baseline HBV co-infection. The STAT study evaluates the feasibility and efficacy of using DTG/3TC in a US test-and-treat setting.

**Materials and methods:** STAT is a single-arm pilot study in which participants started DTG/3TC ≤14 days after HIV-1 diagnosis without availability of screening/baseline laboratory results. Treatment was adjusted if baseline testing indicated presence of HBV, genotypic resistance to DTG or 3TC, or creatinine clearance <30 mL/min/1.73 $m^2$; participants with treatment adjustment remained on study. Efficacy endpoints were the proportions of participants with HIV-1 RNA < 50 copies/mL at Week 24 regardless of ART regimen among all participants ('Intention-to-treat-exposed (ITT-E) Missing=Failure' analysis) and those with available Week 24 HIV-1 RNA data ('Observed' analysis).

**Results:** Sixteen sites enrolled 131 participants. Median age was 31 years, 8% were female, 50% were non-white. Thirty-nine percent, 15%, and 8% of participants had baseline HIV-1 RNA ≥ 100 000, ≥500 000, and ≥1000 000 copies/mL, respectively; 28% had baseline $CD^{4+}$ T-cell count <200 cells/$mm^3$. Median time to enrollment from initial HIV-1 diagnosis was 5 days. Through Week 24, treatment was modified in eight participants: five due to baseline HBV infection, one due to baseline M184V, and two due to other reasons (adverse event [rash] and participant withdrawal). Among all participants, 78% achieved HIV-1 RNA < 50 copies/mL. Among those with available data, 92% had HIV-1 RNA < 50 copies/mL (Table 1). All participants with available data who switched ART and remained on study at Week 24 had HIV-1 RNA < 50 copies/mL. The participant with baseline M184V achieved HIV-1 RNA < 50 copies/mL by Week 4 before regimen modification. Among 10 participants with baseline HIV-1 RNA ≥ 1000 000 copies/mL, eight had HIV-1 RNA < 50 copies/mL at Week 24 (one discontinued before Week 24 and one had HIV-1 RNA ≥ 50 copies/mL).

**Abstract P020-Table 1. Proportion of participants with HIV-1 RNA < 50 and <200 copies/mL at Week 24 in Observed and ITT-E Missing=Failure analyses**

| Outcomes | DTG/3TC, n/N (%) |
|---|---|
| Observed analysis (i.e. participants with HIV-1 RNA data at Week 24 on any ART) | |
| Participants with available HIV-1 RNA data at Week 24 | 111/131 (85%) |
| HIV-1 RNA < 50 copies/mL | 102/111 (92%)[a] |
| HIV-1 RNA < 200 copies/mL | 109/111 (98%)[b] |
| ITT-E Missing = Failure analysis at Week 24 (i.e. all participants) | |
| HIV-1 RNA < 50 copies/mL | 102/131 (78%) |
| ART received at Week 24: on DTG/3TC | 97/131 (74%) |
| ART received at Week 24: on modified ART[c] | 5/131 (4%) |
| HIV-1 RNA ≥ 50 copies/mL | 29/131 (22%) |
| Data in window and HIV-1 RNA ≥ 50 copies/mL | 9/131 (7%) |
| On study but missing data in window | 5/131 (4%)[d] |
| Discontinued study due to LFU/withdrew consent | 12/131 (9%)[e] |
| Discontinued study for other reasons | 3/131 (2%)[f] |

DTG/3TC, dolutegravir/lamivudine; ITT-E, intention-to-treat-exposed; LFU, lost to follow-up.
[a]Of 102 participants, 97 were on DTG/3TC regimen;
[b]of 109 participants, 104 were on DTG/3TC regimen;
[c]the other three participants who switched from DTG/3TC had missing HIV-1 RNA data at Week 24;
[d]three participants missed HIV-1 RNA assessment at Week 24 due to COVID-19;
[e]seven due to LFU; five withdrew consent (three relocations; one incarceration; one no reason reported);
[f]three due to physician decision (two HIV-negative, one participant did not attend several scheduled appointments).

**Conclusions:** These data demonstrate the feasibility and safety of using DTG/3TC as a first-line regimen in a test-and-treat setting; appropriate therapy adjustments in the presence of baseline resistance or HBV co-infection can occur safely via routine clinical care after rapid initiation of DTG/3TC.

# P021

## Fostemsavir exposure-response relationships in treatment-experienced HIV patients

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**Background:** Fostemsavir (FTR), a prodrug of temsavir (TMR), is a first-in-class attachment inhibitor approved for heavily treatment-experienced (HTE) adults with multidrug-resistant HIV-1 infection. Phase III efficacy exposure-response relationships in HTE (multidrug-resistant) HIV-1 patients with FTR 600 mg twice daily (BID), and safety exposure-response relationships from phase IIb (treatment-experienced) and phase III (HTE) with FTR 400, 600, 800 mg BID and 600 and 1200 mg once daily were evaluated.

**Abstract P021-Table 1. Efficacy ER simulation results**

| Scenario | Change in plasma HIV-1 RNA from Day 1 to 8 (log10 copies/mL) | Plasma TMR $C_{tau}$ (ng/mL) | Median (95% CI) Proportion of participants >1.0 log10 copies/mL Decrease in plasma HIV-1 RNA on Day 8 |
|---|---|---|---|
| FTR 600 mg BID (no inducer/inhibitor) | −0.782 (−2.20, 0.600) | 433 (33.6, 2400) | 0.434 (0.386, 0.483) |
| FTR 600 mg BID (mild/moderate CYP3A inducer alone) | −0.685 (−2.11, 0.692) | 205 (17.0, 1290) | 0.368 (0.324, 0.415) |
| FTR 600 mg BID (CYP3A inhibitor alone) | −0.834 (−2.25, 0.535) | 775 (99.2, 3750) | 0.478 (0.428, 0.521) |
| FTR 600 mg BID (mild/moderate CYP3A inducer + CYP3A inhibitor) | −0.925 (−2.34, 0.469) | 414 (31.8, 2340) | 0.431 (0.385, 0.481) |
| FTR 600 mg BID (standard meal) | −0.782 (−2.20, 0.600) | 433 (33.6, 2400) | 0.434 (0.386, 0.483) |
| FTR 600 mg BID (fasted) | −0.725 (−2.14, 0.647) | 257 (20.0, 1430) | 0.393 (0.346, 0.438) |
| 600 mg BID (40-kg body weight) | −0.807 (−2.22, 0.565) | 599 (50.0, 3340) | 0.453 (0.410, 0.500) |
| 600 mg BID (150-kg body weight) | −0.745 (−2.15, 0.627) | 296 (30.0, 1370) | 0.404 (0.357, 0.452) |

BID, twice daily; ER, exposure response.

**Materials and methods:** Individual pharmacokinetic (PK) parameters estimated from a population PK model were used to evaluate exposure-response relationships. Efficacy endpoints were change in plasma HIV-1 RNA from Day 1 to 8 (functional monotherapy); >0.5 and >1.0 log10 decrease in HIV-1 RNA on Day 8 and at Week 24; and proportion of participants with HIV-1 RNA < 40, <200, and <400 copies/mL. Virologic, immunologic, and demographic covariates as predictors of virologic response were investigated. Simulations were conducted to predict virologic responses on Day 8 under different extrinsic and intrinsic factors. Safety endpoints included change from baseline in select laboratory values up to Week 24 and rash. Linear, inhibitory $E_{max}$, and logistic regression models were explored.
**Results:** Exposure-response relationship was established between TMR $C_{tau}$ and change in plasma HIV-1 RNA from Day 1 to 8; however, the relationship was shallow and highly variable. Baseline HIV-1 RNA and $CD^{4+}$ counts were covariates; the higher the baseline value, the greater the reduction. Addition of IC50 did not improve the relationship. Model-predicted probability >0.5 and >1 log10 decrease in HIV-1 RNA on Day 8 was 80% and 58% at plasma TMR $C_{tau}$ 500 ng/mL with median baseline HIV-1 RNA (4.65 log10 copies/mL) and $CD^{4+}$ (>20 cells/$mm^3$). At Week 24, no relationship was established between plasma TMR $C_{tau}$ and HIV-1 RNA or $CD^{4+}$ counts. Simulations showed no clinically relevant changes in Day 8 virologic response (Table 1). No clear correlation was seen between TMR exposure and safety endpoints.
**Conclusions:** Higher reduction in HIV-1 RNA from Day 1 to 8 with increase in TMR $C_{tau}$ in HTE HIV-1 patients taking FTR 600 mg BID was observed. Simulations showed that impact of food, comedications, and body weight was not clinically relevant.

## P022

### Model-based approach of dose selection and optimal pharmacokinetics sampling of fostemsavir for pediatric patients with multidrug resistant HIV-1 infection

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**Background:** Fostemsavir (FTR) is a first-in-class attachment inhibitor approved in combination with other antiretrovirals for heavily treatment-experienced adults with multidrug-resistant HIV-1 infection. FTR is an extended-release prodrug and is hydrolyzed by alkaline phosphatase in the gastrointestinal lumen to its active moiety, temsavir (TMR), which is primarily metabolized by esterase-mediated hydrolysis with contributions from cytochrome P450 3A4 (CYP3A). The current analysis demonstrates application of a model-based approach to design an efficient clinical trial of FTR in pediatric patients leveraging the comprehensive data from the adult program.
**Materials and methods:** The TMR adult population (POP) pharmacokinetics (PK) model with weight-based allometric scaling was used for simulations with parameter uncertainty using the mrgsolve package in R. Five hundred trials were simulated using different doses by weight bands and scenarios accounting for both the presence and absence of CYP3A inducer or inhibitor to evaluate the probability of success based on $C_{max}$ and $C_{tau}$-defined criteria to maintain exposures comparable with those observed in the adult population. Trial simulations were also conducted to assess optimal PK sampling schemes and participant numbers. The final TMR POP PK model was used for parameter estimation and compared to the true values for each participant to calculate the precision of the PK parameter estimates.
**Results:** Dosing simulations demonstrated that the adult dose of FTR 600 mg twice daily (BID) for pediatric participants weighing ≥35 kg and FTR 400 mg BID for participants weighing ≥20 to <35 kg met defined criteria by providing comparable adult TMR exposure that established FTR safety and efficacy. For the intense-sampling portion of the study, six PK sampling times in a dosing interval (one, two, four, six, eight, and twelve hours postdose) ± 30 minutes in ≥12 of 50 participants were identified to provide adequate precision in the PK parameter estimates.
**Conclusions:** These analyses demonstrate that the proposed model-based approach allows implementation of an efficient pediatric study design. It informs critical study aspects such as dosing regimen, PK sampling scheme, and number of participants required for PK sampling while also providing targeted drug exposure levels that are safe and effective.

# P023

## Virological, immunological response and safety of initial antiretroviral treatment in HIV late presenters in HIV Spanish National Cohort

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**Background:** Study aims were: 1) to evaluate the impact of late presentation on the effectiveness and safety of initial ART with modern regimens, and 2) to analyse whether ART initiation with INI-based regimens are associated with a better response at 48 weeks among late presenters (LPs).
**Material and methods:** We analysed ART-naïve adults from the HIV Spanish Cohort (CoRIS) starting ART between 2004 and 2018. We used multivariable regression models to assess differences in viral suppression (VS; viral load ≤50 copies/mL), immunological response (IR; change in CD4 count, CD4% normalisation [>29%] and CD4/CD8 normalisation [>0.4 and >1]) and multiple T-cell marker recovery (MTMR; CD4 >500 cells/μL plus CD4% >29% plus CD4/CD8 >1) and ART discontinuation due to adverse events (AEs) at 48 weeks from ART initiation.
**Results:** Eight thousand and two participants were included: 75.7% were European, 61.4% acquired HIV infection by homosexual and 29.2% by heterosexual route and 48.7% were LPs. VS was similar in LPs and non-LPs [83.4% and 89.4%, aOR 0.94, 95% CI 0.74, 1.19]. LPs were associated with worse IR than non-LPs across all the immune markers: mean CD4 counts [adjusted mean difference (95% CI) −33.7 (−45.4, −22.1)], CD4% normalisation [aOR (95% CI) 0.51 (0.45, 0.57)], CD4/CD8 normalisation cut-offs of 0.4 [aOR (95% CI) 0.50 (0.40, 0.62)] and cut-offs of 1 [aOR 0.69 (0.55, 0.86)] and the MTMR [aOR (95% CI) 0.57 (0.39, 0.82)]. Treatment discontinuation due to AEs was similar in both groups [around 10%, aRR 0.91 (0.75, 1.09)]. In LPs, those initiating with NNRTI- or PI-based regimens had a similar chance to achieve VS and IR, compared to those treated with INI-based regimens. The risk of treatment discontinuation due to AEs was higher with NNRTI-based [aRR (95% CI) 1.62 (1.12, 2.35)] and PI-based [aRR (95% CI) 1.78 (1.22, 2.60)] than with INI-based regimens.
**Conclusion:** LPs had similar VS but worse IR to treatment than people treated at earlier stages. LPs initiating ART with an INI-based regimen showed similar VS and IR but better safety than PI- and NNRTI-based regimens.

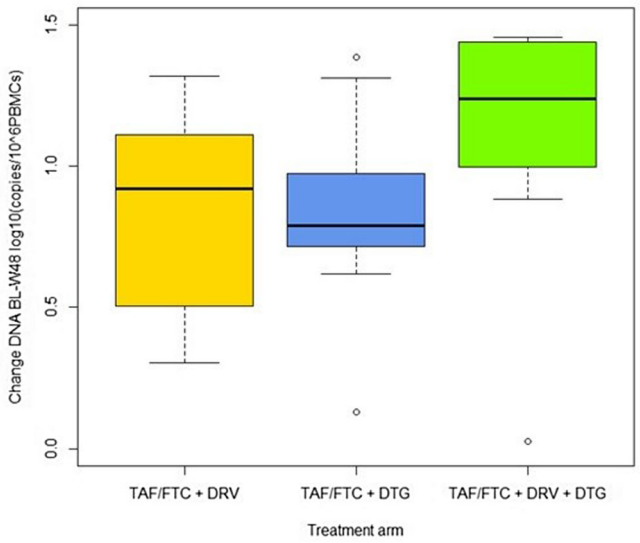
# P024

## HIV-DNA decrease during treatment in primary HIV-1 infection: a randomised clinical trial with three different drug regimens

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**Background:** ART initiation during primary HIV-1 infection (PHI) could restrict establishment of HIV reservoirs. The aim of the study is to assess the effect of three different ART regimens on HIV-DNA load in people who started ART during PHI.
**Methods:** PHI (an incomplete HIV-1 western blot and detectable plasma HIV-RNA) was the inclusion criterion of this randomised, open-label, multicentric Italian study initiated by INACTION (Italian Network of Acute HIV Infection). Participants were randomly assigned (10:10:8) to a fixed-dose combination of tenofovir alafenamide (TAF) 25 mg plus emtricitabine (FTC) 200 mg, darunavir 800 mg and cobicistat 150 mg once daily (group 1), or TAF 25 mg plus FTC 200 mg, dolutegravir 50 mg once daily (group 2) or an intensive four-drug regimen (TAF 25 mg plus FTC 200 mg, dolutegravir 50 mg, darunavir 800 mg and cobicistat 150 mg once daily) (group 3). The primary endpoint was the decrease of HIV-DNA copies/10^6 peripheral blood mononuclear cells (PBMC) at Weeks (W) 12 and 48. HIV-DNA was quantified by Droplet digital PCR (Biorad QX100) and normalised to RPP30 reference gene. Secondary endpoints were increase in $CD^{4+}$ cells, increase in $CD^{4+}/CD^{8+}$ ratio, percentage of




**Abstract P024-Figure 1. Change in HIV-DNA at Week 48 in the three drug regimens.**

participants reaching undetectable HIV-RNA. This study is registered in ClinicalTrials.gov, number NCT04225325.
**Results:** Sixty-four participants were enrolled: 22 were randomly assigned to group 1, 23 to group 2 and 16 to group 3. Median $CD^{4+}$ count was 682/ul (467 to 801), HIV-RNA 5.47 (4.70 to 6.14) log10 copies/mL. At W12 and at W48, HIV-DNA loads were similar between groups (p = 0.189 and $p = 0.747$ respectively). At W48, HIV-DNA decrease was more evident in the intensive four-drug regimen, although not significantly (Figure 1). At multivariate analysis, difference in HIV-DNA delta at W12 was −0.098 (−0.383, 0.187) $p = 0.490$ between group 1 and 3, −0.246 (−0.517, 0.024) $p = 0.073$ between group 2 and 3. Difference at W48 was −1.322 (−2.688, 0.044) $p = 0.057$ between group 1 and 3 and −0.891 (−2.098, 0.316) $p = 0.135$ between group 2 and 3.
**Conclusions:** We observed a decrease in HIV-DNA from baseline to W48 in treatment during PHI. The results suggest a potential, although not significant, effect of intensive regimen on HIV blood reservoirs.

## P025

### Clinical profile, antiretroviral drug exposure and virological status of perinatally HIV-infected adolescents transferred from paediatric to adult HIV care: 20 years of experience in a public hospital in Buenos Aires, Argentina

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**Background:** An increasing number of perinatally HIV (PHIV)-infected adolescents are being transferred from paediatric centres to adult HIV care. Most of them had been exposed to multiple ARTs. Our objective was to describe the clinical, immunological and virological status of PHIV-infected adolescents at the time of transfer to adult care.
**Material and methods:** Retrospective study of PHIV-infected adolescents transferred to Cosme Argerich Hospital, Buenos Aires, Argentina (2000 to 2019). Clinical and virological status, ART exposure and drug resistance profile at the time of transition were assessed. Factors associated with detectable viral load among patients on ART at transfer were analysed using logistic regression.
**Results:** One hundred and fifty-five PHIV-infected adolescents were transitioned during the study period. The median age was 18 years (IQR 17 to 19) and 55% were female. Forty-nine percent were orphans, 30% had low-level education and 7% reported alcohol and/or illicit drugs consumption. Among female patients, 18% had previous or ongoing pregnancy. At transfer to adult care, the median CD4 T-cell count was 501/$mm^3$ (IQR 320 to 674), 10% had CD4 ≤ 200 cells/$mm^3$, 64% had prior CDC category C events and 7% were HCV-coinfected. Thirty-five percent reported poor ART adherence. Forty-one percent had detectable viraemia at admission. The median time of exposure to ART was 15 years (IQR 12 to 17), while median number of previous ARTs was 3 (2 to 5). Sixty-five percent of the patients were exposed to NRTI, NNRTI and PI, 16% to INSTI and 38% to mono- or dual therapy. Seventy-one percent had history of virological failure. Of these, 47% had at least one genotypic resistance test, being 23% done at admission to adult care. Eighty-six percent had drug resistance associated mutations (RAMs) to NRTIs; 66% to NNRTIs; 82% to PIs, 2% to INSTIs, while 46% had triple-class resistance. Eighteen percent required use of salvage ART for multiclass drug-resistant HIV-1 infection. In multivariable analysis, detectable viraemia at transfer was associated with poor ART adherence, previous virological failure and low-level education.
**Conclusions:** At admission to adult care, a high proportion of PHIV-infected adolescents had complex psychosocial conditions, were heavily pretreated and had detectable viraemia. The complexity of their ART history and drug resistance profile is an ongoing challenge for adult HIV care.

## P026

### Abstract withdrawn

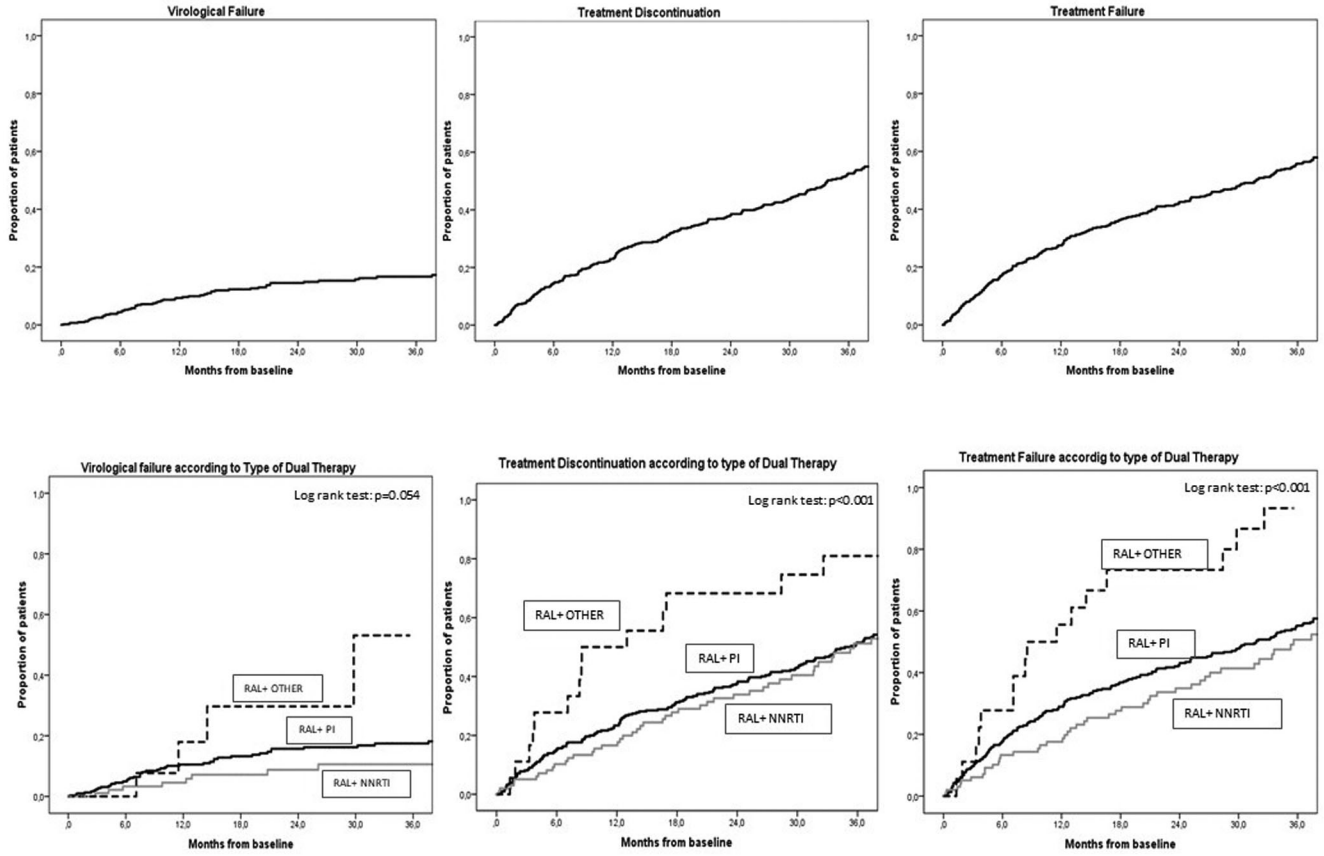
## P027

### Efficacy and durability of raltegravir-based dual therapy

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**Background:** We evaluated the efficacy and durability of treatment switch to raltegravir-based dual therapies, since few data are available on these regimens from clinical practice.
**Methods:** Retrospective observational study within multicentre ARCA cohort. Inclusion criteria: treatment-experienced virologically-suppressed (HIV-RNA < 50 copies/mL) patients, treated with a three-drug combination, switching to a raltegravir-based dual therapy. Patients were followed from treatment switch (baseline [BL]) to regimen discontinuation or last available follow-up. Incidence and predictors of virological failure (VF; defined as two consecutive HIV-RNA > 50 copies/mL or a single HIV-RNA > 1000 copies/mL), treatment discontinuation (TD; defined as regimen stop or changing/adding any drug) and treatment failure (TF; defined as the first of VF and TD) were evaluated.
**Results:** Overall, 428 patients (70.8% males, median age 50 years, median CD4 at baseline 581/mmc, 5.4% with non-B HIV-1 subtype) were enrolled. No patient had pre-BL INSTI-drug resistance mutations (DRM), while PI-DRM and NNRTI-DRM were present in 21.1% and 43.3% of subjects, respectively. At BL, 310 (72.4%) patients were switched to raltegravir+PI (n = 124 darunavir, n = 133 atazanavir, n = 38 lopinavir) (group 1), 100 (23.4%) to raltegravir+NNRTI (n = 43 nevirapine, n = 52 etravirine) (group 2), 18 (4.2%) to raltegravir+other drugs (n = 7 maraviroc, n = 11 NRTIs) (group 3). Incidence of VF, TD and TF were 5.42, 27.05 and 28.71 per 100 PYFU, respectively. Kaplan-Meier estimates of VF, TD and TF were 9.3%, 22.9% and 27.5% at 12 months and 14.5%, 38%, 42.5% at 24 months, respectively (Figure 1). When compared to group 1, group 2 showed a lower risk of TD (aHR 0.67, $p = 0.029$) and TF (aHR 0.67, $p = 0.030$), together with a trend toward a lower risk of VF (aHR 0.42, $p = 0.053$). Non-B subtype was associated to a higher risk of VF (aHR 2.62, $p = 0.046$). When genotypic resistance tests




**Abstract P027-Figure 1. Kaplan-Meier curves for virological failure, treatment discontinuation and treatment failure.**

before BL and after failure (n = 51, 11.9%) were available, DRM influencing dolutegravir susceptibility (Q148H) were acquired by 1/9 (11.1%) patients in group 2, 1/5 (20%) in group 3 and no patient in group 1.

**Conclusions:** Raltegravir-based dual therapies have a substantial TD rate, particularly raltegravir+PI. VF accounts for a low proportion of TF, however DRM impacting dolutegravir can emerge, preferentially in the absence of PI.

## P028

### Effect of online education on physician knowledge and confidence for the immunological drivers of depletion and recovery for CD4 T cells and implications of non-response in HIV-positive individuals

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**Background:** Progressive depletion of CD4 T cells is the hallmark of untreated HIV infection and involves multiple mechanisms such as direct and cytotoxic T-lymphocyte killing of infected T cells [1–4]. ART is key to reversing T cell depletion [5]. However, some HIV-positive individuals fail to adequately recover T cells despite optimised ART [6–8]. We assessed whether online independent medical education could improve the knowledge of both HIV/infectious diseases specialists and primary care physicians (PCPs) regarding immunological mechanisms of $CD^{4+}$ T cell depletion and factors associated with poor $CD^{4+}$ T-cell gain in HIV-positive individuals receiving ART.

**Materials and methods:** The continuing medical education intervention comprised a 30-minute online video lecture with animation. The effects of education were assessed for learners completing all four pre- and post-assessment questions for each activity, using a matched pre-/post-assessment design, with participants serving as their own controls. For all questions combined, the chi-square test assessed differences from pre- to post-assessment. P-values are shown as a measure of significance; $p < 0.05$ were significant. Cramer's V was used to calculate the effect size (<0.05 no effect; 0.06 to 0.15 small effect; 0.16 to 0.30 medium effect; >0.30 large effect). Activity was launched 20 February 2020. Data collected 19 May 2020.

**Results:** From a total target audience of 688 physicians there were 170 assessment completers. Overall, there was a significant increase ($p < 0.0001$) with considerable impact (0.207) in HIV/infectious diseases specialists knowledge gains. A significant increase ($p = 0.0014$) and a noticeable impact (0.151) was reported in overall PCP knowledge gains. HIV/infectious diseases specialists and PCPs reported a total average confidence shift of 21% and 22%, respectively, regarding

their understanding of the role in CD4 T cells in HIV pathogenesis. Furthermore, HIV/infectious diseases specialists had highly significant and impactful knowledge gains regarding patient-associated factors that could lead to poor CD4 T cell recovery, despite optimised ART.
**Conclusions:** Online medical education significantly improves physician knowledge and confidence in the immunological mechanisms associated with $CD^{4+}$ T cell depletion and recovery, clinical predictors and patient-associated factors of inefficient $CD^{4+}$ T-cell gain in HIV-positive individuals, despite optimised ART.

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# Treatment Strategies: Adherence

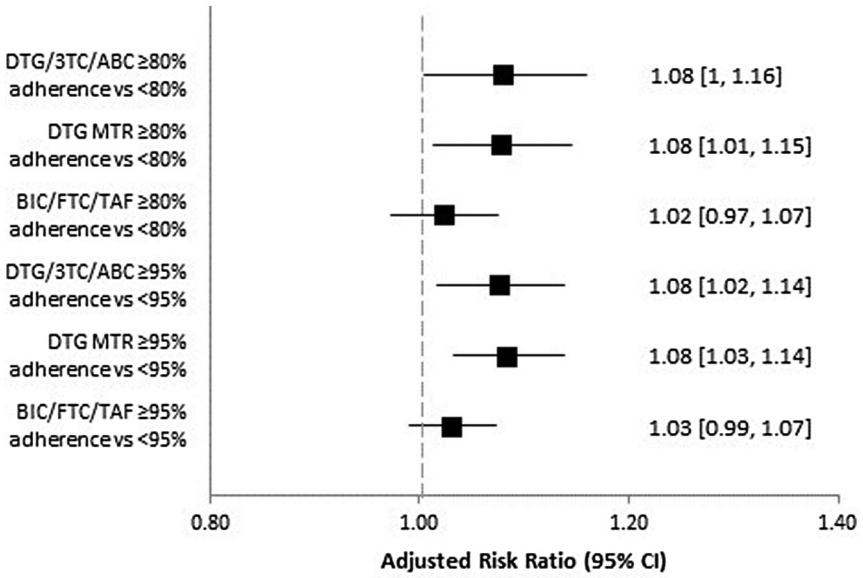
## P029

### Impact of adherence on viral suppression with bictegravir and dolutegravir (DTG) containing triple therapy in clinical practice

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**Background:** Clinical trials have shown comparable efficacy with DTG-containing triple therapy and BIC/FTC/TAF. Here we examine the impact of adherence on outcomes with these integrase inhibitors in US clinical practice.
**Materials and methods:** Using data from Trio Health HIV EMR and dispensing database, we retrospectively evaluated HIV suppression among stable patients switching to single-tablet BIC/FTC/TAF, DTG/3TC/ABC or DTG multi-tablet regimens (MTRs: DTG+FTC/TAF, DTG+FTC/TDF, DTG + 3TC+ABC). Eligibility criteria: HIV diagnosis, ≥18 years, suppressed (<200 copies/mL) at switch (−12 months up to +1 month), with viral measurements at six months after switch, and ≥6 months observation prior to switch. Univariate comparisons were conducted via chi-square for categorical and t-test for continuous variables; negative binomial model with log link function evaluated association between




**Abstract P029-Figure 1. Estimated effects of adherence on viral suppression at six months for PDC ≥ 95% and ≥80% adherence thresholds.**

adherence (proportion days covered [PDC] ≥80 and 95%) and viral suppression six months after switch accounting for gender, race, and CD4 at switch (baseline).

**Results:** Of 2229 eligible patients, 1130 (51%) switched to BIC/FTC/TAF, 520 (23%) to DTG/3TC/ABC, and 579 (26%) to DTG MTRs. Significant differences were observed between groups: male (75% BIC/FTC/TAF vs 81% DTG/3TC/ABC [$p = 0.014$] vs 69% DTG MTR [$p = 0.006$]), black race (25% BIC/FTC/TAF vs 33% DTG/3TC/ABC vs 36% DTG MTR, $p < 0.001$), baseline CD4 < 200 cells/mL (3% BIC/FTC/TAF vs 4% DTG/3TC/ABC [$p = 0.025$] vs 6% DTG MTR [$p = 0.010$]). At six months after switch, viral suppression was not different (90% BIC/FTC/TAF vs 91% DTG/3TC/ABC [$p = 0.833$] vs 90% DTG MTR [$p = 0.677$]) but adherence with BIC/FTC/TAF was greater at PDC ≥ 80% (77% vs 67% DTG/3TC/ABC vs 61% DTG MTR, $p < 0.001$) and PDC ≥ 95% (53% vs 41% DTG/3TC/ABC vs 31% DTG MTR, $p < 0.001$). In adjusted models accounting for differences between groups at baseline, adherence was associated with viral suppression for DTG but not BIC/FTC/TAF regimens (Figure 1).

**Conclusions:** At six months after switching to BIC/FTC/TAF or DTG-containing triple therapy in clinical practice, viral suppression was high and similar for both strategies. Patients switched to BIC/FTC/TAF had an overall higher level of medication adherence. The higher adherence was significantly associated with viral suppression for DTG-containing triple therapy, but not BIC/FTC/TAF.

## P030

### Cost-utility analysis of long-acting cabotegravir + rilpivirine for the treatment of HIV infection in the United Kingdom

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**Background:** ARTs have improved the lives of PLHIV. However, all current ARTs require lifetime adherence to daily oral dosing and some PLHIV need an alternative mode of administration because of medical (e.g. malabsorption, dysphagia), emotional (e.g. fear of disclosure, daily reminder of HIV) or practical considerations (e.g. lifestyle, employment). Cabotegravir + rilpivirine long-acting (CAB+RPV LA) is the first investigational ART administered every two months by a healthcare professional via intramuscular injection. This removes the burden of daily oral dosing and may improve adherence, quality of life and clinical outcomes. We evaluated the costs and quality-adjusted life years (QALYs) associated with use of CAB+RPV LA compared with standard-of-care (SoC) daily oral ARTs.

**Materials and methods:** A previously published Markov cohort state-transition model was adapted to account for adherence and its subsequent impact on viral transmission. As CAB+RPV LA removes the need for adherence to daily dosing, its effectiveness in clinical practice was assumed similar to clinical trial settings, whereas real-world adherence estimates from the literature were used in the SoC arm (5% to 25% reduction from optimal levels observed in clinical trials). The impact of reduced health-related quality of life (HRQoL) associated with daily oral dosing was also explored. A UK health service costing perspective was adopted. Drug acquisition costs assumed price parity, using the average cost of the top three integrase inhibitor single-tablet regimens.

**Results:** Depending on the reduction from optimal adherence levels applied to daily oral dosing, the approach described led to between two and 11 HIV cases averted per 1000 patients, with lifetime cost savings of between £5.2 and £26.2 million and QALY gains of between 53 and 286, compared with SoC (Table 1). Accounting for interfering medical conditions and HIV-specific emotional issues associated with daily oral dosing may further increase the estimated QALY gains.

**Conclusions:** Long-acting treatments such as CAB+RPV LA have the potential to improve adherence and subsequently reduce onward transmission, leading to QALY gains and cost savings. Such regimens offer an alternative for PLHIV for whom daily oral ART is challenging and provide a new choice of modality for the management of this lifelong condition.

## P031

### Beyond viral load: exploring mediating factors for the gap in optimal self-rated health by adherence status among older adults living with HIV

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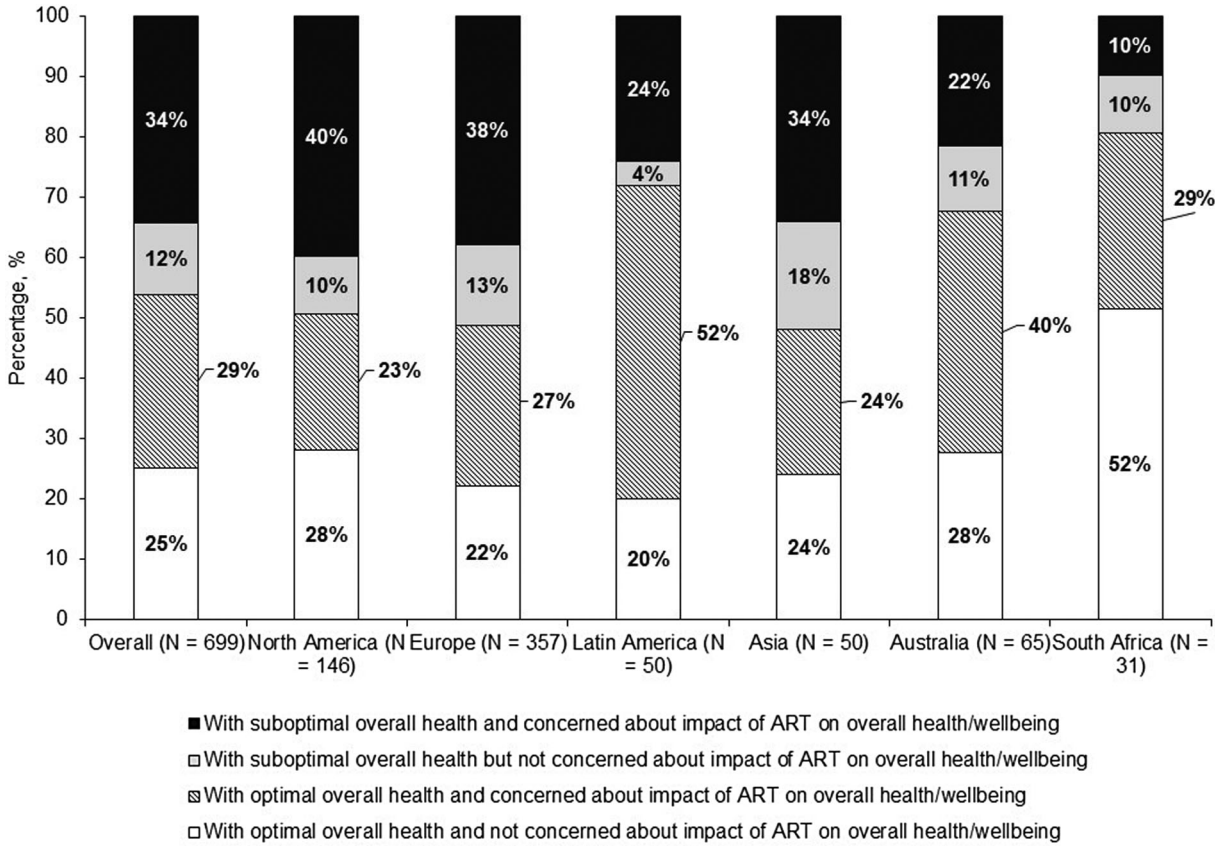
**Background:** Recognition is increasing that attaining and maintaining optimal overall health among older adults living with HIV (OALWH) goes beyond achieving viral control; quality of life is also important. The objective was to determine what factors explained the differences in overall health between optimally versus suboptimally adherent OALWH.

**Materials and methods:** Data were analyzed for 699 OALWH aged ≥50 years from the 25-country 2019 Positive Perspectives survey. Suboptimal adherence was missing antiretrovirals ≥5 times/past month for any reason. Self-rated overall health as "Good"/"Very good" (vs "Neither good nor poor"/"Poor"/"Very poor") was deemed optimal. Blinder-Oaxaca decomposition analyses examined factors accounting for gaps in optimal overall health by adherence status, adjusting for region.

**Results:** Overall, 16.3% (114/699) of OALWH were suboptimally adherent. Optimally adherent individuals were more likely to experience optimal overall health (56.6% [331/585]) versus suboptimally adherent individuals (40.4% [46/114], $p < 0.001$), a gap of 16

**Abstract P030-Table 1. CAB+RPV LA versus SoC varying real-world adherence (results per 1000 patients)**

| Reduction in adherence from optimal clinical trial levels | Incremental costs | Incremental QALYs | Incremental costs (incl. impact of transmissions) | Incremental QALYs (incl. impact of transmissions) | Incremental onwards transmissions |
|---|---|---|---|---|---|
| 5% reduction in adherence | −£4215 924 | 43 | −£5176 123 | 53 | −2 |
| 10% reduction in adherence | −£8546 761 | 86 | −£10 572 999 | 107 | −4 |
| 15% reduction in adherence | −£12 584 576 | 128 | −£15 816 196 | 163 | −6 |
| 20% reduction in adherence | −£16 397 327 | 173 | −£21 006 481 | 222 | −8 |
| 25% reduction in adherence | −£20 018 474 | 220 | −£26 211 872 | 286 | −11 |




**Abstract P031-Figure 1. Distribution of the study population by presence or absence of optimal overall health and presence or absence of concerns about the impact of ART on overall health and wellbeing, by geographic region. Note: Regions were North America, excluding Mexico (i.e. US and Canada); Europe (Austria, Belgium, France, Germany, Italy, the Netherlands, Poland, Portugal, Ireland, Russia, Spain, Switzerland, and the UK); Latin America (Argentina, Brazil, Chile, and Mexico), and Asia (China, Japan, South Korea, and Taiwan). Australia and South Africa were analyzed separately.**

percentage points. Of this gap, differences in viral load explained 5.8%, differences in comorbidities explained 26.9%, while side effects/perceived limitation from HIV treatment/HIV explained 35.2%. Those suboptimally adherent were more likely than optimally adherent individuals to report ART side effects (51.8% [59/114] vs 35.4% [207/585], $p = 0.001$), perceive HIV had a negative impact on their life (48.2% [55/114] vs 38.0% [222/585], $p = 0.04$), perceive room for improvement with their HIV medicines (42.1% [48/114] vs 32.3% [189/585], $p = 0.043$), and report that their HCP did not meet their personal needs (39.5% [45/114] vs 25.6% [150/585], $p = 0.003$). Among OALWH with concerns about the long-term impact of ART on their overall health, those with suboptimal health were significantly more likely to have switched ART in the past year versus those with optimal health (21.9% [59/270] vs 13.4% [35/262], $p = 0.010$). Concerns about poor overall health were not limited to those with suboptimal overall health; 28.8% (201/699) were worried about potential impacts of ART on overall health/wellbeing despite having optimal overall health; this varied geographically (Figure 1).

**Conclusions:** Much of the difference in overall health by adherence level among OALWH was attributable to comorbidities and treatment challenges from ART. Holistic care that considers patients' medical and emotional challenges can improve overall wellbeing.

## P032

### Persistence of antiretroviral therapy regimens among veterans with HIV newly initiating treatment in the US

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**Background:** Single-tablet regimens (STRs) have been associated with improved patient outcomes compared to multi-tablet regimens (MTRs) (Table 1). With the advent of new ART options, the extent to which ART regimen persistence varies between and within STRs and MTRs has not been fully defined. This study aims to assess persistence among treatment-naïve veterans with HIV initiating STRs and MTRs.

**Materials and methods:** Veterans with HIV infection initiating ART between 1 January 2016 and 30 July 2019 were included, with the observational period up to 31 December 2019. Index date was defined as the first ART claim date for STRs or the prescription fill claim date of the last drug in the regimen for MTRs. Persistence was measured via Kaplan-Meier curves as the number of days until treatment discontinuation (>90 days gap between prescription refills). Cox

**Abstract P032-Table 1. Persistence with ART by regimen for STR and MTR in univariate analysis**

| | EVG/COBI/FTC/TAF (N = 760) | | EVG/COBI/FTC/TDF (N = 251) | | DTG/ABC/3TC (N = 794)) | | RPV/FTC/TAF (N = 143) | | RPV/FTC/TDF (N = 116) | | EFV/FTC/TDF (N = 223) | | BIC/FTC/TAF (N = 304) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **STR** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** |
| Number of days on therapy | 469.1 | 334.0 | 337.7 | 296.8 | 507.0 | 374.1 | 427.0 | 317.0 | 369.6 | 351.5 | 294.0 | 289.4 | 251.0 | 121.6 |
| Patients with 6-month persistence[a] | 679 | 89% | 194 | 77% | 703 | 89% | 117 | 82% | 87 | 75% | 162 | 73% | 274 | 90% |
| Patients with 12-month persistence[b] among patients with ≥12 months of follow-up | 504 | 69% | 110 | 44% | 532 | 71% | 85 | 64% | 59 | 52% | 91 | 42% | 92 | 73% |

| | DTG+FTC/TDF (N = 138) | | DTG+FTC/TAF (N = 284) | | DRV/r or c + FTC/TDF (N = 121) | | DRV/r or c + FTC/TAF (N = 89) | | ATV/r or c + FTC/TDF (N = 53) | | ATV/r or c + FTC/TAF (N = 23) | | DRV/r or c + ABC/3TC (N = 20) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **MTR** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** | **Mean/N** | **SD/%** |
| Number of days on therapy | 290.8 | 273.0 | 363.4 | 261.6 | 225.7 | 201.9 | 291.2 | 239.7 | 156.4 | 116.7 | 169.2 | 265.0 | 225.7 | 184.3 |
| Patients with 6-month persistence[a] | 109 | 79% | 236 | 83% | 85 | 70% | 69 | 78% | 30 | 57% | 12 | 52% | 15 | 75% |
| Patients with 12-month persistence[b] among patients with ≥12 months of follow-up | 44 | 32% | 155 | 57% | 37 | 31% | 39 | 46% | 8 | 15% | 3 | 13% | 11 | 58% |

[a]Defined as patients who remain on their index regimen at six months of follow-up;
[b]defined as patients who remain on their index regimen at 12 months of follow-up.

proportional hazards models were used to evaluate risk of discontinuation, controlling for sociodemographic and clinical (viral load and CD4 counts) characteristics. Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) was used as the reference regimen in the analysis.

**Results:** Over the study period, 2591 treatment-naïve veterans with HIV initiated STRs and 728 initiated MTRs (Table 1). Compared with MTR patients, STR patients were younger (49 vs 53 years, $p < 0.001$), with higher CD4 cell counts (>250: 38% vs 30%, $p < 0.001$). At six months of follow-up, 86% of STR initiators and 76% MTR initiators remained on their regimen. At 12 months of follow-up, 57% of STR initiators and 41% MTR initiators remained on their regimen. After adjusting sociodemographic and clinical characteristics, risk of discontinuation was lower for STRs compared to MTRs (HR 0.70, 95% CI 0.61 to 0.81). Compared to the referent BIC/FTC/TAF, risk of discontinuation was higher for EVG/COBI/FTC/TAF (HR 1.49, 95% CI 1.03 to 2.14), DTG/ABC/3TC (HR 1.59, 95% CI 1.10 to 2.30), DTG + FTC/TAF (HR 2.10, 95% CI 1.32 to 3.34), and DTG + FTC/TDF (HR 2.49, 95% CI 1.14 to 5.42).

**Conclusions:** Among US veterans with HIV, STR initiators were significantly less likely to discontinue first-line therapy compared to MTR initiators. Veterans who initiated a BIC/FTC/TAF regimen had a lower risk of discontinuation compared to MTRs and other STRs included in the study.

# P033

## Self-care and involvement in managed care among people living with HIV in Europe

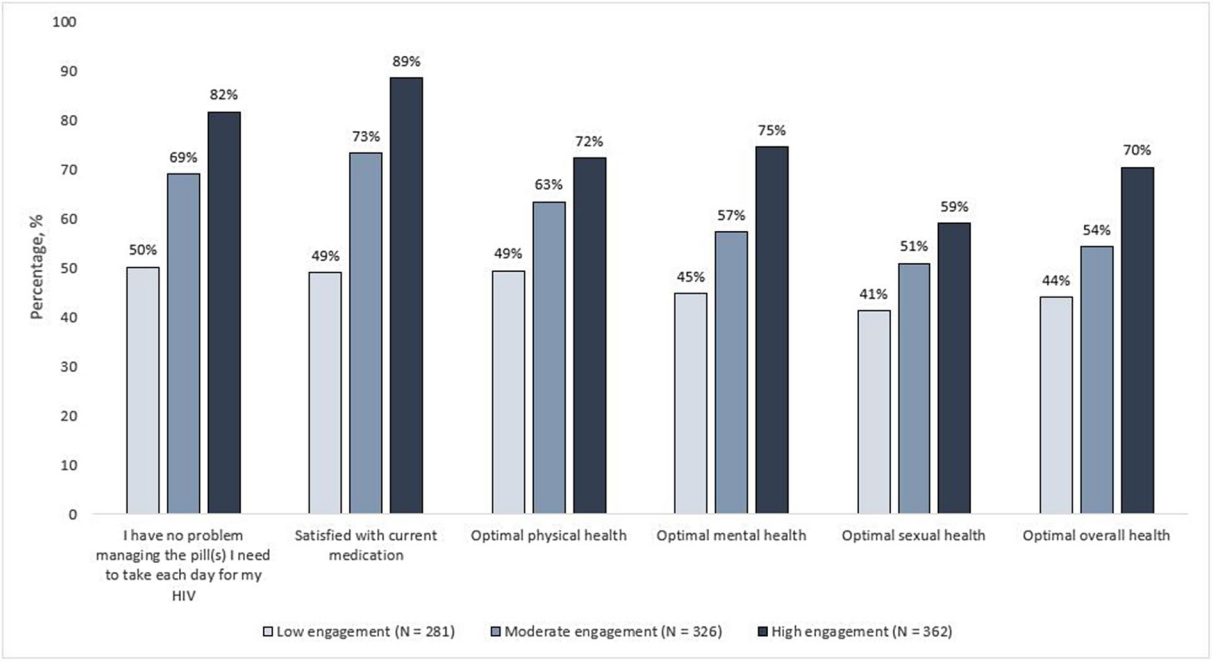
C Okoli[1]; G Corbelli[2]; G Brough[3]; N Van de Velde[4] and P de los Rios[5]
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**Background:** With increasing emphasis on self-care, empowering patients is critical. We examined treatment challenges, efforts at self-care, and communication with healthcare providers (HCPs) among PLHIV.

**Materials and methods:** Self-reported data were from 969 adult PLHIV in the 2019 Positive Perspectives study from 12 EU/Schengen countries. Patient engagement in care (low, moderate, high) was adapted from the Observing Patient Involvement scale. Past-month suboptimal adherence was missing ART ≥5 times. Percentages were compared using c2 tests.

**Results:** Overall, 68.3% [662/969] reported no problems managing their regimen; however, 41.6% [403/969] worried about missing doses, 29.8% [289/969] felt stressed about their daily dosing schedule, 33.4% [324/969] feared daily dosing increased the chances of revealing their status, and 24.8% [240/969] felt daily ART dosing limited their lives. Additionally, 52.6% [510/969] had ever disguised their HIV medication. These challenges were associated with poorer adherence; for example, PLHIV who felt limited by daily ART had 67% lower odds of optimal adherence than those without this perception (aOR 0.33, 95% CI 0.23 to 0.49). Only 7.6% [53/701] of those with concerns about long-term ART impact reported doing "nothing about it"; most engaged in lifestyle changes, 58.1% [407/701]; organ function tests, 57.4% [402/701]; information-seeking from journals, 44.2% [310/701]; and discussing with their HCP, 42.4% [297/701]. Overall, 39.1% [379/969] currently experienced ART side effects; of these, 36.2% [137/379] indicated their HCP did not ask about their side effects, and 42.7% [162/379] were uncomfortable discussing it. Of the 60.2% [583/969] wanting more involvement in their care, 21.8% [127/583] reported they did not understand enough about their treatment, 36.4% [212/583] felt insufficiently informed to make treatment choices, 35.7% [208/583] were not told of new treatment options, and 32.8% [191/583] indicated their viewpoint was not sought before prescribing. Greater HCP engagement was associated with greater self-empowerment, treatment satisfaction, and self-rated health (Figure 1), yet many felt uncomfortable discussing a breadth of salient health issues with HCPs, from concerns about drug-drug interactions (38.0%), to those about having children (53.4%).

**Conclusions:** Treatment-related challenges are common among PLHIV and negatively impact adherence. One-third of those wanting more involvement in care felt uninformed or uninvolved. Critical communication gaps existed, underscoring the need to better engage, educate, and empower PLHIV, to improve their health and well-being.




Note: all differences were statistically significant at $p < 0.05$ using chi-squared tests. Optimal health was a rating of "Good" or "Very good" regarding health status within the past four weeks.

**Abstract P033-Figure 1. Percentage of people living with HIV who reported various positive health-related outcomes, stratified by extent of engagement in care (N = 969).**

## P034

### Role of patient's pathway on HIV service organisation and adherence to treatment

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**Background:** Introducing patient's pathway (PP) may have a key role in effective linkage in care and retention of new HIV patients. By facilitating team roles and responsibilities patient's pathway is essential for HIV service organisation and optimising patients' routes inside the clinic. We decided to explore how PP can improve retention in care of new HIV-positive patients. Patient's pathway was introduced on 28 September 2018 in primary care clinic (T&T Clinic) with free integrated services for PLWH and their families, which opened on 15 December 2017 by AIDS Healthcare Foundation (AHF) in partnership with Odessa AIDS Center in Odessa, Ukraine.
**Materials and methods:** To explore possible association of PP on linkage, retention in care and ART initiation, descriptive and inferential analyses was done among the cohort of newly tested HIV-positive clients (N = 318), out of which 254 clients registered in care at the T&T Clinic, from 22 December 2017 to 21 February 2020. Unadjusted odds ratios were calculated for the association between PP and linkage, PP and retention in care and PP and time of ART initiation.
**Results:** People, who were diagnosed HIV positive in the T&T Clinic facility after PP started operating, present a chance to be registered in care 5.67 greater than people who were not exposed to PP (OR 5.67, CI 2.888 to 11.141). Chance to retain in treatment and care associated with PP is 3.94 times the chance of retention among individuals not exposed to PP (OR 3.94, CI 1.903 to 8.150). Patients, who registered in clinic after PP started operating, have increased odds (OR 6.50, CI 3.573 to 11.823) of initiating ART within 30 days from the date of HIV diagnosis comparing to those who registered before PP was set in operation.
**Conclusions:** Main advantage of the PP is reducing or avoiding gaps in appointment, more effective patients flow, efficient usage of human resources. For patients this means less amount of time spent at the clinic and avoiding lines which is vitally significant in the days of increased risk of respiratory infections. For clinical management PP can be recommended especially for resource-limited settings as a tool to optimise the operation of medical staff and equipment.

## P035

### The relationship between the quality of care perceived by the patient and adherence to antiretroviral treatment

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**Background:** It is necessary to promote a change in the healthcare model, which takes more into account the perceptions of the patient. Optimal adherence requires treatments well tolerated and adapted to the patient's needs. The objective was to analyse whether there is a relationship between the quality of care perceived by the HIV patient in terms of satisfaction with the healthcare received and health-related quality of life (HRQL), and adherence to ART.

**Materials and methods:** Cross-sectional observational study that included all patients in active follow-up in a Spanish hospital. Three questionnaires were delivered with the informed consent between February and November 2017. MOS-SF-30 (Medical Outcomes Study Survey-Short Form of 30 items) [1]. Evaluate HRQL in a range from 0 to 100, with 0 being the lowest HRQL and 100 the highest. SUCE (User Satisfaction for External Queries) [2]. Evaluate patient satisfaction on a scale from 1 to 10, with 1 being the worst rating and 10 the best. SMAQ (Simplified Medication Adherence Questionnaire) [3]. Adherence questionnaire that consists of six questions and considers whoever answers in the "non-adherent" sense to be non-adherent.
**Results:** Of the 241 patients in active follow-up at the centre, 43 were excluded because they refused to participate or because they were unable to answer the surveys (illiteracy, language barrier and significant physical or mental disability). Of the 198 surveys delivered, 172 were collected (response rate: 87%). The mean score of the MOS-SF-30 was 68.2 (95% CI 65.1 to 71.3). The average satisfaction score was 9.04 out of 10 (95% CI 8.90 to 9.20). The adherence questionnaire revealed that 60% of the patients were considered non-adherent. Of the 142 patients who had undetectable VL, more than 57% declared to be non-adherents to ART. HRQL was higher in adherent patients [mean difference 95% CI 10.71 (4.52 to 16.90)]. No association was found between adherence and user satisfaction (Table 1).
**Conclusions:** Patient satisfaction and their HRQL was high at the centre. Despite having increasingly simpler and better tolerated treatments, poor adherence to ART continues to be frequent. The efficacy of current ART allows many non-adherents to maintain an undetectable VL. HRQL was higher in patients adhering to ART.

**Abstract P035-Table 1. Univariate analysis of adherence with satisfaction (SUCE) and with HRQL (MOS-SF-30)**

| | SUCE Mean differences CI 95% | MOS-SF-30 Mean differences CI 95% |
|---|---|---|
| SMAQ | | |
| Non-adherent | 0 | 0 |
| Adherent | 0.24 (−0.06, 0.54) | 10.71 (4.52, 16.90)[a] |

[a]$p < 0.05$.

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# Treatment Strategies: Simplification and Switch Studies

## P036

### Long-term follow-up after a switch to bictegravir, emtricitabine, tenofovir alafenamide, from a boosted protease inhibitor-based regimen

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**Background:** Bictegravir, emtricitabine and tenofovir alafenamide (B/F/TAF) is a guideline-recommended single-tablet regimen for PLWH. Week (W) 48 primary endpoint results of the phase III noninferiority study of switching to B/F/TAF from an atazanavir (ATV) or darunavir (DRV) protease inhibitor (PI)-based regimen established the safety and efficacy of switching to B/F/TAF. Outcomes from an open-label extension (OLE) on B/F/TAF are reported here.
**Methods:** Virologically suppressed (HIV-1 RNA < 50 copies/mL) PLWH on boosted ATV or DRV plus either F/tenofovir disoproxil fumarate or abacavir/lamivudine for ≥6 months prior to screening were randomized 1:1 to B/F/TAF or to stay on baseline PI regimen (SBR). After the W48 primary endpoint, all participants received B/F/TAF in the OLE. All participants who received B/F/TAF initially or switched in the OLE are included in analyses. Efficacy was assessed as the proportion with HIV-1 RNA < 50 copies/mL at each study visit using missing=excluded (M=E) analysis. Safety was assessed by adverse events (AEs) and laboratory results.
**Results:** Five hundred and seventy-seven participants were randomized and treated (290 B/F/TAF, 287 SBR); 272 (93.8%) of participants randomized to B/F/TAF and 244 (85.0%) randomized to SBR entered the OLE and received B/F/TAF (n = 516): 17% women, 26% Black,

**Abstract P036-Table 1. Changes from baseline after switching to B/F/TAF**

| | All B/F/TAF (N = 534) | | |
|---|---|---|---|
| **Median (Q1, Q3)** | **Week 48** | **Week 72** | **Week 96** |
| **eGFR change, mL/min** | (n = 502)<br>−4.2 (−12.6, 5.0) | (n = 430)<br>−6.3 (−15.2, 2.9) | (n = 308)<br>−3.4 (−11.2, 4.5) |
| **Fasting lipids change, mg/dL** | (n = 491) | (n = 399) | (n = 291) |
| Total cholesterol | −1 (−22, 20) | −2 (−24, 18) | −1 (−20, 18) |
| LDL cholesterol<br>(n = 490 W48; n = 398 W72; n = 290 W96) | −3 (−21, 13) | −4 (−23, 12) | −7 (−25, 10) |
| HDL cholesterol | 1 (−4, 7) | 1 (−4, 6) | 1 (−4, 7) |
| Total: HDL cholesterol ratio | −0.1 (−0.6, 0.3) | −0.2 (−0.6, 0.3) | −0.2 (−0.6, 0.4) |
| Triglycerides<br>(n = 490 W48; n = 398 W72; n = 289 W96) | −12 (−48, 20) | −9 (−44, 25) | −11 (−44, 19) |
| **Body weight change, kg** | (n = 502)<br>2.0 (−0.4, 4.6) | (n = 428)<br>2.0 (−0.9, 5.0) | (n = 306)<br>2.2 (−0.5, 5.8) |

median age 48 years (range 20 to 79). The median duration of B/F/TAF treatment was 101 weeks. In the OLE HIV-1 RNA < 50 copies/mL was maintained in 97% to 100% of participants at all timepoints through 156 weeks. No participant developed resistance to B/F/TAF or discontinued due to lack of efficacy in the OLE. Study drug-related AEs occurred in 14.2% on B/F/TAF; most of which were Grade 1; the most common was headache (2%). Six (1%) participants had an AE leading to premature study drug discontinuation, four during the OLE. Estimated GFR, lipids, and weight were relatively stable with minimal changes for most participants through 96 weeks after switching to B/F/TAF (Table 1).

**Conclusions:** Long-term follow-up of PLWH switching to B/F/TAF from a boosted PI regimen demonstrates continued high rates of virologic suppression with no emergent resistance and was safe and well tolerated through a maximum of 156 weeks.

## P037

### Long-term treatment efficacy and safety following switch to doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF): Week 144 results of the DRIVE-SHIFT trial

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**Background:** Doravirine is a NNRTI for treatment of HIV-1 infection in combination with other antiretroviral agents in treatment-naïve and treatment-experienced adults, with favorable safety, lipid and resistance profiles. We report long-term efficacy and safety of switch to a single-tablet maintenance regimen of doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg (DOR/3TC/TDF).

**Materials and methods:** This phase III, open-label, randomized, active-controlled, noninferiority trial (DRIVE-SHIFT; MK-1439A-024; NCT02397096) evaluated switching from a stable antiretroviral regimen of two NRTIs plus boosted PI, boosted elvitegravir or NNRTI, to once-daily DOR/3TC/TDF in adults with ≥6 months' virologic suppression and no previous virologic failure. Participants were randomized (2:1) to switch to DOR/3TC/TDF on Day 1 (immediate switch group [ISG]) or Week 24 (delayed switch group [DSG]). Participants who completed Week 48 could enter Study Extension 1, which continued through Week 144.

**Results:** The analysis included 656 participants (ISG, 447; DSG, 209) who switched to DOR/3TC/TDF; nine ISG participants who completed the Base Study (Week 48 HIV-1 RNA < 40 copies/mL) but did not enter Study Extension 1 were excluded from efficacy analyses. At Week 144, 2.7% (12/438) of ISG and 4.8% (10/209) of DSG had HIV-1 RNA ≥ 50 copies/mL (FDA Snapshot approach); mean increase from baseline in CD4 T-cell count (Observed Failure approach) was 39.5 and 55.9 cells/mm$^3$ for ISG and DSG, respectively (Table 1). Protocol-defined virologic failure (PDVF) following switch occurred in 2.1% (9/438) and 3.3% (7/209) for ISG and DSG, respectively; RNA resistance testing from four participants with PDVF (two with PDVF post-Week 48) revealed no resistance-associated mutations to DOR, 3TC or TDF. Reductions in fasting lipids were observed Weeks 0 to 24 post-switch and maintained through Week 144 (Last Observation Carried Forward approach). Weight change from switch was +1.4 kg and +1.2 kg for ISG and DSG, respectively. The most common AEs were nasopharyngitis (n = 106 [16.2]), headache (n = 81 [12.3%]) and diarrhea (n = 60 [9.1]). Overall, 4.1% (27/656) discontinued due to an AE and no deaths occurred.

**Conclusions:** Findings at Week 144 confirm previous data that show switching to once-daily DOR/3TC/TDF is a generally well-tolerated option for maintaining viral suppression in adults considering a change in therapy.

**Abstract P037-Table 1. Efficacy and safety outcomes at Week 144[a]**

| **Efficacy outcomes** | | |
|---|---|---|
| | **ISG (N = 438)** | **DSG (N = 209)** |
| HIV-1 RNA ≥ 50 copies/mL, n (%) [95% CI] | 12 (2.7) [1.4 to 4.7] | 10 (4.8) [2.3 to 8.6] |
| HIV-1 RNA < 50 copies/mL, % (95% CI) | 80.1 (76.1 to 83.8) | 83.7 (78.0 to 88.5) |
| Protocol-defined virologic failure,[b,c] n (%) | 9 (2.1) | 7 (3.3) |
| Change from baseline in CD4 T-cell count (cells/mm$^3$), mean (95% CI) | 39.5 (17.8 to 61.1) | 55.9 (26.3 to 85.4) |

| **Safety outcomes** | | | | |
|---|---|---|---|---|
| **Fasting lipids** | **ISG (N = 391)** | | **DSG (N = 192)** | |
| | **Mean value at baseline** | **Mean change from baseline (SD)** | **Mean value at baseline** | **Mean change from baseline (SD)** |
| LDL cholesterol (mg/dL) | 113.2 | −14.9 (26.1)[d] | 106.7 | −11.9 (25.6)[e] |
| Non-HDL cholesterol (mg/dL) | 143.8 | −22.2 (31.3) | 137.5 | −18.7 (28.8) |
| HDL cholesterol (mg/dL) | 50.3 | −2.0 (10.7) | 51.2 | −3.2 (11.1) |
| Triglyceride (mg/dL) | 158.1 | −37.8 (104.3) | 158.3 | −36.8 (102.8) |

| **Weight changes** | **ISG (N = 358)** | **DSG (N = 177)** |
|---|---|---|
| Adjusted weight change from switch (kg),[f] mean (95% CI) | 1.4 (0.8 to 1.9) | 1.2 (0.4 to 2.0) |

| **Adverse events,[g] n (%)** | **ISG + DSG (N = 656)** |
|---|---|
| ≥1 AE | 575 (87.7) |
| Drug-related AEs | 146 (22.3) |
| Serious AEs | 70 (10.7) |
| Serious drug-related AEs | 6 (0.9) |
| Deaths | 0 (0.0) |
| Treatment discontinuation due to an AE | 27 (4.1) |
| Treatment discontinuation due to a drug-related AE | 18 (2.7) |
| Treatment discontinuation due to a serious AE | 9 (1.4) |
| Treatment discontinuation due to a serious drug-related AE[h] | 4 (0.6) |

AE, adverse event; CI, confidence interval; DOR/3TC/TDF, doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg; DSG, delayed switch group; HDL, high-density lipoprotein; ISG, immediate switch group; PDVF, protocol-defined virological failure.
[a]Participants were switched to DOR/3TC/TDF at Week 0 (ISG) or Week 24 (DSG);
[b]defined as two consecutive measurements of HIV-1 RNA ≥ 50 copies/mL at least one week apart;
[c]PDVF occurring post-Week 48: ISG n = 3, DSG n = 6;
[d]N = 375;
[e]N = 185;
[f]calculated using a repeated measure mixed model, adjusted for weight at time of switch, race (Black or non-Black), ethnicity (Hispanic or other), gender, age, baseline CD4 T-cell count, and HIV viral load;
[g]analysis includes AEs occurring or worsening after the first dose of DOR/3TC/TDF once daily through last dose of Study Extension 1 medication (or 14 days after the last dose of Study Extension 1 medication if not continuing into the Study Extension 2);
[h]serious drug-related AEs included lipase increase (n = 2), amylase increase (n = 1), depression (n = 1) and renal failure (n = 1).

# P038

## Switching to bictegravir/emtricitabine/tenofovir alafenamide in adults aged >65 years or older: Week 72 results from an international, phase IIIb, open-label trial

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**Background:** As the age of PLWH increases, studies are needed to assess the safety and efficacy of ART in this population. Older individuals are at increased risk of comorbidities and polypharmacy, so ensuring the safety and tolerability of ART in older PLWH is critical. Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a single-tablet regimen with few drug-drug interactions, a high barrier to resistance, no food restrictions, and small tablet size. In this ongoing

96-week study, we evaluated the efficacy and safety of switching participants ≥65 years to B/F/TAF.
**Materials and methods:** Virologically suppressed (HIV-1 RNA < 50 copies/mL) participants >65 years old currently receiving either E/C/F/TAF or a TDF-based regimen were switched to B/F/TAF. The primary endpoint was HIV-1 RNA < 50 copies/mL at Week (W) 24 as defined by the FDA Snapshot algorithm. Here we report efficacy and safety outcomes at W72.
**Results:** Eighty-six participants were enrolled at sites from five European countries; median age was 69 years (range 65 to 80); 13% were female, and 99% were White; 92% were receiving E/C/F/TAF at baseline. At W72, HIV RNA < 50 copies/mL was 93% (80/86); six (7%) had no virologic data in window (four discontinued study drug due to adverse events (AEs) but had last available HIV-1 RNA < 50 copies/mL and two had no data within the window but were still on study drug). Using the missing=excluded analysis, HIV RNA < 50 copies/mL was 100% at W72. There were no virologic failures or emergent resistance. Median change in CD4 count was 53 cells/mm$^3$ (IQR: −49, 120). There were two (2%) Grade 3 to 4 study drug-related AEs. Four AEs led to premature study drug discontinuation: 1) abdominal discomfort (Grade 2, drug-related), 2) alcohol withdrawal, 3) benzodiazepine withdrawal, 4) suicide. There were no serious AEs that were study drug-related. There were seven Grade 3 and one Grade 4 laboratory-related AEs reported, with the Grade 4 being hyperkalemia. There were no discontinuations for renal, bone or hepatic AEs.
**Conclusions:** Through W72, high rates of virologic suppression were maintained in PLWH who switched to B/F/TAF. The safety and efficacy data support the switch to B/F/TAF in virologically suppressed HIV-infected individuals aged ≥65 years.

## P039

### 12-months outcomes of dolutegravir/rilpivirine in virologically suppressed HIV-infected patients: real-world data from the German JUNGLE cohort

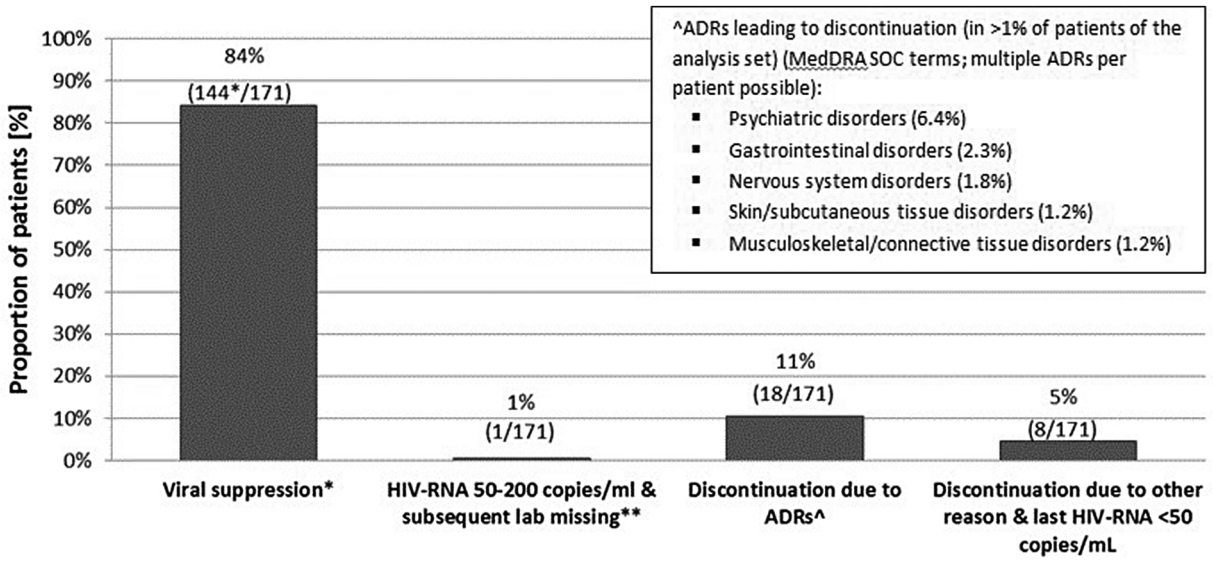
S Noe[1]; K Ummard-Berger[2]; H Hillenbrand[3]; D Beer[4]; C Wyen[5]; R Pauli[6]; N Postel[7]; K Dymek[8]; B Westermayer[9] and J Scherzer[8]
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**Background:** In the SWORD-1&2 studies, the combination of dolutegravir (DTG) and rilpivirine (RPV) maintained viral suppression for 148 weeks with low rates of virological failure. The German JUNGLE cohort, providing real-word data (RWD) on DTG/RPV use, is more extensively pre-treated than in SWORD with a higher prevalence of advanced HIV disease. Here we present the 12-months outcomes.
**Methods:** JUNGLE is a non-interventional, prospective cohort study in virologically suppressed patients switched to DTG/RPV in accordance

**Abstract P039-Table 1. Patient related outcomes: HIV Symptom Distress Module (HIV-SDM) and treatment satisfaction (TSQ) in patients completing baseline and month-12 (M12) questionnaires**

| | N | Baseline | M12 | Change from baseline mean/median (IQR) | *p*-value |
|---|---|---|---|---|---|
| HIV-SDM[a] | 81 | 12.4/8.0 (4.0 to 18.0) | 13.5/9.0 (4.0 to 21.0) | +1.1/±0.0 (−5.0 to + 6.0) | 0.4793 |
| HIV-TSQ[b] | 76 | 53.4/55.5 (51.0 to 59.0) | 56.1/58.0 (55.0 to 60.0) | +2.7/+1.0 (−0.5 to +4.5) | <0.001 |

[a]HIV-SDM: 20 items, range of total score 0 to 80; negative changes indicate improvement;
[b]HIV-TSQ: range of total score 0 to 60; positive changes indicate improvement.




**Abstract P039-Figure 1. Virologic outcomes at month 12 (M12); *n=2/144 with M12 HIV-RNA 50-200 cp/mL and subsequent HIV-RNA <50 cp/mL; **subsequent HIV-RNA level within 120 days was missing.**

with the summary of product characteristics. Month 12 (M12) viral suppression was defined as HIV-RNA < 50 copies/mL in data window (9 to 15 months) or 50 to 200 copies/mL with subsequent HIV-RNA < 50 copies/mL (excluding missing data/loss-to-follow-up); ART persistence was estimated using Kaplan-Meier analysis. Patient-reported outcomes were assessed using validated questionnaires (HIV Symptom Distress Module [HIV-SDM] and treatment satisfaction [HIV-TSQ]).

**Results:** At data-cut, 183 patients were eligible for analysis (90% men, 49 years [median], eight years on ART [median], 18% CDC C, 709 CD4 cells/μL [median]). Primary reasons for switching to DTG/RPV were side effects of previous ART (25%), switch to a single-tablet regimen (23%) and reduction of substance exposure (21%). Most common comorbidities were hypertension (30%), lipid disorders (17%), depression (16%), insomnia (14%) and chronic kidney disease (13%). Persistence on study through M12 was 86%. Twenty-six patients (14%) discontinued the study. Reasons were adverse drug reactions (ADRs; 10%), patient wish (2%), doctor's decision (2%) and withdrawal of consent (<1%). M12 viral suppression rate was 84% (n = 144/171; n = 12 excluded due to missing data) (Figure 1). Of note, in 94% of patients with virological data during follow-up, HIV-RNA measurements were continuously <50 copies/mL (n = 165/175; 4 HIV-RNA measures [median] per individual, range 1 to 7). Until data-cut, 31 ADRs (Grades 1 to 2, 1 × Grade 3) had been documented in 22 patients (12%). In patients completing questionnaires at both time points (baseline, M12), mean changes in HIV-SDM and TSQ were +1.1 ($p = 0.4793$) and +2.7 ($p < 0.001$), respectively (Table 1).

**Conclusions:** Real-world DTG/RPV use showed a high virological suppression rate over one year with no discontinuation attributed to virological failure. Although 10% discontinued DTG/RPV due to ADRs, treatment satisfaction (HIV-TSQ) increased in patients remaining on DTG/RPV for one year.

## P040

### Early discontinuation of ABC/3TC/DTG and BIC/TAF/FTC single-tablet regimens: a real-life multicentre cohort study

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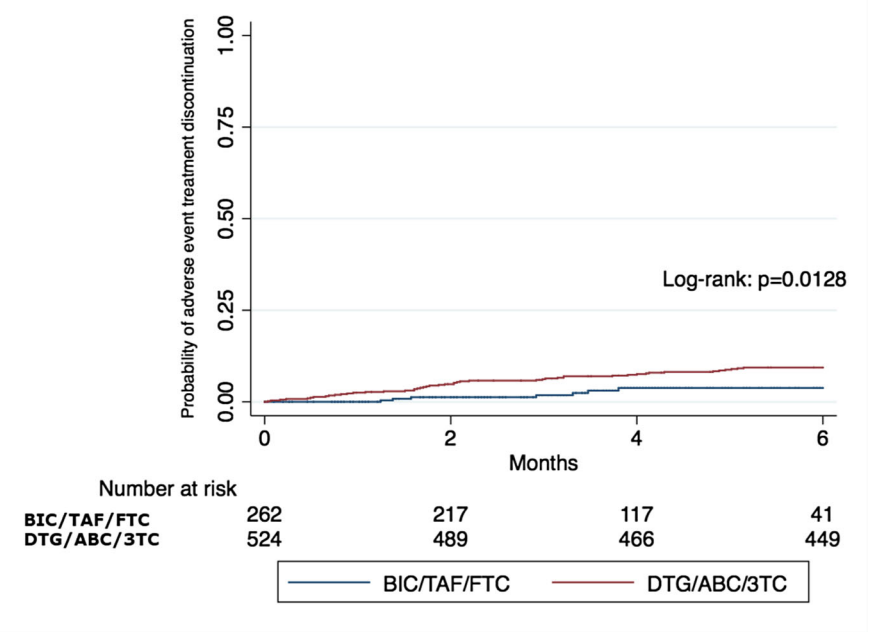
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**Background:** Comparing rates and reasons of early discontinuation within 24 weeks of starting treatment with dolutegravir (DTG) or

**Abstract P040-Table 1. Clinical/demographic characteristics and outcome of the study population grouped by the different single-tablet regimen**

| | BIC/TAF/FTC (n = 262) | DTG/3TC/ABC (n = 524) | *p* |
|---|---|---|---|
| Italian, n (%) | 221 (84.3) | 431 (82.2) | 0.502 |
| Male gender, n (%) | 206 (78.6) | 385 (73.5) | 0.171 |
| Age at entry, median [IQR] | 54 [44 to 60] | 51 [41 to 57] | 0.0032 |
| Route of HIV transmission, n (%) | | | 0.010 |
| Sexual | 196 (74.8) | 415 (79.1) | |
| IVDU | 36 (13.7) | 63 (12.0) | |
| Other | 6 (2.3) | 2 (0.4) | |
| Not known | 24 (9.1) | 44 (8.4) | |
| Months of undetectable viraemia, median [IQR] | 51 [24 to 106] | 42 [14 to 98] | 0.0062 |
| Patients with at least one comorbidity | 115 (43.9) | 117 (22.3) | <0.001 |
| AIDS diagnosis, n (%) | 54 (20.6) | 86 (16.4) | 0.147 |
| HCV Ab positivity, n (%) | 47 (17.9) | 93 (17.7) | 0.947 |
| HIV RNA zenith copies/mL log10, median [IQR] | 5.1 [4.7 to 5.6] | 5.1 [4.6 to 6.0] | 0.5094 |
| Nadir CD4 (cells/mL), median [IQR] | 230 [110 to 342] | 219 [77 to 353] | 0.6184 |
| Years of HIV, median [IQR] | 13 [5 to 22] | 10 [4 to 19] | 0.0081 |
| Years of antiretroviral therapy, median [IQR] | 9 [4 to 18] | 8 [3 to 16] | 0.0030 |
| History of a previous virological failure, n (%) | 104 (39.7) | 194 (37.6) | 0.569 |
| $CD^{4+}$ T cells at baseline/μL, median [IQR] | 690 [470 to 944] | 679 [466 to 949] | 0.6147 |
| CD4 < 350 cells/mL at baseline | 33 (12.6) | 75 (14.3) | 0.510 |
| Median cumulative number of antiretroviral drugs before switch | 7 [5 to 9] | 5 [3 to 7] | <0.0001 |
| Pre-switch therapy, n (%) | | | |
| Monotherapy | 2 (0.8) | 5 (0.9) | 0.788 |
| Dual therapy | 21 (8.0) | 36 (6.9) | 0.560 |
| Three-drug regimen NNRTI-based | 17 (6.5) | 136 (25.6) | <0.001 |
| Three-drug regimen PI-based | 12 (4.5) | 166 (31.7) | <0.001 |
| Three-drug regimen INI-based | 206 (78.6) | 163 (31.1) | <0.001 |
| Other | 4 (1.5) | 18 (3.4) | 0.126 |
| Switch from a previous INSTI regimen, n (%) | 209 (79.8) | 185 (35.3) | <0.0001 |
| Switch from a previous ABC regimen, n (%) | 4 (1.5) | 217 (41.4) | <0.0001 |
| M184V/I, n (%) | | | 0.020 |
| Yes | 12 (4.6) | 40 (7.3) | |
| No | 182 (69.5) | 277 (52.9) | |
| Unknown | 68 (25.9) | 207 (39.5) | |
| Discontinuation due to all cause, n (%) | 13 (5.0) | 57 (10.9) | 0.1970[a] |
| Discontinuation due to adverse event (Grade 1 to 2), n (%) | 7 (2.7) | 48 (9.1) | 0.0323[a] |
| Virological failure, n (%) | 1 (0.4) | 5 (0.9) | 0.6276[a] |

3TC, lamivudine; ABC, abacavir; INSTI, integrase strand transfer inhibitor; IVDU, intravenous drug users; PI, protease inhibitor.
[a]Wald test.




**Abstract P040-Figure 1. Kaplan-Meier analysis for the probability of early discontinuation due to adverse event.**

bictegravir (BIC) single-tablet regimens (STRs) in a large prospective cohort of HIV-infected patients.

**Materials and methods:** A retrospective, multicentre cohort study was carried out. Patients with plasma HIV-1 RNA < 50 copies/mL switching to a STR regimen containing BIC or DTG, in five large Italian out-patient clinics were included and followed up 24 weeks. Major outcome was early discontinuation due to any cause (EDAC) and more specifically due to adverse events (EDAEs). Study entry was the switch date starting STR, study exit the date of virological failure (VF) or EDAC or loss to follow-up (FU)/death. VF was defined as two consecutive HIV RNA > 50 copies/mL. X2/Fisher's and Wilcoxon signed rank test were used where appropriate. Kaplan-Meier for the probability of VF/EDAC/EDAEs and Cox model for regression analysis and Wald test were employed.

**Results:** We included 786 patients: 524 with DTG, 262 with BIC (Table 1). At Week 24, we observed 70 EDAC: five (7.1%) for VF (one with BIC and four with DTG; $p = 0.6276$), 10 for simplification, more frequently with BIC than DTG (n = 5, 38.5% and n = 5, 8.8%; $p = 0.0720$) and 55 EDAEs, seven (2.7%) with BIC, 48 (9.2%) with DTG ($p = 0.0323$). EDAEs due to neurological toxicity was similar between regimens ($p = 0.2398$), gastrointestinal toxicity was more frequent in DTG (37.5% vs 28.6%; $p = 0.0506$). No drug-related AEs were serious or Grade 3/4. There were no significant differences among regimens in the rates of VF and EDAC. The EDAEs rate was significantly higher for DTG than for BIC (20.00 × 100 person-years (py) [95% 15.07 to 26.52] vs 8.62 × 100 py [95% 4.11 to 18.09], respectively) (Figure 1). The adjusted HR for EDAEs in DTG group compared to BIC was 3.28 (95% CI: 1.34 to 8.00; $p = 0.009$). We identified an association between age >60 years old and switch from regimen without abacavir.

**Conclusions:** Patients who received DTG or BIC do not show significant differences in VF or EDAC rates. However, EDAEs is more frequent with DTG especially in the over-60s and in those who come from regimens without abacavir.

## P041

### Real-world experience using bictegravir/emtricitabine/tenofovir-alafenamide (B/F/TAF) in a Scottish HIV cohort

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**Background:** Clinical trials have shown combination bictegravir/emtricitabine/tenofovir-alafenamide to be non-inferior to dual NRTI regimens in combination with an NNRTI, PI or INSTI [1,2]. Biktarvy received European marketing authorisation in June 2018 [3] and was approved for use in NHS Scotland in September 2018 [4]. Recommended for treatment of HIV-1 infection in patients without past or current resistance to any component, B/F/TAF became a recommended regimen in European and US guidelines for naïve and switch patients alike. We aimed to evaluate real-world usage and tolerability of B/F/TAF in a Scottish HIV cohort.

**Materials and methods:** Retrospective analysis using our clinical database identified patients who started B/F/TAF between September 2018 and September 2019. Patients' clinical records were used to determine demographics, indication for regimen, baseline laboratory parameters, resistance profile, whether regimen was stopped, reasons for stopping and subsequent regimen chosen.

**Results:** One hundred and nine patients commenced B/F/TAF within the time-frame. The most common indications for choosing B/F/TAF were high cardiovascular risk (28%), preference for single tablet (28%), drug-drug interactions (24%) and renal risk (22%). Thirty-three percent of patients had some degree of prior antiretroviral resistance (14.7% NRTI, 22% NNRTI, 4.6% PI, 0% INSTI). No patient developed further resistance to any constituent of B/F/TAF. Fifteen of 109 patients (13.8%) stopped the regimen; median time to stop was 70 days. Side-effects were the most common cause for stopping, 13/15 (87%). The most frequently reported side-effects were neuropsychiatric 10/13 (77%) leading to 10/109 (9.2%) of all patients receiving B/F/TAF changing therapy. Nine maintained F/TAF backbone, five switched and one stopped ARVs.

**Conclusions:** Renal and cardiovascular risks along with drug interactions and patient preference for a single tablet were the most

common reasons for using B/F/TAF. Thirteen of 109 (12%) patients started on B/F/TAF were subsequently stopped due to adverse effects, of which neuropsychiatric side-effects were by far most common. These results show real-world cohorts may have greater discontinuation rates due to side-effects compared to the trial cohorts [1,2], and suggest Biktarvy may have comparable incidence of neuropsychiatric side-effects to dolutegravir-based regimens [5]. Further analysis of larger cohorts is required to determine if those at risk of side-effects can be predicted.

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# P042

## Does tuberculosis coinfection increase the risk of being on second-line antiretroviral therapy in Tanzania?

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**Background:** Tuberculosis (TB) and HIV are major public health concerns. The use of ART has significantly reduced TB incidence, recurrence, reactivation and mortality among HIV patients. TB comorbidity is a major contributing factor associated with changing to second-line ART among HIV patients. ART improves treatment outcome for HIV/TB patients, but their use is associated with several challenges such as high pill burden, drug-drug interactions between rifampicin and some other ART and increased risk of developing TB-related immune reconstitution inflammatory syndrome (IRIS).
**Methods:** This was a retrospective cohort study using routinely collected data from the Tanzanian national database of PLHIV attending care and treatment clinics (CTCs) from January 2012 to December 2017, in Northern Tanzania. Logistic regression model with a multilevel component analysis was used to determine the predictors of being on ARTs.
**Results:** The study involved 93 290 HIV patients with the mean age of 36.3 (SD 2.9) years, and 54 105 (58.0%) were on ART, of which 53 590 (99.0%) were on the first line. The study had 2385 (2.6%) patients who had HIV/TB coinfection. Predictors of having being on ART included: age above 24 years was less likely to be on ART compared to those between 15 and 24 years of age, Kilimanjaro and Tanga regions had aORs of 0.73 (95% CI 0.66 to 0.80) and 0.82 (95% CI 0.75 to 0.89) respectively, compared to patients from Arusha, and HIV/TB coinfection had aOR 0.49 (95% CI 0.41 to 0.58). Predictors for being put on second-line ARTs among HIV-positive patients included being a patient from Kilimanjaro, aOR 5.75 (95% CI 2.03 to 16.24), being a patient from Tanga, aOR 2.96 (95% CI 1.01 to 8.66), while having HIV/TB coinfection was significantly less likely associated with being changed to second-line ART, aOR 0.54 (95% CI 0.45 to 0.88).
**Conclusions:** HIV/TB coinfection is significantly associated with reduced chance of being put on first-line ART at enrolment or changed to second-line ART thereafter, we therefore advocate the increased and appropriate use of first-line and/or second-line ART among HIV patients, much so among HIV/TB coinfected patients as recommended by the prevailing guidelines.

# P043

## Effectiveness and safety of darunavir/cobicistat/emtricitabine/tenofovir alafenamide in an observational Italian cohort: interim analysis of DIAMANTE (TMC114FD1HTX4011) study

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**Background:** To improve adherence to ART, a single-tablet regimen (STR) based on the cobicistat-boosted protease inhibitor darunavir (DRV), together with emtricitabine and tenofovir alafenamide (D/C/F/

**Abstract P043-Table 1. Viro-immunological parameters stratified by groups**

| Patients having VL < 50 at V4 | Group 1 55 (N = 60) | Group 2 26 (N = 33) | Group 3 63 (N = 82) |
|---|---|---|---|
| VL missing at V4 (N) | 3 | 4 | 7 |
| Median (Q1 to Q3) CD4 cell count to V1 | 700.5 (494.5 to 806) (N = 60) | 580 (453 to 781) (N = 33) | 481 (282 to 729) (N = 81) |
| Median (Q1 to Q3) CD4 cell count to V4 | 694 (505 to 962) (N = 57) | 662.5 (509.5 to 809.5) (N = 28) | 587 (372 to 760) (N = 75) |
| Median CD4/CD8 (Q1 to Q3) to V1 | 0.7 (0.4 to 0.9) (N = 40) | 0.7 (0.5 to 1.1) (N = 23) | 0.5 (0.2 to 0.6) (N = 49) |
| Median CD4/CD8 (Q1 to Q3) to V4 | 0.8 (0.6 to 1.2) (N = 56) | 0.8 (0.5 to 1.1) (N = 22) | 0.6 (0.3 to 0.9) (N = 60) |

V, Visit; VL, viral load.

TAF), has been developed. This formulation reduces the pill burden and mistakes in drug intake.
**Material and methods:** DIAMANTE is an Italian, retrospective and prospective observational study carried on HIV-positive adult outpatients treated with D/C/F/TAF in 18 centres. Three groups of patients have been enrolled: Group 1 always treated with DRV-based ART; Group 2 patients switching to D/C/F/TAF from a non-DRV-based ART; and Group 3 patients starting D/C/F/TAF as first-line therapy at least one month before enrolment. Here we show the results of an interim analysis related to the effectiveness and safety of D/C/F/TAF in patients (N = 140) who completed the study in June 2020.
**Results:** Two hundred and forty-six patients have been enrolled. Of them, 10% (25) were females. At the June 2020 analysis, the virological suppression (FDA Snapshot algorithm) was 96% in Group 1, 90% in Group 2 and 84% in Group 3. It was noticed an improvement in all groups of the immunological aspect, especially in naïve patients who showed a median CD4 cell count increase of 22% at Visit 4. The data are detailed in Table 1. Thirty (12%) patients withdrew from the study: 5% for tolerability, 2% for virological failure, 1% pregnancies and 4% for other reasons. Sixty-nine out of 246 (28%) patients reported at least one AE of mild severity (77%); three (1%) patients discontinued the study due to AE. Twelve (5%) patients reported SAE, one of them discontinued study; the event was considered related to D/C/F/TAF.
**Conclusions:** In the first 140 patients the treatment based on D/C/F/TAF has shown to be effective and well tolerated in clinical practice.

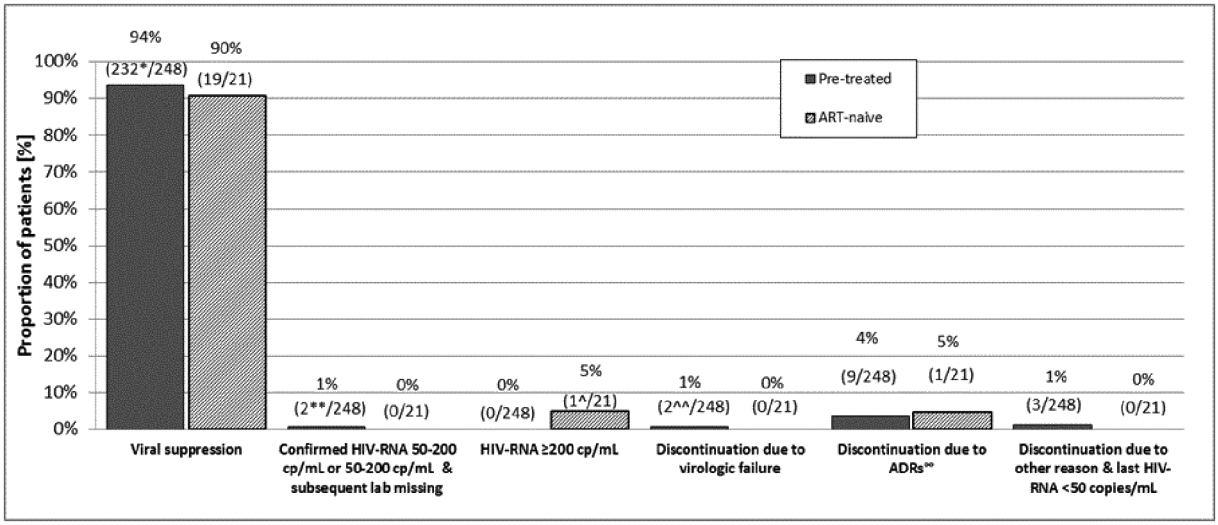
## P044

### Real-world data from the prospective URBAN cohort study on the use of dolutegravir (DTG) + lamivudine (3TC) in ART-naive and pre-treated people living with HIV in Germany

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**Background:** The URBAN cohort study initiated in 11/2018 provides prospective real-world data regarding the effectiveness, patient-reported outcomes (PROs) and tolerability of using DTG plus 3TC in people living with HIV either as two tablets dolutegravir + lamivudine (DTG + 3TC) or—after availability in 7/2019—as single-tablet regimen (STR; DTG/3TC). Here we present the study population and Month 6 (M6) outcomes.
**Methods:** URBAN is a prospective, non-interventional, 3-year German cohort study in ART-naïve and pre-treated patients receiving DTG plus 3TC in accordance with the label. Inclusion criteria for M6 full analysis set (FAS) were a documented M6 follow-up (visit window 4.5 to 9 months) or premature discontinuation. Viral suppression was defined as HIV-RNA level [copies/mL] <50 or 50 to 200 with subsequent HIV-RNA < 50 in the effectiveness set (missings excluded). PRO measures at baseline and M3 involved the HIV Treatment Satisfaction Questionnaire (HIVTSQ) and the HIV Symptom Distress Module (HIV-SDM).




**Abstract P044-Figure 1. Virological outcomes at Month 6 (M6; effectiveness set: N = 269; n = 38/307 with missing data). *including n = 4 with 50 to 200 copies/mL & subsequent HIV-RNA level <50 copies/mL. **n = 1 with confirmed 50 to 200 copies/mL. ^n = 1 with 360 copies/mL at M6 and 1 100 000 copies/mL at baseline. ^^n = 2 with a single HIV-RNA measurement of 128 and 89 copies/mL. ADRs (adverse drug reactions) (MedDRA SOC terms; multiple ADRs per patient possible) leading to discontinuation in >1% of the effectiveness set (N = 269): psychiatric disorders (3%), skin and subcutaneous tissue disorders (1%).**

**Abstract P044-Table 1. Patient-reported outcomes in patients completing baseline and Month 3 (M3) questionnaires**

| | Pre-treated patients | ART-naïve patients |
|---|---|---|
| HIV Symptom Distress Module (HIV-SDM),[a] N | 194 of 282 | 13 of 25 |
| Baseline total score; mean/median (IQR) | 14.5/12.0 (5.0 to 22.0) | 12.2/9.0 (3.0 to 15.0) |
| M3 total score; mean/median (IQR) | 11.4/8.0 (2.0 to 17.0) | 7.6/3.0 (1.0 to 7.0) |
| Change from baseline mean/median (IQR)[b] | −3.1/−3.0 (−8.0 to + 1.0) | −4.6/-3.0 (−9.0 to ± 0.0) |
| *p*-value (Wilcoxon signed-rank test) | <0.001 | 0.068 |
| HIV Treatment Satisfaction (HIVTSQ),[c] N | 193 | 17 |
| Baseline total score; mean/median (IQR) | 53.4/56.0 (50.0 to 60.0) | N/A |
| M3 total score; mean/median (IQR) | 56.0/58.0 (53.0 to 60.0) | 54.6/56.0 (54.0 to 58.0) |
| Change from baseline mean/median (IQR)[d] | +2.5/±0.0 (±0.0 to +4.0) | N/A |
| *p*-value (Wilcoxon signed-rank test) | <0.001 | N/A |

[a]HIV-SDM: 20 items, range of total score 0 to 80;
[b]negative changes indicate improvement;
[c]HIVTSQ: range of total score 0 to 60;
[d]positive changes indicate improvement.

**Results:**
M6 FAS included 307 patients (92% pre-treated, 93% men, median age 48 years). Of pre-treated participants, 33% had ≥3 prior ART changes. Baseline HIV-RNA was <50 copies/mL in 96% of pre-treated patients; median HIV-RNA in ART-naïves was 37 100 copies/mL (interquartile range 5100 to 66 550). Primary reasons for use of DTG plus 3TC (in >15%) were 'preference of 2-drug regimen (2DR)' (29%) and 'side effects of previous ART' (23%) in pre-treated, and 'preference of 2DR' (48%) and 'easiness to take' (16%) in ART-naives. Persistence on study through M6 was 95% (Kaplan-Meier estimate). Five percent of patients (n = 15/307) discontinued the study; reasons were adverse drug reactions (ADRs; 3.3%), virological failure (0.7%; n = 2 with <200 copies/mL), patient decision (0.7%) and doctor's decision (0.3%). Until M6, 22 ADRs (Grades 1 to 2) were documented in 17 patients (6%). Viral suppression rates are depicted in Figure 1. Of note, in 94% of pre-treated with ≥1 HIV-RNA follow-up, HIV-RNA was continuously <50 copies/mL. In pre-treated patients completing PRO questionnaires at both time-points, mean changes in HIV-SDM and HIVTSQ were −3.1 ($p < 0.001$) and +2.5 ($p < 0.001$), respectively (Table 1).
**Conclusions:** DTG/3TC showed a high acceptance in ART-naïve and pre-treated patients with a persistence of 95% until Month 6. Patients reported significant improvements in symptom distress and treatment satisfaction.

# P045

## Dual HIV treatment in experienced HIV patients

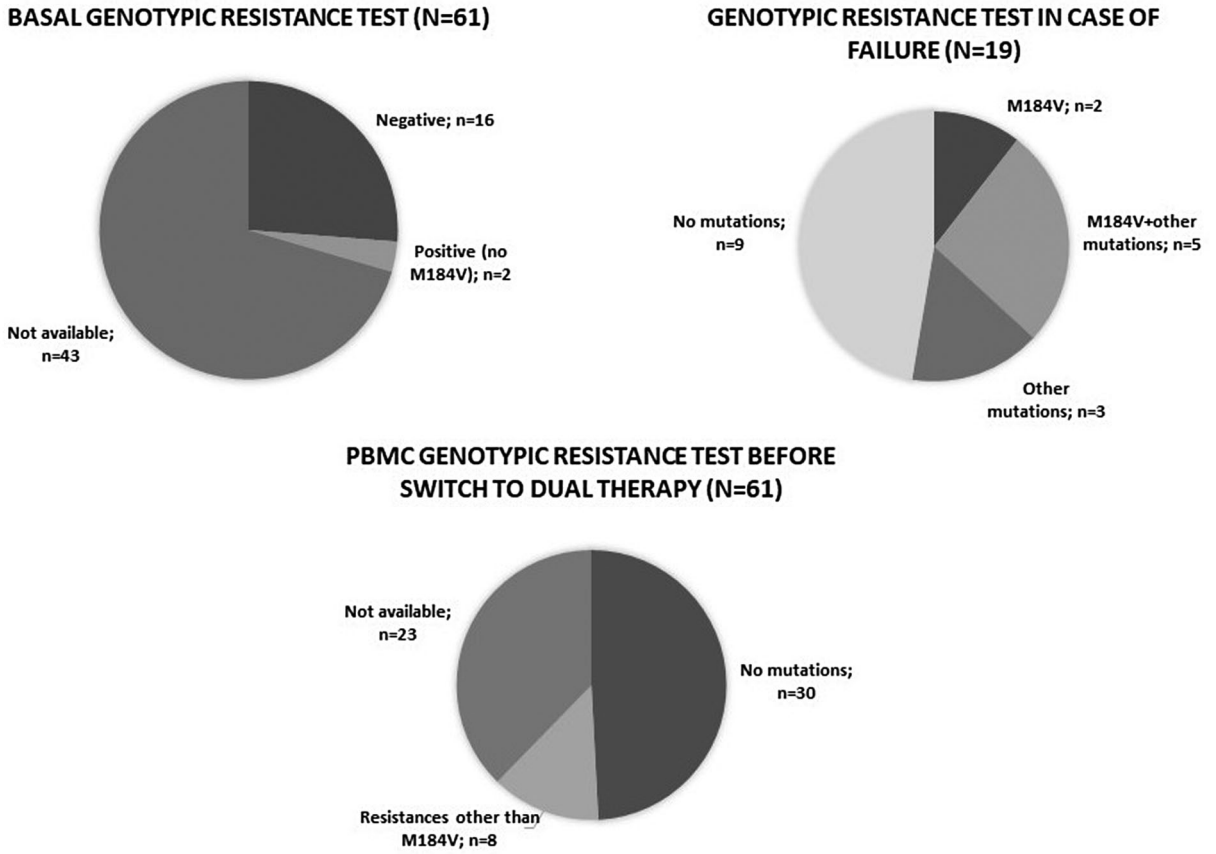
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**Background:** Treatment simplification in HIV suppressed patient is an accepted strategy that can reduce drug exposition, treatment side effect and costs. Published trials demonstrate safety even in the long-term period [1–3]. However little is known on its impact, especially in very experienced patients with archived HIV resistances. In this study we enrolled HIV suppressed patients exploring their genotypic resistance test at diagnosis, during past HIV breakthrough or before switching to dual.

**Materials and methods:** We retrospectively evaluated patients having HIV VL <20 copies/mL for at least six months while on ART. Patients were assigned to simplified treatment irrespectively of previous ART and treatment failures or archived genotypic mutations. In some patients (38) we performed PBMC (peripheral blood mononuclear cells) genotypic resistance test before switch to dual therapy with lamivudine (3TC) 300 mg/daily + dolutegravir (DTG) 50 mg/daily. All subjects were prospectively followed up to Week 24 and all remained on dual therapy during the whole period.
**Results:** Sixty-one individuals were included, and 71% were men. The median time from HIV diagnosis at switching to dual was 12 years. More than a half patients had a CD4 + cells nadir of less than 200 cells/mL and 16 patients (26%) experienced AIDS event. Nineteen patients (31%), during the past HAART history, experienced drug failure and performed a genotypic resistance test during viral breakthrough: seven of them had 184V (archived) mutation. None of the 184V patients experienced treatment failure during dual therapy. During the study period, two out of 61 patients had virological failure (from undetectability before dual to VL more than 20 copies/mL) due to lack of adherence. Treatment was well tolerated with no significant side effects (Figure 1).
**Conclusions:** Switching to a dual ART regimen based on 3TC+DTG maintained virological efficacy up to Week 24, even in patients with history of AIDS events, treatment failures and an archived 184V mutation. A dolutegravir-based dual therapy in combination with lamivudine shows promising results. The very thing that is determinant to start dual therapy, rather than previous history, is, in our opinion, adherence.

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**Abstract P045-Figure 1. Genotypic resistance tests at diagnosis, in case of failures and before switch to dual therapy.**

# Treatment Strategies: Other

## P046

### Starting or switching to bictegravir/emtricitabine/tenofovir alafenamide in clinical practice: pooled 12-month results from the global BICSTaR study

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**Background:** The ongoing observational BICSTaR study aims to demonstrate effectiveness, safety, and tolerability of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in routine clinical practice in at least 1400 ART-naïve (TN) and ART-experienced (TE) PLHIV.

**Materials and methods:** This 12-month analysis of PLHIV receiving B/F/TAF in Europe and Canada assessed HIV-1 RNA (missing data=excluded analysis), drug-related (DR) adverse events (AEs), persistence, and weight/body mass index (BMI) change.

**Results:** At the time of data cut-off (Mar 2020), 513 participants (n = 84 TN/n = 429 TE) completed a 12M visit. Most were male (91%) and white (89%); the median age was 38 (TN) and 49 (TE) years. Prevalence of comorbidities at baseline was 76%; the most common were neuropsychiatric (28%), hyperlipidemia (18%), and hypertension (18%). Seventy-one percent/18%/13% of TE participants switched from INSTI-/NNRTI-/PI-based regimens, respectively (26% TDF); 8% had a history of prior virologic failure. Baseline primary resistance prevalence by historical genotype was 9% (n = 43/513; 5% had resistance mutations associated with NNRTIs, 3% PIs, 3% NRTIs [n = 8 M184V/I, n = 1 K65R], and 0.2% with INSTIs [n = 1 G140S]). At month 12, 100% of TN (n = 74/74) and 96% (n = 357/373) TE participants had viral load (VL) < 50 copies/mL. Comparable and high effectiveness was observed in both male and female participants, including older individuals (Table 1). No major resistance substitutions to the components of B/F/TAF emerged. DRAEs occurred in 14% (n = 12/84) of TN and 15% (n = 64/429) of TE participants, with the most common being gastrointestinal (5%) and neuropsychiatric (4%); discontinuations due to DRAEs were low (TN 3.6% and 7.2% TE) and 90% of study participants remained on B/F/TAF (n = 462/513). Serious DRAEs were rare (0.4%; all in TE participants [n = 2 depression]). At 12M, median (Q1, Q3) weight change was + 2.5 kg (0.5, 6.3) for TN (n = 48) and + 0.9 kg (−1.0, 3.0) for TE (n = 269), with small changes in BMI of + 0.8 kg/m$^2$ (0.1, 1.9) for TN and + 0.3 kg/m$^2$ (−0.3, 1.0) for TE. Weight increase > 10% was observed in 19% (n = 9/48) and 5% (n = 15/269) of TN and TE participants, respectively.

**Abstract P046-Table 1. Effectiveness and BMI categories**

| Effectiveness of 12M (HIV RNA < 50 copies/mL) | TN (n = 84) | | TE (n = 429) | |
|---|---|---|---|---|
| Overall, % (n/N) | 100 (74/74) | | 96 (357/373) | |
| Female, % (n/N) | 100 (6/6) | | 97 (29/30) | |
| Male, % (n/N) | 100 (68/68) | | 96 (328/343) | |
| ≥50 years of age, % (n/N) | 100 (16/16) | | 93 (170/182) | |
| <50 years of age, % (n/N) | 100 (58/58) | | 98 (187/191) | |
| Baseline resistance mutations, % (n/N) | | | | |
| M184V/I | — | | 100 (1/8) | |
| K65R | 100 (1/1) | | — | |
| G140S | — | | 0 (0/1)[a] | |
| BMI categories[b] | TN (n = 48) | | TE (n = 269) | |
| | Baseline | 12M | Baseline | 12M |
| Underweight, <18.5 kg/m$^2$, % (n) | 6 (3) | 2 (1) | 2 (6) | 1 (3) |
| Normal, 18.5 to 24.9 kg/m$^2$, % (n) | 60 (29) | 58 (28) | 49 (132) | 47 (125) |
| Overweight, 25 to 29.9 kg/m$^2$, % (n) | 25 (12) | 29 (14) | 34 (91) | 37 (99) |
| Obese, ≥30 kg/m$^2$, % (n) | 8 (4) | 10 (5) | 15 (40) | 16 (42) |

[a]M12 viral load was 71 copies/mL and participant was still on B/F/TAF treatment;
[b]BMI category according to WHO's BMI classification.

**Conclusions:** The use of B/F/TAF in this real-world clinical cohort was associated with a high level of effectiveness and safety through 12 months, inclusive of male, female, and older PLHIV.

## P047

### Analysis of protocol-defined virologic failure through 96 weeks from a phase II trial (P011) of islatravir and doravirine in treatment-naïve adults with HIV-1

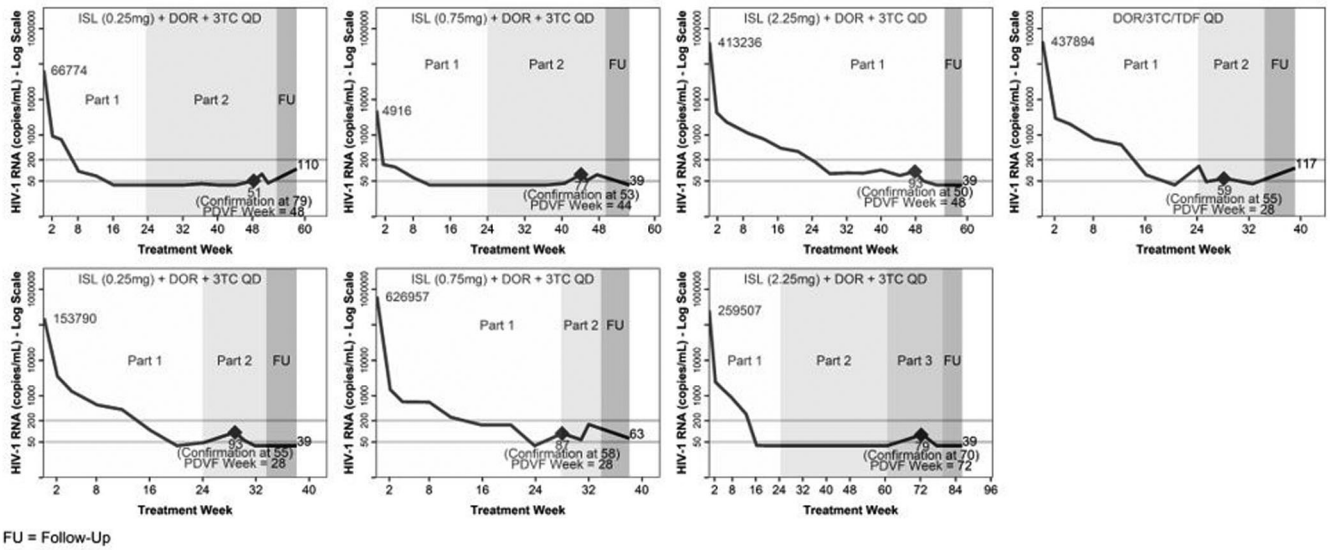
C Orkin[1]; J Molina[2]; Y Yazdanpanah[3]; C Chahin Anania[4]; E DeJesus[5]; J Eron[6]; S Klopfer[7]; A Grandhi[7]; J Xu[7]; K Eves[7]; D Hepler[7]; M Robertson[7]; C Hwang[7]; G Hanna[7] and T Correll[7]

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**Background:** Islatravir (ISL, MK-8591) is the first nucleoside reverse transcriptase translocation inhibitor (NRTTI) in development for treatment and prevention of HIV-1. This analysis describes detailed outcomes for participants who discontinued due to protocol-defined virologic failure (PDVF) from the phase II trial of islatravir and doravirine (DOR) through Week 96.

**Materials and methods:** Randomized, double-blind, dose-ranging trial in which participants initially received ISL (0.25, 0.75, or 2.25 mg) with DOR (100 mg) and lamivudine (3TC, 300 mg) or a fixed-dose combination of DOR, 3TC, and tenofovir disoproxil fumarate (DOR/3TC/TDF) daily. Participants receiving ISL achieving HIV-1 RNA < 50 copies/mL at Week 20 or later stopped 3TC at next visit. PDVF was conservatively defined as rebound with confirmed HIV-1 RNA ≥ 50 copies/mL after suppression anytime during the trial or non-response with failure to achieve HIV-1 RNA < 50 copies/mL by Week 48.

**Results:** One hundred and twenty-one participants received study drug and were included in the analyses. At Week 96, 86.2% (25/29), 90.0% (27/30), 67.7% (21/31) of participants maintained HIV-1




**Abstract P047-Figure 1. HIV-1 RNA levels over time for participants with PDVF.**

RNA < 50 copies/mL in the 0.25, 0.75, and 2.25 mg ISL groups, respectively, compared to 80.6% (25/31) with DOR/3TC/TDF (FDA Snapshot approach). During the first 48 weeks of the trial, six participants discontinued due to PDVF; two rebounders each in the 0.25 and 0.75 mg ISL groups, one non-responder in the 2.25 mg ISL group, and one rebounder in the DOR/3TC/TDF group. After Week 48 one additional participant discontinued due to PDVF; this participant, randomized to the 2.25 mg ISL group, met criteria for PDVF as a rebounder at Week 72 with an HIV-1 RNA level of 79 copies/mL and confirmatory value of 70 copies/mL. All participants who discontinued due to PDVF had confirmatory HIV-1 RNA levels <80 copies/mL (Figure 1); none met criteria for resistance testing. After changing to new regimens, three of the seven participants (one each from the 0.25 and 0.75 mg ISL groups and one from the DOR/3TC/TDF group) continued to have low-level viremia during 42-day post-discontinuation assessment.

**Conclusions:** Rates of PDVF were low and all participants who discontinued due to PDVF had HIV-1 RNA levels below the clinically significant level of 200 copies/mL. Only one additional PDVF occurred between Week 48 and Week 96.

## P048

### Renal safety through 96 weeks from a phase II trial (P011) of islatravir and doravirine in treatment-naïve adults with HIV-1

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**Background:** Islatravir (ISL, MK-8591) is the first nucleoside reverse transcriptase translocation inhibitor (NRTTI) in development for the treatment of HIV-1 infection. Some antiretroviral drugs have been associated with worsening renal function and nephrotoxicity. We evaluated changes in serum creatinine and estimated glomerular filtration rate (eGFR) among treatment-naïve adults with HIV-1 who received ISL as part of combination antiretroviral therapy for up to 96 weeks in a double-blind, phase II clinical trial.

**Methods:** One hundred and twenty-one participants were randomized to once-daily ISL (0.25, 0.75, or 2.25 mg) with doravirine (DOR, 100 mg) and lamivudine (3TC, 300 mg) or to a fixed-dose combination of DOR, 3TC, and tenofovir disoproxil fumarate (DOR/3TC/TDF). ISL participants with HIV-1 RNA < 50 copies/mL at Week 20 or later (up to Week 48) stopped 3TC at their next study visit (usually Week 24), continued their initial DOR+ISL dosage until at least Week 60, and switched to DOR+ISL 0.75 mg by Week 84. Serum creatinine was measured at each study visit, including Day 1, Week 48, and Week 96. eGFR was calculated by the Modification of Diet in Renal Disease (MDRD) formula.

**Results:** Median changes in serum creatinine and eGFR were minimal in all treatment groups at Weeks 48 and 96 (Table 1). Two participants (both receiving ISL 0.25 mg) had isolated instances of ≥ 0.5 mg/dL increase from baseline in serum creatinine: at Week 16 (1.7 mg/dL) in one participant; at Week 60 (1.7 mg/dL) and Week 84 (1.9 mg/dL) in the other. No participants had ≥1.0 mg/dL increase or doubling of serum creatinine. eGFR reductions >30% from baseline occurred in 11 (12%) ISL participants and five (16%) DOR/3TC/TDF participants and were transient in most cases. eGFR < 60 mL/min/1.73 $m^2$ occurred in four (4%) ISL participants and were transient in three (the fourth had eGFR < 60 mL/min/1.73 $m^2$ from baseline through Week 96). No participant discontinued treatment due to a renal adverse event.

**Conclusions:** This exploratory analysis of a small phase II trial did not find a dose-response relationship for ISL or clinically meaningful changes in serum creatinine or eGFR with DOR+ISL or DOR/3TC/TDF. Renal safety will be further examined in the DOR+ISL phase III program.

## P049

### The occurrence of hypersensitivity reaction and hepatotoxicity in individuals receiving integrase strand transfer inhibitors: results from the EuroSIDA study

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**Abstract P048-Table 1. Renal safety endpoints by treatment group in DOR+ISL P011**

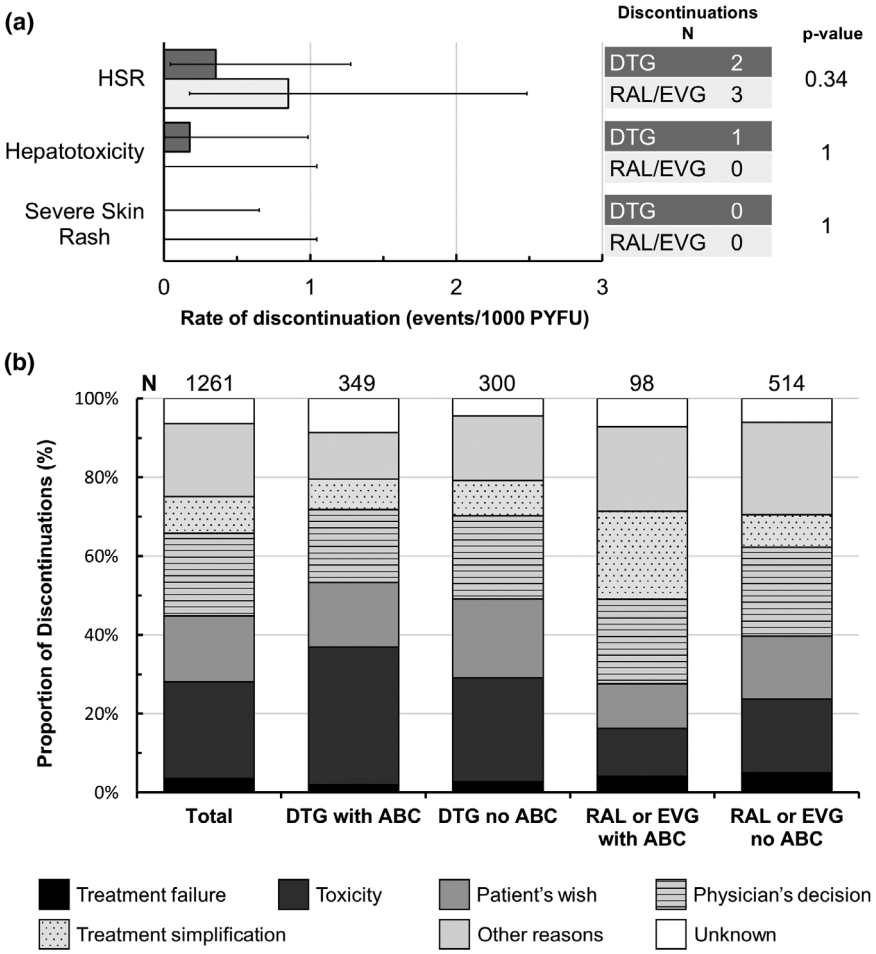
| | n | ISL 0.25 mg + DOR QD | n | ISL 0.75 mg + DOR QD | n | ISL 2.25 mg + DOR QD | n | DOR/3TC/TDF QD |
|---|---|---|---|---|---|---|---|---|
| Serum creatinine (mg/dL), median | | | | | | | | |
| Baseline (BL) | 29 | 0.9 | 30 | 0.8 | 31 | 0.9 | 31 | 0.8 |
| Week 48 change from BL | 29 | 0.06 | 30 | 0.00 | 25 | 0.00 | 28 | 0.10 |
| Week 96 change from BL | 25 | 0.10 | 27 | 0.05 | 21 | 0.09 | 26 | 0.10 |
| eGFR (mL/min/1.73 $m^2$), median | | | | | | | | |
| Baseline (BL) | 28 | 105.75 | 30 | 115.15 | 31 | 108.20 | 30 | 117.35 |
| Week 48 change from BL | 28 | −7.95 | 30 | −1.25 | 25 | −0.90 | 28 | −15.65 |
| Week 96 change from BL | 24 | −10.95 | 27 | −2.10 | 21 | −12.00 | 26 | −18.20 |
| eGFR > 30% decrease from baseline, n (%)[a] | | | | | | | | |
| Week 0 to 48 | 29 | 5 (17.2) | 30 | 3 (10.0) | 31 | 2 (6.5) | 31 | 4 (12.9) |
| Week 0 to 96 | 29 | 6 (20.7) | 30 | 3 (10.0) | 31 | 2 (6.5) | 31 | 5 (16.1) |
| eGFR < 60 mL/min/1.73 $m^2$, n (%)[a] | | | | | | | | |
| Week 0 to 48 | 29 | 3 (10.3) | 30 | 0 (0.0) | 31 | 0 (0.0) | 31 | 0 (0.0) |
| Week 0 to 96 | 29 | 3 (10.3) | 30 | 0 (0.0) | 31 | 1 (3.2) | 31 | 0 (0.0) |

[a]Percentages are based on the number of participants with at least one postbaseline test result.

Hospital and UCL Medical School, London, UK. [10]Centre for HIV/AIDS & and Infectious Diseases, Kaliningrad, Russian Federation. [11]Hospital JM Ramos Mejia, Buenos Aires, Argentina. [12]Nordsjællands Hospital, Hillerod, Hillerod, Denmark. [13]Ospedale L. Sacco, Milan, Italy. [14]Otto Wagner Hospital, Sozialmedizinisches Zentrum Baumgartner Höhe 1, Vienna, Austria. [15]J.W. Goethe University Hospital, Frankfurt, Germany. [16]Ichilov Hospital, Tel Aviv, Israel. [17]ViiV Healthcare, Research Triangle, NC, USA

**Background:** Hypersensitivity reaction (HSR) and hepatotoxicity are rare but potentially serious side effects of antiretroviral use. This study aimed to establish the incidence of discontinuations due to HSR, hepatotoxicity or severe skin rash among users of dolutegravir (DTG) compared to raltegravir (RAL) or elvitegravir (EVG).
**Methods:** HIV-positive individuals in EuroSIDA aged ≥ 18 years starting DTG-, RAL- or EVG-based combination ART (cART) between 16/01/2014 and 23/01/2019 were analysed in four groups: DTG ± abacavir (ABC) and RAL/EVG±ABC with independent review of discontinuations to identify HSR, hepatotoxicity or severe skin rash. The incidence of discontinuation within each group was calculated.

**Results:** In total, 4366 individuals started 5116 cART regimens including DTG, RAL or EVG, contributing 9180 person-years of follow-up (PYFU), with median follow-up 1.6 (interquartile range [IQR] 0.7 to 2.8) years per treatment episode. Median age was 51 (IQR 44 to 56) years, 3215 (73.6%) individuals were male, 2500 (57.3%) had CD4 cell counts >350 cells/μL, 166 (3.8%) were ART naïve and 3587 (82.2%) integrase inhibitor naïve at baseline. Of the treatment episodes, 3074 (60.1%) were with DTG (1738 with ABC, 1336 without) and 2042 (39.9%) were with RAL or EVG (286 with ABC, 1756 without). There were 649 discontinuations of DTG-containing regimens and 612 of RAL-/EVG-containing regimens. The discontinuation rate for any reason for DTG was 115 (95% CI 106 to 124)/1000 PYFU and 173 (95% CI 160 to 188)/1000 PYFU for RAL/EVG. The most common reasons for discontinuing an integrase inhibitor-containing regimen were toxicity and physician's decision (Figure 1). After independent review, there were five HSR discontinuations, two for DTG (one with and one without ABC, discontinuation rate 0.35, 95% CI 0.04 to 1.28/1000 PYFU) and three for RAL/EVG without ABC (0.85, CI 0.18 to 2.48/1000 PYFU). There was one hepatotoxicity discontinuation on DTG with ABC (0.18, CI 0.00 to 0.99/1000 PYFU), and no severe skin rash discontinuation.




**Abstract P049-Figure 1. Discontinuations of cART regimens with DTG (649 discontinuations during 5649 PYFU) or with other integrase inhibitors (RAL or EVG, 612 discontinuations during 3531 PYFU). (a) Rates of discontinuations (with 95% confidence intervals) for independently reviewed HSR, hepatotoxicity or severe skin rash events. Numbers of discontinuations are shown, with *p*-values for the discontinuation incidence rate ratios. (b) Discontinuation reasons by treatment group. 'Other reasons' includes concern for comorbidities, dyslipidaemia, abnormal fat redistribution, allergic reactions (not HSR), pregnancy related and other treatment changes. The number of discontinuations for each treatment group is shown above the bars.**

**Conclusions:** During a 5-year study period in this real-world observational cohort, discontinuation rates of integrase strand transfer inhibitors (INSTI)-containing cART regimens were 50% higher among users of RAL or EVG compared to DTG. After independent review, discontinuations due to HSR or hepatotoxicity in INSTI users were very rare, indicating a low rate of severe adverse events.

## P050

### Effectiveness, persistence and safety of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF), rilpivirine/F/TAF (R/F/TAF) or F/TAF + another 3rd agent in HIV-1 + patients over 24 months - Results from the German TAFNES cohort study

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**Background:** The prospective TAFNES cohort study evaluates the effectiveness and safety of F/TAF-based single-tablet regimens (STRs) with boosted elvitegravir or rilpivirine or F/TAF-based multi-tablet regimens in PLWH in a real-life setting.

**Methods:** The analysis population consisted of treatment-naïve (TN) and treatment-experienced (TE) adult PLWH initiated on E/C/F/TAF, R/F/TAF or F/TAF + 3rd agent. Here we present the final 24-months outcomes (data cut 03/2020, visit window 21 to 27 months) including ART/study persistence (Kaplan-Meier estimates), virological effectiveness (HIV RNA < 50 copies/mL, discontinuation=failure, loss-to-follow-up/missing=excluded) and non-serious and serious adverse drug reactions (ADRs/SADRs).

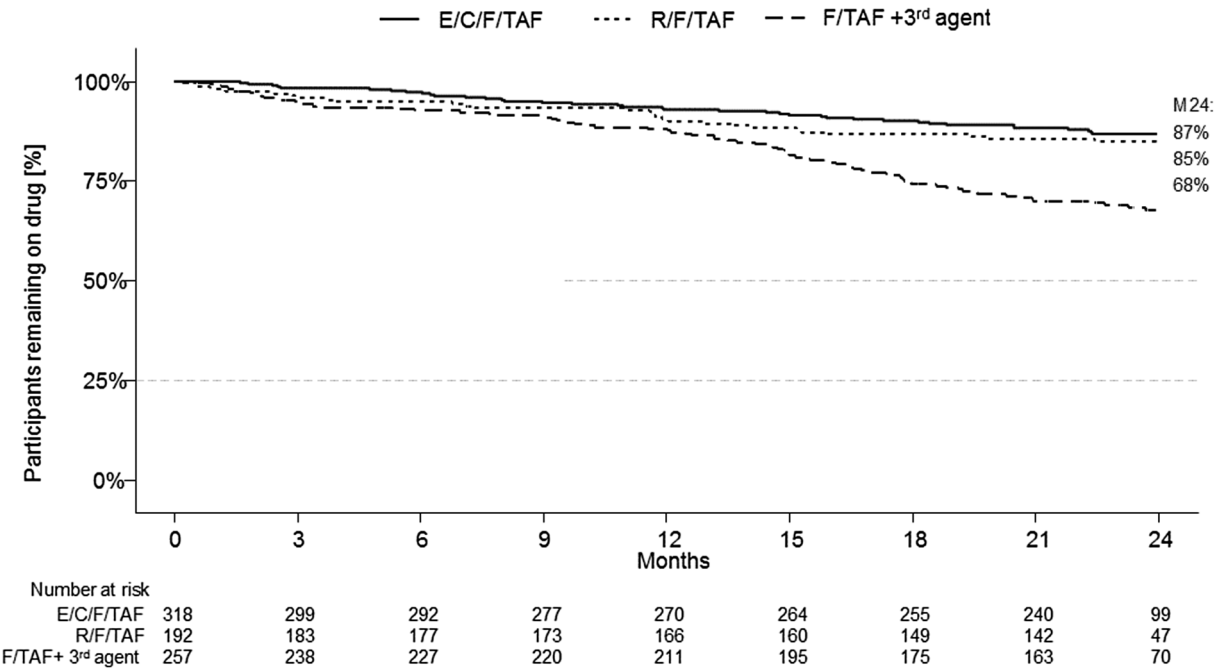
**Results:** A total of 767 patients were included in the final analysis population (92% men, median age 46 years, 301 TN; E/C/F/TAF: n = 318; R/F/TAF: n = 192; F/TAF + 3rd agent: n = 257 [52% dolutegravir, 11% nevirapine, 10% darunavir/ritonavir, 9% raltegravir]). Among TN, 35% were late presenters (CD4 count < 350/μL and/or AIDS). Late presentation was most common in the F/TAF + 3rd agent group (49%). Of TE, 95% were on suppressive ART prior to switch (Table 1). At Month 24, overall persistence on F/TAF-based ART was 80% (TN: 78%; TE: 81%). Persistence in the E/C/F/TAF, R/F/TAF and F/TAF + 3rd agent subgroups was 87%, 85% and 68%, respectively (Figure 1). In total, 28% of patients (n = 218/767) discontinued before Month 24 (discontinuations due to ADRs [3.9%], ART simplification [4.4%], patient decision/withdrawal of consent [3.3%], drug-drug interactions [1.4%], investigator's decision [1.8%], virological failure [VF; 1.6%], death [0.7%], loss-to-follow-up [9.3%], other/unknown [2.1%]). Discontinuation of F/TAF + 3rd agent was driven by ART simplification in 13.2% (n = 34/257). At Month 24, overall virological effectiveness was 74% (n = 479/648) (3% with HIV RNA ≥ 50 copies/mL, 23% discontinuations): 83% on E/C/F/TAF (n = 219/264), 79% on R/F/TAF (n = 127/160), 59% on F/TAF + 3rd agent (n = 133/224). Up to Month 24, 45 ADRs (in 4.6% of patients [n = 35]) and three SADRs (in 0.3% of participants [n = 2]) were documented.

**Conclusions:** Overall 24-month persistence on F/TAF-based regimens in the TAFNES cohort was 80% and 87% for the STR E/C/F/TAF. Discontinuations were dominated by loss-to-follow up and simplification of non-STR regimens. Virological effectiveness and safety were demonstrated in a real-world setting with 4% of discontinuations due to ADRs and 2% due to virological failure.

**Abstract P050-Table 1. Baseline characteristics**

| | Treatment-naive (TN) patients (N = 301, 100%) | | | Treatment-experienced (TE) patients (N = 466, 100%) | | |
|---|---|---|---|---|---|---|
| | E/C/F/TAF (n = 159, 53%) | (TN) R/F/TAF (n = 42, 14%) | (TN) F/TAF + 3rd agent (n = 100, 33%) | E/C/F/TAF (n = 159, 34%) | (TE) R/F/TAF (n = 150, 32%) | (TE) F/TAF + 3rd agent[a] (n = 157, 34%) |
| Male gender, n (%) | 152 (96) | 38 (90) | 93 (93) | 142 (89) | 133 (89) | 148 (94) |
| Age, years, median (IQR) | 36 (30 to 46) | 35 (30 to 43) | 40 (30 to 48) | 45 (36 to 54) | 45 (35 to 52) | 56 (53 to 61) |
| CD4 count, cells/μL, median (IQR) | 498 (316 to 640) | 483 (382 to 642) | 353 (155 to 548) | 632 (484 to 882) | 667 (514 to 811) | 568 (431 to 795) |
| HIV-1 RNA > 100 000 copies/mL, n (%) | 34 (22) | 0 (0) | 59 (60) | — | — | — |
| HIV-RNA < 50 copies/mL, n (%) | — | — | — | 145 (93) | 136 (95) | 149 (97) |
| CDC stage C, n (%) | 10 (6) | 1 (2) | 17 (17) | 37(23) | 22 (15) | 39 (25) |
| Previous third agent class,[b] n (%) | | | | | | |
| - INI | | | | 102 (64) | 6 (4) | 57 (36) |
| - NNRTI | | | | 26 (16) | 126 (84) | 33 (21) |
| - PI | | | | 27 (17) | 15 (10) | 48 (31) |
| - Other | | | | 4 (3) | 3 (2) | 19 (12) |
| TDF-based previous antiretroviral regimens, n (%) | | | | 144 (91) | 141 (94) | 150 (96) |

IQR, interquartile range.
[a]Inclusion criteria age ≥50 y. Annotation: groups not comparable due to different inclusion criteria;
[b]other ART combinations not presented.




**Abstract P050-Figure 1. ART/study persistence (Kaplan-Meier estimates; event=discontinuation of the study and/or F/TAF-based study medication). Annotation: groups not comparable due to different inclusion criteria.**

## P051

### Use of generic antiretroviral drugs and single-tablet regimen de-simplification for the treatment of HIV infection in Spain

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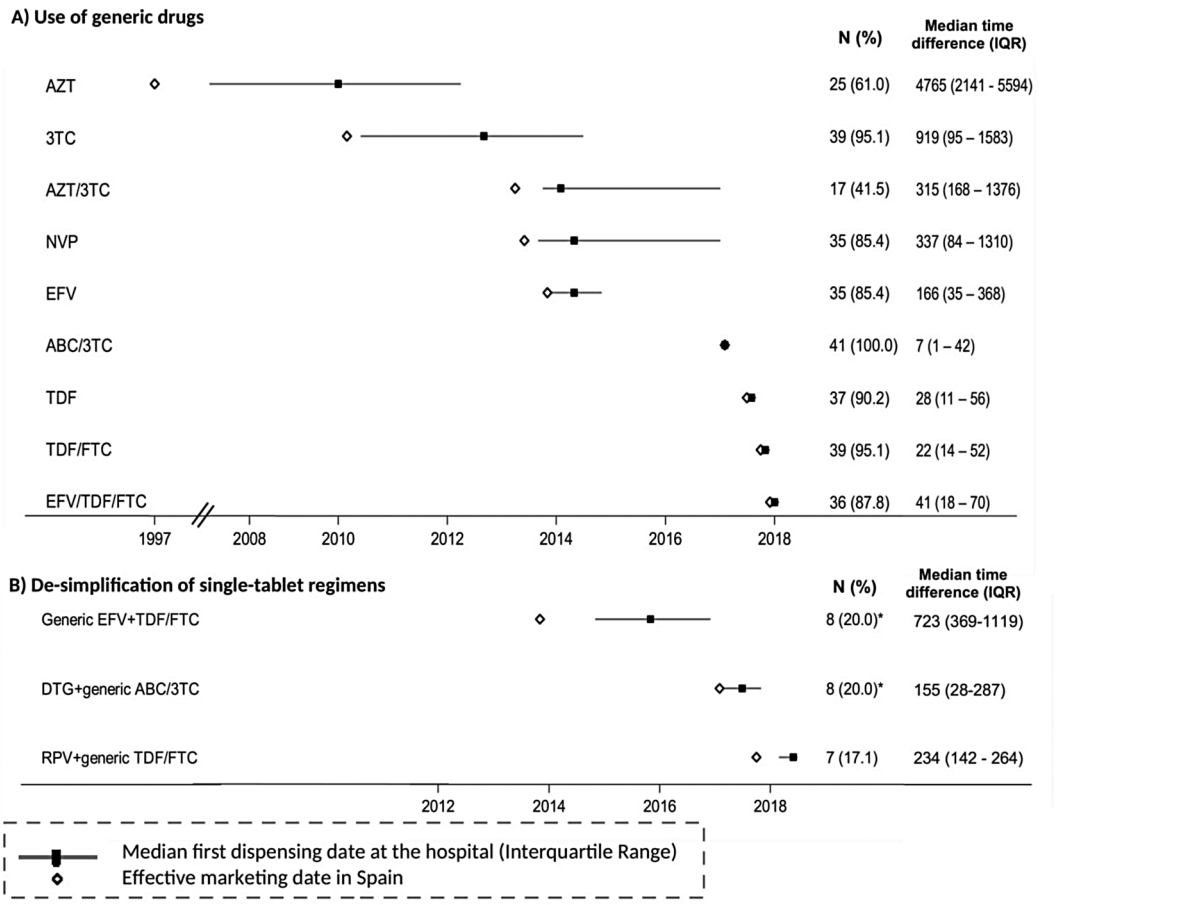
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**Background:** As some ARVs lose their patents, generic ARVs have become available that allow the treatment of HIV with affordable and effective drugs. Although some studies have been published in low-income settings describing the use of generic ARVs, the information about their use, and about STR (single-tablet regimen) de-simplification, is very scarce in high-income countries. Our objective was to describe the use of generic drugs and STR de-simplification for the treatment of HIV infection in real clinical practice among the hospitals participating in the cohort of the Spanish HIV/AIDS Research Network (CoRIS).

**Materials and methods:** In June 2018, we collected information from the pharmacy departments and CoRIS principal investigators on both the use of generic antiretroviral drugs and STR de-simplification by their equivalent generic multiple-tablet regimens.

**Results:** A total of 41 hospitals, treating 8891 patients at the time of the study, were included. Most of the nine available generic ARVs in Spain by June 2018 had been introduced in at least 85% of the participating hospitals, except for AZT/3TC and AZT (Figure 1). The time difference between the effective marketing date of each generic ARV and its first dispensing date in the hospitals was much shorter for the more recently approved generic ARV since the year 2017. However, just 20% or less hospitals de-simplified EFV/TDF/FTC, DTG/ABC/3TC and RPV/TDF/FTC (to DTG+generic ABC/3TC, RPV+generic TDF/FTC and generic EFV+TDF/FTC respectively) while the generic STR EFV/TDF/FTC was introduced in 87.8% of the centres. The median times between the date of effective marketing of generic TDF/FTC and the date of de-simplification of EFV/TDF/FTC and RPV/TDF/FTC were 723 (IQR: 369 to 1119) and 234 (IQR: 142 to 264) days, respectively; this time was 155 (IQR: 28 to 287) days for de-simplification of DTG/ABC/3TC.

**Conclusions:** In spite of the widespread use of generic ARVs, STR de-simplification was only undertaken in less than 20% of the hospitals. There was wide variability in the timing of the introduction of each generic ARV after they were available in the market.




*N (%): Number of participating hospitals that have introduced each generic antiretroviral drug or de-simplification of single-tablet regimens.*
*Median time difference (IQR): Median time between effective marketing date and first dispensing date or de-simplification of single-tablet regimens date*
** 40 participants hospitals has previously introduced EFV/FTC/TDF and DTG/ABC/3TC single-tablet regimens*

**Abstract P051-Figure 1. Use of generic drugs and de-simplification of single-tablet regimens.**

## P052

### Systematic review of patient-reported outcome measures (PROMs) used in clinical trials of HIV-infected adults on combination antiretroviral therapy (cART)

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**Background:** New combined antiretroviral therapy (cART) regimens are highly effective in achieving viral suppression and reducing HIV-related morbidity and mortality. Assessments employing patient-reported outcome measures (PROMs) have thus become a growing focus in current HIV trials. This systematic review aims to identify PROMs reported in recently published clinical trials on cART, and the domains they measure.

**Materials and methods:** Four databases, PubMed, Embase, PsycInfo, and CINAHL, were systematically searched for clinical trials published between January 2015 and January 2020. To be included, articles needed to present original research evaluating cART in adults living with HIV with at least one PROM. Two reviewers independently screened article titles and abstracts for eligibility. Relevant data from the full-text articles were extracted independently, and any discrepancies were resolved in consultation with a third reviewer. PROMs were categorized as HIV-specific or generic. The domains of PROMs were mapped to the three following health concepts of Wilson and Cleary's health-related quality of life (QoL) model: functional status, general health perceptions, and overall QoL.

**Results:** Of the 3774 records identified through the database search, 38 articles met the inclusion criteria. A total of 29 PROMs were identified, five HIV-specific, 18 generic, and six unvalidated single items. The most frequently used HIV-specific PROM was the HIV-Treatment Satisfaction Questionnaire (HIV-TSQ; n = 14). The most frequently used generic PROMs were the Short Form 36 (SF-36) and EuroQol 5-dimensions—3-level (EQ-5D-3L; n = 5 each). Over one-third (14/38) of trials used PROMs as a primary outcome. Elements of functional status were assessed in 13 PROMs, with the most commonly measured domain being physical and mental function. General health perception was assessed in 10 PROMs, with treatment satisfaction as the most frequently measured domain. Sixteen PROMs integrated components of overall QoL, and mood was the most frequently assessed domain.

**Conclusions:** Preliminary analysis suggests that domains associated with the health concept of general health perception are underrepresented in HIV clinical trials reporting PROMs as primary or secondary outcomes. Additionally, the overlap between multiple PROMs in the evaluation of specific health domains highlights the need for further work to reach a consensus on the most appropriate PROMs to be used in HIV clinical trials.

# P053

## Patient-reported outcomes after one year of routine clinical practice with bictegravir/emtricitabine/tenofovir alafenamide in PLWH: the BICSTaR cohort

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**Background:** Patient-reported outcome (PRO) measures are directly completed by the patient to capture aspects of patient's health, such as mental health status, health-related quality of life (HRQoL) and treatment satisfaction. The observational BICSTaR study prospectively collected PROs in PLWH initiating or switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF).

**Materials and methods:** PRO analysis from the BICSTaR study in antiretroviral treatment-naïve (TN) and treatment-experienced (TE) participants from Germany, Canada, France and the Netherlands who completed PRO questionnaires at both baseline (BL) and Month 12 (M12). PRO measurements included HRQoL (SF-36: Physical Component Score [PCS] and Mental Component Score [MCS]), health status (HIV-Symptom Index [HIV-SI]) and patient satisfaction (HIVTSQs and HIVTSQc in TE only).

**Results:** Availability of PRO data at BL and M12 follow-up visits varied by instrument and treatment group. Participants were mainly male and TN were younger than TE participants, median age 36 (Q1, Q3: 29, 44) versus 49 (40, 55) years old, respectively. At baseline, mean summary scores in TN were PCS: 53.7 (standard deviation [SD]: 6.3) and MCS: 54.1 (7.4); PCS remained stable and MCS increased by a mean of 0.2 (10) by M12. In TN participants the most frequently

**Abstract P053-Table 1. HRQoL (SF-36), HIV-SI, HIVTSQs total score and HIVTSQc total score change results at baseline and Month 12 by treatment-naïve and -experienced patients**

| PRO measures<br>SF-36[a] n | Treatment naïve<br>38 | Treatment experienced<br>183 |
|---|---|---|
| Physical Component Score (PCS) | | |
| Baseline, mean (95% CI) | 53.7 (51.7, 55.8) | 54.1 (53.0, 55.2) |
| Month 12, mean (95% CI) | 54.0 (51.7, 56.2) | 53.8 (52.7, 54.8) |
| BL-M12 Δ change mean (95% CI) | Δ 0.2 (−2.2, 2.7) | Δ −0.3 (−1.3, 0.6) |
| Mental Component Score (MCS) | | |
| Baseline, mean (95% CI) | 42.9 (39.1, 46.8) | 46.8 (45.0, 48.6) |
| Month 12, mean (95% CI) | 47.6 (44.1, 51.1) | 48.1 (46.4, 49.7) |
| BL-M12 Δ change mean (95% CI) | Δ 4.7 (1.4, 7.9) | Δ 1.3 (0.0, 2.5) |
| HIV-SI bothersome symptoms n | 42 | 207 |
| Fatigue or loss of energy | | |
| Baseline n (%) | 29 (69.0) | 94 (45.9) |
| Month 12 n (%) | 17 (39.5) | 100 (48.5) |
| BL-M12 Δ change % | Δ −29.5% | Δ +2.6% |
| *Missing* | *1 (BL)* | *2 (BL); 1 (M12)* |
| Felt sad, down or depressed | | |
| Baseline n (%) | 21 (48.8) | 64 (31.4) |
| Month 12 n (%) | 14 (32.6) | 56 (27.1) |
| BL-M12 Δ change % | Δ −16.2% | Δ −4.3% |
| *Missing* | | *3 (M12)* |
| Felt nervous or anxious N | | |
| Baseline n (%) | 16 (38.1) | 51 (25.0) |
| Month 12 n (%) | 12 (27.9) | 46 (22.3) |
| BL-M12 Δ change % | Δ −10.2% | Δ - 2.07% |
| *Missing* | *1 (BL)* | *3 (BL) 1 (M12)* |
| Skin problems, such as rash, dryness or itching | | |
| Baseline n (%) | 20 (46.5) | 48 (23.5) |
| Month 12 n (%) | 8 (18.6) | 48 (23.5) |
| BL-M12 Δ change % | −27.9% | Δ −0.3% |
| *Missing* | | *3 (BL)* |
| HIVTSQs n[b] | – | 395 |
| Total score at baseline, median (Q1, Q3) | – | 56.0 (50.0, 60.0) |
| HIVTSQs n[b] | | 223 |
| Total score change, median (Q1, Q3) | | 20.0 (4.0, 28.0) |

[a]Summary scores were normed to a mean of 50. Higher scores represent better QoL;
[b]HIVTSQs and HIVTSQc were only evaluated in treatment experienced patients. The treatment satisfaction total score is ranged from 0 to 60. The higher the score, the greater the satisfaction with treatment. The treatment satisfaction (change) total score is ranged from −30 to 30. The higher the score, the greater the improvement in satisfaction with treatment; the lower the score, the greater the deterioration with treatment. A score of 0 represents no change.

reported bothersome symptoms at BL were fatigue (69%), feeling sad/down/depressed (49%), nervous or anxious (38%) and having skin problems (47%). The frequency of these symptoms decreased after M12 on B/F/TAF (Table 1). In TE patients, mean summary scores at baseline were PCS: 54.1 (7.4) and MCS: 46.8 (12.5); these remained stable at M12. The most frequently reported bothersome symptoms at BL were fatigue (48%), feeling sad/down/depressed (31.4%) and feeling anxious/nervous (25%). The frequency of symptoms changed slightly at M12: fatigue increased by 2.6% while the remainder decreased by 4.3% and 2.7%, respectively. Baseline HIVTSQs total score was high in TE, median 56 (50, 60), with further improvements following switch to B/F/TAF at M12, with an HIVTSQc median total score change of 20.

**Conclusions:** Analysis of PROs from BICSTaR showed that the greatest improvements from baseline after 12 months of B/F/TAF treatment were seen in the HRQoL MCS and in the most commonly reported symptoms among the TN population and in treatment satisfaction among TE.

## P054

### Narrative medicine as PROs to understand living with HIV from patients' experiences: TMC114FD1HTX4011 - DIAMANTE study

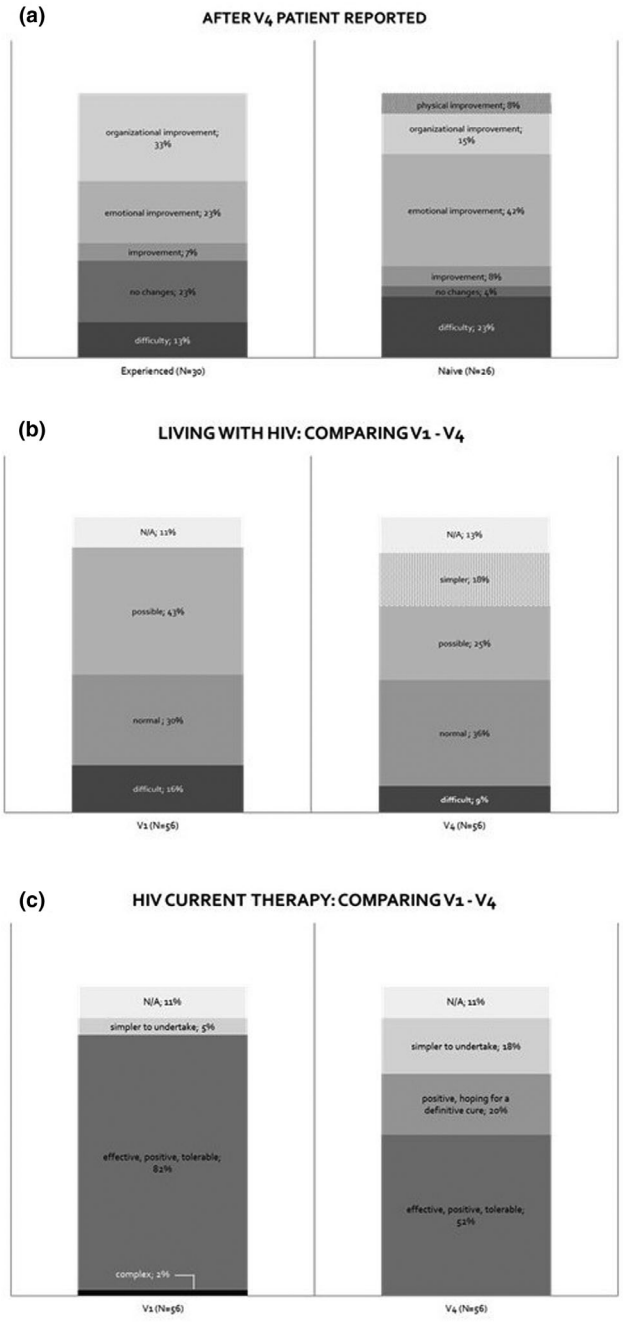
A Antinori[1]; A Vergori[1]; V Esposito[2]; M Carleo[2]; M Andreoni[3]; V Malagnino[3]; S Rusconi[4]; F Castelli[5]; E Focà[5]; E Manzillo[6]; T Pizzella[6]; A Cappuccio[7]; L Reale[7]; A Fiorencis[7]; M Marini[7]; M Portaro[8]; D Mancusi[8]; R Termini[8] and A Uglietti[8]

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**Background:** HAART significantly reduced HIV morbidity and mortality, nevertheless its impact on PLWH remained less examined at an individual level. Narrative medicine unveils the more intimate illness aspects investigating patients' narrative, also allowing the comparison of different moments in the living with HIV experience.

**Materials and methods:** The non-interventional DIAMANTE study aimed to collect data on PLWH treated with D/C/F/TAF addressing therapy effectiveness and patient-reported outcomes (PROs). The study started in June 2018 and involved 18 centres across Italy; enrolled patients were both naïve and previously HAART treated and then followed up for 48 weeks. PROs, HIV Treatment Satisfaction Questionnaires and written narratives were collected at enrolment (V1) and at the last study visit (V4). Narratives were independently analysed by two researchers through NVivo 10 software on the basis of content analysis.

**Results:** The study enrolled 246 PLWH: 137 (56%) have completed V1 narrative, and 65 of them also V4 narratives (26%) so far. We compared the treatment experience in 56 patients having both V1 and V4. At V4, 38/56 (68%) reported improvements, especially at an emotional level (18/56-32%) – *I [. . .] feel taken care of and more protected* – and at an organisational level (14/56-25%) – *Only one pill a day allows better management*. In Figure 1a, we detailed improvements in naïve and experienced group. At V4, 5/56 (9%) reported difficult HIV condition – *Always saying, "Why me?"* – compared to 9/56 (16%) at V1 and 10/56 (18%) introduced simpler HIV management (Figure 1b). Overall, at V4, 29/56 (52%) patients remarked treatment effectiveness and tolerability; 18% stated current therapy is simpler to undertake – *It is effortless since it is the simple ingestion of a tablet* – while 11/56 (20%) also reported hoping for a definitive cure (Figure 1c).




**Abstract P054-Figure 1. Differences between V1 and V4.**

**Conclusions:** Compared narratives pointed out how D/C/F/TAF-based therapy had a positive emotional and organisational impact. Therapy allowed greater well-being and better management of the HIV condition – [. . .] *Today, living with HIV is not a tortuous path [. . .], but a feeling of being "taken care of" and helped to live to the best [. . .] this co-habitation with the virus.*

## P055

### Perceptions of HIV-infected men who have sex with men as regards functional cure of HIV infection

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**Background:** While HIV cure and functional cure research are underway, perceptions of HIV patients, the potential primary beneficiary, have yet to be examined. We aimed to understand the awareness and attitude of HIV+ MSM about HIV functional cure by their treatment history.
**Methods and materials:** Two groups of HIV+ MSM were recruited from respective cohorts of newly diagnosed treatment-naïve and treatment-experienced patients. A self-administered questionnaire was given with brief description on HIV functional cure and questions on: three most important impacts of an HIV cure, knowledge of functional cure, desirability in receiving treatment for functional cure, willingness of joining a functional cure trial and factors associated with the attitude. Differences in proportions between two groups were assessed by z-test.
**Results:** Totally 217 HIV+ MSM were included in the analysis, of whom 115 have been on treatment for a median of seven years. The most important perceived impacts of HIV cure were "restoration and stabilisation of effective immune function" (66%) and "no longer being infectious" (56%). A higher proportion of newly diagnosed patients chose the former ($p = 0.01$) and "not getting HIV again" ($p = 0.02$). Over half (55%) have never heard of functional cure while the majority (94%) considered this a desirable option by scoring 6 or above in a scale of 0 to 10 and expressed an interest in joining a clinical trial (92%). The most important factors affecting the decision of joining the clinical trial were its safety (97%), advice from healthcare professionals (88%), credibility of the research institution (87%) and the need for interruption of antiretroviral treatment (84%). Major concerns included progression to AIDS or complications (84%), increased viral load (83%) and becoming infectious (73%). The proportions did not differ between two groups.
**Conclusions:** HIV functional cure is well accepted by HIV+ MSM in Hong Kong, despite a low level of awareness about it. Their perceptions and concerns do not differ much by treatment status. Health and HIV transmissibility statuses were major benefits and concerns. When conducting a clinical trial on functional cure, explanation of its safety issues by healthcare professionals would be important.

## P056

### Durability of F/TAF in a large cohort of PLWH seen for care in Italy

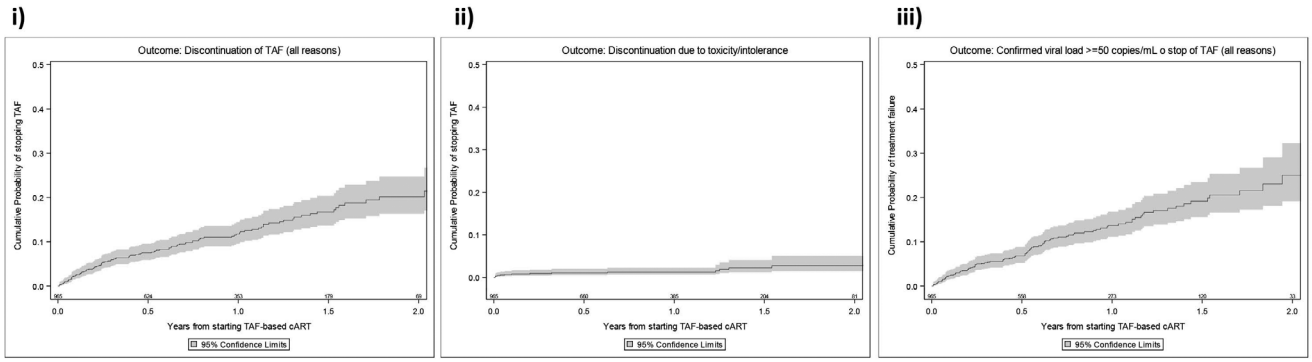
A Vergori[1]; A Cozzi Lepri[2]; N Gianotti[3]; A Calcagno[4]; G Guaraldi[5]; G Orofino[6]; M Moioli[7]; I Gentile[8]; S Loredana[9]; S Cicalini[1]; A d'Arminio Monforte[10] and A Antinori[1]
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**Abstract P056-Table 1. Main characteristics of 4110 patients receiving F/TAF according to ART history**

| Characteristics | ART-naive (N = 965) | ART-experienced (N = 3145) | *p*-value[a] |
|---|---|---|---|
| Gender, female, n (%) | 157 (16.3) | 603 (19.2) | 0.042 |
| Age, years, median (IQR) | 40 (32 to 50) | 46 (37 to 53) | <0.001 |
| Mode of HIV transmission, n (%) | | | <0.001 |
| IDU | 50 (5.2) | 291 (9.3) | |
| Homosexual contacts | 489 (50.7) | 1478 (47.0) | |
| Heterosexual contacts | 368 (38.1) | 1197 (38.1) | |
| Other/unknown | 58 (6.0) | 1197 (38.1) | |
| Nationality, not Italian, n (%) | 236 (24.5) | 514 (16.3) | <0.001 |
| AIDS diagnosis, n (%) | 80 (8.3) | 397 (12.6) | <0.001 |
| Months HIV diagnosis-cART start, median (IQR) | 1 (0 to 2) | 69 (34 to 128) | <0.001 |
| Calendar year of baseline, n (%) | | | <0.001 |
| 2015 to 2017 | 303 (31.4) | 1897 (60.3) | |
| 2018 | 469 (48.6) | 1163 (37.0) | |
| 2019 | 193 (20.0) | 85 (2.7) | |
| CD4 count, cells/mmc, median (IQR) | 337 (125 to 543) | 685 (498 to 901) | <0.001 |
| CD4 ≤ 200 cells/mmc, n (%) | 310 (33.0) | 96 (3.1) | <0.001 |
| CD4 count nadir, cells/mmc, median (IQR) | 329 (121 to 527) | 299 (162 to 435) | 0.010 |
| CD8 count, cells/mmc, median (IQR) | 848 (565 to 1222) | 807 (593 to 1082) | 0.037 |
| HIV-RNA, log10 copies/mL, median (IQR) | 4.85 (4.22 to 5.45) | 0.00 (0.00 to 1.56) | <0.001 |
| Follow-up time, months, median (IQR) | 7 (2 to 13) | 14 (9 to 18) | <0.001 |
| Type of regimen, n (%) | | | <0.001 |
| Single-tablet regimen (STR) | 434 (45.0) | 2231 (70.9) | |
| Multiple-tablet regimen (MTR) | 531 (55.0) | 914 (29.1) | |
| Regimen used, n (%) | | | <0.001 |
| F/TAF/EVG/cobi | 265 (27.4) | 999 (31.8) | |
| F/TAF and DTG | 342 (35.4) | 202 (6.4) | |
| F/TAF/RPV | 116 (12.0) | 1207 (38.4) | |
| F/TAF/DRV/cobi | 173 (17.9) | 287 (9.1) | |
| F/TAF and RAL | 50 (5.2) | 186 (5.9) | |
| F/TAF and other third drug | 19 (2.0) | 264 (8.4) | |

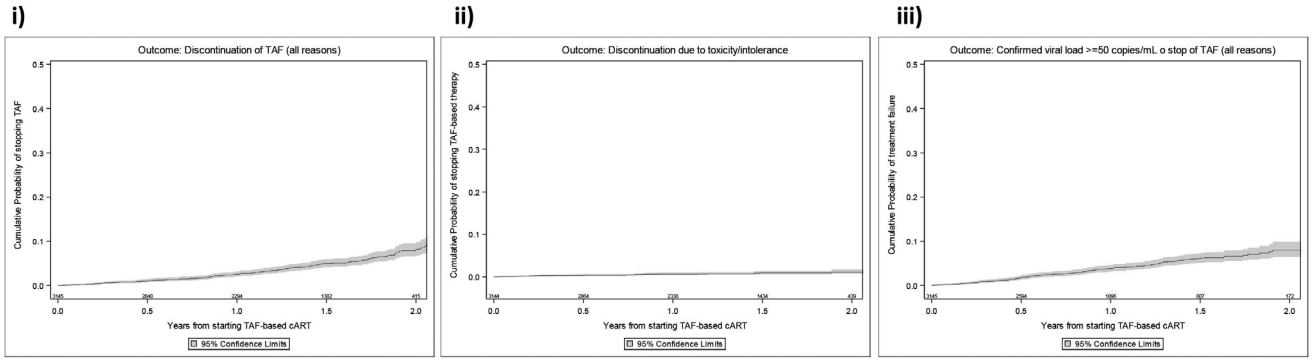
[a]Chi-square or Kruskal-Wallis test as appropriate.

**(a) ART-Naive**




| | No. of stops by 2 years | 2-year Probability (95% CI) |
|---|---|---|
| **i) TAF discontinuation for any reasons** | 106 | 19.4 (15.5, 23.4) |
| **ii) TAF discontinuation for toxicity** | 14 | 2.7 (1.1, 4.4) |
| **iii) Treatment Failure (TF)** | 101 | 21.6 (16.9, 26.3) |

**(b) ART-experienced**




| | No. of stops by 2 years | 2-year Probability (95% CI) |
|---|---|---|
| **i) TAF discontinuation for any reasons** | 121 | 5.2 (4.3, 6.1) |
| **ii) TAF discontinuation for toxicity** | 25 | 1.1 (0.6, 1.6) |
| **iii) Treatment Failure (TF)** | 135 | 6.5 (5.3, 7.6) |

**Abstract P056-Figure 1. KM estimates of discontinuation for i) any reason, ii) toxicity and iii) time to TF in ART-naïve (a) and in ART-experienced patients (b).**

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**Background:** F/TAF showed a comparable efficacy to F/TDF with a better safety profile, nevertheless data from the real-life setting are sparse.
**Materials and methods:** ART-naïve and virologically suppressed (HIV-RNA ≤ 50 copies/mL before F/TAF start) patients from Icona cohort who started TAF-based triple regimens, in 2015 to 2019 were included. Cumulative probability of TAF discontinuation for any cause, for toxicity and treatment failure (TF; confirmed HIV-RNA > 50 copies/mL, >6 months for ART-naïve, or discontinuation for any cause) were estimated by Kaplan-Meier curves. Factors associated with the risk of the same outcomes were identified using multivariable Cox proportional-hazard model with time-fixed covariates, separately in the two groups.
**Results:** Four thousand, one hundred and ten patients included: 965 ART-naïve and 3145 ART-experienced. Characteristics are described in Table 1. The main reason of discontinuation was simplification (57% ART-naïve, 52% ART-experienced). In the ART-naïve group, the 2-year risk of discontinuing F/TAF was 19.4% (95% CI 15.5 to 23.4) for any causes and 2.7% (1.1 to 4.4) for toxicity, the 2-year probability of TF was 21.6% (16.9 to 26.3) (Figure 1a). In the ART-experienced group, the 2-year risk was at 5.2% (4.3 to 6.1), 1.1% (0.6 to 1.6) and 6.5% (5.3 to 7.6) for discontinuation for any cause, for toxicity and TF, respectively (Figure 1b). In the subset of people using F/TAF in single-tablet regimen (STR) the 2-year TF rate was even lower: 13.4% (6.6 to 20.3) in the ART-naïve and 5.4% (4.1 to 6.7) in the ART-experienced group. In a multivariable regression model, in the ART-naïve group, using F/TAF as multiple-tablet regimen (MTR) was associated with an increased risk of TF [AHR 2.59 (1.45 to 4.61); $p = 0.001$]. In the ART-experienced group, the risk of discontinuation was higher per more recent time of baseline [per six months AHR 1.47 (1.03 to 2.10); $p = 0.034$], while using F/TAF as MTR was associated with higher risk of both discontinuing TAF [AHR 1.67 (1.19 to 2.35); $p = 0.003$] and of TF [AHR 1.67 (1.18 to 2.36); $p = 0.004$]. A longer

duration of virological suppression before baseline was associated with a reduced risk of TF [AHR 0.95 (0.91 to 0.98); $p = 0.002$].
**Conclusions:** Approximately 1/5 ART-naive starting TAF-based regimens in the real-life setting discontinue this drug by two years, only 3% for toxicity. As expected, rates were even lower in the ART-experienced group. Our analysis suggests that a low pill burden is a key factor for longer durability of modern TAF-based cART.

## P057

### Improving methods for patient-reported outcome (PRO) analyses in observational HIV studies

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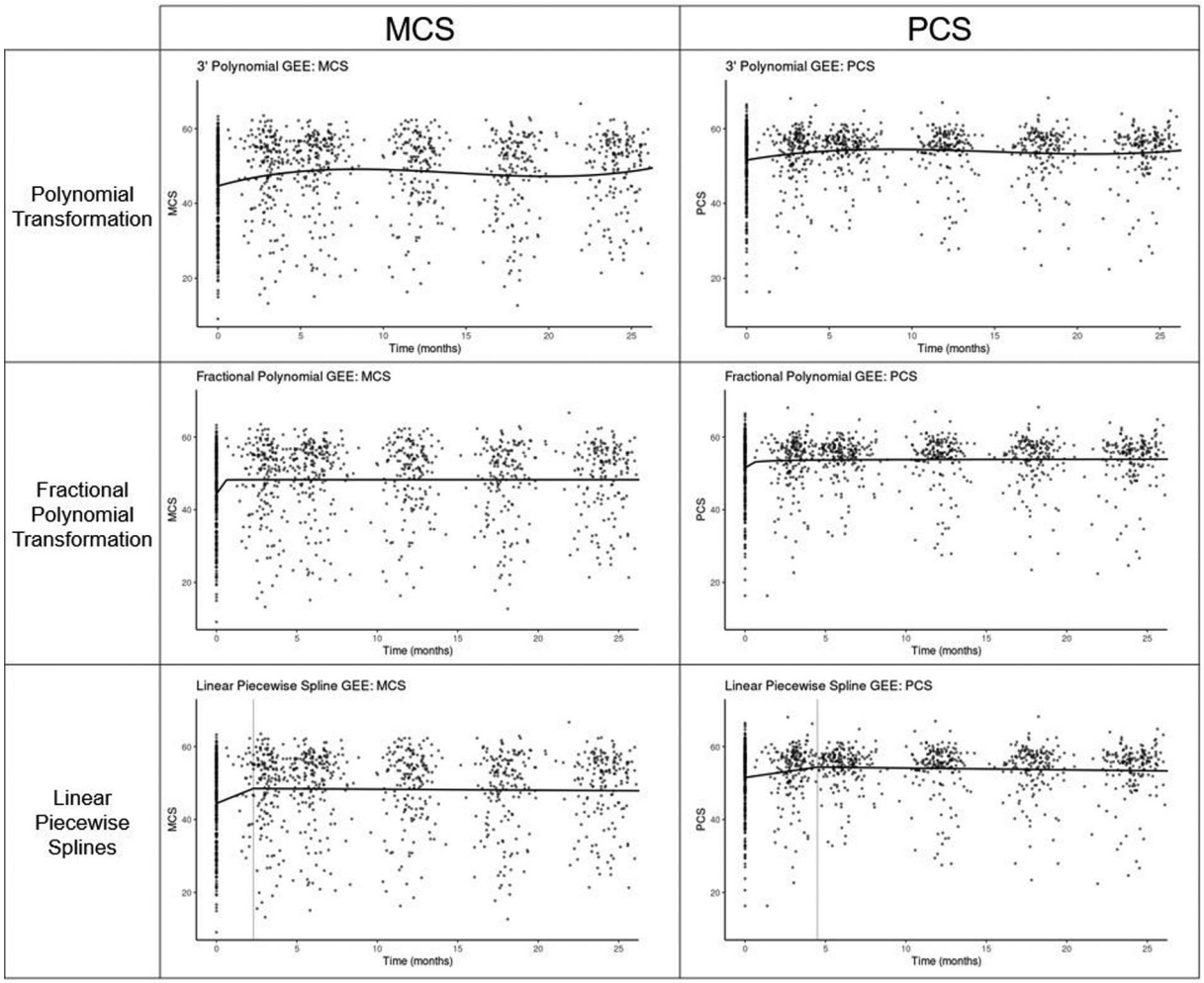
**Background:** Patient-reported outcomes (PROs) provide a unique opportunity to tailor clinical care and therapeutic pathways to patients' needs, priorities and experience [1]. Analysing PROs for PLWH is increasingly important for understanding their health-related quality of life (HRQoL). Pharmaceutical industry analyses of PROs often utilise simplistic pairwise comparisons of data obtained at predefined follow-up periods to baseline, yielding limited information on the nature of the change in PRO. Conversely, in cancer research, a range of methods have been proposed [2].
**Materials and methods:** Pairwise comparison, ANOVAs, linear mixed models (LMMs) and generalised estimating equations (GEEs) were applied to the analysis of the SF-36 mental component score (MCS) and physical component score (PCS) from treatment-naïve patients in TAFNES, a German observational cohort of PLWH at zero, three, six, twelve, eighteen and twenty-four months after initiation of an F/TAF-based treatment regimen. Methods for PRO analysis were assessed against previously identified essential statistical features (Table 1). Changes in MCS and PCS were assessed to compare the benefits of each approach.
**Results:** Two hundred and eighty-six participants provided an MCS and PCS observation between treatment initiation (M0) and Month 24 (M24). The paired Wilcoxon rank sum test demonstrated statistically significant increases in mean MCS (+3.35, M24) and PCS (+2.12, M24) from baseline to every follow-up visit, assuming, however, that missing data are missing completely at random (MCAR). Use of ANCOVA was limited due to unbalanced data and non-normally distributed residuals. While controlling for covariates including age, sex and comorbidities, LMMs and GEEs (Figure 1) illustrated a statistically significant increase in MCS and PCS, with a steep increase over the first few months followed by a plateau. Statistically significant differences were observed for age (PCS), for participants with comorbidities at baseline, viral load at baseline and late presentation (PCS).
**Conclusions:** GEEs offer a robust approach to longitudinal modelling, with fewer assumptions than LMMs, facilitating interpretation of results on the original scale of the PRO. However, one limitation is lower certainty of estimates (larger standard errors). Alternative methods to pairwise comparison can better handle missing data, control for confounding factors and thereby produce more informative conclusions.

**Abstract P057-Table 1. Evaluation of statistical methods based on important statistical features for patient-reported outcome analyses in HIV studies [2]**

| | Compare two treatment arms | Adjust for baseline score | Allow for confounding factors | Handle missing data | Handle clustered data | Robust | Allow for time varying covariates | Handle unbalanced designs |
|---|---|---|---|---|---|---|---|---|
| Pairwise comparisons ANOVAs | No<br>Yes (ANCOVA) | Yes<br>Yes | No<br>Yes (ANCOVA) | Missing completely at random<br>Missing completely at random | Yes<br>Yes (Repeated measures ANOVA) | Yes<br>Relatively | No<br>No | No<br>No |
| Linear mixed model | Yes | Yes | Yes | Missing completely at random or Missing at random | Yes | Relatively | Yes | Yes |
| Generalised estimating equation | Yes | Yes | Yes | Missing completely at random or Missing at random (Weighted GEE) | Yes | Yes | Yes | Yes |

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**Abstract P057-Figure 1. GEE results for the change in MCS and PCS in treatment-naïve patients after F/TAF-based treatment initiation. Demonstrated by three non-linear modelling approaches: polynomial transformation, fractional polynomial transformation and linear piecewise splines. MCS and PCS range 0 to 100, higher scores indicate better HRQoL.**

## P058

### Factors associated with quality of sexual life among women with HIV and HCV

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**Background:** The quality of sexual life is a neglected concern in women living with HIV (WHIV) or HCV (WHCV) which can further be affected by their experience with stigma, social instability, substance use and reduced access to HCV treatment. Therefore, the objective of this study was to identify sociodemographic and psychosocial factors associated with quality of sexual life in WHIV and WHCV as assessed by the PROQOL-SexLife questionnaire [1–5].

**Methods:** PROQOL-SexLife questionnaire was proposed and filled in in five countries: Brazil (N = 145), Canada (N = 24), Australia (N = 50), France (N = 123) and USA (N = 62) by 404 women overall. Four dimensions: positive sexual perception (*Psp*), stigma and social distress (*Sti*), soft sexual practices (*Sof*) and sexual practices with partner (*Sp*), which were scored from 0 to 100, were considered as main outcomes. Multiple linear regression models were used to found associations with the four outcomes.

**Results:** In the study group, 191 WHCV, 180 WHIV and 33 HIV/HCV co-infected were included, median [IQR] age was 48. Among WHIV, being Hispanic, smoking cigarette and a higher satisfaction about health care improved their sexual satisfaction, with a regression coefficient of ($\beta$=−19, SE = 6.6, $p < 0.001$), ($\beta$=−9, SE = 4, $p < 0.05$) and ( $\beta$ = −14, SE = 5.2, $p < 0.05$), respectively. For WHCV, living with a partner ($\beta$ = −24, SE = 4.8, $p < 0.001$) improved their perception of sexual satisfaction in 24 points, while a hopeless mood make it worse in 12 points ($\beta$ = 11, SE = 3.4, $p < 0.001$). Among WHIV and WHCV depression was related with an increase in stigma and social distress, while a high satisfaction about health care was related with a decrease in *Sti* dimension. Moreover, a hopeless mood ($p < 0.02$) decreased soft sexual practices in WHIV, while among WHCV, being older than 40 years also decreased soft sexual practices. A high awareness about risk of transmission and a higher satisfaction with health care increased sexual practices with a partner.

**Conclusions:** Factors associated impacting the quality of sexual life in WHIV and WHCV were related to substance consumption, origin, level of studies, mental health and satisfaction about health care. And no HIV- or HCV-specific parameters were found statistically significative. These findings draw attention to the different interventions that can be proposed for improving their sexual life.

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## Opportunistic Infections

## P059

### Nontuberculous mycobacteria infections in Russian HIV patients: clinical features and outcomes

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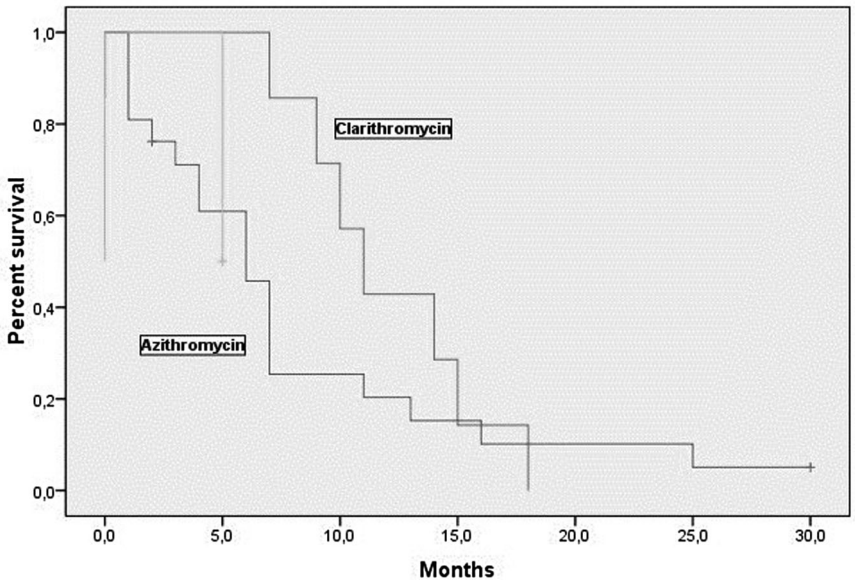
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**Background:** The incidence of nontuberculous mycobacteria (NTM) is growing worldwide [1]. People living with HIV are at risk of developing either pulmonary or disseminated form of mycobacterial infections, especially those who are diagnosed at late stages, who fail to stay on treatment or fail to maintain viral suppression. Meanwhile treatment of the disease is complex and still lacks efficacy, since the question of macrolide resistance has never been solved [2]. This study was conducted to investigate nontuberculosis mycobacterial rates in HIV patients in Russian infectious diseases hospital for a last decade, describe clinical features and analyse outcomes on different treatment regimens.

**Materials and methods:** Data was collected at the Saint-Petersburg Botkin Clinical Infectious Diseases Hospital from January 2006 to

**Abstract P059-Table 1. Laboratory data for patients with pulmonary and disseminated forms**

| | Form | Mean | Standard deviation | Standard error |
|---|---|---|---|---|
| CD4 account (cells/mm$^3$) | Pulmonary | 47.7 | 50.9 | 9.9 |
| CD4 account (cells/mm$^3$) | Disseminated | 19.8 | 33.6 | 3.9 |
| CD3 account (cells/mm$^3$) | Pulmonary | 470.9 | 454.2 | 94.7 |
| CD3 account (cells/mm$^3$) | Disseminated | 331.4 | 413.8 | 53.8 |
| Haemoglobin (g/L) | Pulmonary | 108.1 | 23.8 | 4.5 |
| Haemoglobin (g/L) | Disseminated | 88.7 | 19.6 | 2.3 |
| CD4 account on treatment (cells/mm$^3$) | Pulmonary | 125.7 | 78.8 | 20.3 |
| CD4 account on treatment (cells/mm$^3$) | Disseminated | 55.7 | 70.8 | 10.0 |
| Alkaline phosphatase (U/L) | Pulmonary | 128.1 | 140.2 | 38.9 |
| Alkaline phosphatase (U/L) | Disseminated | 156.1 | 217.6 | 33.1 |
| Lactate dehydrogenase (LDH) (U/L) | Pulmonary | 333.5 | 177.1 | 41.7 |
| Lactate dehydrogenase (LDH) (U/L) | Disseminated | 291.0 | 138.8 | 21.6 |




**Abstract P059-Figure 1. Kaplan-Meier survival analysis comparing clarithromycin- and azithromycin-based treatment regimens.**

January 2019. Cases were divided by aetiology, forms of process. Student's t-test was used, survival time on different treatment regimens was evaluated with Kaplan-Meier estimator.
**Results:** We enrolled 104 HIV patients with different forms of NTM infections. A prominent increase of NTM incidence was observed. In the absolute majority of cases M. avium (86; 82.7%) acted as an aetiological agent. Disseminated infection developed in 75 (72.1%) of cases, pulmonary NTM infection—in 29 (27.9%). CD4 was significantly higher in patients with pulmonary than disseminated forms: 47.7 ± 9.9 and 19.8 ± 3.9 cells/mm$^3$ ($p < 0.05$). Significant difference as well was obtained in the haemoglobin level: 108.1 ± 4.5 and 88.7 ± 2.3 g/L ($p < 0.05$) (Table 1). A high death rate of 34.6% (36 patients) was recorded regardless of prolonged antibacterial therapy (5.0 ± 0.9 months of treatment). Clarithromycin showed advantage over azithromycin when analysing survival by the method of Kaplan-Meier ($p < 0.05$ Breslow) (Figure 1). Interestingly, there was no difference in outcomes when adding aminoglycoside to treatment.
**Conclusions:** Despite the widespread introduction of antiretroviral therapy, unlike other countries in Russia there is a significant increase in the number of cases of infections caused by NTM in HIV patients. Pulmonary forms are characterised by higher levels of CD4 and good immunological response. Clarithromycin is preferable when choosing a macrolide base in the treatment regimen.

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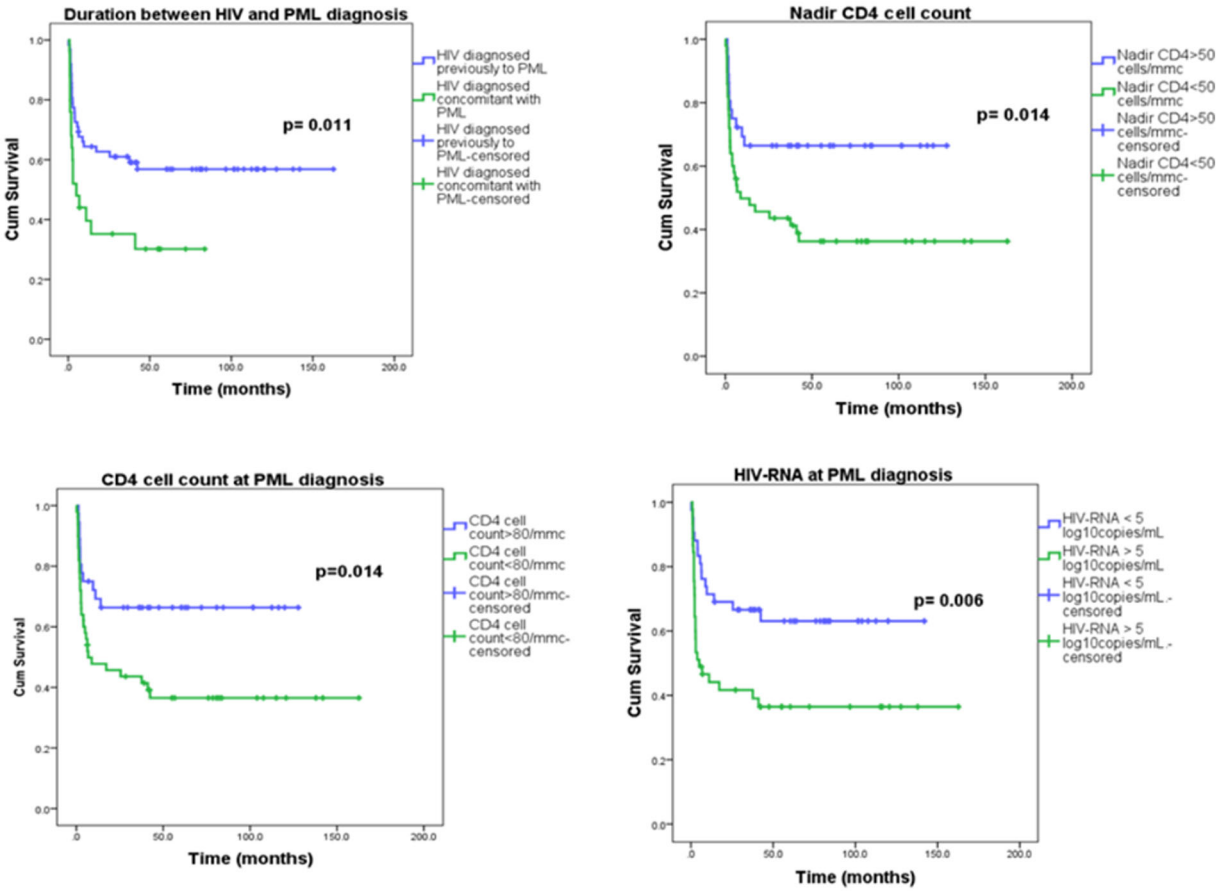
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# P060

## Progressive multifocal leukoencephalopathy, still a challenge in the combined antiretroviral therapy era

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**Background:** The aim of our study was to assess prevalence, clinical outcomes and survival in HIV-infected patients diagnosed with progressive multifocal leukoencephalopathy (PML) in a Romanian tertiary care facility.
**Materials and methods:** Retrospective study on HIV-infected patients hospitalised with PML at Victor Babes Hospital, Bucharest, between January 2006 and December 2018. PML diagnosis was based on clinical symptoms, neuroimaging, positive CSF PCR-DNA JC virus and neurohistopathology. Statistical analysis was performed using SPSS v.20.0.
**Results:** During the study period 87 HIV-infected patients, 63.2% males, were diagnosed with PML, with a prevalence of 3.5/1000 PY (87/24,315). Thirty patients were confirmed by positive CSF PCR-DNA-JCV. The median age at PML diagnosis was 27 years (IQR: 23 to 33). Modes of HIV acquisition were: parenteral, during early childhood (PI) 54.0%, sexual contact (SI) 40.2% and injecting drug use (IDU) 5.7%. The median CD4 cell count/μL and plasma HIV-RNA (log10 copies/mL) at PML diagnosis were 53 (IQR: 16 to 129) and 4.72 (IQR: 2.92 to 5.40), respectively. The median HIV-RNA in CSF




**Abstract P060-Figure 1. Risk factors for short survival time.**

(log10 copies/mL) was 3.89 (IQR: 2.71 to 4.59). Brain MRI showed lesions in brainstem and/or cerebellum in 25 (28.7%) patients and four were diagnosed with PML IRIS. Out of 62 patients previously diagnosed with HIV, 45 were on ART and 41 had severe immunosuppression due to poor adherence. PI patients were younger at PML and HIV diagnosis ($p < 0.0001$) and had lower CD4 cell count ($p = 0.006$) compared to SI and IDUs. The overall mortality and early mortality rates (within three months) were high, 49.4% and 29.8%, respectively. Forty-four patients (50.5%) were alive at the end of the study, with a median survival of 68.0 months (IQR: 41.4 to 102.3). The main risk factors for short survival were nadir CD4 cell count lower than 50/μL ($p = 0.014$), severe immunosuppression (CD4 ≤ 80/μL) and HIV-RNA > 5.00 log10 copies/mL ($p = 0.006$) at PML diagnosis (Figure 1).

**Conclusions:** PML prevalence was high due to late diagnosis and/or poor adherence to ART. SI and IDU patients were frequently diagnosed simultaneously with HIV and PML and had more severe immunosuppression, compared to PI. High HIV viral load at PML diagnosis was a predictor for short-term survival and increased mortality rate.

# Co-morbidities and Complications of Disease and/or Treatment: Ageing

## P061

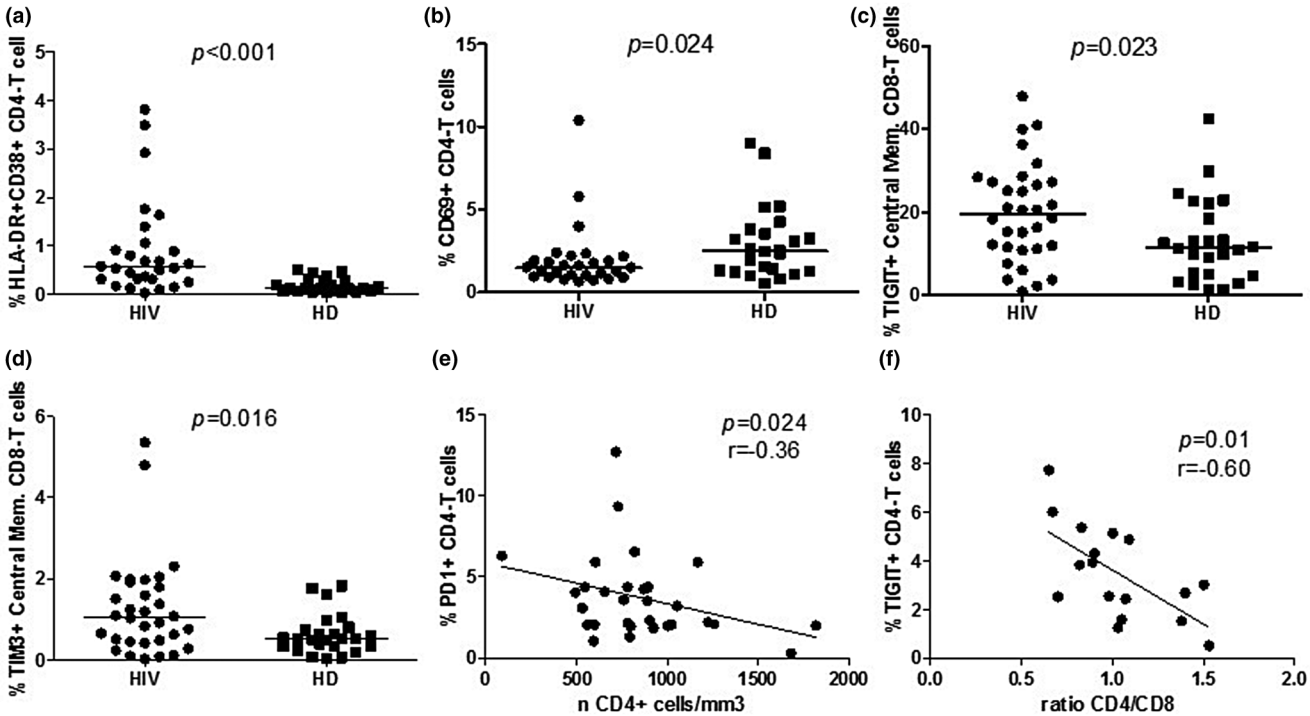
### Increased levels of immune activation and exhaustion in vertically HIV-1 infected young adults

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**Background:** HIV-1 vertically infected children show irreversible immune damage associated with HIV-1 infection and early antiretroviral treatment (cART) exposure during immune system development [1]. Most of these patients were born at the beginning of the HIV pandemic and are now reaching adulthood, and immunological data on this population remain scarce. The objective of this study is to assess the level of immune activation and immunosenescence of HIV-1 vertically infected young adults compared to non-HIV-infected subjects.

**Material and methods:** HIV-1 vertically infected patients (n = 32) under suppressive cART for at least five years were selected from the Paediatric AIDS Research Network of Spain (CoRISpe) and cryopreserved samples were selected from the Spanish HIV BioBank. The




**Abstract P061-Figure 1. Representative examples of activation (a), proliferation (b) and exhaustion (c–d) markers CD4- and CD8-T cell subsets in young adult HIV patients (HIV) and healthy donors (HD). Representative correlations between exhaustion markers and CD4 + counts and ratio CD4/CD8 (e–f). Values are expressed as medians and compared by Mann–Whitney U-test. Correlations between variables were assessed using Spearman's rank test.**

HIV group was compared to a group of non-HIV-infected subjects (healthy donors [HD], n = 28) matched by age and sex (Table 1). The expression of activation (HLA-DR and CD38), proliferation (CD127 and CD69) and exhaustion markers (CD57, TIM-3, PD-1, TIGIT and LAG-3) in CD4- and CD8-T cell subsets (defined by CD27 and CD45RA) was studied on peripheral blood mononuclear cells by multiparametric flow cytometry using Gallios cytometer (Beckman Coulter).
**Results:** HIV patients showed significantly higher percentage of activation (HLA-DR+CD38+) and lower levels of proliferation markers (CD127+and CD69+) on both CD4- and CD8-T cell subsets compared with HD (Figure 1a–b). Regarding exhaustion phenotype, the expression of CD57 + in total CD4-T cell and the levels of TIGIT+ and TIM-3 + in central memory (CD45RA-CD27 + ) CD8-T cells was also higher in HIV compared with HD (Figure 1c–d). Focusing only on HIV patients, strong and inversed correlations were found between the expression of exhaustion markers, in both CD4- and CD8-T cells (PD-1 + and TIGIT+), with clinical parameters traditionally associated with disease progression in HIV population: CD4 counts and ratio CD4/CD8 (Figure 1e–f).

**Abstract P061-Table 1. Patients' characteristics**

| Subject characteristics | HIV (n = 32) | HD (n = 28) |
|---|---|---|
| Age, years | 24.4 [22.48 to 28.19] | 26 [23.5 to 27] |
| Sex (male), n (%) | 12 (37) | 9 (36) |
| CD4 + , % | 35.5 [32 to 41.25] | 37.8 [35.1 to 41.35] |
| CD8 + , % | 36 [32.6 to 39] | 20.3 [17.9 to 22.9] |
| CD4 + cells/$mm^3$, n | 794 [599 to 981] | |
| CD8 + cells/$mm^3$, n | 774 [622 to 938] | |
| Ratio $CD^{4+}/CD^{8+}$ | 1 [0.82 to 1.23] | |
| Nadir CD4 + cells/$mm^3$ | 198 [76 to 330] | |
| Age at cART initiation, months | 49 [14 to 70] | |
| Time since cART initiation, years | 20 [18 to 23] | |
| Time under virological control, years | 8 [7 to 10] | |

**Conclusions:** An early infection and cART exposure deals with an irreversible immune damage, shown by increased activation and exhaustion marker levels, not normalised once adulthood is reached. The premature exhaustion profile observed in our series could be responsible of future comorbidities generally developed in the elderly population. It could be interesting to study exhaustion and clinical variables association in clinical practice.

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# P062

## Prevalence of pain in women living with HIV aged 45 to 60: associated factors and impact on patient-reported outcomes

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**Background:** As the population of women with HIV ages, an increasing proportion are experiencing the menopause, with potential associated pain. We report prevalence of pain, associated factors and impact on patient-reported outcomes among women with HIV aged 45 to 60.
**Materials and methods:** The PRIME study included 869 women with HIV aged 45 to 60 in England who provided information on physical/mental health, including current pain. Multivariable logistic regression determined factors independently associated with pain extent (no, moderate, extreme pain) and quantified associations with severe depressive symptoms (PHQ-4 > 6) and insomnia symptoms.
**Results:** Of the 844 participants (72.3% black African; median age 49 [interquartile range 47 to 53] years; 20.9%, 44.0% and 35.1% pre-, peri- and post-menopausal), 376 (44.6%) and 73 (8.7%) reported moderate or extreme pain. Women had been diagnosed with HIV for 14 (9 to 18) years, 97.7% were receiving antiretroviral therapy and 88.4% had a suppressed viral load. Although there was no significant age difference between those reporting no, moderate and extreme pain (median ages of 50, 50 and 49 years, respectively, $p = 0.11$), women reporting extreme or moderate pain were more likely to be peri-/post-menopausal (extreme pain: 46.5%/38.0%; moderate pain: 49.6%/34.3%) than those reporting no pain (38.2%/35.4%, $p = 0.002$). After adjustment (Table 1), peri-menopausal status, current smoking, medical conditions and longer duration of HIV were independently associated with increased pain, whereas being in full-time work and having enough money for basic needs were associated with decreased pain. Overall, 331 women (39.7%) reported insomnia symptoms (80.8%, 50.0% and 22.1% of those reporting extreme, moderate or no pain, respectively, $p = 0.0001$); 189 women (25.1%) had severe depressive symptoms (65.6%, 34.8%, 9.2%, $p = 0.0001$). Increasing pain was independently related to insomnia symptoms (moderate: adjusted odds ratio 2.76 [95% confidence interval 1.96 to 3.90]; extreme: 8.09 [4.03 to 16.24], $p = 0.0001$) and severe depressive symptoms (moderate: 3.96 [2.50 to 6.28]; extreme: 9.13 [4.45 to 18.72], $p = 0.0001$).

**Abstract P062-Table 1. Factors independently associated with pain extent in women living with HIV.[a] Provides the estimated odds of pain being in each higher category (no vs moderate vs extreme) associated with each factor**

| | | Adjusted OR[a] | 95% CI | *p*-value |
|---|---|---|---|---|
| Full-time employment | | 0.61 | 0.45 to 0.83 | 0.002 |
| Enough money for needs | | 0.47 | 0.34 to 0.64 | 0.0001 |
| Current smoking | | 1.85 | 1.11 to 3.09 | 0.02 |
| Total medical conditions | /additional condition | 1.95 | 1.64 to 2.33 | 0.0001 |
| Duration of diagnosed HIV | /additional year | 1.02 | 1.00 to 1.04 | 0.04 |
| Menopausal status | Pre-menopausal | 1 | — | |
| | Peri-menopausal | 1.80 | 1.22 to 2.67 | 0.003 |
| | Post-menopausal | 1.25 | 0.83 to 1.89 | 0.29 |

**Conclusions:** Pain was commonly reported in women with HIV aged 45 to 60 years, more extreme in peri- and post-menopausal women and associated with markers of socioeconomic disadvantage. Increasing pain was strongly associated with poorer mental health and sleep problems. Our findings point to the importance of eliciting a history of pain and addressing symptoms in order to improve wellbeing.

# P063

## Impact of baseline comorbidities on ART persistence and effectiveness in PLWH receiving F/TAF-based regimens: final 24-month results from the German TAFNES cohort study

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**Background:** With an ageing HIV population, comorbidity burden increases and represents a major challenge in the management of HIV care. Here we present 24-month (M24) effectiveness and safety outcomes of the TAFNES cohort (for F/TAF-based ART) stratified by the presence of comorbidities.

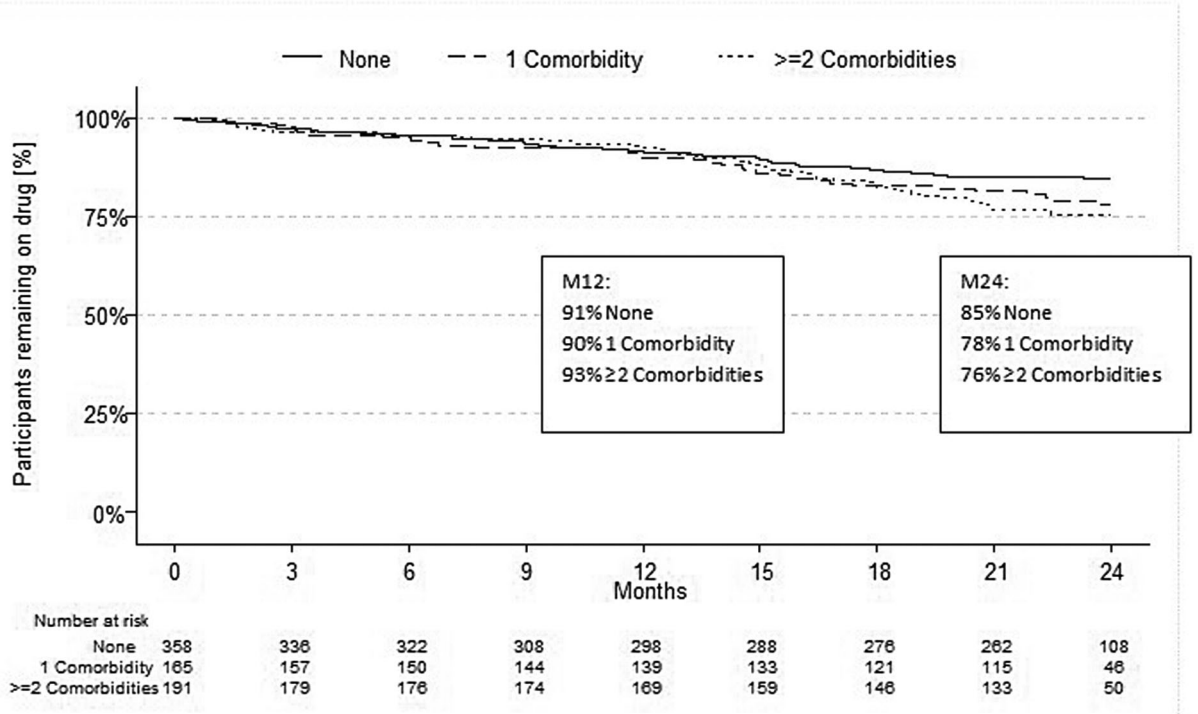
**Materials and methods:** M24 evaluation of treatment with F/TAF-based single-tablet regimen with elvitegravir/cobicistat (E/C/F/TAF), rilpivirine (R/F/TAF) or F/TAF-based multi-tablet combinations with a third agent (F/TAF + 3rd agent). Inclusion criteria for the treatment-experienced latter group was age ≥50 years. Effectiveness outcomes comprise viral response (HIV-RNA < 50 copies/mL; missing excluded) and ART and/or study persistence (Kaplan-Meier estimates). Documentation of comorbidities was based on predefined comorbidity categories and free-text entries for "others".

**Results:** Seven hundred and fourteen PLWH were evaluable for analysis (92% men, median age 45 years, 16% CDC stage C, 39% treatment naïve [TN]; E/C/F/TAF: n = 308; R/F/TAF: n = 179; F/TAF + 3rd agent: n = 227). Comorbidities (documented in 50% of patients) were more common among treatment experienced (TE: 58% vs TN: 36%) and elderly (≥50 years: 70% vs <50 years: 36%). Distribution across treatment groups is shown in Table 1. Comorbidities present in ≥ 5% of patients were hypertension (15%), neuropsychiatric disorders (11%), hyperlipidaemia (6%) and cardiovascular diseases (5%). "Gastrointestinal disorders" (6%) and "metabolism/nutrition disorders" (10%) (including vitamin D deficiency [8%]) were highest among

**Abstract P063-Table 1. Documented comorbidities among treatment groups with respect to baseline characteristics**

| | Overall (n = 714) | E/C/F/TAF (n = 308) | R/F/TAF (n = 179) | F/TAF + 3rd agent (n = 227) |
|---|---|---|---|---|
| With documented comorbidities: | n = 356 (50%) | 37% | 55% | 63% |
| By treatment status: TE vs TN | 58% vs 36% | 46% vs 29% | 54% vs 61% | 78% vs 39% |
| By age: ≥50 years vs <50 years | 70% vs 36% | 59% vs 29% | 70% vs 49% | 75% vs 36% |
| With ≥2 documented comorbidities | n = 191 (27%) | 16% | 26% | 41% |

TE, treatment experienced; TN, treatment naïve.




**Abstract P063-Figure 1. ART/study persistence (Kaplan-Meier estimates censoring loss-to-follow-up; event=discontinuation of the study and/or F/TAF-based study medication).**

"others". Overall ART/study persistence through M24 was 81% (Figure 1). Persistence with 0, 1 or ≥2 comorbidities was 85%, 78% and 76%, respectively. Main reasons for ART/study discontinuation were treatment simplification (in 3.1%, 4.2% and 6.3% of patients, respectively) and drug-related adverse events (AEs, in 3.1%, 5.5% and 3.1%). Discontinuation due to virological failure was reported in 0.8%, 2.4% and 1.0%, respectively. Overall virological effectiveness was 75% (n = 452/602): 79% in patients without comorbidities (n = 239/301), 73% with one (n = 99/136), 69% with ≥ 2 comorbidities (n = 114/165). Regarding subgroups with specific comorbidities, rates were 74% (hypertension; n = 72/97), 73% (hyperlipidaemia; n = 30/41), 69% (neuropsychiatric disorders; n = 47/68) and 64% (cardiovascular disease; n = 23/36).

**Conclusions:** Patients included in TAFNES reflect the ageing HIV population with accumulating comorbidities. Despite different patient and treatment characteristics, persistence on study/ART was similar; discontinuation rates due to virological failure or drug-related AEs were low in patients presenting without, with one or ≥2 comorbidities.

## P064

### Frailty of Greek PLWHIV in association with clinical markers and psychological factors: preliminary results of a nationwide study

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**Background:** Access to ART has transformed HIV to a chronic illness for PLWHIV. Frailty, despite being a geriatric syndrome, is known to progress prematurely in PLWHIV [1]. The aim was to observe the prevalent frailty criteria in Greek PLWHIV and investigate associations with clinical and psychological factors, towards a comprehensive view of the HIV condition.

**Materials and methods:** Between January 2020 and April 2020, data were recorded for each patient (n = 212) by health care providers of participating HIV clinics (N = 3) in two distinct geographic areas in Greece (Attika, Thrace). Data included clinical markers, frailty assessment points and responses to questionnaires: Beliefs about Medicines (BMQ), EuroQol (EQ-5D-5L including Visual Analog Scale EQ-VAS) and Brief Illness Perception (BIPQ).

**Results:** EQ-VAS (AUC = 0.756, a < 0.001) and BIPQ (AUC = 0.722, a < 0.001) were tested as indicators of frailty and the Youden index (y.i.) [2] was used to determine cut-off values (EQ-VAS: y.i. = 80.5, BIPQ: y.i. = 34.5). 79.7% (169) of Greek PLWHIV were non-frail and 14.6% (31) were pre-frail. Among frail PLWHIV (12, 5.7%), 66.7% had been diagnosed with AIDS (x2 = 12.665, df = 2, a = 0.01). The slow walking frailty criterion was correlated with the last available CD4 count (r=−0.144, a = 0.05). The strength frailty criterion was correlated with medication concerns, BMQ (r = 0.146, a = 0.05) and BIPQ total score (r = 0.146, a = 0.05). The exhaustion frailty criterion was correlated with BIPQ total score (r = 0.266, a = 0.01) and EQ-VAS (r=−0.367, a = 0.01). Individuals fulfilling the exhaustion frailty criterion had strong medication concerns (r = 0.246, a = 0.01) such as dependence (r = 0.186, a = 0.01), long-term toxicity (r = 0.138, a = 0.01), long-term effects (r = 0.132, a = 0.05) and disruptive medication effects (r = 0.213, a = 0.01).

**Conclusions:** PLWHIV's own perception of their health status and their illness are useful indicators of frailty assessment or need for frailty evaluation. The majority of PLWHIV in Greece are not frail. The presence of frailty in PLWHIV is significantly dependent on history of AIDS diagnosis. As health status declines with frailty, their perception of their own health status worsens, and a more threatening view of illness prevails. More medication concerns were expressed among PLWHIV who met the exhaustion criterion for frailty.

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# Co-morbidities and Complications of Disease and/or Treatment: Cardiovascular

## P065

### The association of incidental coronary calcification and imaging covariates in people living with HIV. Results from the Liverpool Multiparametric Imaging Collaboration

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**Background:** PLWHIV have an increased risk of myocardial infarction compared to risk matched non-HIV populations. This is driven in part by chronic inflammation and insulin resistance from ectopic fat deposition which is increased in PLWHIV. The principal sites for ectopic fat deposition are hepatic and cardiac tissues. This proinflammatory phenotype predisposes vascular tissue to injury. We sought to investigate the association between incidental coronary calcifications seen on computed tomography (CT) with hepatosteatosis (HS) and important clinical covariates.

**Methods:** Data were collected from the prospective Liverpool Multiparametric Imaging Collaboration (LMIC). Chest and abdominal CT imaging studies from the last 10 years were analysed for the presence of coronary calcification and HS. We compared covariates in those with coronary calcifications and those without coronary calcification. We constructed a binary logistic regression model using significant covariates to assess for independent associations with coronary calcification. This was used to calculate odds ratios and *p*-values for covariates. Correlations between covariates were assessed using Pearson correlation coefficient.

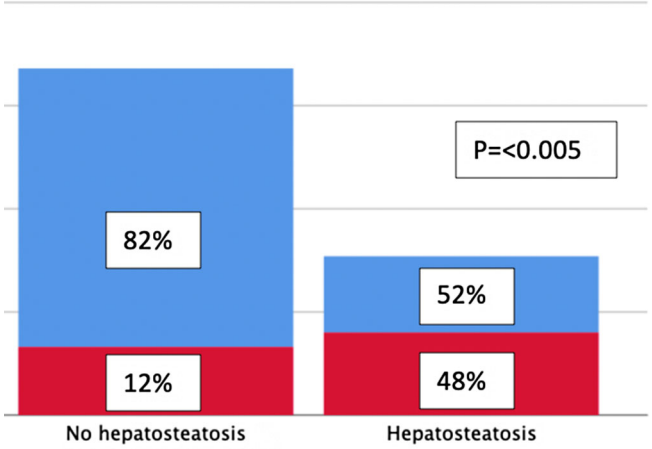
**Results:** The LMIC database contained 1295 patients. There were 245 cases where assessment for coronary calcifications was possible. Coronary calcifications were detected in 73 (29.8%) (Figure 1). The clinical covariates significantly associated with coronary calcification are shown in Table 1. In the final multivariate model increasing age had an odds ratio of 1.1 (95% CI 1.04 to 1.16, $p = 0.001$) for the presence of coronary calcification. Beyond age HS was the only significant risk factor predictive of coronary calcification (OR 3.46, 95% CI 1.76 to 6.82, $p < 0.005$). Correlation between HS and FRS was poor (Pearson correlation 0.21, $p = 0.002$).

**Abstract P065-Table 1. The association of important clinical and imaging covariates with the presence and absence of coronary calcifications**

| Variable | Coronary calcification (n = 73) | No calcification (n = 172) | *p*-value |
|---|---|---|---|
| Age | 56.9 (±9.8) | 46.8 (±8.7) | <0.005 |
| Male sex | 65 (89%) | 119 (69.2%) | <0.005 |
| Hypertension | 15 (20.5%) | 26 (15.1%) | 0.328 |
| DMII | 4 (5.5%) | 9 (5.2%) | 0.937 |
| Renal dysfunction | 13 (17.8%) | 13 (7.6%) | 0.017 |
| Dyslipidaemia | 10 (13.7%) | 7 (4.1%) | 0.007 |
| Current smoking | 21 (28.8%) | 49 (28.5%) | 0.965 |
| Ex smoking | 5 (6.8%) | 4 (2.3%) | 0.328 |
| Hepatosteatosis | 40 (55%) | 37 (21.5%) | <0.005 |
| FRS score, % | 14.2 (±7.7) | 7.1 (±5.8) | <0.005 |
| Length of HIV diagnosis, years | 12.8 (±8.1) | 10.7 (±6.3) | 0.173 |
| eGFR | 70.1 (±15.7) | 75.6 (±15.0) | 0.006 |
| Total cholesterol | 4.9 (±1.3) | 4.7 (±1.0) | 0.449 |
| Triglyceride | 2.2 (±1.7) | 1.7 (±1.3) | 0.002 |
| LDL cholesterol | 2.6 (±1.3) | 2.5 (±1.0) | 0.685 |
| HDL cholesterol | 1.2 (±0.4) | 1.4 (±0.5) | 0.025 |
| HBA1C | 39.8 (±11.0) | 38.8 (±12.3) | 0.506 |
| Triglyceride/HDL cholesterol | 2.2 (±2.7) | 1.6 (±1.6) | 0.002 |
| Total cholesterol/ HDL cholesterol | 4.2 (±1.6) | 3.7 (±1.4) | 0.029 |

Continuous data is presented as means ± standard deviations and compared using an independent test. Where not normally distributed the Mann–Whitney U test is used. Categorical data is presented with overall prevalence and proportions. It was compared using a chi-squared test. Data was considered statistically significant where $p < 0.05$.

**Conclusions:** The presence of HS was the most significant predictor of the presence of coronary calcification ($p < 0.005$) even after adjustment for traditional CVD risk factors. The poor correlation between FRS and HS illustrates the limited value in FRS in predicting presence of plaque in PLWHIV. This finding highlights the unique pathophysiological role of ectopic fat deposition in development of CVD in PLWHIV. These results are hypothesis generating and further study is required to fully elicit the interaction of HIV and CVD development.




**Abstract P065-Figure 1. A clustered bar chart demonstrating the relationship between hepatosteatosis and presence of coronary calcification.**

## P066

### Examining associations between HIV status and high blood pressure (hypertension) in a high HIV prevalence population in Manicaland, east Zimbabwe: a cross-sectional study of adults

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**Background:** Evidence from high-income countries indicates that PLHIV experience a higher hypertension prevalence than HIV-negative individuals. However, it is unclear whether this applies in sub-Saharan Africa, where behaviour and healthcare access differ. It is also unclear whether reported differences in hypertension prevalence result from socio-demographic differences between PLHIV and HIV-negative individuals or from HIV infection and treatment. We analysed data from Manicaland, Zimbabwe, to test the hypothesis that PLHIV had a higher hypertension prevalence than HIV-negative individuals and assess whether controlling for socio-demographic factors affected this relationship.

**Materials and methods:** A cross-sectional study, including interviews and HIV testing, was performed at two urban sites, a town and a roadside trading area (07/2018 to 03/2019). All young women (15 to 24 years) and men (15 to 29 years), and a random sample of 2/3 of older adults were eligible. Individuals were considered hypertensive if they reported ever being diagnosed with hypertension by a doctor/nurse. Logistic regression was used to estimate odds ratios (ORs) for prevalent hypertension, controlling for socio-demographic confounders. Weights were used in all analyses to compensate for unequal selection probabilities.

**Results:** Among 3404 participants (2169 men; 1235 women), the weighted HIV prevalence was 10.8% (95% CI 9.7 to 11.9%). There were more women among PLHIV (PLHIV: 62.5%, 57.2 to 67.8%; HIV-negative: 53.2%, 52.2% to 54.2%) and PLHIV were older (>45 years: PLHIV: 40%, 31.8% to 48.2%; HIV-negative: 25.3%, 23.9% to 26.6%). Hypertension prevalence was higher among PLHIV (20.6%, 16.3% to 25.0%) than HIV-negative individuals (16.4%, 15.1% to 17.6%; OR 1.33, 1.01 to 1.76, $p = 0.048$). However, hypertension prevalence was higher in older individuals and women, so after adjusting for age and gender the difference in hypertension between PLHIV and HIV-negative individuals was non-significant (OR 0.94, 0.69 to 1.29, $p = 0.709$). Introducing other confounders (marital status, employment, wealth, site) did not alter this (OR 0.93, 0.65 to 1.32, $p = 0.674$).

**Conclusions:** Hypertension prevalence was higher among PLHIV than HIV-negative individuals, mirroring high-income countries and suggesting that integration care for HIV and hypertension may be needed. The prevalence difference appears to arise from demographic patterns, rather than HIV infection directly, suggesting standard interventions, such as counselling on alcohol consumption, would be effective. However, this study relied on self-reported hypertension diagnosis; future studies should measure participant blood pressure to confirm these findings.

## P067

### Comparing the prevalence of hypertension by HIV status in sub-Saharan African adults: a systematic review and meta-analyses of cross-sectional studies

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**Background:** Some evidence from high-income countries (HICs) suggests that PLHIV experience a higher hypertension prevalence than HIV-negative individuals. It is unclear whether this is the case in sub-Saharan Africa (SSA), where large-scale integration of hypertension services into HIV programmes is being considered. We examined the hypothesis that living with HIV is associated with higher hypertension prevalence among adults in SSA.

**Materials and methods:** A systematic review of MEDLINE, EMBASE, Global Health, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials and African Journals Online was performed, following PRISMA guidelines, to identify cross-sectional studies assessing hypertension prevalence in PLHIV and HIV-negative individuals >15 years, in SSA. Only studies defining hypertension as "study-ascertained blood pressure ≥140/90 mmHg", or as "study-ascertained blood pressure ≥140/90 mmHg and/or history of antihypertensive medication usage", were included. Risk of bias assessments addressed adequacy of sample sizes, participant selection and HIV and hypertension status measurement. Random effects models were used to pool odds ratios (ORs) for prevalent hypertension.

**Results:** We identified 1431 unique studies, of which 12 were selected for quantitative analysis, providing data on 107 425 participants (49.4% to 69.6% female). The 12 studies collected data between 2003 and 2015, in South Africa, Tanzania and Uganda. Risk of bias was low to moderate, with participant selection a key source of bias. Hypertension prevalence ranged from 5.3% to 51.7% among PLHIV and 8.2% to 65.4% in HIV-negative individuals. Overall, hypertension prevalence was 41% lower among PLHIV than HIV-negative individuals when using the ≥140/90 mmHg definition (n = 5, OR 0.59, 95% CI 0.55 to 0.64) and 34% lower when using the definition that included medication (n = 7, OR 0.66, 95% CI 0.47 to 0.99).

**Conclusions:** Robust studies comparing hypertension prevalence in PLHIV and HIV-negative individuals from SSA are scarce and concentrated in three countries. In contrast to evidence from HICs, our results suggest hypertension prevalence is lower among PLHIV than HIV-negative individuals in SSA. The disparity between SSA and HICs may reflect differences in health status of PLHIV and in hypertension risk behaviours by HIV status, although further evidence from across SSA is needed to clarify this. If confirmed, these findings should be considered in decisions around implementing integrated HIV-hypertension services.

## P068

### The prevalence and risk factors for peripheral artery disease in chronic kidney disease in HIV-infected persons

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**Background:** Cardiovascular disease is an important cause of morbidity among an ageing HIV population [1]. Despite the current evidence and known risk factors it is still challenging to determine to what extent HIV infection increases risk of peripheral artery disease (PAD) in comparison to general population. Here we examined the association between HIV infection, PAD and chronic kidney disease (CKD) in predominantly male HIV-infected persons compared with uninfected population. We also analysed risk factors related to PAD.

**Materials and methods:** The cohort was comprised of 191 persons ≥18 years old: 50 HIV-infected patients from the University Hospital for Infectious Diseases (UHID) in Zagreb and 141 non-HIV-infected patients from the Nephrology and Dialysis Department, Riuniti Hospital, Italy. HIV care in Croatia is centralised and all people living with HIV are treated at the UHID. Included were HIV-infected patients from 1 February 2018 to 30 September 2019, and non-HIV-infected patients from 4 September 2007 to 18 March 2019. CKD was defined as an eGFR of less than 60 mL/min/1.73 $m^2$ on at least two occasions 90 days apart. PAD was assessed using duplex colour Doppler and was defined as having any of focal or diffuse medial or intimal calcification in iliac, common femoral, superficial femoral or tibial artery, diagnosed by grey scale vascular ultrasound. PAD was also considered present if there were haemodynamically significant stenosis or occlusion.

**Results:** Of 191 participants 57.6% (110/191) were male with median age of 51 (IQR: 42 to 57) years. Fifty were HIV-infected (25 had

**Abstract P068-Table 1. Crude and adjusted odds of peripheral atherosclerosis by patient characteristics in HIV-infected (n = 50) and non-HIV-infected (n = 141) participants**

| | Crude analysis | | Multivariate analysis | |
|---|---|---|---|---|
| | Odds ratio (95% confidence interval) | *p*-value | Odds ratio (95% confidence interval) | *p*-value |
| Female vs male | 0.21 (0.09 to 0.50) | <0.001 | 0.27 (0.09 to 0.82) | 0.021 |
| Current smoker vs non-smoker | 0.66 (0.32 to 1.37) | 0.268 | 0.75 (0.29 to 1.95) | 0.551 |
| BMI, per 5 kg/$m^2$ | 0.73 (0.49 to 1.10) | 0.135 | | |
| HIV-positive vs HIV-negative | 4.73 (2.07 to 10.77) | <0.001 | 5.62 (1.67 to 18.94) | 0.005 |
| CKD yes vs no | 4.16 (1.88 to 9.18) | <0.001 | 5.70 (1.69 to 19.25)[a] | 0.005 |
| Hypertension yes vs no | 2.28 (1.08 to 4.84) | 0.031 | 2.19 (0.65 to 7.44) | 0.208 |
| Diabetes yes vs no | 1.21 (0.39 to 3.76) | 0.747 | 1.41 (0.31 to 6.46) | 0.656 |

BMI, body mass index; CKD, chronic kidney disease. Crude analysis: adjusted for age (significant) and one characteristic. Multivariate analysis: adjusted for age, gender, current smoking status, BMI, HIV status, CRD, hypertension and diabetes.

[a]There was a significant interaction of BMI and CKD indicating that patients with GFR < 60 mL/min/1.73 m² had more frequently peripheral atherosclerosis than those with a GFR ≥ 60 mL/min/1.73 m² up to a BMI of 30 kg/$m^2$. The values in the table present the OR and 95% CI at 25 kg/$m^2$ whereas the OR at 30 kg/$m^2$ and above showed no difference.

CKD) and of 141 non-HIV-infected 68 had CKD. The prevalence of PAD was 76% (19/25, HIV+ CKD-yes), 32% (8/25, HIV+ CKD-no), 22% (15/68, HIV- CKD-yes) and 14% (10/73, HIV- CKD-no). Both HIV infection and CKD were associated with PAD (Table 1). Multivariable analysis showed a significant interaction of body mass index (BMI) and CKD indicating that patients with CKD had more frequently PAD than those without CKD up to a BMI of 30 kg/m$^2$.

**Conclusions:** HIV-infected persons have PAD more frequently than non-HIV-infected patients and CKD worsens the findings. HIV infection and CKD are independent risk factors for PAD.

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## P069

### Influence of CD4 + /CD8 + ratio on early age of stroke in persons living with HIV: a single university centre study in Portugal

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**Background:** In the era of effective antiretroviral therapy, ischaemic stroke (iSk) is one of the important causes of morbidity in PLWH [1], either due to the virus itself and immunosuppression at all ages, or due to the traditional risk factors (RFs) which, generally, increase with age [2,3]. CD4+ /CD8+ ratio is proposed as a potential marker for PLWH at increased risk for non-AIDS comorbidities [4]. The current study aims to relate low CD4+ /CD8+ ratios with the early ages of a diagnosis of iSk, compared to the ages of its occurrence in uninfected individuals.

**Patients and methods:** A population of 6446 hospitalised patients with iSk, during a 6-year period in a single centre, was analysed, divided into two groups (Gr.): Gr. 1 - population uninfected with HIV (n = 6395), Gr. 2 - PLWH (n = 51). Gr. 2 was further divided into three subgroups according to the CD4+ /CD8+ ratio (<0.4; 0.4 to 1; ≥1). Statistical analysis was carried out with tests for equality of means for all variables and n-way analysis of variance for the entire population (HIV+ and HIV–) including both the effect of HIV infection and the CD4+ /CD8+ ratio, while maintaining control of the remaining potential RFs.

**Results:** The average age of an iSk in Gr. 2 was 12.2 years earlier ($p < 0.001$) than the one observed in Gr. 1. PLWH had less RFs than Gr. 1 patients. Multivariate analyses confirmed the association of a low CD4+ /CD8+ ratio with the anticipation of the ischaemic stroke in Gr. 2, about 9.3 years earlier in the subgroup with a ratio <0.4 when compared to the subgroup with a normalised (≥1) ratio ($p = 0.0366$). The reduction in the number of years in the diagnosis of an iSk among PLWH with a CD4+ /CD8+ ratio <0.4 and the uninfected population was 18 years.

**Conclusions:** The CD4+ /CD8+ ratio can distinguish PLWH requiring more aggressive control of modifiable RFs in the prevention of early iSk, particularly when it remains < 0.4.

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## P070

### Left ventricular systolic dysfunction assessed by speckle tracking in asymptomatic HIV patients: prevalence and associations with clinical characteristics

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**Background:** HIV primarily affects young, otherwise healthy, individuals. Cardiomyopathy in these persons has been attributed to the combined effect of inflammation, immune dysregulation, opportunistic infections, myocyte invasion and cardiac steatosis, while peripheral artery disease to immune activation, abnormalities in lipid metabolism associated with antiretrovirals, and increased prevalence of traditional risk factors. Pre-symptomatic diagnosis of myocardial dysfunction and peripheral artery damage could enable prompt and potentially more effective implementation of therapeutic measures. However, the data that are available to date on the specific topic are limited.

**Materials and methods:** We investigated the association between global longitudinal strain (GLS), an established index of subclinical left ventricular systolic dysfunction (SLVSD), assessed by 2-D speckle tracking and a) patient history, b) demographic and clinical baseline characteristics, c) carotid intima-media thickness (IMT) and presence of carotid atheromatic plaque(s), measured by ultrasonography, d) temperature difference ($\Delta$T) along each carotid artery, measured by microwave radiometry and e) basic blood panel measurements, including high-sensitivity troponin-T (hsTnT) and NT-proBNP in PLWHIV and no history of cardiovascular disease. Peak GLS of −18.7 is defined as normal for a healthy individual and the higher the value (i.e. closer to zero), the more likely it is for strain to be abnormal.

**Results:** We prospectively enrolled 102 consecutive PLWHIV. Ninety-eight individuals (95%) were male; mean age was 47 ± 11 years. SLVSD was detected in 44% of PLWHIV. Univariate analysis results are presented. The value of GLS was significantly associated with body mass index (BMI, $r = 0.345$, $p < 0.001$), CD4/CD8 ($r = 0.206$, $p = 0.036$), natural killer cell percentage counts ($r = -0.221$, $p = 0.025$) and HDL cholesterol ($r = -0195$, $p = 0.048$). hsTnT levels were significantly associated with age ($r = 0.547$, $p < 0.001$), serum creatinine ($r = 0.336$, $p = 0.001$), CD4 counts ($r = -0.226$, $p = 0.023$) and presence of carotid plaque ($r = 0.302$, $p = 0.004$). Levels of NT-proBNP were significantly associated with age ($r = 0.373$, $p < 0.001$), history of diabetes ($r = 0.277$, $p = 0.007$), CD4/CD8 ($r = -0.222$, $p = 0.031$) and serum creatinine ($r = 0.306$, $p = 0.003$).

**Conclusions:** Our results indicate that apart from age, a dysmetabolic component may be implicated in the pathogenesis of premature systolic myocardial dysfunction. The multiple intricate effects of immune dysregulation on myocardial function are not yet fully understood.

## P071

### Transcranial Doppler pulsatility index as a marker of endothelial dysfunction, especially useful when before persistently low CD4+ /CD8+ ratios

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**Background:** Even under effective ART, some HIV (PLWH) patients never normalise their CD4+ /CD8+ ratio, keeping in low values [1,2]. This is associated with an increased morbidity/mortality risk despite the recovery of the CD4+ T cells count. This phenomenon may reach clinical importance given the association between HIV and ischaemic strokes/myocardial infarctions, particularly in middle-aged adults, with lesser conventional vascular risk factors. In PLWH an increased subclinical atherosclerosis was suspected as evaluated by the carotid intima-media thickness (IMT) [3–5] and/or transcranial Doppler (TCD) pulsatility index (PI) when compared with the control groups.
**Patients and methods:** Seventy-nine HIV1 men aged <65 years, under ART for more than two years, with no history of cardiovascular events, were selected by convenience sampling from our immunodeficiency hospital clinic during the year of 2019. Data were collected from both carotid ultrasound and TCD examinations. Sequential CD4+ /CD8+ ratios were calculated by lymphocyte subpopulations counts, during the previous 5-year period. Two groups were established according to ratios as: "very low" (<0.4) and "immunologically normal" (>1). Possible associations were statistically sought, using linear regression models and controlling additional risk variables and non-linear regression models (by branches).
**Results:** Only 49 individuals underwent carotid ultrasound and TCD evaluation. Overall, the CD4+ /CD8+ ratio showed a trend to stabilisation over the five years. The ratio shows a negative impact of −0.10 over PI ($p < 0.05$). Additionally the adjustment of a non-linear model shows that the impact of the CD4+ /CD8+ ratios over the PI is more significant for ratios below .4 (impact on PI of −0.72, $p < 0.01$). This relationship is still significant, but attenuated for ratios above .4 (impact on the PI of −0.19, $p < 0.05$). No association between IMT with CD4+ /CD8+ ratios was found to be statistically significant ($p = 0.68$).
**Conclusions:** There is a negative impact of CD4+ /CD8+ ratio over PI, that is more intense for values below 0.4 and attenuated as this ratio approaches normal values. TCD PI seems to be an accurate marker of cerebrovascular changes in PLWH, particularly for those keeping low ratios of CD4+ /CD8+ , despite the efficacy of ART.

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# Co-morbidities and Complications of Disease and/or Treatment: Malignancies

## P072

### A 10-year case series of HHV8-related diseases in an ethnically diverse HIV cohort: is human herpesvirus 8 level a clue to the underlying pathology?

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**Introduction:** Kaposi's sarcoma (KS), multicentric Castleman's disease (MCD) and primary effusion lymphoma (PEL) are driven by human herpesvirus 8 (HHV8). HHV8 levels are a tool to support diagnosis but whether they can differentiate between the different pathologies is not clear [1,2]. We describe the burden of HHV8-related disease in an ethnically diverse cohort seen at a single centre in South East London between 2010 and 2020.
**Materials and methods:** This is a retrospective cross-sectional study of patients with biopsy-proven HHV8-related disease between March 2010 and March 2020. Patients were identified via a search of the virology database for plasma HHV8 DNA requests and cross-referenced with HIV inpatient and histopathology lists covering the same timeframe. Values are expressed as medians (IQR). A Mann–Whitney U test was applied to CD4 nadir, plasma HHV8 DNA level, CD4 count and time on ART at diagnosis of HHV8 disease to compare KS and MCD.
**Results:** Forty-three patients were identified, 28/43 (65.1%) were diagnosed with KS, 14/43 (32.6%) with MCD of which 5/43 (11.6%) had concurrent KS, and 1/43 (2.3%) PEL. The median age at diagnosis was 42 (35 to 53). Twenty-five of 43 (58.1%) patients were Black, 12/43 (27.9%) Caucasian, 5/43 (11.6%) Hispanic and 1/43 (2.3%) Asian. Eleven of 43 (25.6%) patients were female. HHV8 DNA levels were available at time of diagnosis in 22/28 (78.6%) of KS patients, and in all patients with MCD/PEL. Both HHV8 DNA levels and CD4 count at disease diagnosis were significantly higher in patients with MCD than with KS (Table 1). Ten of 28 (35.7%) KS patients received chemotherapy and 5/28 (17.9%) received radiotherapy. Eleven of 14 (78.6%)

**Abstract P072-Table 1. Average laboratory parameters at time of HHV8 disease diagnosis by disease group**

| | KS (n = 28) | MCD (n = 14) | *p*-value |
|---|---|---|---|
| CD4 nadir | 66 (21 to 165) | 136 (46 to 219) | 0.159 |
| CD4 | 75 (27 to 165) | 219 (134 to 489) | 0.003 |
| Plasma HHV8 DNA, copies/mL | 290 (100 to 14 500) | 150 000 (19 000 to 1050 000) | 0.003 |
| Time on ART, months | 0.9 (0 to 7.8) | 23.9 (2.4 to 62.4) | 0.048 |
| Proportion HIV virally suppressed | 3/28 (10.7%) | 7/14 (50%) | |

patients with MCD received chemotherapy and the patient with PEL died before treatment could be initiated.
**Discussion:** We describe a cohort of patients with HHV8-driven disease. KS was seen in immunocompromised patients with uncontrolled HIV whilst patients with MCD had significantly higher CD4 counts and half had well-controlled HIV. Our results show the diagnosis of MCD was associated with significantly higher HHV8 levels, therefore this is a potentially useful diagnostic tool.

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## P073

### Results of HPV testing from three anatomical locations among men with different HIV status and sexual behaviour

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**Background:** Oncopathology of various organs and systems is probably associated with the human papillomavirus high carcinogenic risk (HPV HCR).
**Objectives:** To study the prevalence of HPV HCR among men with different HIV status and sexual behaviour: MSM, heterosexual men (HT).
**Materials and methods:** The work was conducted during the period from February 2018 to October 2019. The study included 256 men from Moscow and Moscow region: 73 MSM/HIVpos, 66 MSM/HIVneg, 58 HT/HIVpos and 59 HT/HIVneg. All men were tested for 14 types of HPV HCR (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). Smears were taken from three anatomical locations: urethra, anus, oropharynx. We used real-time PCR assay, AmpliSens reagent kits were used.
**Results:** Among study participants predominated young men aged 35 473 ± 7362 (18 to 65, median 35) years, in 138 of them (53.9%) were diagnosed HPV HCR by the HPV-test: MSM/HIVpos – 82.2% (60/73), MSM/HIVneg – 59% (39/66), HT/HIVpos – 43% (25/58), HT/HIVneg – 20.3% (12/59) (Table 1). The structure of the anatomical location of HPV-positive test differed in the study groups. In group MSM/HIVpos HPV HCR was more often detected in the anus (79.5%); MSM/HIVneg – in the anus (54.5%); HT/HIVpos – in the urethra (24%); HT/HIVneg – in the urethra (16.9%). Detection of HPV HCR at once in several anatomical locations was recorded in 17.4%. All types of HPV HCR were diagnosed at each anatomical locus. The structure of the HPV genotypes differed by the anatomical location. In the urethra prevailed 16 (27.5%) and 45 (15%) genotypes; in the oropharynx – 16 (38.8%) genotype, 35 (22.2%) and 45 (16.7%) genotypes; in the anus – 16 (25.7%), 68 (25.7%) and 18 (20.2%) HPV HCR genotypes.
**Conclusions:** HPV screening algorithm development is required for men considering their HIV status and sexual behaviour. We recommend HPV testing with 14 HPV HCR genotypes determination in three locations (urethra, anus, oropharynx).

**Abstract P073-Table 1. Results of HPV-testing from three anatomical locations among men with different HIV status and sexual behaviour**

| Groups/anatomical locations | Urethra | Oropharynx | Anus | All locations |
|---|---|---|---|---|
| MSM/HIVpos (n = 73) | 10 (13.7%) | 10 (13.7%) | 58 (79.5%) | 60 (82.2%) |
| MSM/HIVneg (n = 66) | 6 (9%) | 4 (6.1%) | 36 (54.5%) | 39 (59%) |
| HT/HIVpos (n = 58) | 14 (24%) | 3 (5.2%) | 13 (22.4%) | 25 (43%) |
| HT/HIVneg (n = 59) | 10 (16.9%) | 1 (1.7%) | 2 (3.4%) | 12 (20.3%) |
| All (n = 256) | 40 (15.6%) | 18 (7%) | 109 (42.6%) | 138 (53.9%) |

# Co-morbidities and Complications of Disease and/or Treatment: Metabolic

## P074

### NAFLD with significant fibrosis in people living with HIV informs the natural history of cardiovascular disease

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**Background:** The aim of the study was to compare the performance of transient elastography as a measure of NAFLD and significant fibrosis with ASCVD algorithm in the prediction of subclinical cardiovascular disease (CVD) and major CVD event (MACE) in PLWH.
**Materials and methods:** This was a cross-sectional study including consecutive PLWH attending Modena HIV Metabolic Clinic (MHMC) from June 2018 to October 2019. We included ART-experienced PLWH who were evaluated for NAFLD, subclinical and clinical CVD. NAFLD was assessed by transient elastography as presence of liver steatosis (controlled attenuation parameter ≥248 dB/m), while significant liver fibrosis or cirrhosis as liver stiffness >7.1 kPa. NAFLD with fibrosis was defined as the contemporary presence of steatosis and significant liver fibrosis. The study outcomes were: 1) cardiovascular risk, assessed by ASCVD risk score; a 10-year risk for CVD was categorised as low (<7.5%) and high (≥7.5%); 2) subclinical CVD, assessed by ultrasound carotid intima-media thickness, pulse wave velocity and coronary calcium score by computed tomography; 3) MACE including myocardial infarction, coronary artery disease, peripheral vascular disease, stroke and angina pectoris. Receiver operating characteristic curve (ROC) analysis was conducted to assess the performance of NAFLD and NAFLD with significant fibrosis in the prediction of CVD compared to ASCVD algorithm.
**Results:** We analysed 616 PLWH. Mean age was 56 (±7.8) years, 79.2% were males. Characteristics of study population are described in Table 1. Low ASCVD, high ASCVD, subclinical CVD and MACE were present in 209 (33.9%), 123 (20%), 216 (35.1%), 68 (11%),

**Abstract P074-Table 1. Study population divided according to low and high cardiovascular risk and presence of subclinical and clinical cardiovascular disease**

| | Low ASCVD (N = 209) | High ASCVD (N = 123) | Subclinical disease (N = 216) | CVD (N = 209) | *p* |
|---|---|---|---|---|---|
| Age, years, mean (SD) | 50.38 (6.16) | 57.54 (5.2) | 59.1 (7.53) | 60.13 (7.38) | <0.001 |
| Sex, males, % | 148 (70.81%) | 99 (80.49%) | 178 (82.41%) | 63 (92.65%) | <0.001 |
| Body mass index, kg/m², mean (SD) | 24.52 (3.62) | 24.21 (3.81) | 24.69 (3.75) | 25.24 (3.84) | 0.33 |
| Obesity, % | 18 (8.61%) | 6 (4.88%) | 22 (10.28%) | 7 (10.29%) | 0.37 |
| Nadir CD4, c/microL, median (IQR) | 235 (120 to 353) | 200 (110 to 282) | 200 (78 to 288.5) | 222 (91 to 300) | 0.01 |
| HIV duration, months, median (IQR) | 232 (136 to 315) | 317 (249.5 to 385.5) | 303.5 (234 to 345.5) | 309.5 (260.75 to 355) | <0.001 |
| CD4/CD8 ratio, mean (SD) | 1.03 (0.46) | 0.99 (0.5) | 1.02 (0.55) | 1.05 (0.64) | 0.62 |
| Current CD4, c/microL, median (IQR) | 712 (545 to 923) | 681.5 (497.25 to 882.25) | 719 (529 to 907) | 745 (595 to 937) | 0.35 |
| Multimorbidity, % | 69 (33.5%) | 89 (73.55%) | 135 (64.59%) | 63 (94.03%) | <0.001 |
| Polypharmacy, % | 8 (5.41%) | 16 (19.75%) | 24 (19.83%) | 32 (68.09%) | <0.001 |
| Diabetes mellitus, % | 10 (4.78%) | 33 (26.83%) | 54 (25%) | 27 (39.71%) | <0.001 |
| Use of statins, % | 26 (23.64%) | 22 (31.43%) | 60 (45.11%) | 19 (76%) | <0.001 |

respectively. NAFLD and NAFLD with significant fibrosis were present in 443 (39.7%) and 92 (8.2%), respectively. Subclinical CVD was well predicted by NAFLD and NAFLD with fibrosis (ROC = 0.738 and ROC = 0.727, respectively) and it was not inferior to ASCVD risk score (ROC = 0.738), $p > 0.05$. MACE was also well predicted by NAFLD and NAFLD with fibrosis (ROC = 0.71 and ROC = 0.714, respectively) and it was not inferior to ASCVD risk score (ROC = 0.710), $p > 0.05$.

**Conclusions:** NAFLD and NAFLD with fibrosis have similar performance in prediction of CVD as ASCVD risk algorithm and may be used as biomarkers of metabolic age in the prediction of CVD.

## P075

### Differential effects of raltegravir, dolutegravir and bictegravir on human adipocytes

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**Background:** Recent data have raised concerns about weight gain associated with the use of integrase strand transfer inhibitors (INSTIs). The pathophysiological basis of this effect is unknown. The goal of our study was to assess the potential direct effects of raltegravir, dolutegravir and bictegravir on human adipose cells.

**Methods:** Human Simpson-Golabi-Behmel syndrome (SGBS) adipose cells were used and cultured using standard procedures. In controls, sub-optimal differentiation was achieved with the use of 0.5 μM rosiglitazone at the time of differentiation induction. Drugs were included in the differentiation medium at concentrations ranging from 0.1 to 10 μM (which includes $C_{min}$ and $C_{max}$). Morphological adipogenesis (accumulation of lipid droplets) was followed. Gene expression for markers of adipogenesis, adipocyte metabolism, adipokines and cytokines was determined using qRT-PCR 12 days after induction of differentiation.

**Results:** None of the three INSTIs tested caused substantial effects on overall adipogenesis, either positive or negative. Accordingly, marker genes of adipogenesis, such as leptin and GLUT4, were unaltered. INSTIs did not induce the expression of inflammation-related cytokines (IL-6, MCP-1) significantly. However, both raltegravir and dolutegravir lowered adiponectin gene expression in a dose-dependent manner. Maximal inhibition noted at 10 μM (~ 60% and 40% inhibition for raltegravir and dolutegravir, respectively), relative to expression in controls. Bictegravir did not show such an effect.

**Conclusions:** INSTIs do not cause large effects on human adipose cells. However, dolutegravir and raltegravir show alterations in adiponectin expression, which does not occur with bictegravir. Further studies are necessary to ascertain the pathophysiological relevance of these findings with respect to the effects of INSTI-containing treatments on body weight and metabolism in people living with HIV.

## P076

### Genetic markers of NAFLD associated with NASH in HIV-infected patients

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**Background and aims:** NAFLD is a common cause of liver damage in PLWHIV. NAFLD aetiology is multifactorial, involving interacting genetic and environmental factors. Studies have investigated candidate genes for susceptibility to NAFLD and to NASH: PNPLA3-adiponutrin (enzyme involved in triglyceride metabolism), TM6SF2 (involved in hepatic very-low density lipoproteins [VLDL] secretion), MBOAT7-TMC4 (involved in the hepatic phosphatidylinositol acyl-chain remodelling) have been previously reported to be associated with elevated ALT levels, and histological parameters of NASH and fibrosis severity. Our objective was to analyse the relation between PNPLA3, TM6SF2 and MBOAT7-TMC4 and NAFLD (NAS, NASH and liver fibrosis) in HIV-infected subjects.

**Method:** A prospective cohort of PLWHIV with persistently elevated aminotransferases levels who underwent liver biopsies and genetic variants determination between 2016 and 2018 was assessed at two large teaching hospitals in Spain. All participants included in the current study were genotyped for rs58542926 (TM6SF2 E167K), rs738409 (PNPLA3 I148M) and rs641738 (MBOAT7/TMC4). DNA was obtained from stored peripheral blood mononuclear cells. The TaqMan SNP genotyping assays (C_7241_10 and C_15875080_10) were performed on a QuantStudio 12 K Flex PCR System (Applied Biosystems).

**Results:** Seventy-one PLWHIV receiving stable ARV therapy were included, 8.5% women, median age of 49.8 (44 to 53.9); median years living with HIV 14.5 (7.4 to 20.7); median CD4 of 829 (620 to 999). Sixty percent fulfilled the metabolic syndrome criteria, and 19.7% were diabetic. The median BMI was 28.9 (25.4 to 31.3). Subjects with NAS (any grade) versus non-NAS had a tendency in PNPLA3 G allele

variants [97% vs 3% ($p < 0.08$)], but no in TM6SF2 and MBOAT7 variants. However, subjects with NASH had a significant higher proportion of PNPLA3 G allele variants 71% versus 34% ($p < 0.01$) and MBOAT7 A allele variant [34% vs 66% ($p = 0.05$)]. In our cohort TM6SF2 gene variant had not showed any relation with NAS or NASH. Due to the low proportion of advanced liver fibrosis we could not explore its association with genetic variants.

**Conclusions:** PNPLA3 G allele variant and MBOAT7 A allele variant were associated with NASH in PLWHIV with persistently elevated aminotransferases. We suggest including the analysis of this genetic variants to improve the diagnosis of NASH in PLWHIV.

## P077

### Associations with HIV-related symptoms and weight change after switching from efavirenz/emtricitabine/tenofovir disoproxil fumarate to bictegravir/emtricitabine/tenofovir alafenamide

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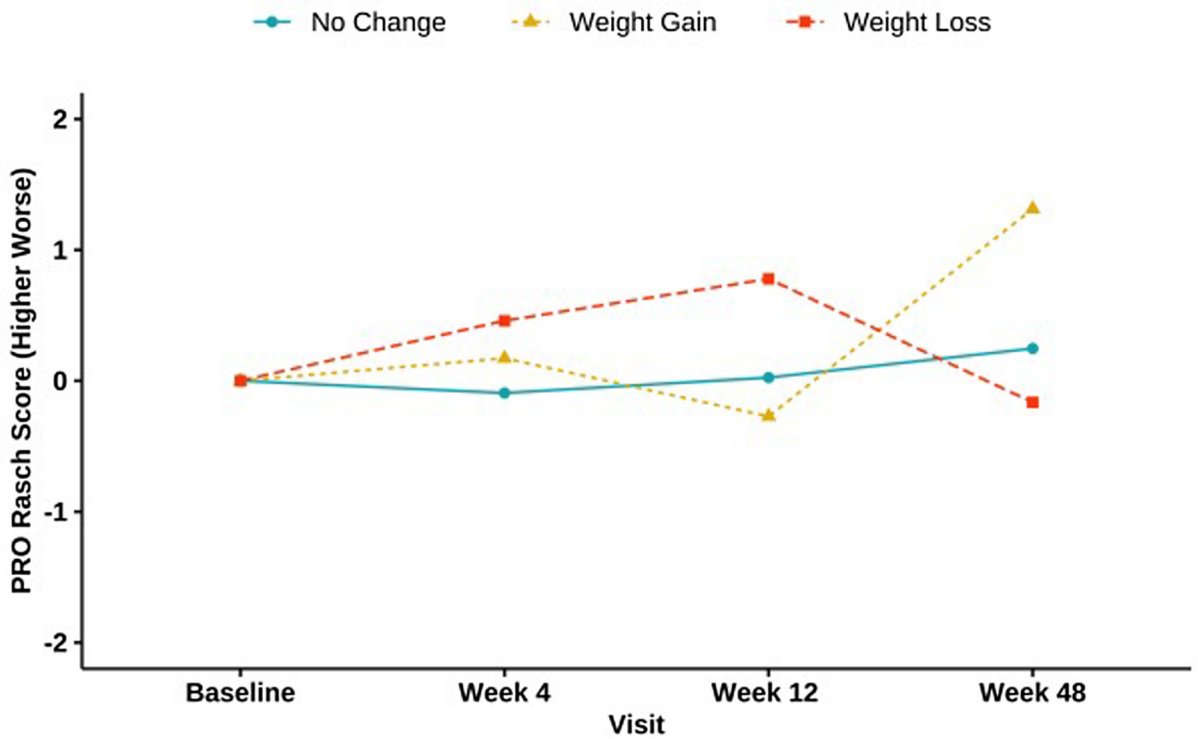
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**Background:** In treatment-naïve patients, both BIC and dolutegravir are associated with significantly more weight gain than EFV; however, little is known about weight change in patients specifically switched to bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) from efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF), and whether weight change is related to improvement in patient-reported outcomes (PROs), namely HIV-related symptoms and sleep quality. In this secondary analysis, we aim to determine if there are any associations with PROs and weight change at Week 48 after switching from EFV/FTC/TDF to BIC/FTC/TAF.

**Methods:** We conducted a 48-week, open-label, single-center, single-arm, prospective study evaluating the efficacy, safety, and tolerability of switching from EFV/FTC/TDF to BIC/FTC/TAF in PLWH > 18 years of age who were virologically suppressed. A secondary analysis was conducted to identify associations with PROs (using the HIV Symptom Index), sleep quality and weight change at Week 48. We defined weight change as loss (≥3% decrease), neutral (±3%) and gain (≥3% increase). Using Rasch analysis with repeated measurements we examined the relationship between weight change as a function of symptoms and sleep quality.

**Results:** A total of 87 participants completed the study and were included in the analysis. Median age 55 (range 28 to 75); 97% male; 94% white, 5% black; 19% identified as Latinx. Weight change from baseline to Week 48 was 0.64 kg (95% CI −0.46 to 1.75, $p = 0.250$). Weight loss was seen in 15% of participants, 34% gained weight and 51% experienced no change. Initially, a numeric decline in PRO Rasch scores was seen with weight loss; however, differences disappeared longitudinally ($p = 0.240$) (Figure 1). Overall, there were no associations with weight change and PROs or sleep quality ($p > 0.05$ for all).

**Conclusions:** Switching virologically suppressed PLWH from EFV/FTC/TDF to BIC/FTC/TAF did not result in weight gain. There were no associations with weight change and changes in HIV-related symptoms or sleep quality, suggesting that symptomatic improvement or worsening did not contribute to either weight gain or loss.




**Abstract P077-Figure 1. Association between weight change and PRO Rasch scores.**

# P078

## Hepatic fibrosis in people with HIV and non-alcoholic fatty liver disease: baseline data from an open-label, feasibility randomised trial of maraviroc plus optimised background therapy (OBT) versus OBT alone

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**Background:** Although non-alcoholic fatty liver disease (NAFLD) is a major hepatic comorbidity in people with HIV, few therapies are available. CCR5 antagonism may reduce hepatic fibrosis progression and warrants further exploration.

**Materials and methods:** We conducted a 96-week, prospective, open-label, non-invasive, feasibility randomised trial of maraviroc + optimised background therapy (OBT) versus OBT in people with HIV-1 and NAFLD. Individuals were identified in seven UK HIV clinics. Inclusion criteria included steatosis on liver imaging or biopsy and HIV VL < 50 copies/mL. Exclusion criteria included cirrhosis (Fibroscan liver stiffness measurement (LSM) >13 kPa), ALT > 5 × ULN, other liver disease, alcohol excess (>26/>17 units/week in men/women respectively) and severe cardiovascular disease. Randomisation was in a 1:1 ratio and maraviroc was dosed according to SmPC recommendations. Primary endpoints include safety, recruitment and retention rates and adherence. Secondary outcomes include Fibroscan assessed LSM and controlled attenuation parameter (CAP) scores, and Enhanced Liver Fibrosis score. Baseline demographic and clinical characteristics are presented.

**Results:** Fifty-three individuals of a target of 60 were enrolled between July 2018 and January 2020; 23 received maraviroc; 89% male; median age 54 (IQR 47 to 60) years; 89% white (see Table 1). Median BMI was 30 (IQR 26 to 35) kg/m$^2$; 11%, 21% and 43% were receiving therapy for diabetes, hypertension or dyslipidaemia, respectively. Median CD4 count 702 (IQR 545 to 1035) cells/mm$^3$; cART was INSTI- , NNRTI- or PI-based in 53%, 32% and 15% respectively. Median ALT, AST and GGT levels were 44 (IQR 31 to 69), 32 (IQR 24 to 44) and 42 (IQR 30 to 72) IU/L respectively. Median fasting glucose was 5.2 (IQR 4.6 to 6.3) mmol/L, and HbA1c 38 (IQR 33 to 43) mmol/mol; fasting LDL, HDL cholesterol and triglyceride levels were 2.8 (IQR 2.1 to 3.3), 1.1 (IQR 0.9 to 1.3) and 1.7 (IQR 1.3 to 2.5) mmol/L respectively. Median LSM and CAP scores were 6.2 (IQR 4.6 to 7.8) kPa and 320 (IQR 267 to 347) dB/m respectively. For 12/53 (23%) individuals with F2 or F3 fibrosis (LSM ≥ 8 kPa), three (25%) had normal ALT, AST and GGT levels.

**Abstract P078-Table 1. Baseline characteristics of people with HIV and NAFLD**

| | OBT + maraviroc (N = 23) | | OBT (N = 30) | | Total (N = 53) | |
|---|---|---|---|---|---|---|
| | Med/n | IQR/% | Med/n | IQR/% | Med/n | IQR/% |
| Age, years | 51 | 38 to 59 | 55 | 49 to 61 | 54 | 47 to 60 |
| Male | 20 | 87 | 27 | 90 | 47 | 89 |
| Caucasian | 19 | 83 | 28 | 93 | 47 | 89 |
| BMI, kg/m$^2$ | 28 | 26 to 32 | 31 | 26 to 35 | 30 | 26 to 35 |
| Waist circumference, cm | 102 | 95 to 13 | 108 | 96 to 116 | 106 | 95 to 115 |
| Systolic blood pressure, mmHg | 129 | 124 to 136 | 132 | 121 to 141 | 130 | 123 to 140 |
| Receiving antihypertensive therapy | 4 | 17 | 7 | 23 | 11 | 21 |
| Receiving lipid lowering therapy | 9 | 39 | 14 | 47 | 23 | 43 |
| Receiving hypoglycaemic therapy | 2 | 9 | 4 | 13 | 6 | 11 |
| Duration HIV infection, years | 16 | 12 to 23 | 14 | 9 to 22 | 15 | 11 to 22 |
| CD4 cell count, cells/mm$^3$ | 702 | 546 to 1007 | 745 | 514 to 1055 | 702 | 545 to 1035 |
| HbA1c, mmol/mol | 38 | 32 to 42 | 39 | 35 to 45 | 38 | 33 to 43 |
| ALT, U/L | 45 | 31 to 62 | 44 | 29 to 69 | 44 | 31 to 69 |
| AST, U/L | 32 | 24 to 39 | 33 | 23 to 58 | 32 | 24 to 44 |
| GGT, U/L | 45 | 33 to 97 | 41 | 26 to 58 | 42 | 30 to 72 |
| Fasting glucose, mmol/L | 5.0 | 4.6 to 6.5 | 5.2 | 4.8 to 6.3 | 5.2 | 4.6 to 6.3 |
| Fasting LDL cholesterol, mmol/L | 2.8 | 2.3 to 3.3 | 2.8 | 1.8 to 3.1 | 2.8 | 2.1 to 3.3 |
| Fasting HDL cholesterol, mmol/L | 1.2 | 1.0 to 1.5 | 1.1 | 0.9 to 1.2 | 1.1 | 0.9 to 1.3 |
| Fasting triglycerides, mmol/L | 1.7 | 1.2 to 3.0 | 1.7 | 1.3 to 2.5 | 1.7 | 1.3 to 2.5 |
| Metabolic syndrome | 11 | 48 | 16 | 53 | 27 | 51 |
| Fibroscan median liver stiffness, kPa | 6.4 | 4.9 to 8.9 | 5.7 | 4.5 to 7.3 | 6.2 | 4.6 to 7.8 |
| Fibroscan CAP score, dB/m | 335 | 235 to 349 | 313 | 267 to 347 | 320 | 267 to 347 |
| NNRTI-based cART | 9 | 39 | 8 | 27 | 17 | 32 |
| INSTI-based cART | 10 | 43 | 18 | 60 | 28 | 53 |
| PI-based cART | 4 | 17 | 4 | 13 | 8 | 15 |
| Prior exposure to D drugs | 2 | 9 | 5 | 17 | 7 | 13 |

**Abstract P079-Table 1. Reasons for treatment and CPE-score changes**

| Reasons for treatment changes | N (%) | Mean CPE-score at baseline | Mean CPE-score at follow-up | Mean CPE-score changes from baseline to follow-up |
|---|---|---|---|---|
| Simplified treatment options | 153 (23.7) | 7.7 | 8.2 | 0.5 |
| Toxicity | 91 (14.1) | 7.4 | 8.0 | 0.6 |
| Comorbidities | 31 (4.8) | 7.8 | 7.9 | −0.1 |
| Treatment failure | 7 (1.1) | 7.7 | 9.6 | 1.9 |
| Neurological/neuropsychiatric side effects | 22 (3.4) | 7.5 | 7.4 | −0.1 |
| Enrolment in clinical trial | 9 (1.4) | 7.7 | 7.1 | −0.6 |
| Other/unknown | 20 (3.1) | 7.9 | 7.5 | −0.4 |
| No change | 311 (48.3) | 7.5 | 7.5 | 0 |
| Total | 644 (100) | 7.6 | 8.0 | 0.4 |

**Conclusions:** In this HIV/NAFLD cohort, 88% of the recruitment target was met. Almost one-quarter of participants had F2 or F3 liver fibrosis, including individuals with normal liver function. The feasibility of adding maraviroc as a potential therapy for NAFLD is being assessed over 96 weeks.

# P079

## The Neurocognitive Assessment in the Metabolic and Aging Cohort (NAMACO) study: central nervous system penetration effectiveness (CPE) score evolution from baseline to 2-year follow-up

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**Background:** We previously reported a non-association between CPE-score and neurocognitive impairment (NCI) among patients enrolled in the NAMACO study at baseline [1]. In the current study, we examined the evolution of the CPE-score over two years from baseline, and factors associated with CPE-score changes.

**Methods and materials:** The NAMACO study is an ongoing prospective, longitudinal, multicentre and multilingual study embedded within the Swiss HIV Cohort Study in which patient participants undergo neuropsychological assessment at baseline, two years and four years. For this analysis, cross-sectional CPE-score and CPE-score changes were examined at baseline and 2-year follow-up (N = 644). NCI was diagnosed using Frascati criteria [2]. Neurocognitive complaints were assessed using EACS screening questions [2]. Univariable and multivariable linear regression models were used to assess associations between ART changes and neurocognitive performance, based on annualised mean z-score changes from baseline to follow-up.

**Results:** Between baseline and 2-year follow-up, 333 patients (51.71%) changed ART. Table 1 shows reasons for treatment and CPE-score changes. Of 82 patients (24.6%) taking efavirenz at baseline, seven (2.1%) remained on this treatment at follow-up. Dolutegravir treatment increased from 18 patients (5.4%) at baseline to 49 patients (14.7%) at follow-up. Mean CPE-score at baseline and follow-up was 7.7 and 8.2, respectively. Only 22 patients (3.4%) underwent ART change due to neurological or neuropsychiatric adverse effects: of these, 19 (86.4%) changed from efavirenz to other ART. Of note, only 27.3% of patients with neurological or neuropsychiatric adverse effects had NCI, and only 19.2% had neurocognitive complaints. Patients with ART changes were not associated with NCI (95% CI −0.02, 0.1, $p = 0.7$). However, an increase in CPE-score from baseline to follow-up was associated with a small improvement in neurocognitive performance at follow-up (95% CI 0.0007 to 0.01, $p = 0.032$), although this association disappeared in the presence of other covariables.

**Discussion:** In this patient population, CPE-score changes were not associated with the decision to increase CPE-score or with neuropsychological findings, but were related to the availability of new simplified ART regimes. Although CPE-score increases appeared to be associated with increased neurocognitive performance, changes in mean z-scores were very small.

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# Co-morbidities and Complications of Disease and/or Treatment: Neurological

## P080

### Clinical utility of β-amyloid PET imaging in people living with HIV with cognitive symptoms

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**Background:** Imaging with β-amyloid (Aβ) PET has the potential to aid the diagnosis of the cause of cognitive impairment affecting PLWH when neurodegenerative disorders are considered. We evaluated the clinical utility of [18F]Florbetaben (FBB) in PLWH with cognitive symptoms.
**Methods:** Imaging with FBB PET was performed in 20 patients with cognitive concerns about dementia. Neuropsychological testing, plasma neurofilament light protein, plasma Aβ40, Aβ42 and CSF Aβ42, tau and HIV RNA were obtained. FBB PET images were assessed visually by three readers blinded to the clinical diagnosis, and quantitatively by obtaining a composite cortical to cerebellar cortex standardised uptake value ratio (SUVR). FBB SUVR from 10 age-matched healthy controls were compared to SUVR of PLWH. The level of diagnostic confidence in the suspected imaging diagnosis by the memory clinic was estimated using a scale that ranged from 0 to 100.
**Results:** Most participants were male (90%) of white ethnicity (90%) with a median age (IQR) of 59 (43 to 79) years. Median CD4 count was 682 (74 to 1056). All patients were on cART with plasma and CSF HIV RNA < 40 copies/mL. Fourteen patients had objective cognitive impairment including two who met clinical criteria for a diagnosis of dementia (Table 1). No significant differences in composite SUVRs between PLWH and controls [mean (SD): 1.18 (0.03) vs 1.16 (0.09); $p = 0.37$] were observed. Four patients were FBB+ with the highest SUVR in the posterior cingulate, superior temporal and frontal superior lobe. Overall mean confidence levels (SD) in aetiological diagnosis as a result of FBB imaging increased from 83% to 90% ($p = 0.074$). This effect was mainly driven by a FBB positive scan (from 75% to 95%; $p = 0.031$) compared to a FBB negative scan (from 85% to 89%; $p = 0.39$). Amyloid PET results contributed to a change in diagnosis and treatment for 10 patients.
**Conclusion:** [18F]Florbetaben PET has potential as an adjunctive tool in the diagnosis of PLWH with cognitive impairment, increasing diagnostic certainty and optimising management.

## P081

### CNS HIV viral escape syndrome presenting with persistent HIV viremia

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**Background:** A 54-year-old male was diagnosed with HIV in March 2018 with an initial viral load of 333 692 copies/mL and a CD4 count of 9 (1.8%). He had concurrent pneumocystis pneumonia (PCP), cytomegalovirus (CMV) retinitis, esophageal candidiasis and disseminated *Mycobacterium avium* complex infections at the time of diagnosis, which were all appropriately treated. Antiretroviral therapy was initiated on April 24, 2018 with emtricitabine/tenofovir alafenamide (TAF) and dolutegravir. Despite initial standard ART and an HIV genotype indicating susceptibility to this regimen, he failed to achieve virologic suppression. Over time, his ARV regimen was intensified to include drugs from four classes (tenofovir disoproxil fumarate/emtricitabine, dolutegravir, ritonavir boosted darunavir and doravirine at standard dosing). Adherence was confirmed. HIV genotype resistance testing was done on multiple occasions which failed to show treatment-emergent resistance. Therapeutic drug monitoring was also done on different occasions which showed adequate serum concentrations of his ART components during this time.
**Materials and methods:** Despite these efforts, after 20 months of ongoing antiretroviral therapy, the patient was unable to achieve virologic suppression with peripheral HIV viral loads remaining between 100 and 1000 copies/mL. Following the development of new neurocognitive changes, a lumbar puncture was performed. The CSF HIV viral load was 182 000 copies/mL compared to 464 copies/mL in his peripheral blood. This led to the consideration of CNS HIV viral escape syndrome with resultant HIV encephalitis. His MRI also suggested possible Marchiafava-Bignami disease. HIV genotyping was

**Abstract P080-Table 1. Individual clinical characteristics and biomarkers for FBB+ patients**

| Age (years) | Gender | Clinical diagnosis | Composite SUVR | Visual PET diagnosis | Plasma Aβ42/Aβ40 ratio | CSF Aβ40/tau ratio | NFL (Pg/mL) | Other imaging |
|---|---|---|---|---|---|---|---|---|
| 60 | Female | Mild cognitive impairment | 1.31 | Positive | 0.062 | 1.79 | 7.2 | Brain MRI: cortical white matter hyperintensities |
| 79 | Male | Mild cognitive impairment | 1.81 | Positive | 0.065 | 1.53 | 24 | Brain MRI: age-related cortical atrophy |
| 68 | Male | Dementia suspected AD | 1.41 | Positive | 0.05 | 0.98 | 9.4 | Brain MRI: cortical atrophy FDG-PET/CT: posterior cortical hypometabolism |
| 62 | Male | Dementia suspected AD | 1.27 | Positive | 0.066 | 3.8 | 29 | MRI: amyloid angiopathy |

Aβ, amyloid beta; CSF, cerebrospinal fluid; NFL, neurofilament light; SUVR, standard uptake value ratio.

performed on the CSF and it was found to be fully susceptible to all agents.
**Results:** Following this, the patient's ART was intensified to one with a higher CNS penetration effectiveness (CPE) score, consisting of once-daily abacavir 600 mg/lamivudine 300 mg, dolutegravir 150 mg, maraviroc 300 mg, doravirine 100 mg and darunavir/ritonavir (1200 mg/100 mg). He showed improvement in his neurocognitive status on this regimen and his peripheral blood HIV viral load decreased to a nadir of 58 copies/mL and his repeat CSF HIV viral load dropped to 32 500 copies/mL.
**Discussion:** We believe that the persistent HIV viral replication in his CNS compartment, despite standard ART, led to a neurocognitive decline related to HIV encephalitis and led to an unsuppressed peripheral HIV viral load.

## P082

### Utility of Pittsburgh Sleep Quality Index (PSQI) in PLWH for assessment and monitoring of sleep disturbance in a community HIV clinic

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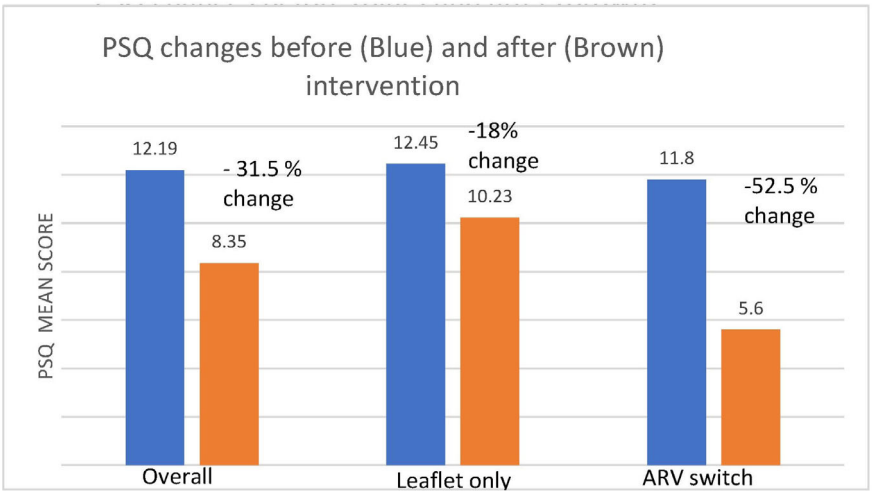
**Background:** Despite being virologically suppressed with CD4 counts >500 mm³, PLWH frequently complain of poor functional outcomes such as sleep disturbance. We therefore aimed to assess this in clinic, implement an intervention and re-assess to monitor subsequent changes.
**Materials and methods:** The PSQI is an established validated self-assessment tool covering seven sleep domains. A total composite score of ≥6 indicating a significant sleep disturbance. We used it to assess patients who were attending routine HIV monitoring clinic. Forty were selected for PSQI assessment of whom 37 (92.5%) scored ≥6 and were recruited for intervention of: a) all given sleep hygiene information leaflets; and b) ARV switch if indicated (40%). Participants were re-assessed using PSQI at least a month following intervention and compared to pre-intervention score. Mean total scores were used to compare with unpaired t test for statistical significance.
**Results:** Baseline - mean CD4-960 mm³, undetectable V/L < 200 to 92%. Total mean PSQ score was 12.0, with no significant difference for gender, race, or duration of HIV. There was a trend for age < 50 (PSQ- 12.9) versus ≥ 50 (PSQ-9) to have greater sleep disturbance. Recent STI (PSQ-13.5 vs 12) and recreational drugs misuse (13.6 vs 11.8) both had trend for higher PSQ. Mental health issues were reported in 60% of cohort with significantly higher PSQ (13.45 vs 9.6) and for antidepressants/psychotropic drugs (14.82 vs 10.45) than without. ARVs at baseline: INIs-67.5%, NNRTIs-30% and PIs-2.5%. There was no PSQ difference between INI and non-INI regimens. However dolutegravir scores (12.6 vs 9.8) were significantly greater than other INIs. Post intervention results (Figure 1).
**Conclusions:** PSQI appears to be an effective assessment tool for sleep disturbance and simple to conduct in clinic setting. Mental health issues were found to be both prevalent in this highly selected cohort and associated with significantly greater sleep disturbance compared to those without. A package of intervention including sleep hygiene information, together with ARV switch if appropriate, significantly improved sleep disturbance, including those with a mental health history. Sleep disturbance assessment should be considered in routine clinical practice and is in keeping with the UNAID fourth 90%.

## P083

### Neuropsychiatric, clinical and laboratory changes in patients prospectively switching from elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide to bictegravir/emtricitabine/tenofovir alafenamide

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**Background:** In recent years, data from various cohorts have raised concerns about the safety of integrase strand transfer inhibitors (INSTI) in clinical practice, especially in relation to the appearance of specific adverse events such as neuropsychiatric (NP) symptoms. NP adverse events leading to discontinuation were more often reported in real-life data than in clinical trials. Weight gain on INSTI (mainly second-generation compounds) is also a matter of concern. We report NP, clinical and laboratory changes in patients switching from elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (EVG/Cobi/FTC/TAF) to bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in clinical practice.




**Abstract P082-Figure 1. Mean PSQI changes following intervention for overall (sleep hygiene leaflets plus ARV switch), sleep hygiene leaflet(s) only and ARV switch n = 3.**

**Materials and methods:** All subjects switching from EVG/Cobi/FTC/TAF to BIC/FTC/TAF from June 2019 to September 2019, in a single centre, were prospectively followed. A validated sleep quality questionnaire [Pittsburgh Sleep Quality Index (PSQI)] as well as the Hospital Anxiety and Depression Scale (HADS) were administered after four weeks from treatment switch. Adverse events, side effects and discontinuation were recorded at Weeks 4 and 24. Pre-treatment switch and Week 24 body weight and laboratory data were compared.
**Results:** A total of 96 virologically suppressed patients (86% male) were included. All patients received EVG/Cobi/FTC/TAF at least one year before treatment switch. Median (IQR) nadir CD4 was: 367 (263). Most common comorbidities were dyslipidaemia, HTA and diabetes: 26%, 14% and 7%, respectively. Depression was reported by 8%. Five patients discontinued BIC/FTC/TAF before Week 4 due to intolerance (two insomnia, one headache and two GI symptoms). No changes in sleep quality, anxiety and depression outcomes were observed at Week 4 ($p = 0.5$ and $p = 0.6$, respectively). After six months, median body weight change was not statistically significant ($p = 0.2$). All patients maintained HIV suppression. Median CD4 count increased in 78 cells/mm$^3$. Median eGFR decreased significantly (−5 mL/min $p = 0.08$) as well as triglycerides and total cholesterol (−0.1 mmol/L; $p = 0.02$ and −0.3 mmol/L; $p < 0.001$).
**Conclusions:** Except in a few patients, treatment switch from EVG/Cobi/FTC/TAF to BIC/FTC/TAF was not associated with poorer sleep outcomes. Anxiety and depression remained unchanged. BIC/FTC/TAF did not affect body weight in this short period of time and seems to present a more favourable lipids profile.

## P084

### Perception of Spanish HIV physicians towards diagnosis and management of neuropsychiatric comorbidities in people with HIV

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**Background:** The degree of compliance of clinical guidelines recommendations for diagnosing and managing of neuropsychiatric comorbidities (NPC) in PWH is unknown in our setting.
**Materials and methods:** First, we designed and validated a structured and validated 20-minutes interview for HIV physicians to evaluate compliance of clinical recommendations for diagnosing and managing NPC in PWH and identify gaps for improvement. This interview was completed by March 2020 by a geographically representative sample of Spanish HIV physicians. Through closed questions physicians were asked about a) how they perceive the impact of NPC, b) their ability to identify NPC, c) thoughts on initial management should be and d) knowledge of neuropsychiatric disorders.
**Results:** One hundred and fifteen Spanish HIV physicians completed the survey (female 40%, mean age: 53, median number of patients attended: 125) with a mean time of 20 years taking care of PWH. Respondents estimated that up to 50% of their patients had NPC, mainly emotional (47%), sleep (35%) and substance use (9%) disorders, but less than half reported actively these comorbidities. Almost all physicians (97%) considered important to diagnose NPC because their impact on adherence and ART selection. However, 41% did not routinely interview for NPC, 79% did not use any screening tool and only 23% of them followed clinical guidelines for diagnosing NPC. Most physicians (80%) recognised that 1) NPC were underdiagnosed, mainly due to lack of proactive screening strategies (46% reported lack of diagnostic tools), time during visits and specific training in neuropsychiatric skills, and 2) that detection need to be improved (92%). Finally, most physicians believed that some antiretrovirals, mainly efavirenz (85%) and dolutegravir (89%), and HIV itself (65%) may induce NPC or worsened preexisting ones. Therefore, up to 85% considered the potential ART-related neurotoxicity as an important factor when selecting ART.
**Conclusions:** HIV physicians reported low compliance of recommendations for diagnosing NPC in PWH, mainly due to lack of time, personal skills, appropriate diagnostic tools; but high compliance of recommendations for avoiding and managing ART-related neurotoxicity. Based on the results of this survey, training diagnosis NPC in PWH, as well as the use of effective screening tools, would be useful to improve the diagnosis of NPC in PWH.

# Co-morbidities and Complications of Disease and/or Treatment: Other

## P085

### Important factors related to the sexual quality of life among men living with HIV/AIDS

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**Objective:** The high prevalence of sexual difficulties among PLWH implies the importance of evaluating the different dimensions of sexual quality of life (SQoL) among them. The objective of this study was to determine the factors associated with SQoL and to establish the prevalence of sexual dysfunction amongst HIV-positive men.
**Methods:** We conducted a cross-sectional study in HIV centres in five countries (France, Australia, Brazil, USA and Canada) among HIV-positive men. Data related to physical and mental health status and HIV parameters were self-reported. *Main outcome measure:* SQoL was assessed with PROQOL-SexLife questionnaire through six dimensions: positive sexual perception (Pop), sexual dysfunction (Dys), stigma/fear (Sti), sexual practices with partner (Par), soft sexual practices (Sof) and drug consumption (DRG). PROQOL-SexLife dimensions are scored from 0 (best) to 100 (impaired). A linear mixed model was adapted to explore the relationship between explanatory variables (sociodemographic variables, general health status, HIV biological related factors, HIV treatment) and values of PROQOL-SexLife dimension, by treating countries as random effects.
**Results:** One hundred and seven heterosexual men and 474 MSM were included (Australia: 109; Brazil: 139; Canada: 77; France: 192; USA: 64). Amongst MSM, SQoL was associated with being in relationship, health care satisfaction in Pop dimension, while in Sti dimension the relevant factors were condom usage and cardiovascular complication. Using Viagra and anti-cholesterol treatment were significant in Dys dimension. Amongst heterosexual men, unemployment, African ethnicity in Pop dimension and preoccupation in Sti and Dys dimension were found relevant. Mental health related variables such as depression or feeling hopeless during the last four weeks were associated with negative outcomes of SQoL between both populations in these three dimensions. Type of HIV treatment was not significant in any of the PROQOL-SexLife dimensions.
**Conclusion:** The considerable presence of psychological/stress-related factors and the absence of HIV-related biological parameters (CD4,

viral load, HIV stage), our study emphasises the necessity to understand factors beyond clinical ones to have comprehensive vision of elements determining SQoL.

## P086

### Meeting the fourth 90: evaluating the mental health of an urban population of people living with HIV in a Greater London clinic

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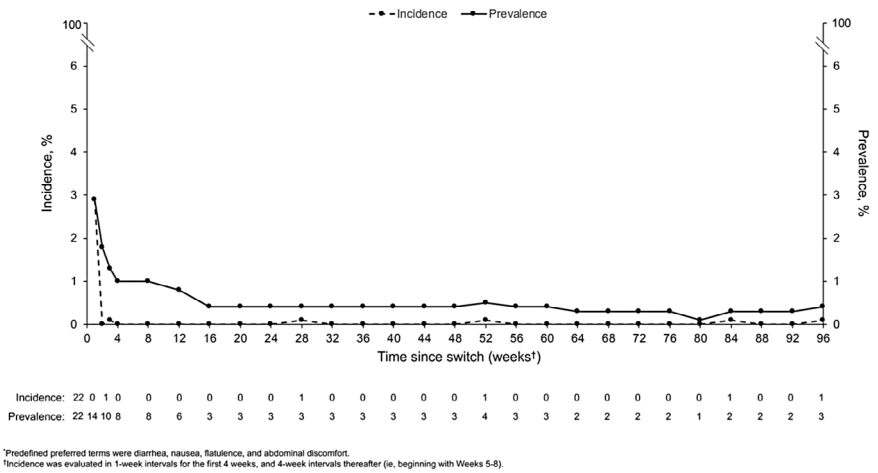
**Background:** Looking beyond achieving an undetectable viral load as the goal of therapy has been iterated in recent international targets for HIV management: the so-called 'fourth 90' encompassing working towards a better quality of life for PLWH. It is well documented that PLWH, especially women, have a disproportionate burden of mental health problems and improving the identification and treatment of mental health problems in PLWH has been identified as a priority. Annual screening for mental health problems is recommended by the British HIV Association Standards of Care 2018. We prospectively studied and evaluated mental health problems in a Greater London HIV clinic using validated self-report questionnaires.
**Methods:** Clinic attenders at Croydon University Hospital from June 2019 to January 2020 were asked to complete the Insomnia Severity Index (ISI), Generalised Anxiety Disorder Assessment (GAD-7) and Patient Health Questionnaire 9 (PHQ9). Scores were recorded along with patient demographics, drug history and social behaviours.
**Results:** Of the 265 clinic attenders over the period, 135 (51%) identified as black African, 29 (11%) as black Caribbean and 131 (51%) were women. Eighty-six (33%) of the 258 who completed the questionnaires had scores consistent with at least moderate depression, with 50 (19%) scoring for severe depression. Thirty-nine (15%) patients had scores consistent with clinical insomnia; of these eight (21%) were on efavirenz. Ninety-two (36%) scored for at least moderate anxiety with 46 (18%) scoring for moderately-severe anxiety; of these 13 (28%) were on efavirenz. Ethnicity, gender and drug and alcohol use was also compared between the groups.
**Conclusions:** High rates of depression and anxiety were identified reflecting the challenges in achieving good emotional health to meet the 'fourth 90' target in this population. Routine screening using mental health questionnaires was found to be feasible and acceptable to patients. Where specific antiretroviral agents were thought to be contributing to poor mental health these patients were offered alternative therapies where appropriate. Further investigation into existing services is ongoing to identify unmet needs and look into opportunities to improve support with psychiatric interventions to improve emotional wellbeing.

## P087

### Gastrointestinal (GI) adverse events with darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) through Week 96: an EMERALD post-hoc analysis

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**Background:** GI intolerance has been associated with ritonavir boosted protease inhibitors (bPIs). Tolerability is an important consideration for virologically suppressed patients who switch regimens for simplification or pre-existing tolerability issues. A post-hoc analysis was conducted to assess GI tolerability in patients switched to D/C/F/TAF.
**Materials and methods:** The phase III EMERALD trial (ClinicalTrials.gov: NCT02269917) randomized (2:1) virologically suppressed patients to switch to D/C/F/TAF 800/150/200/10 mg or continue their current bPI regimen. This post-hoc analysis assessed the incidence, prevalence, and duration of GI adverse events of interest (AEOIs) through Week 96. Using MedDRA v.21 preferred terms, related GI AEOIs were defined as diarrhea, nausea, abdominal discomfort, and flatulence assessed by the investigator to be very likely, probable, or possibly related to study drug. Incidence and prevalence were evaluated at weekly intervals during the first month and monthly thereafter. Percentage of patients receiving a concomitant medication for treatment of a GI AEOI was assessed. For patients whose AEs had start and stop dates, duration of the AE was calculated.
**Results:** In EMERALD (N = 1141), 763 patients were randomized to D/C/F/TAF (Table 1). Through both Weeks 48 and 96, 3% of patients had a D/C/F/TAF-related GI AEOI; all were Grade 1/2 and none were serious. Incidence and prevalence of D/C/F/TAF-related GI AEOIs remained low through Week 96 (Figure 1). Incidence of D/C/F/TAF-related diarrhea and nausea were both ≤2% in Week 1 and ≤0.1% after Week 2; prevalence of each was < 1% after Week 2. There was one case of D/C/F/TAF-related abdominal discomfort reported in Week 1 and none thereafter. Incidence of D/C/F/TAF-related flatulence was 0.4% at Week 1 and remained <0.1% through Week 96. Of




**Abstract P087-Figure 1. Incidence and prevalence of study drug–related GI AEOIs* over time among patients randomized to switch to D/C/F/TAF (n = 763).**

interest, one patient discontinued due to D/C/F/TAF-related diarrhea and one patient discontinued due to D/C/F/TAF-related abdominal pain. Through Week 96, <1% of patients required treatment with concomitant medication for a D/C/F/TAF-related GI AEOI. Among patients with a D/C/F/TAF-related GI AEOI, the median duration was 8.5 days.

**Abstract P087-Table 1. Baseline demographic and clinical characteristics**

| | D/C/F/TAF (n = 763) |
|---|---|
| Demographic | |
| Age, median (interquartile range), y | 46 (19 to 75) |
| Male, n (%) | 623 (82) |
| Race, n (%) | |
| White | 573 (75) |
| Black/African American | 155 (20) |
| Other | 35 (5) |
| Clinical | |
| $CD^{4+}$ cell count, median (interquartile range), cells/μL | 630 (468 to 806) |
| Boosted PI at screening, n (%) | |
| Darunavir | 537 (70) |
| Atazanavir | 167 (22) |
| Lopinavir | 59 (8) |

**Conclusions:** In EMERALD, incidences and prevalence of D/C/F/TAF-related GI AEOIs were low and tended to present within the first week. These findings, together with a rapid decrease in prevalence, suggest prompt resolution of these AEs.

# P088

## Prevalence of HIV-related stigma among participants of the Swiss HIV Cohort Study: a pilot study

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**Background:** HIV-related stigma presents a challenge to the health and well-being of PLWH. As a first step to address such stigma, we aimed to quantify its prevalence in Switzerland.
**Material and methods:** We conducted a pilot study at Lausanne University Hospital, Switzerland, between March and June 2020 using a validated 12-item HIV Stigma Scale [1]. This questionnaire examined personalised stigma, disclosure concerns, beliefs regarding public attitudes and negative self-image. Two questions were added regarding healthcare-related stigma. The Stigma Scale was translated and back-translated from English into French, German and Italian and completed electronically by the treating physician during a standard follow-up visit. Inability to speak one of the four available languages was the only exclusion criterion. Responses were graded using a 4-point Likert-type scale (strongly disagree, disagree, agree, and strongly agree) to give a score of 1 to 4 for each item (higher scores indicating higher stigma).
**Results:** Three hundred and fifty-one participants were included: 118 (34%) were women, median age was 51 years (IQR 42 to 59); 227 (65%) patients were from Europe; 93 (26%) from Africa. HIV acquisition mode was men having sex with men in 126 participants (36%), heterosexual in 177 (50%), other in 48 (14%). Median duration of HIV infection was 15.2 years (IQR 8 to 25). Disclosure concerns represented the highest stigma burden across all demographic subgroups (age, sex, origin, mode of HIV acquisition). The item 'I am very careful who I tell that I have HIV' had a positive answer (agree or strongly agree) in 89% of participants and the highest score (median 4; IQR 3 to 4). Personalised stigma was significantly higher in African patients ($p < 0.001$), as was health-care associated stigma ($p = 0.02$) (Table 1).
**Conclusions:** Stigma is prevalent in our study population across all demographic groups while stigma subtypes vary. This pilot study will be expanded into a multicentre cross-sectional study across Switzerland. Quantifying stigma and stigma subtypes is key in designing interventions and improving care for PLWH.

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# P089

## The prevalence of major comorbidities among people living with HIV in Croatia

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**Background:** The burden of HIV care is influenced by AIDS-related and non-AIDS-related comorbidities (NAIDSC). All PLWHIV in Croatia are treated at the University Hospital for Infectious Diseases (UHID) in Zagreb. The aim of our study was to provide national period prevalence data of major comorbidities in PLWHIV in Croatia in 2019.
**Materials and methods:** Included were Croatian citizens/residents ≥18 years who were seen at UHID in 2019 who ever had at least two visits >6 months apart. The following comorbidities were analysed: AIDS-defining diseases, myocardial infarction (MI), stroke,

**Abstract P088-Table 1. Stigma subtypes in different demographic subgroups**

| | Total score, median (IQR) | Personalised stigma, median (IQR) | Disclosure concerns, median (IQR) | Beliefs regarding public attitudes, median (IQR) | Negative self-image, median (IQR) | Healthcare-related stigma, median (IQR) |
|---|---|---|---|---|---|---|
| Africa (n = 93) | 35 (27 to 39) | 9 (3 to 12) | 11 (9 to 12) | 9 (6 to 11) | 5 (4 to 7) | 4 (2 to 5) |
| Americas (n = 17) | 29 (23 to 31) | 7 (3 to 8) | 9 (8 to 12) | 7 (6 to 8) | 6 (4 to 8) | 2 (2 to 4) |
| Asia (n = 14) | 31 (22 to 39) | 10 (3 to 12) | 10 (7 to 12) | 8 (6 to 11) | 5 (3 to 7) | 3 (2 to 4) |
| Europe (n = 227) | 29 (24 to 35) | 5 (3 to 10) | 10 (8 to 12) | 8 (6 to 9) | 5 (3 to 7) | 3 (2 to 5) |
| MSM (n = 126) | 28 (23 to 32) | 4 (3 to 8) | 9 (8 to 11) | 8 (6 to 9) | 5 (4 to 7) | 3 (2 to 5) |
| Heterosexual (n = 177) | 32 (25 to 37) | 7 (3 to 12) | 11 (9 to 12) | 8 (6 to 10) | 5 (3 to 7) | 3 (2 to 5) |
| IDU (n = 26) | 30 (23 to 36) | 6 (3 to 12) | 10 (7 to 11) | 8 (7 to 10) | 5 (3 to 6) | 4 (2 to 5) |

invasive cardiovascular procedures (ICPs), cancer both AIDS- (ADC) and non-AIDS-defining (NADC), end-stage liver disease (ESLD), end-stage renal disease (ESRD), bone fractures and diabetes mellitus. All major comorbidities were expressed as percentages of the total HIV population in care and those ≥50 years old.

**Results:** Of 1168 PLWHIV included into the study, 90.2% (1053/1168) were male, median age was 44.6 (Q1 to Q3: 37.6 to 53.5) with age ≥50 years in 405 (34.7%), main mode of transmission was sex between men (858, 73.5%) and heterosexual contact (239, 20.5%). Median age of those ≥50 was 56.5 years. The overall duration of HIV-1 infection was 7.5 (for those ≥50 years: 13.2) years, exposure to antiretrovirals was 6.4 (for those ≥50 years: 11.2) years. Chronic hepatitis B had 32 (2.7%) persons; hepatitis C antibodies were positive in 57 (4.9%) of whom 39 (68.4%) had an undetectable HCV viral load. Overall major NAIDSC (without skin cancer) were present in 175 (15.0%, 95% CI: 13.0 to 17.2; in those ≥50 years: N = 90, 22.2%) persons (Table 1). NAIDSC occurred after an HIV-diagnosis in 100 (8.6%) and 74 (18.3% of those ≥50 years old); the most frequent being diabetes followed by ICP, MI and NADC. Of NADC after an HIV-diagnosis Hodgkin's lymphoma was most frequent (n = 5). Fractures were predominantly traumatic and there were four cases of ESRD and no cases of ESDL. Clinical AIDS and ADC after HIV diagnosis occurred in 90 and 18 persons, respectively.

**Abstract P089-Table 1. The prevalence of major comorbidities in 1168 people living with HIV in Croatia in 2019 for the whole HIV population and those ≥50 years old**

| Major comorbidity | Total N = 1168 N (%, 95% CI) | Age ≥ 50 years N = 405 N (%, 95% CI) |
|---|---|---|
| Had an AIDS-defining condition previously | 276 (23.6, 21.2 to 26.2) | 137 (33.8, 29.3 to 38.7) |
| Myocardial infarction | 20 (1.7, 1.1 to 2.7) | 14 (3.5, 2.0 to 5.9) |
| Stroke | 16 (1.4, 0.8 to 2.3) | 10 (2.5, 1.3 to 4.6) |
| Invasive cardiovascular procedures | 23 (2.0, 1.3 to 3.0) | 16 (4.0, 2.4 to 6.5) |
| Cancer, total | 74 (6.3, 5.0 to 7.9) | 42 (10.4, 7.7 to 13.9) |
| ADC | 46 (3.9, 2.9 to 5.3) | 24 (5.9, 3.9 to 8.8) |
| NADC including skin carcinoma[a] | 31 (2.7, 1.8 to 3.8) | 30 (7.4, 5.1 to 10.5) |
| NADC excluding skin carcinoma | 25 (2.1, 1.4 to 3.2) | 15 (3.7, 2.2 to 6.2) |
| End-stage renal disease | 4 (0.3, 0.1 to 0.9) | 4 (1.0, 0.3 to 2.7) |
| Bone fractures, total | 22 (1.9, 1.2 to 2.9) | 18 (4.4, 2.7 to 7.1) |
| Bone fractures, traumatic | 21 (1.8, 1.1 to 2.8) | 17 (4.2, 2.5 to 6.8) |
| Bone fractures, traumatic, pathologic (including osteoporotic/fragility) | 1 (0.1, 0.0 to 0.6) | 1 (0.2, 0.0 to 1.6) |
| Diabetes mellitus | 44 (3.8, 2.8 to 5.1) | 36 (8.9, 6.4 to 12.2) |

ADC, AIDS-defining cancers; NADC, non-AIDS defining cancers.
[a]All skin malignancies were nonmelanoma cancers.

**Conclusions:** The overall prevalence of major clinical NAIDSC was 15.0% for the total HIV population and 22.2% for those ≥50 years old. The prevalence of individual major NAIDSC for the whole HIV population ranged from 0.0% to 3.8% with diabetes being the most frequent.

# P090

## Frailty prevalence in people living with HIV from three HIV clinics in Lisbon

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**Background:** Ageing with HIV increases the risk of HIV-associated non-AIDS-defining conditions [1]. Studies have demonstrated HIV patients have a heightened burden of frailty [2,3] – a clinical condition characterised by functional decline and reduced capacity for daily activities [4]. This study aimed to evaluate the prevalence of frailty and pre-frailty in a cohort of people living with HIV in Lisbon.

**Materials and methods:** We performed a transversal observational multicentric study including randomly selected PLWH, older than 40 years, evaluated at three clinics in Lisbon, from October 2018 to December 2019, with a follow-up longer than six months and who provided informed consent. Frailty was assessed using Fried Frailty Phenotype (FFP) scale and Short Physical Performance Battery functional evaluation. The primary outcome (frailty and pre-frailty's prevalence) was expressed by frequencies of frailty with a 95% confidence interval. For the comparisons on the secondary outcomes (association of patients' characteristics and frailty) all statistical analyses were done for a significance level of 0.05.

**Results:** The study included 200 patients, 60% males, median age 53 (40 to 87) years, 92% HIV-1, 76% on triple therapy, 34% hypertensive, 22% smokers, 21% obese and 10% diabetic. The prevalence of frailty was 15% [10.4% to 20.7%]. The most affected FFP domains were low resistance/exhaustion (90%), weakness [hand grip] (90%) and low physical activity (83%). Frailty presented a direct significant relation with gender ($p = 0.015$), age ($p = 0.045$), marital status ($p = 0.036$), stroke ($p = 0.011$), hypertension ($p = 0.045$), diabetes ($p = 0.001$), metabolic syndrome (0.024), falls ($p = 0.024$) and HIV type ($p = 0.030$). The prevalence of pre-frailty was 57% [50% to 64%] and the most affected FFP domain was low physical activity (52%). Pre-frailty had a significant association with migrant status ($p = 0.040$), obesity ($p = 0.013$), smoking ($p = 0.041$) and HBV coinfection ($p = 0.043$).

**Conclusion:** Frailty and pre-frailty were very prevalent in our population, the latter to a greater extent, presenting significant association with several patients' characteristics. Lack of physical activity was identified as one of the most relevant domains for both conditions. Identifying these modifiable factors may provide targets for medical interventions aimed at tackling frailty and pre-frailty in PLWH.

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# P091

## Importance of screening for depression in people living with HIV in Ukraine

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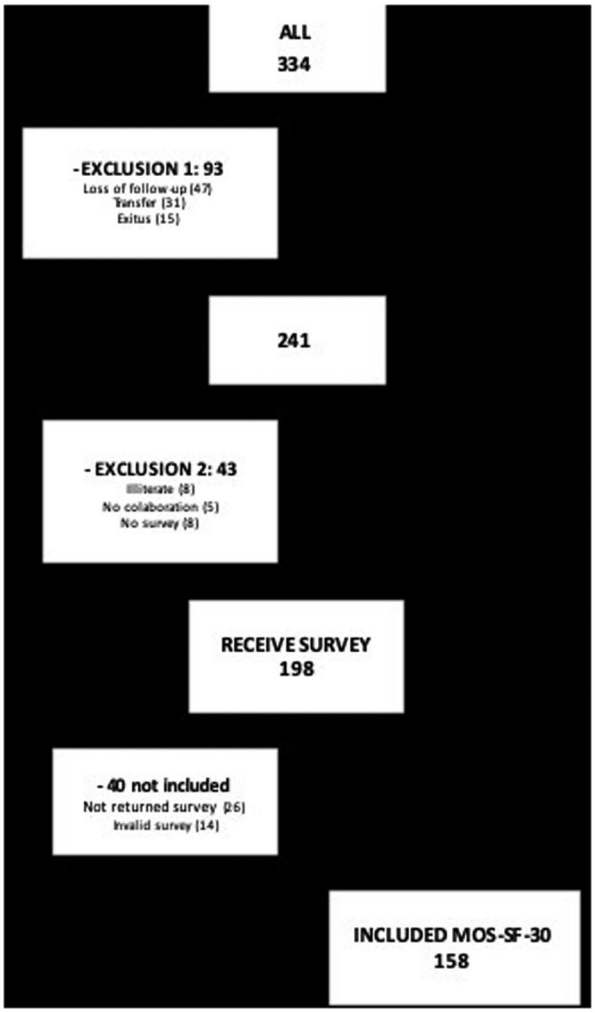
**Background:** PLHIV are more likely to have depression, impacting quality of life, retention in care, and possibly impairing health outcomes. In Ukraine, routine depression screening for PLHIV is not widely used and mental care initiatives for PLHIV are rare.
**Materials and methods:** A cohort of 976 HIV-positive patients with positive depression screening result was studied between May 2018 and August 2019 to investigate distribution of depression. Patients were screened for anxiety and depression and were referred to psychiatrist. Univariate and bivariate analysis were performed. Logistics regression was used to assess odds of patients being injecting drug users and having delayed ART initiation (≥1 year).
**Results:** Of 976 people, 355 (36.4%) were diagnosed with depression, 287 (29.4%) had no data on diagnosis. Of those with depression, 86 (24.2%) received no related treatment. There was no significant gender difference after screening (female 45.9% and men 54.1%)—though after psychiatric diagnoses, more women were depressed (62%, $p < 0.0001$). Among people with positive depression screening result who were referred to psychiatrist, 19.9% did not have access to proper consultation and also had unavailable CD4 ($p < 0.0001$). People using drugs had higher odds (OR 1.351, CI 1.040 to 1.755) of delayed ART. Most patients who underwent depression screening are on ART (82.61%). Thirty-one patients with depression and VL > 1000 were selected for follow-up on treatment response one year after depression treatment. Of 31 people, 20 had suppressed VL to <1000 by August 2019.
**Conclusions:** Results underline the need to support early ART initiation for PLHIV with mental disorders and addiction in Ukraine, where attention towards the issue is currently low. Focus should be placed on training and motivating medical personnel on depression screening in routine HIV care in Ukraine with a focus on PLHIV who delay treatment initiation.

# P092

## Analysis of adherence to HIV-positive quality of care indicators and their impact on health-related quality of life: a Spanish cross-sectional study

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**Background:** Medical care must be effective and meet quality requirements from a professional knowledge but must also be perceived as beneficial by the patient. The objective of this work was to assess the degree of compliance with the current quality of care indicators and check whether their adherence improves the health-related quality of life (HRQL) perceived by the patient, in a Spanish cohort of HIV patients.
**Materials and methods:** All HIV patients attended in a Spanish hospital between 2011 and 2017 were included for compliance with HIV quality indicators proposed by *GeSIDA* (Spanish AIDS Study Group) [1]. HRQL was evaluated using the Medical Outcomes Study Survey-Short Form questionnaire of 30 items (MOS-SF-30). It provides a score from 0 to 100, with 0 being the lowest grade of HRQL and 100 the highest [2]. The questionnaire was given between February and November 2017 to those who signed the informed consent.
**Results:** In the indicator analysis 334 patients were included, whose compliance was high: of the 47 indicators evaluated, 35 met the established standard (74.46%). Reminders have been implanted in the clinical history to improve some indicators whose compliance is suboptimal. The HRQL of 158 patients was assessed: 93 were excluded for loss of follow-up, transfer or decease, 43 for illiteracy or declined to participate. Of the 198 surveys delivered, 26 were not returned, and 14 were invalid (Figure 1). The mean score of the MOS-SF-30 was 68.2 (95% CI 65.1 to 71.3). Only compliance with two of the 47 indicators evaluated was related to an increase in HRQL (Table 1): *13-Health education in the initial assessment* and *17-Basic renal study in HIV patients*. Compliance with indicator *26-Evaluation of alcohol intake* is associated with a worse HRQL. The association between harmful alcohol consumption and worse HRQL is known in the HIV population [3].
**Conclusions:** Compliance with the quality indicators showed little relationship with the HRQL reported by the patients. Achieving the classic health goals does not imply meeting the patient's expectations or improving their HRQL. It is necessary to analyse our clinical practice in the care of HIV patients to identify areas of improvement in medical care and improve their HRQL.




**Abstract P092-Figure 1. Study outline.**

**Abstract P092-Table 1. Univariate analysis of quality indicators related to HRQL**

| Number | Indicator | Mean difference CI 95% |
|---|---|---|
| 6 | Delay in referral to specialised care | −10.15 (−29.98, 9.68) |
| 7 | Late diagnosis of HIV in specialised care | −5.07 (−14.61, 4.46) |
| 8 | HIV diagnosis with previous negative serology | 1.01 (−7.77, 9.80) |
| 10 | Complementary tests in the initial assessment | −1.49 (−24.25, 21.28) |
| 11 | HIV plasma viral load | – |
| 12 | Determination of lymphocyte subpopulations (CD4) | – |
| 13 | Health education at initial assessment | 10.57 (4.35, 16.80)[a] |
| 15 | Indication of treatment with <350 CD4 and without prior ART | – |
| 16 | Periodicity of visits (regular follow-up) | 7.30 (−3.58, 18.19) |
| 17 | Basic renal study in HIV+ patients | 37.36 (−0.85, 75.57)[a] |
| 20 | Latent tuberculosis infection detection | 5.61 (−1.66, 12.87) |
| 21 | Vaccination against hepatitis A | 9.60 (−17.33, 36.52) |
| 22 | Vaccination against hepatitis B | −0.17 (−26.97, 26.63) |
| 23 | Vaccination against pneumococcal infection | 9.51 (−4.75, 23.77) |
| 24 | Prophylaxis against Pneumocystis jirovecii and Toxoplasma | −5.38 (−47.42, 36.66) |
| 25 | Treatment and prevention of smoking | 3.30 (−8.84, 15.43) |
| 26 | Alcohol intake assessment | −18.06 (−34.04, −2.08)[a] |
| 29 | Syphilis screening | 3.93 (−3.08, 10.95) |
| 30 | Latent tuberculosis infection treatment | −2.31 (−42.04, 37.42) |
| 31 | Loss to follow-up | – |
| 35 | Adaptation of initial ART to the guidelines | – |
| 36 | Initiation of ART in patients with symptomatic B/C events | – |
| 37 | First visit after the establishment of ART | −8.85 (−24.87, 7.17) |
| 38 | Undetectable viral load (<50 copies/mL) at Week 48 | −1.30 (−37.26, 34.65) |
| 39 | Treatment with abacavir (ABC) without previous HLA-B 5701 | – |
| 40 | Treatment changes during the first year | −8.63 (−22.11, 4.84) |
| 41 | Record of adherence to treatment | −8.91 (−19.12, 1.30) |
| 42 | Study of resistance in case of virological failure | 14.60 (−15.28, 44.48) |
| 44 | Average expenditure per patient in first treatment | – |
| 45 | ART in pregnant women with HIV | – |
| 47 | Vertical transmission incidence | – |
| 49 | Evaluation by CHILD or MELD for chronic liver disease | 11.33 (−53.32, 75.98) |
| 50 | Evaluation of hepatitis C virus coinfection | – |
| 54 | HBsAg patients receiving effective treatment | – |
| 55 | Ultrasound control in cirrhotic patients | 11.00 (−275.10, 297.10) |
| 56 | Cardiovascular risk assessment | 3.20 (−3.57, 9.96) |

[a]$p < 0.05$.

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# P093

## Real-world characterisation of the Portuguese population living with HIV who initiated raltegravir-based regimen between 2015 and 2017 - REALITY study

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**Background:** Raltegravir (RAL) was approved as the first integrase inhibitor for the treatment of HIV-1. Although there is large amount of evidence regarding its effectiveness and safety, there is still a lack of data on the characterisation of Portuguese HIV-infected population under RAL. This work aims at characterising patients, in Portugal, who

started RAL therapy between January 2015 and December 2017, and compare those who continued versus discontinued RAL regimens at inclusion visit.
**Methods:** Non-interventional retrospective study conducted in 11 Portuguese sites. Data were collected through analysis of clinical files and an HIVTSQs® (range 0 to 60, the higher the score, the greater satisfaction on treatment).
**Results:** A total of 302 patients were recruited between July 2018 and April 2019, with mean age of 49 years, mostly men (70%) of Portuguese nationality (83%), infected via heterosexual transmission (58%). The median duration in RAL was 2.1 years. At baseline (RAL start date), 34.1% patients were treatment naïve, whereas 65.9% of patients were treatment experienced. Of these, 52.3% received up to 2 treatments (median) before RAL. The most frequent previous regimens were PI (50.8%) and NNRTI (40.2%). At baseline, 53.3% had non-AIDS-related comorbidities (median of 2), the most reported being hypercholesterolaemia (44.1%), arterial hypertension (42.2%), diabetes mellitus and depression (each 17.4%). 17.1% patients were coinfected with HCV and/or HBV. The mean $TCD^{4+}$ cell value was 530.2 cells/μL and 49% of patients had detectable viral load. At study inclusion, 80.8% of patients were on RAL. Their average total satisfaction score was 55.4 points. The proportion of patients with any non-AIDS related comorbidity at baseline was higher for RAL-continuing users (56.6%) compared to RAL non-continuing patients (39.7%; $p = 0.0204$). No statistically significant differences were observed between the two groups (RAL-continuing vs RAL non-continuing) regarding prevalence of each comorbidity at baseline and the median values of $TCD^{4+}$ and viral load at baseline. At last measurement, 97.5% (n = 238) of RAL-continuing users were suppressed. Within these patients, when comparing RAL treatment-naïve group versus RAL treatment-experienced, 96.3% (n = 78) and 98.2% (n = 160) were suppressed, respectively.
**Conclusion:** REALITY study confirms the clinical utility of RAL-based regimens as revealed by RAL-user satisfaction scores and effectiveness.

# Viral Hepatitis

## P094

### Phylodynamics of sexually acquired HCV-3a in HIV co-infected patients in Hong Kong

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**Background:** Previous studies showed that HCV transmission in Hong Kong was mainly driven by the continued subtype 3a outbreaks in HIV-positive MSM after HIV infection. A study was conducted to examine the origin and transmission dynamics of this outbreak.
**Materials and methods:** HCV NS5B sequences (nucleotides: 8348 to 8658) were collected from the largest HIV specialist clinic in Hong Kong where over half of all diagnosed patients received clinical care. After subtyping by Oxford HCV Subtyping Tool, all sequences assigned with subtype 3a were selected for subsequent analyses. A phylogenetic tree was constructed by maximum likelihood method using generalised time-reversible substitution model incorporating proportion of invariable sites and rate of variation across sites with 1000 bootstraps. Bayesian phylodynamic approach was applied and Bayesian coalescent skyline analysis was conducted by BEAST2 using uncorrelated lognormal relaxed molecular clock with Markov Chain Monte Carlo (MCMC) chain length of 100 000 000 and 10% burn-in to determine time of introduction and its population dynamics.
**Results:** Between 2013 and June 2019, a total of 93 HCV sequences were collected from HIV patients, 64 of which were of subtype 3a and therefore analysed. Seventeen of the 3a sequences were identical, forming a closely knit network. From the phylogenetic tree, no distinct transmission clusters could be identified within the 3a network. Phylodynamic analysis revealed that the date of most recent common ancestor was 2011.2 (95% highest posterior density interval: 2008.9 to 2012.8). Bayesian skyline plot illustrates that the effective population size of HCV-3a has increased between early 2014 and late 2016, but the rise in 2015 was less steep. A constant effective population size was maintained after 2017.
**Conclusions:** The HCV-3a epidemic in HIV-positive MSM population was introduced a decade ago. The spread of HCV-3a could be characterised by two growth periods in 2014 and 2016 respectively. The reason for the decrease in transmission rate or increase in the number of infections during the two periods required further investigation.

## P095

### Efficacy, safety and convenience of integrase strand transfer inhibitors-based ART regimens in people living with HIV coinfected with hepatitis C and/or B viruses

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**Background:** Limited studies exist to describe the performance outcomes of integrase strand transfer inhibitors (INSTI) among PLWH by their hepatitis coinfection status. The purpose of this study was to compare the efficacy, safety and convenience of INSTI-based ART regimens in a large cohort of PLWH by hepatitis infection status (coinfected vs not) using survival analysis.
**Material and methods:** We used data from 4942 subjects (of which 1709 coinfected with hepatitis viruses) enrolled in the Italian MaSTER cohort which systematically collects data at three time points (baseline, six and twelve months). The patients were categorised by hepatitis infection status, ART status (naives vs experienced) and regimens (three- or two-drug regimen). Three different metrics were used to study ART interruptions: efficacy, defined as interruption due to inability to achieve or maintain viral suppression; safety, defined as interruption linked to laboratory alterations and/or clinical progression; and convenience, defined as absence of HIV RNA above 50 copies/mL and no laboratory alterations and/or clinical progression. Cox proportional hazards regression models were fitted to associate sociodemographic and clinical factors with performance outcomes stratified by hepatitis status.
**Results:** In the analysis of ART interruption due to efficacy or safety concerns, the hazards were higher among individuals with injection drug use (IDU) risk compared to individuals with heterosexual (HET) risk and for ART naives versus experienced individuals. In the analysis of ART interruptions due to inconvenience, higher hazards were

observed among MSM compared to HET individuals and persons with three-drug regimens (3DR) compared to two-drug regimens (2DR). Additionally PLWH coinfected with HBV had higher hazards of treatment interruption (HR 2.75; CI 1.13 to 6.71), whereas PLWH with HCV had lower hazards of treatment interruption due to convenience (HR 0.77; CI 0.67 to 0.88).
**Conclusions:** To our knowledge, this was the first study to investigate the performance outcomes of INSTI-based ART regimens by hepatitis status. We observed different hazards of treatment interruption by hepatitis status. These results warrant further research on this topic.

## P096

### Hepatitis C infection and treatment outcomes in the direct-acting antiviral era

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**Background:** HCV infection remains a significant public health concern in the United Kingdom. With improved access to direct-acting antiviral (DAA) therapy from 2016, HCV elimination should be achievable.
**Methods:** A retrospective case note review of patients diagnosed with HCV infection in a sexual health service from 2016 to 2019 was performed. Data included HIV status, acute or chronic infection, genotype, treatment regimen and outcomes.
**Results:** One hundred and fourteen patients were included compiling 115 episodes of infection. Of those 96 (83.5%) were male. The median age was 39.5 (range 20 to 69). Sixty-eight (59.1%) were HIV co-infected with a median CD4 and HIV viral load of 601.5 cells/mm$^3$ (range 20 to 1315) and 38 300 copies/mL (<50 to 1200 000) at the time of HCV diagnosis. Of the 75 (65.1%) men who have sex with men/bisexual, 33 (44%) were intravenous drug users compared to 25 (62.5%) of 40 heterosexuals. Fifty-eight (50.4%) were acute infections and 18 (15.7%) were re-infections. Twenty-seven (23.5%) cleared the infection spontaneously. The most common genotype was 1a (n = 46; 40%). Twenty-five (21.7%) either lost to follow-up or moved to other services. Of the 63 patients who received treatment, 62 received DAA treatment. One did not complete treatment and one did not have sustained virological response (SVR). Seven are waiting for treatment outcomes and 54 (85.7%) achieved SVR. There was a steady increase in the number of acute infections from 2017 to 2019 (5, 11, 19 respectively). Twenty-two were diagnosed prior to 2016 and received treatment during the look back period. One did not complete treatment and one did not achieve SVR. Two are waiting for the outcomes and 19 (86.4%) achieved SVR.
**Conclusions:** Our study indicates that HCV treatment is effective, irrespective of HIV co-infection. The lack of engagement is a common finding which not only results in poorer health outcomes but facilitates onward transmission. There is a steady increase in the number of acute infections. Increase screening of at-risk populations, improving re-engagement and treatment for acute infection are useful strategies to reduce the pool of infection and therefore elimination of HCV infection.

## P097

### Features of HIV and HCV epidemics in central part of Ukraine

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**Background:** Two severe epidemics observe in Ukraine – HIV infection and hepatitis C. HIV-infected persons demonstrated high prevalence of HCV - up to 44% to 260%. We estimated the morbidity of HIV infection and chronic hepatitis C in Poltava region in 2003 to 2019 and the predictors of HCV infection in HIV-infected patients.
**Materials and methods:** Routine clinical data 1700 HIV-infected patients aged 18 to 65 years admitted to Poltava HIV/AIDS clinic in 2003 to 2019 were analysed as a retrospective cohort. Multinomial logistic regression models were used to identify the predictors of HCV infection among HIV-infected patients in region.
**Results:** The prevalence of HIV/HCV coinfection in the cohort of the first diagnosed cases of HIV infection in Poltava region during the period of 2003 to 2019 was recorded at the level of 56.1% to 65.9% and was characterised by the predominance of male (63.4%), age group of 30 to 49 years (69.3%), with IV drug using (77.2%). The rates of the prevalence of HIV infection and chronic hepatitis C revealed the highest in cities and districts, located around the regional and federal highways with places concentration of sexual workers. Despite the changing of HIV infection route of transmission to sexual from 2008, the prevalence of HCV coinfection was recorded at the 55.4% to 61.7%. HCV infection in HIV-infected patients after 2008 was associated with male sex (OR 1.20, $p = 0.045$), age ≥ 40 years (OR 1.11, $p = 0.038$), experience of incarceration (OR 2.13, $p = 0.013$) and using of drugs (OR 3.242, $p = 0.022$).
**Conclusions:** This study suggests association between the male sex, age ≥ 40 years, experience of incarceration, using of drugs and presence of HCV infections in HIV-infected patients.

# Clinical Pharmacology

## P098

### Evaluation and clinical application of fostemsavir co-administration with tuberculosis medications

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**Background:** Fostemsavir (FTR) is a first-in-class attachment inhibitor approved in combination with other antiretrovirals for heavily treatment-experienced adults with multidrug-resistant HIV-1 infection. FTR is a prodrug of temsavir (TMR), which binds to viral gp-120 and prevents viral attachment and entry into host CD4 + T-cells. TMR is primarily metabolized by esterase-mediated hydrolysis with contributions from cytochrome P450 (CYP) 3A4. TMR does not inhibit/induce major CYP or uridine diphosphate glucuronosyltransferase (UGT) enzymes

**Abstract P098-Table 1. Mean ratio of TMR pharmacokinetic parameters**

| Co-administered drug(s) and dose(s) | FTR dose | N | Mean ratio of TMR pharmacokinetic parameters (90% CI); no effect = 1.00 | | |
|---|---|---|---|---|---|
| | | | Cmax | AUCτ or AUC∞ | Cτ or C-12 |
| RBT ± RTV 150 mg QD/100 mg QD | 600 mg BID | 16 | 1.50 (1.38 to 1.64) | 1.66 (1.52 to 1.81) | 2.58 (1.95 to 3.42) |
| RBT 300 mg QD | 600 mg BID | 19 | 0.73 (0.65 to 0.83) | 0.70 (0.64 to 0.76) | 0.594 (0.46 to 0.77) |
| RIF 600 mg QD | 1200 mg single dose | 15 | 0.24 (0.21 to 0.28) | 0.18 (0.16 to 0.2) | N/A |

and is a P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) substrate. TMR and/or its metabolites inhibit BCRP and organic anion transporter protein 1B1/3 (OATP1B1/3). Because of the high prevalence of tuberculosis (TB) or multidrug-resistant tuberculosis (MDR-TB) and HIV co-infected patients in developing countries, consideration of drug-drug interaction (DDI) potential of co-administering FTR and TB regimen(s) is important.

**Materials and methods:** Review of two phase I FTR DDI studies with rifampin (RIF), rifabutin ± ritonavir (RBT ± RTV), and evaluation of the DDI potential of FTR with 17 MDR-TB drugs based on victim or perpetrator enzyme and/or transporter profiles along with external DDI databases informed options for co-administration therapy. Proposals were based on expected pharmacokinetic (PK) impact, FTR exposure-response relationships, and review of relevant treatment guidelines.

**Results:** Co-administration of FTR with RIF (strong CYP3A inducer) or RBT (moderate CYP3A inducer) decreased TMR AUC by 82% and 30%, respectively; addition of RTV (CYP3A inhibitor) to RBT mitigated moderate induction from RBT where TMR AUC increased by 66% (Table 1). Clofazimine and isoniazid (CYP3A4 inhibitors) suggest up to 50% potential increase in TMR concentration using a static model with in vitro data. TMR and its metabolites inhibit OATP1B1/3 and DDI study with rosuvastatin (OATP1B and BCRP substrate) showed ~70% increase in rosuvastatin AUC; therefore, TMR may increase P-aminosalicylic acid (PAS; OATP1B1/OCT1 substrate) concentrations. Bedaquiline, moxifloxacin, pyrazinamide, prothionamide, thioacetazone, ethambutol, levofloxacin, ethionamide, kanamycin, and linezolid had low PK DDI risk; caution required with drugs that prolong QT interval.

**Conclusions:** Co-administration of FTR and drugs commonly used to treat TB are not expected to result in clinically meaningful interactions, except for RIF which is contraindicated due to the potential loss of therapeutic effect of TMR.

## P099

### Safety, tolerability, and pharmacokinetics following single- and multiple-dose administration of the novel NNRTI MK-8507 with a midazolam interaction arm

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**Objective:** To evaluate safety, tolerability, and pharmacokinetics (PK) of single and multiple oral doses of MK-8507 and drug-drug interaction (DDI) with midazolam, a CYP3A substrate, in healthy participants.

**Background:** MK-8507 is a novel, highly potent oral non-nucleoside reverse transcriptase inhibitor in development for once-weekly (QW) administration for the treatment of HIV-1.

**Methods:** Two randomized, double-blind, placebo-controlled phase I clinical trials were conducted: Study I – rising single doses and Study 2 – single and multiple QW rising doses and midazolam DDI. In Study 1, 16 healthy males (24 to 53 years) received single doses from 2 to 400 mg of MK-8507 or placebo. In Study 2, 24 healthy males and females (21 to 54 years) received single doses of MK-8507 or placebo from 400 to 1200 mg and multiple doses (QW for three weeks) from 100 to 400 mg of MK-8507 or placebo. At the 400 mg QW dose level, participants also received 2 mg midazolam prior to MK-8507 dosing and coadministered with the third QW dose. Study drug was administered fasted except a food effect panel in Study 1. Safety/tolerability and PK were evaluated; C168 hours (QW trough concentrations) is the parameter associated with antiviral efficacy.

**Results:** MK-8507 had a $T_{max}$ of 2 to 7 hours and a mean terminal $t_{1/2}$ of ~58 to 83 hours. Pharmacokinetics were approximately dose proportional from 2 to 1200 mg. Steady state was reached after the first QW dose; minimal accumulation was noted after subsequent QW doses. At doses ≥100 mg of MK-8507, C168 hours exceeded the threshold associated with antiviral efficacy. A high-fat meal did not meaningfully impact MK-8507 PK. Three QW doses of 400-mg MK-8507 had no clinically meaningful effect on midazolam PK (AUC and $C_{max}$ decreased 12% and 18%, respectively). MK-8507 was generally well tolerated. All adverse events were non-serious, mild in intensity. There were no trends in vital signs, ECGs, or safety labs. The most common adverse events were headache and cough.

**Conclusions:** The PK of MK-8507 supports once-weekly administration for the treatment of HIV infection. Single and multiple doses of MK-8507 up to 1200 and 400 mg, respectively, were generally well tolerated.

## P100

### The clinical relevance of potential drug-drug interactions with bictegravir/emtricitabine/tenofovir alafenamide - Real-world data from the German IQVIA prescription database

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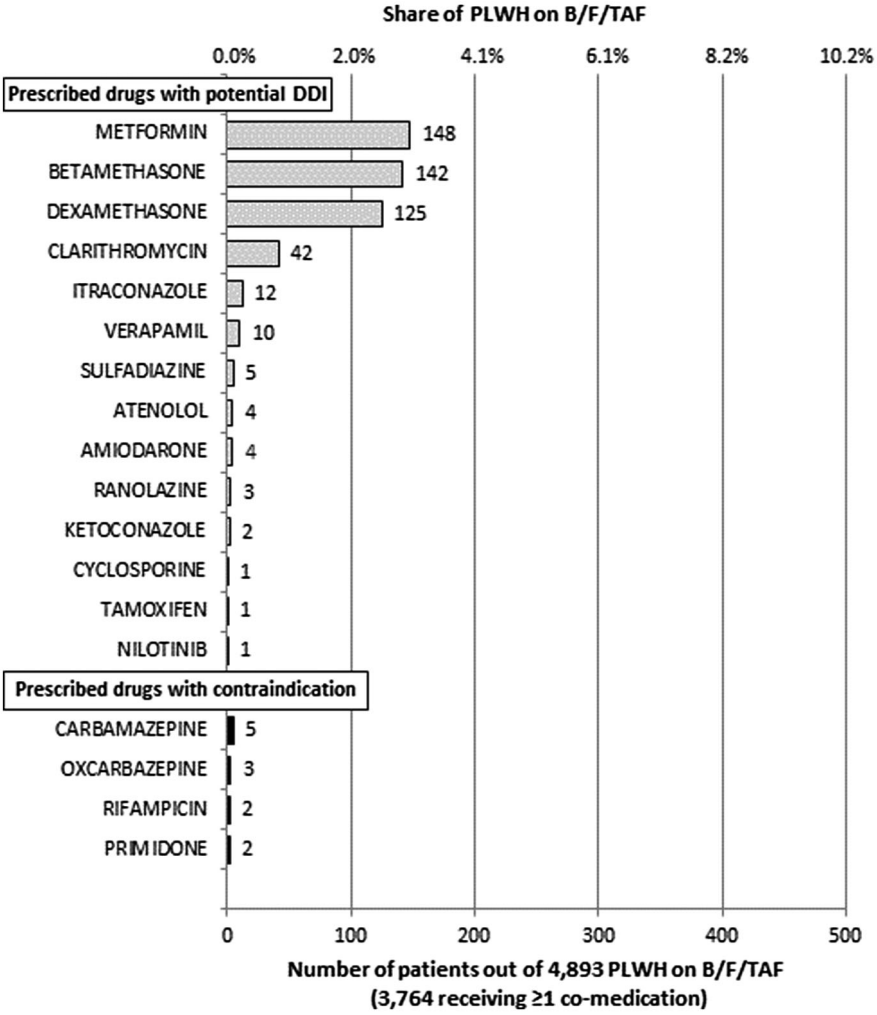
**Background:** As PLWH age on ART, safe co-medication is an increasing concern in everyday clinical practice. This analysis of longitudinal prescription information in PLWH in Germany focusses on the frequency of concomitant drugs and potential drug-drug interactions (DDIs) with ART in PLWH receiving bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF).

**Materials and methods:** Data were obtained using the IMS® LRx database (IQVIA), which covered about 80% of prescriptions reimbursed by German statutory health insurance providers from 07/2018 to 06/2019. The study population consists of PLWH on continuous B/F/TAF for ≥3 months. The Liverpool HIV Drug Interaction database was used to determine the potential DDIs between prescribed concomitant medications and B/F/TAF.

**Results:** Among 4893 PLWH on B/F/TAF, 3764 PLWH (77%) received ≥1 co-medication: 69% men, 13% women, 18% gender unknown; 59% aged 41 to 60 years; average number of co-medications was 4.0 for men, 4.3 for women. Most commonly prescribed drugs classified by Anatomical Therapeutic Chemical level 3 (ATC3) were non-steroidal anti-rheumatic drugs (in 23% of patients on concomitant medications [N = 857]), anti-ulcerants (23%, N = 849), anti-

**Abstract P100-Table 1. Top 10 concomitant medications classes among PLWH on bictegravir/emtricitabine/tenofovir alafenamide (in > 10% of men and/or women) receiving ≥1 concomitant medication stratified by age group**

| ATC3[a] class | 10 most commonly prescribed co-medication classes at MAT (moving annual total) as of 06/2019 | Age group <30 N = 235 | Age group 30 to 40 N = 871 | Age group 41 to 50 N = 1044 | Age group 51 to 60 N = 1159 | Age group 61 to 70 N = 327 | Age group >70 N = 128 |
|---|---|---|---|---|---|---|---|
| A2B | Anti-ulcerants | 32 (14%) | 131 (15%) | 229 (22%) | 331 (29%) | 95 (29%) | 31 (24%) |
| M1A | Anti-rheumatics, non-steroidal | 48 (20%) | 167 (19%) | 251 (24%) | 287 (25%) | 71 (22%) | 33 (26%) |
| N6A | Anti-depressants & mood stabilisers | 19 (8%) | 95 (11%) | 189 (18%) | 200 (17%) | 47 (14%) | 16 (13%) |
| N2B | Non-narcotics and antipyretics | 32 (14%) | 109 (13%) | 156 (15%) | 189 (16%) | 49 (15%) | 31 (24%) |
| C10 | Lipid-regulating preparations | 2 (1%) | 10 (1%) | 82 (8%) | 233 (20%) | 113 (35%) | 59 (46%) |
| J1F | Macrolides and similar types | 45 (19%) | 162 (19%) | 152 (15%) | 98 (8%) | 23 (7%) | 8 (6%) |
| H3A | Thyroid preparations | 5 (2%) | 36 (4%) | 50 (5%) | 81 (7%) | 33 (10%) | 17 (13%) |
| C9A | Angiotensin-converting enzyme (ACE) inhibitors, plain | 2 (1%) | 38 (4%) | 79 (8%) | 190 (16%) | 71 (22%) | 29 (23%) |
| C7A | Beta-blocking agents, plain | 2 (1%) | 21 (2%) | 70 (7%) | 178 (15%) | 86 (26%) | 39 (30%) |
| J1C | Broad-spectrum penicillins | 27 (11%) | 85 (10%) | 89 (9%) | 107 (9%) | 26 (8) | 9 (7%) |




**Abstract P100-Figure 1. Prescribed drugs with potential DDIs and contraindicated drugs with bictegravir/emtricitabine/tenofovir alafenamide. Potential DDI: exercise caution, close monitoring and dose adjustments may be required for certain patients.**

depressants (15%, N = 566) and other analgesics/antipyretics (15%, N = 566) (Table 1). Several of the top ATC3 co-medication classes posed no interaction risk, among them anti-ulcerants (most commonly pantoprazole [16% of 3764, N = 620]), anti-rheumatics (ibuprofen 15%, N = 565), anti-depressants (mirtazapine 3%, N = 102) and lipid-lowering agents (atorvastatin 7%, N = 270). Potential relevant DDIs

identified in ≥10 patients included metformin, betamethasone, dexamethasone, clarithromycin, itraconazole and verapamil. Contraindicated medications were used in < 0.25% of the cohort (Figure 1). In ≥ 90% of PLWH receiving B/F/TAF, concomitant medications posed no or no relevant risk for interaction.
**Conclusions:** In comprehensive overview of concomitant medication, 77% of PLWH on B/F/TAF received ≥1 co-medication. Contraindicated medications were used in < 0.25% of the cohort. In those cases with potential relevant DDI, the individual medications can be replaced by other compounds of the same drug class member without potential interaction with B/F/TAF according to the Liverpool HIV database. Although this evaluation was limited by the exclusion of over-the-counter drugs with potential for DDIs (e.g. mineral supplements or St. John's wort), the overall potential for DDIs with B/F/TAF is low in clinical practice.

## P101

### Development and clinical validation of an liquid chromatography with ultraviolet detection method to quantify dolutegravir in dried blood spots

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**Background:** Dolutegravir (DTG) is now the preferred component of first-line ART in all population groups [1]. Facilitating clinical pharmacology studies of dolutegravir in key populations (e.g. neonates and pregnant women), quantitative analysis methods compatible with micro-sampling and adaptable in resource-limited settings are desirable. Here, a method to quantify dolutegravir in dried blood spots (DBS) using liquid chromatography with ultraviolet detection (LC-UV) was developed, validated and applied in a pharmacokinetic (PK) study in HIV-positive women receiving DTG-containing ART.
**Methods:** Calibration standards and quality control samples were prepared by spotting 50 μL of DTG-spiked whole blood on DBS cards. Extraction was by simple protein precipitation using methanol. Chromatographic separation was achieved with a gradient elution of acetonitrile/potassium phosphate monobasic buffer (pH 5) on a reverse-phase C18 column, at a flow rate of 1 mL/min using pioglitazone as the internal standard. Detection was by UV at a wavelength of 260 nm. For the clinical validation, DBS was collected from participants (n = 10) at eight time points (0.25 to 24 hours) after dose (paired plasma at one and twelve hours) from finger prick. The method was used to quantify DTG and PK parameters were estimated from concentration-time data using non-compartmental analysis. Agreement between DBS and plasma concentrations was evaluated using Bland-Altman plots.
**Results:** The method was validated in three batches over the concentration range of 400 to 10 000 ng/mL. Accuracy ranged from 102.4% to 114.8% and precision ranged from 3.4% to 14.7%. The mean recovery was 41.3% (%CV: 13.6). The method was specific and selective for dolutegravir with no interference at its retention time. Compared with plasma, DBS concentration was 37.5% (6.1) lower. DBS predicted plasma and measured plasma concentrations were linear (R2 = 0.9804) and Bland-Altman plot showed no bias. Mean (%CV) of $AUC_{0-24}$, $C_{max}$ and $C_{24}$ from DBS predicted plasma concentrations were 37.8 μg.h/mL (23.2), 2.7 μg/mL (24.7) and 1.34 μg/mL (31.6) respectively.
**Conclusions:** The developed method is simple, accurate and precise. Its application will expand opportunities to undertake clinical PK studies of DTG in key populations. The reasons for lower PK parameters for DTG compared to previous studies [2] using plasma samples warrant further investigation.

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## P102

### Fostemsavir and ethinyl estradiol drug interaction: clinical application for coadministration

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**Background:** Fostemsavir (FTR), a prodrug of temsavir, is a first-in-class attachment inhibitor approved in combination with other antiretrovirals for heavily treatment-experienced adults with multidrug-resistant HIV-1 infection. For individuals taking FTR and hormonal therapy, understanding drug–drug interactions is important. In a drug-drug interaction study (Study 206279), temsavir increased ethinyl estradiol (EE) concentrations but not norethindrone. Applying the results of Study 206279 and other relevant antiretroviral– contraceptive studies, proposals for coadministering hormones with FTR are provided.
**Materials and methods:** Data were applied to other contraceptive methods and hormone therapies to predict the impact of FTR coadministration. Proposals were based on minimizing risk of thromboembolic events associated with higher estrogen exposure, ensuring adequate hormonal concentrations to maintain a targeted effect, and relevant treatment guidelines.
**Results:** In Study 206279, FTR had no effect on norethindrone pharmacokinetics but increased EE maximum observed plasma concentration and area under the concentration-time curve ~40%. FTR is not expected to impact progestin-only contraceptives. Pharmacokinetics of hormonal contraception with FTR and boosted protease inhibitors (bPIs) has not been studied; therefore, alternative/additional contraceptive methods, guided by PI–prescribing recommendations, should be considered. Because lopinavir/ritonavir coadministration with oral and transdermal contraceptives has been shown to affect EE concentration, a bPI/FTR–EE drug interaction may be expected regardless of delivery mechanism, and caution is advised. We provide recommendations for use of integrase inhibitors and non-nucleoside analogues based on predicted interactions with hormones. FTR and estradiol for gender-affirming hormone therapy (GAHT) can be coadministered with routine monitoring of hormone concentrations and clinical effects, titrating estradiol dose in line with guidelines. Menopause hormone therapy (MHT) should utilize individualized risk–benefit assessment using the lowest effective dose of systemic estrogen consistent with treatment goals, with or without vaginal estrogen. For coadministering FTR and MHT, estrogen dose should start low and be titrated according to clinical effect.
**Conclusions:** FTR coadministration with hormone therapy is not expected to impact efficacy. When FTR is coadministered with oral estrogen–based therapies, the EE dose should be ≤30 μg/day to minimize risk. Estrogen-containing GAHT and MHT can be coadministered with FTR, with monitoring of estrogen concentrations and dose adjustments as needed.

# Community Initiatives

## P103

### Awareness and perception of accuracy of the Undetectable=Untransmittable (U=U) message in people living with HIV/AIDS (PLWHA) in Italy and correlation with the level of confidence in reference physicians

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**Background:** Recent studies confirmed no risk of HIV sexual transmission with undetectable HIV-RNA (<200 copies/mL), leading to worldwide campaign "U=U" (undetectable=untransmittable). Purpose of this study was to evaluate the perceived accuracy of this message among PLWHA, HIV-negative people with sexual risky behaviours (PWSRB) and infectious diseases physicians, to guide subsequent efforts and implementation of HIV prevention strategies.

**Materials and methods:** An Italian nationwide web survey among ICONA cohort centres, community-based voluntary test & counselling centres and fast-track cities websites has been conducted. Three different anonymous questionnaires (for physicians, PLWHA and PWSRB) were set up. In this analysis we explored the awareness of U=U ("have you ever heard of") and the perception of accuracy of U=U [Likert scale from 1 = completely inaccurate (low) to 4 = completely accurate (high)]. Logistic regression models have been fitted to investigate factors associated with the binary outcomes (i) awareness of U=U (Y/N) and (ii) perceived high accuracy of U=U (Y/N).

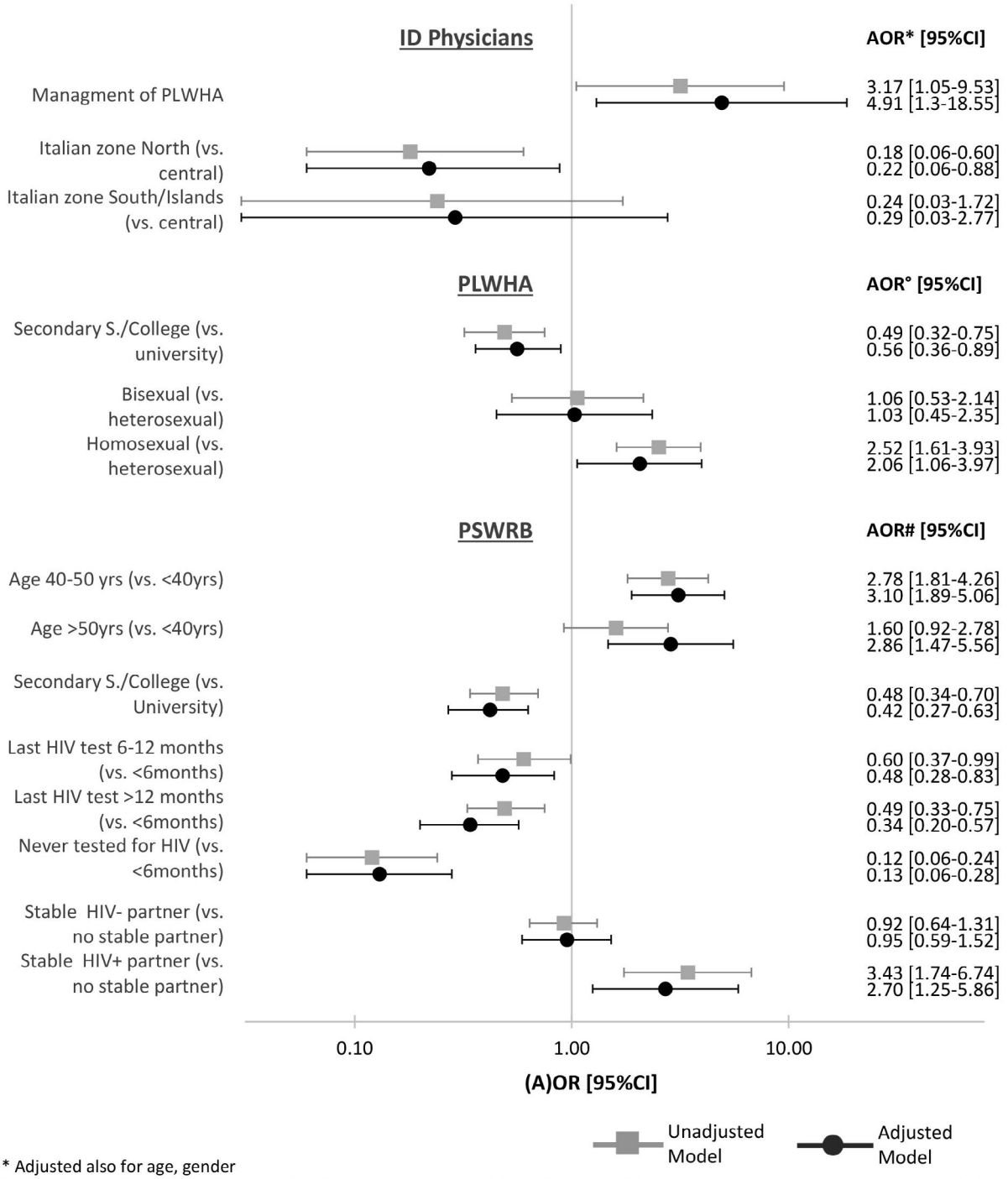
**Results:** One thousand, one hundred and twenty-one participants filled the questionnaires: 397 PLWHA, 90 physicians, 634 PWSRB. Participants' characteristics are shown in Table 1. Awareness of U=U message has been reported in 74%, 46% and 92% of PLWHA, PWSRB and physicians. Accuracy of U=U message has been reported as 'high' in 80% of PLWHA, 66% of PWSRB and 79% of physicians. Physicians perceived that 11% of PLWHA have a high perception of U=U; 34% of PLWHA reported a definitive positive messages received from physicians. Among PLWHA, factors associated with the awareness of U=U were level of education (university vs lower AOR 1.77, 95% CI 1.03 to 3.04), being MSM/bisexual (vs heterosexual AOR 3.16, 95% CI 1.03 to 3.04), being on cART for five to ten years (vs < 5 years AOR 2.71, 95% CI 1.32 to 5.55) and age (40 to 50 years vs < 40 years AOR 0.47, 95% CI 0.24 to 0.93). Factors associated with perception of accuracy of message in the three groups are reported in Figure 1.

**Abstract P103-Table 1. Participants' characteristics**

| | ID physicians (N = 90) | PLWHA (N = 397) | PWSRB (N = 634) |
|---|---|---|---|
| Age, years, n (%) | | | |
| <40 | 49 (54.4) | 122 (30.79) | 461 (72.7) |
| 40 to 50 | 18 (20.0) | 124 (31.2) | 110 (17.3) |
| >50 | 23 (25.6) | 151 (38.0) | 63 (9.9) |
| Gender, male, n (%) | 37 (41.1) | 324 (81.6) | 431 (68.0) |
| Nationality, Italian, n (%) | N/A | 375 (94.5) | 610 (96.4) |
| Italian geographical zone, n (%) | | | |
| Northern Italy | 46 (51.1) | 235 (59.2) | 415 (65.7) |
| Central Italy | 38 (42.2) | 117 (29.5) | 115 (18.2) |
| Southern Italy/Islands | 6 (6.7) | 45 (11.3) | 102 (16.1) |
| Education, university, n (%) | 90 (100.0) | 157 (39.6) | 392 (61.8) |
| Management of PLWHA, Yes, n (%) | 73 (81.1) | N/A | N/A |
| Years of management of PLWHA, n (%) | | | |
| <10 years | 39 (53.4) | N/A | N/A |
| 10 to 20 years | 15 (20.6) | N/A | N/A |
| >20 years | 19 (26.0) | N/A | N/A |
| Number of PLWHA in care, n (%) | | | |
| <100 | 36 (49.3) | N/A | N/A |
| 100 to 400 | 15 (20.6) | N/A | N/A |
| >400 | 22 (30.1) | N/A | N/A |
| Years with HIV infection | | | |
| <5 years | N/A | 112 (28.2) | N/A |
| 5 to 10 years | N/A | 98 (24.7) | N/A |
| >10 years | N/A | 187 (47.1) | N/A |
| Years of cART | | | |
| <5 years | N/A | 125 (31.5) | N/A |
| 10 to 5 years | N/A | 113 (28.5) | N/A |
| >10 years | N/A | 159 (40.0) | N/A |
| HIV-RNA undetectable, yes, n (%) | N/A | 372 (95.6) | N/A |
| Number of sexual partners, median (IQR) | N/A | 2 (1 to 10) | 2 (1 to 10) |
| Sexual orientation, n (%) | | | |
| Heterosexual | N/A | 131 (33.0) | 224 (35.3) |
| Bisexual | N/A | 41 (10.3) | 42 (6.6) |
| Homosexual | N/A | 225 (56.7) | 368 (58.0) |
| Stable sexual partner, n (%) | | | |
| No | N/A | 190 (47.9) | 322 (50.8) |
| Yes, HIV-positive | N/A | 53 (13.3) | 40 (6.3) |
| Yes, HIV-negative | N/A | 154 (38.8) | 272 (42.9) |
| Last HIV test, n (%) | | | |
| <6 months | N/A | N/A | 242 (38.2) |
| 6 to 12 months | N/A | N/A | 95 (15.0) |
| >12 months | N/A | N/A | 176 (27.8) |
| Never done | N/A | N/A | 121 (19.1) |

ID, infectious diseases; N/A, not applicable; PLWHA, people living with HIV/AIDS; PWSRB, people with sexual risky behaviours.

**Conclusions:** Although selection bias of web surveys cannot be overlooked, results highlight a low concordance between awareness and perception of accuracy in PLWHA and physicians, suggesting still insufficient certainty. More efforts should be implemented to spread the U=U message among subgroups who might benefit from targeted educational campaigns. Dissemination of the message among PWSRB is far from being efficaciously implemented and should represent a priority for increasing knowledge and decreasing HIV stigma.




* Adjusted also for age, gender

° Adjusted also for age, gender, sexual preferences, years on cART, stable partnership, n. of partners in the last year, geographical site

# Adjusted also for gender, sexual preferences, n. of partner in the last year, geographical site

**Abstract P103-Figure 1. Factors associated with perceiving accuracy of U=U message as 'high' identified by multivariable logistic regression analyses separately for each of the questionnaire recipient groups.**

## P104

### What's trending in Asia? Drawing inferences from online HIV support seeking patterns of risk groups in Asia using regional Adam's Love and TemanTeman.org big datasets

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**Background:** Data on online HIV support seeking behaviours provide real-time, highly accurate estimation of HIV epidemic, outbreak conditions, and offer proactive data-driven insights into individual support needs. To inform robust HIV prevention interventions targeting risk groups, we harnessed Adam's Love regional datasets.
**Methods:** Big data gathered between September 2011 and December 2019 were extracted and analysed from www.adamslove.org and www.temanteman.org regional websites in Thailand, Indonesia, Malaysia, Taiwan and South Korea. Data captured risk demographics and country-specific HIV support seeking patterns in Asia.
**Results:** The hybrid data from 13.6 million users included search trends on Adam's Love and TemanTeman.org websites (>8 million users), YouTube (>5 million viewers), eCounselling platforms (>75 000 inquiries) and social media channels (>160 000 followers). Adam's Love and Temanteman.org videos featuring medical doctors from Asia's leading university hospitals garnered nearly 5.24 million views, watch-time 10.3 million minutes (equivalent to 19 years, 161 days), primarily via mobile phones (72%), computers (20%) and tablets (8%). Indonesia and Thailand had approximately 35% of youth (aged 13 to 24 years) engaged in HIV support seeking, while 25 to 34 year group engagement was higher (>60%) in Malaysia, Taiwan and South Korea. Thailand and Indonesia saw relatively higher female engagement in online sexual health seeking with male/female ratio of 68:32, compared with predominantly male HIV support seeking in Malaysia (80:20) and Taiwan (90:10). We found an upward trend for search terms 'STIs - syphilis, herpes, gonorrhea, warts, HPV' (825 471 + searches), 'HIV - early signs/symptoms/characteristics' (700 010 + searches), 'HIV testing/procedure' (672 366 + searches) and 'HIV treatment access and medications' (489 563 + searches). There were interesting parallels between support needs and local policy and prevention infrastructure. For example, acute HIV infection, PrEP and PEP were emerging trends originating from Thailand and Taiwan and leveraged up reaching 198 552 + searches. Remarkable peaks were found on Sunday until Thursday, and peak hours for seeking support were evenings (18:00 to 24:00 hours) with sharp falls during daytime (04:00 to 12:00 hours).
**Conclusions:** Our study shares evidence of high sexual health and HIV/STI support seeking in Asia. We propose intensive real-time interventions targeting risk groups' search patterns to enable early online-to-offline transitions and successful HIV testing and treatment linkages.

## P105

### HIV prevention among MSM in Japan: current opinions on achieving the first 90 among Japanese MSM

T Anand[1]; C Nitpolprasert[1]; T Shirasaka[2]; Y Iwatani[3]; Y Yokomaku[3]; M Imahashi[3]; N Kaneko[4]; K Iwahashi[5]; Y Ikushima[6]; R Aoki[7]; T Ishida[8]; S Shiono[9]; M Yamaguchi[10]; K Takemura[11] and A Iwamoto[12]

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**Background:** Japan is a developed nation with an HIV epidemic concentrated among MSM [1]. Despite success in exceeding the second and third UNAIDS 90-90-90 targets, Japan has lagged behind on first 90. Approximately 30% of newly reported cases have been annually identified by AIDS onset [2], implying reaching subpopulations for early HIV testing remains primary challenge.
**Methods:** In 2019, interviews were conducted with medical professionals at AIDS Core Hospitals (serving >6000 HIV-positive people), HIV researchers, governmental agencies and community staffs in Tokyo, Nagoya, Kanagawa and Osaka. We sought to understand current HIV testing alternatives, reasons behind late diagnosis, and identified immediate strategies for scaling-up early HIV testing.
**Results:** Municipal healthcare centres remain key sites delivering free/anonymous HIV/STI testing, although their women/child health focus limits uptake among MSM. Primary reasons for late HIV diagnosis included challenges in reaching and engaging MSM in HIV cascades, structural barriers i.e. testing capacity, schedule/accessibility, lack of MSM-friendly services and regulatory issues with HIV self-testing. In Japan, community organisations are spearheading HIV testing initiatives by implementing prefecture-based models. For example, HIVCheck.jp Tokyo, an HIV self-testing research piloted in collaboration with clinical laboratory led to increased HIV testing uptake among MSM (1127 DBS samples collected), with provisional positive rate of 2.4% [3]. In Nagoya, HIV testing during 2018 LGBT event has seen two-fold year-on-year increase in HIV testing (approx. 700 MSM). In Osaka, bimonthly, weekend-based HIV/STI testing programme (engaging 30 to 40 MSM) offers low-cost HIV testing during late hours at collaborated private clinics. Japanese MSM actively use internet for seeking sex partners, e.g. gay dating app 9monsters has reportedly >300 000 active members. While traditional outreach approaches at gay hotspots are widely prevalent, sexual health campaigns (e.g. Sailor Moon) to stem rapid rise of STI cases by government has had limited impact among MSM.
**Conclusions:** To reach the first 90, Japan needs diffusion of innovative technology to streamline its HIV service delivery and develop a culturally sensitive communications strategy. To ensure seamless virtual to critical offline HIV services transition, Japan should implement an integrated Online-to-Offline (O2O) model offering real-time eCounselling and online bookings (QR codes) to ensure privacy and real-time monitoring features to help track/validate participants [4,5].

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## P106

### Abstract withdrawn

## P107

### Thinking outside the box: evaluating the impact of a virtual classroom model to deliver HIV primary care education to physicians and nurse practitioners across Saskatchewan, Canada

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**Background:** Addressing high rates of HIV and limited HIV specialists, the HIV Virtual Classroom (VC) was created by Saskatchewan Infectious Disease Care Network (SIDCN) in 2018 as a novel education model to increase the capacity of primary care providers (PCPs) to test, treat, and manage HIV in Saskatchewan, Canada. Using an online platform, it delivered accredited continuing medical education sessions to physicians and nurse practitioners seeking best practices for delivering HIV primary care. Presentations were facilitated by local Infectious Diseases and HIV experienced physicians. After attending four required presentations, graduates were encouraged to participate in HIV preceptorship opportunities coordinated by SIDCN and become approved ARV prescribers.
**Materials and methods:** Between May 2018 and March 2020, seven VC sessions were delivered to 62 PCPs from 14 communities. A post-participation survey was administered immediately post VC sessions to evaluate knowledge of HIV primary care. A follow-up survey was sent to VC graduates to assess the impact on their clinical practices.
**Results:** Twenty-one follow-up surveys were collected (34% response rate) and 90% of respondents indicated using knowledge from the VC to educate others and 81% of the respondents making changes to their clinical practices. The top five reported impacts were, increased: comfort in recognizing HIV and ARV therapy complications (85%); confidence in providing primary care to people living with HIV (81%); understanding of ARV therapy and HIV treatment (81%); comfort in recognizing a patient with an opportunistic infection (77%); comfort discussing the results of HIV testing (72%). After completing the VC, 24% participants became approved ARV prescribers in Saskatchewan. Twelve of the 21 respondents report increased comfort in managing primary care in PLWH but not initiating ARVs, while five of the 21 respondents are comfortable initiating ART and providing primary care for PLWH.
**Conclusions:** The VC education is a unique model that offers live interaction with HIV experts; provides Saskatchewan specific content and uses a curriculum that reflects local realities. Findings suggest the VC is an effective model for educating primary care providers and enrolling new ARV prescribers in Saskatchewan. Based on the positive response, six additional cohorts will occur, and the VC model will be adapted to create a HCV VC.

## P108

### Abstract withdrawn

## P109

### Sexual behaviours and associated factors among men living with HIV in Istanbul, Turkey

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**Background:** In order to control epidemic, it is very important to determine the risk factors specific to the region. Low awareness of the disease and prevention methods is among the most important obstacles in preventing the epidemic. The primary transmission route of HIV infection is unprotected sexual contact and risky sexual behaviours are known to have an important role in spreading the disease. We aimed to determine the sexual behaviours and related factors of male individuals living with HIV.
**Materials and methods:** This retrospective study was conducted in a training and research hospital in the centre of Istanbul where a large number of PLHIV were admitted. Between January 2015 and September 2018, 830 naïve HIV-infected patients applied to our HIV outpatient clinic. One hundred thirteen male living with HIV who questioned completely about their marital status, condom use, number of partners in the last two years and changes in sexual behaviours after diagnosis were included in the study. The sexual behaviour characteristics and related factors of men living with HIV were analysed.
**Results:** A total of 113 male were included in the study. The mean age of patients was 34 ± 10.4 years. MSM consisted of 79 (70%) and this group was younger (31.2 ± 9.3 vs 37.8 ± 11.1; $p < 0.001$), mostly single (64% vs 14%; $p < 0.001$), had more sexual partners (86% vs 56%; $p < 0.001$) and had higher rates of condom use (78% vs 50%; $p < 0.001$). One-fifth of the MSM were married. The percentage of married and single MSM having multiple partners was similar (81% vs 86%; $p = 1.0$). Thirty-four (30%) of the patients stated that they did not use any condoms. These patients were older (38.5 ± 11.8 vs 30.9 ± 8.7; $p < 0.001$), mostly married (58.8% vs 19%; $p < 0.001$) and heterosexual (50% vs 21.5%; $p = 0.002$). No significant relationship was found between having multiple partners and condom use (81% vs 65%; $p = 0.13$).
**Conclusions:** In our country, there is a dramatic increase in the incidence of HIV infection. Larger research to determine sexual behaviour characteristics of cases may make a significant contribution to identify the causes of the epidemic and to develop prevention strategies.

## P110

### Capacity building for youth coalitions, critical for sustaining gains in HIV prevention sphere

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**Background:** Reports from a 2017 National Health Survey showed that only 29% of women and 27.9% of men between the ages of 15 to 24 could correctly identify ways of preventing sexual transmission of HIV, and reject major myths around transmission.
**Objective:** To train 16 Adolescent and Young Person (AYP) peer educators from different youth-led organisations for eight weeks to become HIV/Sexual Reproductive Health and Rights (SRHR) champions.
**Methodology:** A well-structured curriculum was used to train peers. Topics taught ranged from the update on HIV prevention research to adolescent sexual and reproductive health needs. The peer educators were provided with HIV prevention literacy field guides developed by New HIV Vaccine and Microbicide Advocacy Society, which they used to step down training to their peers within their communities and schools. Simplified PrEP fact sheets were also given to the peers for distribution. Qualified counsellor testers joined the peers in some of the community outreach programme to carry out HIV testing and counselling services for persons above 18 years and those younger were tested with their parents' consents.
**Result:** A total of 604 adolescent and young persons were reached and sensitised on new HIV prevention tools, including mode of transmission. About 8% of people reached underwent HIV counselling and testing. Twenty-two percent of the clients who were HIV positive were placed on treatment. Forty-four percent of people who tested negative but had substantial risk to HIV infection were enrolled on PrEP. A total of 516 PrEP fact sheets were distributed.
**Conclusions:** Capacity building of HIV prevention and SRHR peer educators could create a cascading effect throughout the community,

which essentially allows limited resources to be efficiently managed. There is a need for more investment in training peer educators in order to sustain gains in HIV prevention.

# Models of Care: Cost Effectiveness and Evaluation of Delivery and Coverage

## P111

### EmERGE: feasibility and uptake of a co-designed digital health supported pathway of care for people living with medically stable HIV

J Whetham[1]; C Jones[2]; S Bremner[2]; L Apers[3]; J Begovac[4]; M Borges[5]; A Leon[6]; J Vera[7]; S Zekan[4]; B West[8]; P Chausa[9]; E Gomez[9]; F Garcia[6] and EmERGE Consortium[1]

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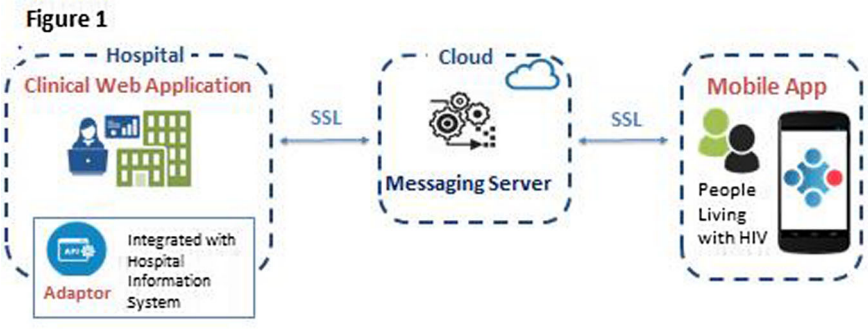
**Background:** New digital approaches to clinical management of HIV have potential to manage capacity whilst maintaining excellent clinical outcomes. This study examined the feasibility and uptake of a digital care pathway for people living with medically stable HIV at five clinical sites in Europe.
**Materials and methods:** The EmERGE platform (Figure 1) was co-designed, developed and integrated into the IT systems at the five sites. Participants were seen once a year by their clinician with interim results checked, encrypted and pushed through to an app on their mobile phone. A pre-post study design was used with clinical and questionnaire data collected including: viral load outcomes; serious adverse events (SAEs); patient activation [PAM-13]; adherence [M-MASRI]; quality of life [EQ-5D-5L; PROQOL-HIV]; system usability score [SUS] and patient experience at baseline [M0], 12 [M12] and 24 months [M24]. Changes over time were estimated using mixed effects regression models.
**Results:** The GDPR-compliant EmERGE platform was successfully integrated at all sites during 2017. Two thousand, two hundred and fifty-one participants (mean 23.1% of clinic cohorts) were enrolled and followed up for between 12 and 30 months each. Demographics were representative of clinic cohorts: 91% male (2048/2251); 71% MSM (1598/2251); 27.9% aged over 50 (629/2251); 20.4% (460/2251) non-national at site. Virological outcomes remained excellent (10/2251 with confirmed VL > 50; none lost to clinical follow-up); no SAEs related to the pathway were reported. Patients were highly activated, no clinically important change was observed in PAM-13 score; adjusted average continuous PAM-13 score at M12 compared to M0 -0.95 (99% CI -2.10, 0.19). Median self-reported adherence was 100% at each time point. Health-related quality of life was generally good although pain/discomfort and anxiety/depression were common (up to 34% and 44% respectively at M12) on EQ-5D-5L. Stigma was the lowest scoring domain of PROQOL-HIV. The usability of the platform was excellent [SUS score 85 at M12 and M24]; 94.6% would recommend EmERGE to a friend.
**Conclusions:** This co-designed digital health supported pathway offers a secure, safe, feasible and acceptable option for routine care to people living with medically stable HIV: providing individuals with access to their data and other information whilst helping clinics to manage capacity.

## P112

### Differences in patient-reported outcomes among single- and multi-tablet regimens

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**Background:** Single-tablet regimens (STRs) have become the golden standard in antiretroviral therapy. However, there are calls to reintroduce (generic) components as multi-tablet regimens (MTRs) because of cost savings. Patient-reported outcome measures (PROMs) are an important touchstone to support or to renounce this proposal. As such, our aim was to compare PROMs of people living with HIV taking a STR versus a MTR.
**Materials and methods:** One hundred and eighty-eight people living with HIV participated in a longitudinal study. One hundred and thirty-one remained on their MTR and 57 switched to a STR. At baseline, Months 1, 3, 6, 12, 18 and 24, participants filled in questionnaires on health-related quality of life (HRQoL; EuroQol and MOS-HIV), depressive symptoms (Beck Depression Inventory II), HIV symptoms (HIV Symptom Index), neurocognitive complaints (NCC; screening questions), treatment satisfaction (HIV Treatment Satisfaction Questionnaire) and adherence to ART (CASE Adherence Index and a visual analogue scale). Generalised linear mixed models and generalised estimation equations mixed models were built.
**Results:** At baseline, the two groups did not differ in clinical parameters and PROMs. The mixed models revealed differences among the groups regarding neurocognitive complaints and treatment satisfaction. The odds of having NCC increased by 3.9% per month in the STR group as compared to the stable group ($p = 0.035$). Nonetheless, treatment satisfaction (TS) also increased in the STR group: at Month 6, median TS-change score was highly positive: 24 (IQR 7.5 to 29), and STR 24 m TS-state score was 3.1 points higher than MTR 24 m TS-state score ($p = 0.021$). Treatment satisfaction showed a




**Abstract P111-Figure 1. The EmERGE platform.**

significantly different evolution in the groups: the estimated TS-state score increased by 3.4 in the STR group while it decreased by 0.2 in the MTR group ($p = 0.003$). In both groups, the visual analogue scale score of the EuroQol increased over time. The other HRQoL measures, HIV symptoms, depressive symptoms and adherence did not differ between the groups and/or over time.
**Conclusions:** Neurocognitive complaints and treatment satisfaction differed between the two groups. More people on a STR reported NCC over time compared to the MTR group. Contrarily, treatment satisfaction in the STR group increased significantly over time. In this study, higher treatment satisfaction was, however, not translated into better HRQoL or adherence.

## P113

### Community responses on variability in the frequency of patient visits to HIV clinics in the EU

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[1]European AIDS Treatment Group, Brussels, Belgium. [2]European AIDS Treatment Group, Edinburgh, UK. [3]European Patients' Forum, Brussels, Belgium. [4]Brighton and Sussex University Hospitals NHS Trust, Brighton, UK

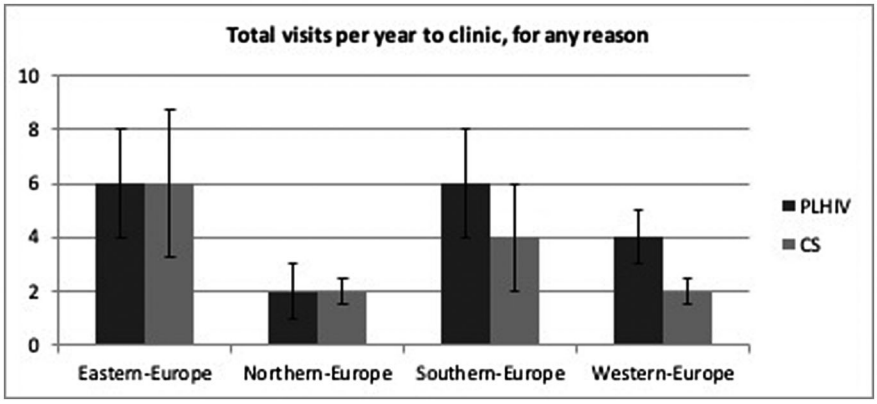
**Background:** EATG, an EmERGE project partner, conducted a survey in July 2019 on the frequency and purpose of HIV clinic visits amongst PLHIV and HIV clinic staff (CS) in the EU, and access to telemedicine services. The purpose was to map patient visits to HIV clinics to analyse the diversity of practices at EU level where telemedicine solutions currently exist.
**Materials/method:** Online surveys for PLHIV and CS containing 10 questions were published in 16 European languages and disseminated widely by EATG community networks and EACS. Eligibility criteria were: PLHIV respondents - stable on ARV therapy (undetectable viral load for at least six months); CS - those treating PLHIV stable on ARV therapy. Data were collected and processed anonymously.
**Results:** Responses were received from 407 PLHIV (26 countries) and 153 CS responses (22 countries). In total, 63.3% of PLHIV attended their clinic to give blood samples twice yearly, confirmed by 80.8% of CS. PLHIV reported a statistically significant higher number of clinic visits than were reported by CS. Of visits for any reason, 49.1% of PLHIV reported up to 4 visits, 36.8%: 4 to 8 visits; and 14.1%: more than 8 visits (some countries indicating up to 20 visits). For this question, CS reported significantly lower counts of clinic visits for any reason than PLHIV (median of 3 visits/CS and 5/PLHIV). Regionally, PLHIV from Northern/Western Europe reported a median of 2 visits and 4 visits respectively, whereas PLHIV from Eastern/Southern Europe reported a significantly higher median of 6 visits per year for any reason (Figure 1).
**Conclusions:** Across the EU, frequency of visits to give blood samples for PLHIV is more aligned than frequency of total number of visits per year for other reasons, where responses were highly diverse. The data for overall visits suggests CS may have a different understanding of amounts of total clinic visits than PLHIV have in reality. Data collected in the pre-COVID-19 era provides context to understanding service delivery before service restrictions began. Effects of current changes in service delivery due to COVID-19 on frequency, reasons of visits and regional variations should be explored through further research.

## P114

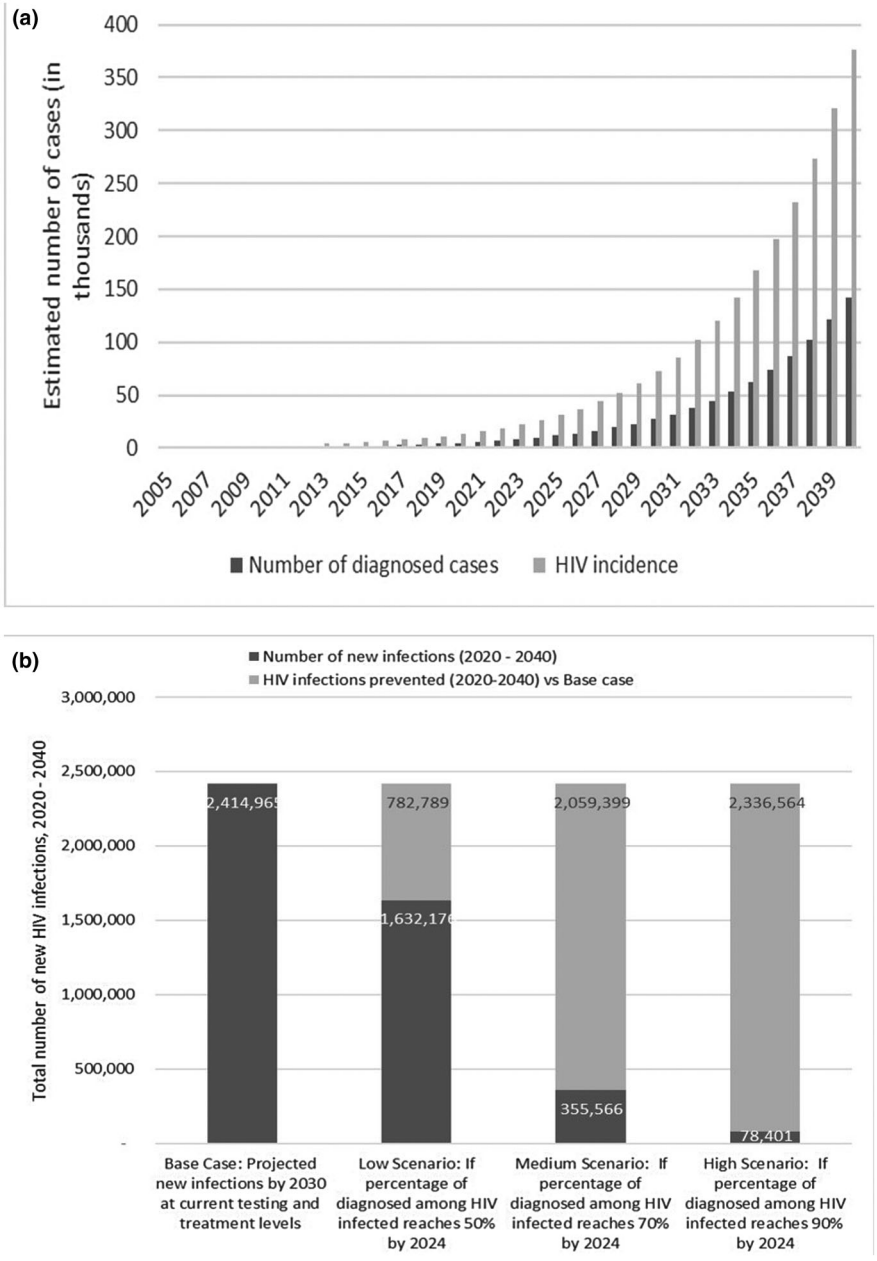
### Modelling the future of HIV in Turkey: disease implications of improving prevention, diagnosis and treatment

E Yaylali[1]; D Gökengin[2]; V Korten[3]; F Tabak[4]; S Ünal[5]; Z Erdogan[1]; F Calısır[1]; B Özelgün[6] and T Sahin[7]
[1]Istanbul Technical University, Department of Industrial Engineering, Istanbul, Turkey. [2]Ege University, Infectious Diseases and Clinical Microbiology, Izmir, Turkey. [3]Marmara University, Department of Infectious Diseases, Istanbul, Turkey. [4]Istanbul University Cerrahpasa, Department of Infectious Diseases, Istanbul, Turkey. [5]Hacettepe University, Department of Infectious Diseases, Ankara, Turkey. [6]Gilead Sciences, Medical Affairs, Istanbul, Turkey. [7]Gilead Sciences, External Affairs, Istanbul, Turkey

**Background:** In 2019 3944 new HIV diagnoses were reported in Turkey, which yielded a total of 26 164 cases [1]. If this trend continues, the burden of HIV on the Turkish healthcare system could be substantial. Therefore, this study aims to calculate HIV incidence and prevalence, define the current continuum of care and the likely impact of improving diagnosis in the next 20 years.
**Materials and methods:** A dynamic compartmental model was developed for HIV transmission and progression and was calibrated against the number of confirmed cases by the Ministry of Health. The model considered the timeframe between 2005 and 2019 as its calibration period, and 2020 and beyond as its prediction period. The model population aged 15 to 64 years was stratified by disease status and transmission risk. HIV-positive population was divided into subpopulations based on disease stages and continuum of care. The model is populated with demographic, epidemiological, behavioural and clinical data from several sources. To assess the effect of improving testing and diagnosis, three scenarios were developed assuming there would be additional funding, which would be expected to improve the number of undiagnosed. The model generated the number of new HIV cases by transmission risk and CD4 + T cell level, HIV diagnoses, HIV prevalence, continuum of care, HIV-related deaths and the expected number of infections prevented.
**Results:** Under the base case, the model estimated HIV incidence around 13 000 annual cases in 2020; 57% of those infections (8000




**Abstract P113-Figure 1. Total visits per year to clinic, for any reason.**




**Abstract P114-Figure 1. (a) Estimated number of diagnosed cases and HIV incidence, 2005 to 2040. (b) Total number of new infections, HIV infections prevented for low, medium and high scenarios, 2020 to 2040.**

cases) would be undiagnosed (Figure 1a). The number of infections was estimated to increase by 27% yielding an HIV incidence of 375 000 infections, and an HIV prevalence around 2.4 million cases by 2040. If testing and diagnosis are improved by 50%, 70% and 90%, infections prevented will increase to around 780 000 (32%), 2M (85%), and 2.3M (97%) in 20 years, respectively (Figure 1b).

**Conclusions:** If there is no improvement in the current continuum of care, HIV incidence and prevalence will significantly increase over the next 20 years and place a significant burden on the Turkish healthcare system. However, improving strategies around prevention, testing and diagnosis will substantially reduce the number of infections.

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# P115

## To 90-90-90 and beyond: feasibility and clinical outcomes of same-day ART initiation among PLHIV in a real-life, middle-income setting

J Barletta[1]; M Jaume[1]; M De Ilzarbe[1]; D Bruno[1]; A Romero[1]; N Tokumoto[1]; G Vigo[1]; L Díaz[2]; O Cando[2] and M Rolón[1]
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**Background:** Achieving the WHO 90-90-90 targets requires additional efforts, particularly in low- and middle-income settings. In PLHIV, commencing ART on the same day of diagnostic confirmation is recommended when the patient is ready and willing to start, but

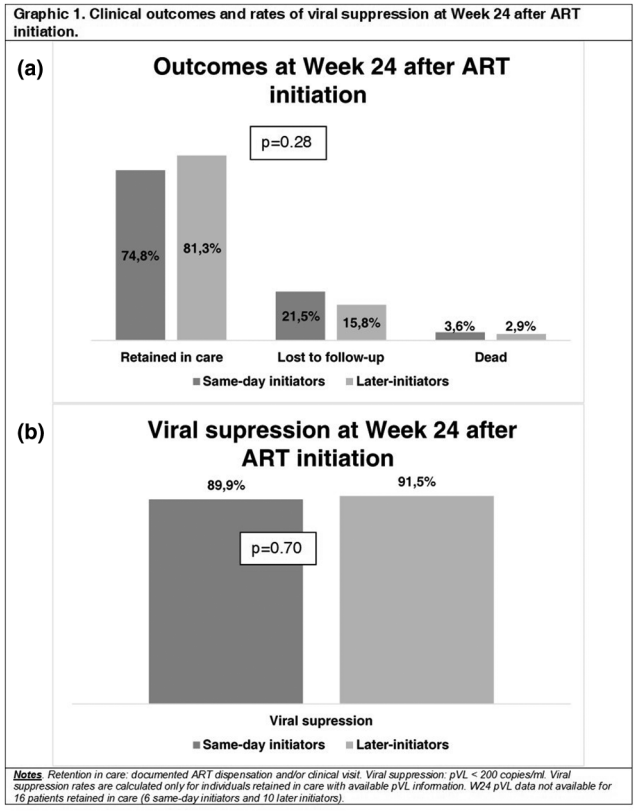
**Abstract P115-Table 1. Baseline characteristics of study population. Baseline pVL information missing for two patients in the same-day ART initiation group**

| | Same-day initiators, n/median (%/Q1-Q3) [N = 274] | Later initiators, n/median (%/Q1-Q3) [N = 171] |
|---|---|---|
| Cisgender men | 198 (72.3) | 129 (75.4) |
| Cisgender women | 66 (24.1) | 36 (21.1) |
| Transgender women | 10 (3.6) | 6 (3.5) |
| Age at diagnosis, years | 33 (26 to 43) | 34 (26 to 44) |
| Baseline CD4 count, cells/mm$^3$ | 291 (106 to 442) | 338 (113 to 520) |
| Late stage at diagnosis | 125 (45.6) | 81 (47.4) |
| Baseline HIV pVL, copies/mL | 59 073 (12 291 to 210 407) | 58 998 (14 899 to 367 311) |
| Time to ART initiation, days | N/A | 31 (9 to 55) |

Late-stage: baseline CD4 < 200 cells/mm$^3$ and/or symptomatic disease (related and/or AIDS-defining illness).

local data regarding feasibility and clinical outcomes associated with this strategy is limited.

**Methods:** Retrospective cohort study. Individuals with newly confirmed HIV infection who were linked to care and initiated ART between January 2016 and December 2018 in our centre were included. Descriptive and continuum of care-related variables were analysed. Local ethics approval was obtained as appropriate.




**Abstract P115-Figure 1. Outcomes and rates of viral suppression at Week 24 after ART initiation. Retention in care: documented ART dispensation and/or clinical visit. Viral suppression: pVL < 200 copies/mL. Viral suppression rates are calculated only for individuals retained in care with available pVL information. Week 24 pVL data not available for 16 patients retained in care (six same-day initiators and 10 later initiators).**

**Results:** Four hundred and forty-five patients were included (62% same-day initiators, 38% later initiators), 73.5% male, median age 33 years (Q1 to Q3 26 to 43). Median baseline CD4 count was lower among same-day initiators versus later initiators (291 cells/mm$^3$ Q1 to Q3 106 to 442 vs 338 cells/mm$^3$ Q1 to Q3 113 to 520 $p = 0.06$), other characteristics of study population are shown in Table 1. There were no significant differences in outcomes or viral suppression rates (Figure 1) at 24 weeks after ART initiation in same-day versus later initiators.

**Conclusions:** Same-day ART initiation is feasible in a middle-income setting. Further research is warranted in order to evaluate its cost-effectiveness and potential impact on long-term outcomes and HIV transmission.

## P116

### Community responses about access to and importance of telemedicine by PLHIV and clinical staff in the EU

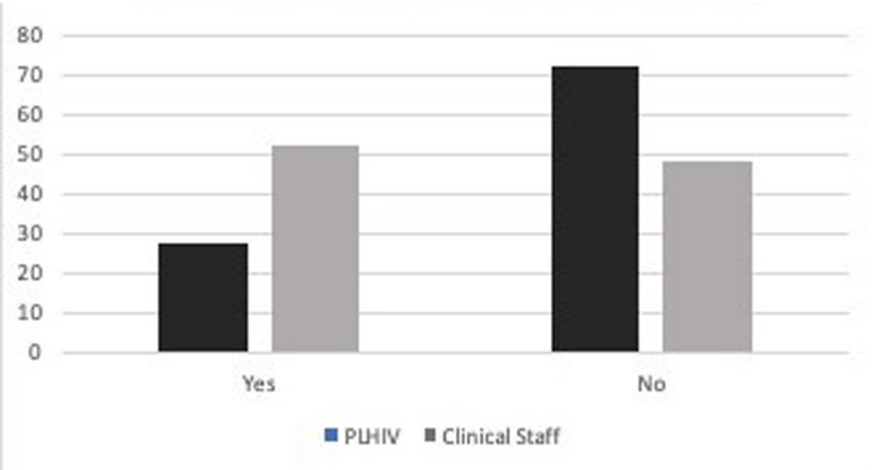
F Greenhalgh[1]; B West[2]; A Von Lingen[1]; M Dutarte[3] and J Whetham[4]
[1]European AIDS Treatment Group, Brussels, Belgium. [2]European AIDS Treatment Group, Edinburgh, UK. [3]European Patients' Forum, Brussels, Belgium. [4]Brighton and Sussex University Hospitals NHS Trust, Brighton, UK

**Background:** As part of the EmERGE project, EATG conducted a survey in July 2019 about the frequency and purpose of HIV clinic visits amongst PLHIV and HIV clinic staff (CS) in the EU. The survey included questions about access to telemedicine (e.g. mobile and web-based services). The overall aim was to understand the diversity of practices and the context in which telemedicine solutions were being rolled out across EU countries.

**Method and materials:** Online surveys to PLHIV and clinical staff containing 10 questions were published in 16 European languages and disseminated widely by EATG partners' community networks and EACS. Eligibility criteria for PLHIV respondents was being stable on ARV therapy (with an undetectable viral load for at least six months). CS were defined as those treating PLHIV stable on ARV therapy. The data were collected and processed anonymously.

**Results:** A total of 407 responses from PLHIV from 26 countries and 153 from CS from 22 countries were received. In total, 27.8% (n = 113/407) of PLHIV indicated that they had access to telemedicine services compared to 52% (n = 78/153) of clinical staff (Figure 1). Using a chi-square test, CS access was found to be significantly higher than the access levels of PLHIV. Over all regions, telemedicine services were mostly found to be either very important or quite important to healthcare by both PLHIV and CS, with no significant differences between the median answers of the two groups.

**Conclusions:** In general, telemedicine solutions are found to be important to healthcare for those who have access to them, yet only a




**Abstract P116-Figure 1. Access to telemedicine by PLHIV and clinical staff (%).**

quarter of PLHIV and one half of CS have such access. Reported access between the two populations varies extensively. Given the changes to service delivery instigated rapidly in the context of COVID-19, the use of telemedicine should be explored through further research which should additionally capture the reasons influencing access discrepancies such as regional differences, healthcare structure, awareness and personal preferences, as these factors may impact the effective roll-out and uptake of telemedicine solutions in a wider European context.

## P117

### Ensuring continuity of care for people living with HIV in five European countries: the efficiency of the EmERGE platform

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**Background:** Calculate the efficiency of the EmERGE Pathway of Care for medically stable people living with HIV managed at five European HIV clinics (Table 1). The Pathway allows for EmERGE participants to communicate virtually with their caregivers.
**Methods:** EmERGE participants, followed up between 2016 and 2019, mainly used HIV outpatient services. Micro-costing studies were performed at each site. Unit and annual costs were calculated in national currencies and converted to US$ 2018 OECD purchasing parity prices (PPPs). Costs were linked to mean per patient year (MPPY) use of outpatient services. Data on use of services were collected retrospectively one year before and prospectively one year after the introduction of EmERGE. Annual costs of HIV outpatient services were combined with primary outcome measures (CD4 count, viral load) to assess efficiency. Out-of-pocket expenditure data were also collected.
**Results:** Two thousand, two hundred and fifty-one participants recruited: 87% to 93% men, mean age at recruitment 41 to 47 years; 70% to 84% had full-time employment, median 37.5 hours/week and monthly income $1580; 5% to 16% participants received social services support, median $318 to 1558/month. Median sick days three months before enrolment was zero days (IQR 0 to 1); 50% to 82% participants did not take days off to visit clinic and the return trip took a median 1.5 to 2.0 hours at a median cost $5 to 41. MPPY outpatient visits decreased in four sites from 9% to 31% and associated costs from 5% to 33% (Table 1); use and costs increased by 8% in one site. Cost of ARVs comprised 83% to 91% annual outpatient costs. Annual costs of use of HIV services was similar across four clinics, but one site, located in one of the least affluent countries, had higher ARV costs. Primary outcome measures of participants did not change substantially during the study.
**Conclusions:** Implementation of the EmERGE Pathway was efficient in all sites. ARVs were the main cost drivers; a country's national socio-economic situation should be considered when setting ARV prices. Other structural changes also affect costs, as demonstrated in two clinics, where changes resulted in reductions and increases of annual costs respectively. Future efficiencies can be anticipated by the introduction of the Pathway for all people living with HIV or those with other chronic diseases as has been demonstrated during the Covid-19 pandemic.

**Abstract P117-Table 1. Average annual mean outpatient visits and average service cost PPY and 95% CIs (2018 US$ PPPs) and gross domestic product: purchasing power parity (GDP PPP; 2017 OECD estimates) for Institute of Tropical Medicine (ITM), Antwerp, Belgium; University Hospital for Infectious Diseases (UHID), National Infectious Diseases Referral Hospital in Zagreb, Croatia; Infectious Diseases Department, Hospital Clínic-IDIBAPS (HC-IDIBAPS), University of HC-IDIBAPS, Barcelona, Spain; Hospital Capuchos, HC-CHLC Centro Hospitalar De Lisboa Central, EPE (HC-CHLC), Lisbon, Portugal; Brighton and Sussex University Hospitals Trust (BSUHT), Brighton, United Kingdom**

| | Pre-EmERGE<br>Per patient year & 95% confidence interval | Post- EmERGE<br>Per patient year & 95% confidence interval | Percentage change |
|---|---|---|---|
| ITM annual mean outpatient visits | 2.6 (95% CI 2.4 to 2.8) | 1.8 (95% CI 1.6 to 2.0) | 31% decrease |
| ITM annual average service costs | $1804 (95% CI $1730 to 1882) | $1558 (95% CI $1505 to 1622) | 14% decrease |
| ITM ARV costs | $11 477 | $11 477 | 0% |
| ITM annual service costs & ARVs (%) | $13 281 (95% CI 13 207 to 13 359) (86%) | $13 035 (95% CI $12 982 to 13 099) (88%) | 2% decrease |
| Belgium GDP PPP | $529 200 000 000 | $529 200 000 000 | 0% |
| UHID annual mean outpatient visits | 4.0 (95% CI 3.8 to 4.3) | 3.3 (95% CI 3.1 to 3.5) | 17% decrease |
| UHID annual average service costs | $2143 (95% CI $2031 to 2260) | $1435 (95% CI $1352 to 1523) | 33% decrease |
| UHID ARV costs | $10 671 | $10 671 | 0% |
| UHID annual service costs & ARVs (%) | $12 814 (95% CI $12 702 to 12 931) (83%) | $12 106 (95% CI $12 023 to 12 194) (87%) | 6% decrease |
| Croatia GDP PPP | $102 100 000 000 | $102 100 000 000 | 0% |
| HC-IDIBAPS annual mean outpatient visits | 5.2 (95% CI 5.0 to 5.4) | 5.6 (95% CI 5.4 to 5.8) | 8% increase |
| HC-IDIBAPS annual average service costs | $1690 (95% CI $1573 to 1822) | $1824 (95% CI $1707 to 1950) | 8% increase |
| HC-IDIBAPS ARV costs | $11 586 | $11 586 | 0% |
| HC-IDIBAPS annual service costs & ARVs (%) | $13 276 (95% CI $13 159 to 13 408) (87%) | $13 410 (95% CI $13 293 to 13 535) (86%) | 1% increase |
| Spain GDP PPP | $1 778 000 000 000 | $1778 000 000 000 | 0% |
| HC-CHLC annual mean outpatient visits | 3.1 (95% CI 3.0 to 3.3) | 2.0 (95% CI 1.9 to 2.1) | 35% decrease |
| HC-CHLC annual average service costs | $3615 (95% CI $3577 to 3648) | $3427 (95% CI $3400 to 3456) | 5% decrease |
| HC-CHLC ARV costs | $17 230 | $17 230 | 0% |
| HC-CHLC annual service costs & ARVs (%) | $20 845 (95% CI $20 807 to 20 878) (83%) | $20 657 (95% CI $20 630 to 20 686) (83%) | 1% decrease |
| Portugal GDP PPP | $314 100 000 000 | $314 100 000 000 | 0% |
| BSUHT annual mean outpatient visits | 5.6 (95% CI 5.4 to 5.8) | 5.1 (95% CI 4.9 to 5.3) | 9% decrease |
| BSUHT annual average service costs (%) | $1093 (95% CI $1051 to 1135) | $987 (95% CI $951 to 1026) | 9% decrease |
| BSUHT ARV costs | $9595 | $9595 | 0% |
| BSUHT annual service costs & ARVs (%) | $10 688 (95% CI $10 646 to 10 730) (90%) | $10 582 (95% CI $10 546 to 10 621) (91%) | 1% decrease |
| United Kingdom GDP PPP | $2 925 000 000 000 | $2 925 000 000 000 | 0% |

## P118

### To 90-90-90 and beyond: a community-focused multimodal, interdisciplinary intervention to optimise continuum of care among recently diagnosed PLHIV in a middle-income setting

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**Background:** Achieving the WHO 90-90-90 targets requires additional efforts, particularly in low- and middle-income settings. Community-centred, individual-focused interventions may significantly contribute to reach these goals. Leading the way to the WHO 90-90-90 targets, a multimodal, interdisciplinary intervention consisting in personalised phone call/SMS reminders from peer navigators to those individuals who did not spontaneously pick up their positive HIV test, same day healthcare provider appointment when confirmatory test results became available and active promotion of same day HAART initiation was implemented at the HIV clinic of a general hospital in Buenos Aires, Argentina. The aim of this study was to evaluate the impact of this intervention on the continuum of care of PLHIV.

**Methods:** This is a retrospective, quasi-experimental study. PLHIV diagnosed between 2016 and 2018 were included. Continuum of care key indicators were analysed in pre-intervention (2016 to 2017) and

post-intervention periods (2018). Local ethics approval was obtained as appropriate.

**Results:** Seven hundred and eighty-five patients (531 in the pre-intervention and 254 in the post-intervention period) were included (Table 1). The proportion of patients who were aware of their HIV diagnosis after spontaneously picking up their HIV result was lower in the post-intervention period (80% vs 57.5% $p < 0.01$); 57 of those individuals who had not picked up their HIV result spontaneously became aware of their diagnosis as a result of the intervention. Median time to HAART initiation was reduced in eight days after intervention (22 days SD 48 vs 14 days SD 46 $p < 0.01$). Table 1 shows key indicators of the HIV continuum of care among study population in pre- and post-intervention periods. Rates of linkage to care and viral suppression at Week 24 increased in the post-intervention period although the difference did not reach statistical significance (72.7% vs 78.4% $p = 0.3$ and 88.4% vs 93.4% $p = 0.17$).

**Abstract P118-Table 1. Patient characteristics and continuum of care-related outcomes at Week 24**

| | Pre-intervention, n = 531 (n/mean [%/SD]) | Post-intervention, n = 254 (n/mean [%/SD]) |
|---|---|---|
| Cisgender men | 380 [72.7%] | 181 [71.3%] |
| Cisgender women | 112 [21.4%] | 55 [21.7%] |
| Transgender women | 31 [5.9%] | 18 [7%] |
| Age, years | 34 [11] | 35 [11] |
| Baseline CD4 count, cells/mm$^3$ | 357 [273] | 391 [313] |
| Individuals who picked up their positive HIV test spontaneously | 425 [80%][a] | 146 [57.5%][a] |
| Individuals who picked up their positive HIV test after intervention | N/A | 57 [52.8%] |
| Linkage to care: linked to care | 309 [72.7%] | 159 [78.4%] |
| Linkage to care: transferred | 89 [20.9%] | 36 [17.7%] |
| Linkage to care: lost to follow-up | 27 [6.4%] | 8 [3.9%] |
| Individuals linked to care who initiated HAART during follow-up | 290 [93.3%] | 155 [96.9%] |
| Time from diagnosis to HAART initiation, days | 22 [48][a] | 14 [46][a] |
| Retained in care at Week 24 | 241 [78%][a] | 108 [67.9%][a] |
| pVL < 200 copies/mL at Week 24 | 198 [88.4%] | 99 [93.4%] |

Percentage of individuals who picked up their positive HIV test after intervention is calculated including only those who did not pick up the test spontaneously. Linkage to care=clinical visit with confirmatory test. HAART initiation calculated for patients linked to care. Median time to HAART initiation calculated for patients who initiated HAART. Retention in care: HAART prescription and/or clinical visit.
[a]Shows statistical significance for $p < 0.05$. Seventeen patients in the pre-intervention and two in the post-intervention period were retained in care but had missing Week 24 pVL data.

**Conclusions:** A multimodal, interdisciplinary intervention with active community involvement has the potential to contribute significantly to lead the way to the WHO 90-90-90 targets. Further research is warranted in order to evaluate its impact on long-term outcomes and cost-effectiveness.

## P119

### Comprehensive retention to care model: results of the pilot in Krasnoyarsk, Russia 2016 to 2019

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**Background:** Low adherence and ART discontinuation is one of the main reasons of opportunistic infections and fatal conditions among PLHIV. Retention interventions are an important way to increase adherence, return people to healthcare and reduce HIV transmission by increasing proportion of virally suppressed patients, and reduce mortality.

**Materials and methods:** Krasnoyarsk NGO "We against AIDS" with support of AIDS Healthcare Foundation (AHF) Russia has initiated the programme in 2016. Programme targets PLHIV on ART who missed their appointments more than three months, patients not on ART who missed appointment for six months, all pregnant women and newborns who missed their regular appointment. Programme includes: follow-up calls, appointment reminder and home visits. Additional available services: assistance with receiving new passport, peer and psychological support at the AIDS clinic, home-based support for the clients not visiting the clinic and monitoring after return to medical care.

**Results:** Between the years 2016 and 2019 4375 patients were involved into retention activities. The programme performed approximately 4000 home visits and 9000 calls each year. Three thousand, one hundred and thirty-eight patients were returned to HIV care (72%), 36% out of the returned patients had CD4 less than 200 cells. Forty-three percent of the patients were females, 54% of them reported sexual transmission as a possible way to acquire HIV. Sixty-seven percent males were reporting IVDU. Age median was 38.4 years. Main reason (79%) for patients to stop ART and miss their visits was active IVDU. Two thousand and ninety-nine (67%) patients initiated and continue ART. One thousand, six hundred and twelve receive ART >12 months and 1815 >6 months. Eighty percent of receiving ART >12 months and 77% of receiving ART >6 months have undetectable VL. Median CD4 increase in 48 weeks was 81.

**Conclusions:** Comprehensive retention to care model which includes home visits, peer counselling, psycho-social support, documents restoration and continuous monitoring after re-linkage to care shows to be effective in reaching both females and males, including the men who have experience of IDUs. The approach is efficient in reaching undetectable VL in the population and epidemic control. This model has a potential to be replicated in other regions.

# Virology and Immunology

## P120

### Islatravir selects for HIV-1 variants in MT4-GFP cells that profoundly reduce replicative capacity in peripheral blood mononuclear cells

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**Background:** Islatravir (ISL; formerly MK-8591) is a first-in-class nucleoside reverse transcriptase translocation inhibitor (NRTTI) with

multiple mechanisms of action. ISL has potent activity against nucleos(t)ide reverse transcriptase inhibitor (NRTI) resistance-associated variants and inhibitory quotients (IQs) that suggest it will have a high barrier to resistance in the clinic. ISL is in clinical development for the treatment and prevention of HIV-1 infection. In this study, we conducted studies to increase our understanding of resistance pathways that may alter susceptibility of HIV-1 to ISL.

**Materials and methods:** Viral resistance selection studies were conducted with HIV-1 subtype B in MT4-green fluorescent protein (GFP) cells and with subtypes A and C in MT4-GFP/CCR5 cells with escalating ISL concentrations. Antiviral activity of ISL on variants bearing emergent substitutions or NRTI resistance-associated substitutions was assessed in MT4-GFP cells and/or PBMCs. Replication capacity was examined for select variants.

**Results:** In subtype A, B, and C viruses, ISL selected for M184I and M184V mutations; however, their impact on its antiviral activity was modest. M184I and M184V conferred 6.2- and 6.8-fold potency ($IC_{50}$) reductions to ISL, respectively. In subtype B virus, a rare A114S variant (observed in a single replicate experiment at passage 38) was detected. Phenotypic analysis showed A114S conferred a marginal potency loss (≤2-fold) to ISL while variants containing A114S+M184V conferred a > 24-fold potency loss to ISL. Variants containing A114S+M184V had profoundly reduced replicative capacity which is consistent with them being rarely observed in the clinic. In contrast to the decreased susceptibility to ISL, A114S increased susceptibility to NRTIs, tenofovir disoproxil fumarate, zidovudine, lamivudine, and emtricitabine, by 1.6- to 14.3-fold in PBMCs. Combinations of A114S and thymidine analog mutations enhanced susceptibility to the NRTIs but not ISL suggesting distinct inhibitory mechanisms on reverse transcription.

**Conclusions:** Variants selected by intensive ISL selective pressure in vitro exhibit low replicative capacity and confer modest fold-shifts on antiviral activity of ISL. The high potency of ISL against reverse transcriptase variants, coupled with its high IQs (previously reported), continue to support the likelihood of a high barrier to the development of ISL resistance in the clinic.

## P121

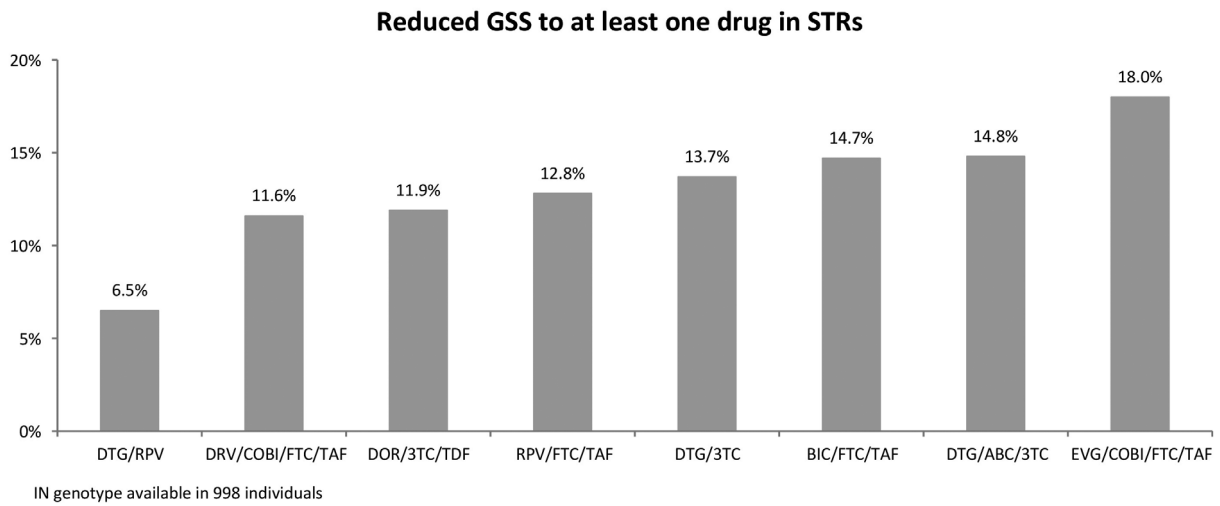
### Impact of resistance to antiretroviral drugs on predicted HIV-1 susceptibility to current single-tablet regimens (STRs)

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**Abstract P121-Table 1. Baseline characteristics of population**

| Variables | Overall (n = 1959) | Naïve (n = 890) | Virosuppressed (n = 307) | Viraemic (n = 762) |
|---|---|---|---|---|
| Female gender, n (%) | 551/1924 (28.6) | 192/876 (21.9) | 89/307 (29.0) | 270/742 (36.4) |
| Age, median (IQR) | 46 (35 to 54) | 40 (31 to 49) | 53 (47 to 59) | 49 (40 to 54) |
| Risk factor, n (%) | | | | |
| Heterosexual contacts | 570/1959 (29.1) | 148/890 (16.6) | 115/307 (37.5) | 307/762 (40.3) |
| MSM/bisexuals | 311/1959 (15.9) | 130/890 (14.6) | 68/307 (22.1) | 113/762 (14.8) |
| IVDU | 250/1959 (12.8) | 13/890 (1.5) | 94/307 (30.6) | 143/762 (18.8) |
| Other/unknown | 828/1959 (42.2) | 599/890 (67.3) | 30/307 (9.8) | 199/762 (26.1) |
| HIV-1 B subtype, n (%) | 1345/1959 (68.7) | 539/890 (60.6) | 263/307 (85.7) | 543/767 (71.3) |
| HIV-1 RNA log10, copies/mL, median (IQR) | 4.1 (2.5 to 5.0) | 4.9 (4.3 to 5.5) | 1.6 (1.3 to 1.6) | 3.5 (2.5 to 4.5) |
| Time on ART, years, median (IQR) | 12.5 (6.1 to 19.5) | — | 15.3 (7.5 to 19.3) | 11.3 (5.2 to 18.6) |
| Nadir CD4 + , cells/$mm^3$, median (IQR) | 209 (66 to 387) | 309 (110 to 506) | 188 (81 to 310) | 150 (44 to 319) |
| Years from HIV-1 RNA < 50 copies/mL, median (IQR) | 6.0 (2.9 to 10.6) | — | 6.0 (2.9 to 10.6) | — |
| Calendar year of genotype, median (IQR) | 2017 (2015 to 2018) | 2016 (2015 to 2018) | 2017 (2016 to 2019) | 2017 (2015 to 2018) |
| Last previous ART regimens, n (%) | | — | | |
| 2NRTI+PI | 237/955 (24.8) | | 55/301 (18.3) | 182/654 (27.8) |
| 2NRTI+INSTI | 252/955 (26.4) | | 61/301 (20.3) | 191/654 (29.2) |
| 2NRTI+NNRTI | 178/955 (18.6) | | 65/301 (21.6) | 113/654 (17.3) |
| Dual therapy | 106/955 (11.1) | | 48/301 (15.9) | 58/654 (8.9) |
| Other | 122/955 (12.7) | | 72/301 (23.9) | 110/654 (16.8) |
| STR-cumulative GSS < 3 or 2 (reduced susceptibility to at least 1 drug), n (%) | | | | |
| RPV/FTC/TAF | 250/1959 (12.8) | 11/890 (1.2) | 58/307 (18.9) | 181/762 (23.8) |
| DOR/3TC/TAF | 233/1959 (11.9) | 8/890 (0.9) | 56/307 (18.2) | 169/762 (22.2) |
| DRV/COBI/FTC/TAF | 227/1959 (11.6) | 9/890 (1.0) | 56/307 (18.2) | 162/762 (21.3) |
| EVG/COBI/FTC/TAF | 180/998 (18.0) | 8/352 (2.3) | 46/239 (19.2) | 126/407 (31.0) |
| DTG/ABC/3TC | 148/998 (14.8) | 6/352 (1.7) | 45/239 (18.8) | 97/407 (23.8) |
| BIC/FTC/TAF | 147/998 (14.7) | 6/352 (1.7) | 45/239 (18.8) | 96/407 (23.6) |
| DTG/RPV | 65/998 (6.5) | 1/352 (0.3) | 16/239 (6.7) | 48/407 (11.8) |
| DTG/3TC | 137/998 (13.7) | 6/352 (1.7) | 41/239 (17.2) | 90/407 (22.1) |
| Previous virological failure, n (%) | 992/1069 (92.8) | — | 265/307 (86.3) | 727/762 (95.4) |
| Number of previous regimens, median (IQR) | 3 (1 to 7) | — | 5 (3 to 9) | 3 (1 to 7) |
| Previous PI RAMs, n (%) | 112/1959 (5.7) | 14/890 (1.6) | 32/307 (10.4) | 66/762 (8.7) |
| Previous NRTI RAMs, n (%) | 455/1959 (23.2) | 82/890 (9.2) | 110/307 (35.8) | 263/762 (34.5) |
| Previous NNRTI RAMs, n (%) | 238/1959 (12.1) | 28/890 (3.1) | 49/307 (16.0) | 161/762 (21.2) |
| Previous INSTI RAMs, n (%) | 74/998 (7.4) | 5/352 (1.4) | 4/239 (1.7) | 65/407 (16.0) |
| Any previous RAM, n (%) | 563/1959 (28.7) | 117/890 (13.1) | 123/307 (40.1) | 323/762 (42.2) |




| Significant comparisons among STRs according to reduced GSS | |
|---|---|
| DTG/RPV vs. DOR/3TC/TDF p<0.001 | DRV/COBI/FTC/TAF vs. EVG/COBI/FTC/TAF vs p<0.001 |
| DTG/RPV vs. DRV/COBI/FTC/TAF p<0.001 | DRV/COBI/FTC/TAF vs. DTG/ABC/3TC p=0.01 |
| DTG/RPV vs. RPV/FTC/TAF p<0.001 | DRV/COBI/FTC/TAF vs. BIC/FTC/TAF p=0.01 |
| DTG/RPV vs. DTG/3TC p<0.001 | RPV/FTC/TAF vs EVG/COBI/FTC/TAF p<0.001 |
| DTG/RPV vs. DTG/ABC/3TC p<0.001 | DTG/3TC vs EVG/COBI/FTC/TAF p<0.001 |
| DTG/RPV vs. BIC/FTC/TAF p<0.001 | DTG/ABC/3TC vs. EVG/COBI/FTC/TAF p=0.04 |
| DTG/RPV vs. EVG/COBI/FTC/TAF p<0.001 | BIC/FTC/TAF vs. EVG/COBI/FTC/TAF p=0.04 |
| DOR/3TC/TDF vs DRV/COBI/FTC/TAF p=0.03 | |
| DOR/3TC/TDF vs DTG/ABC/3TC p=0.02 | |
| DOR/3TC/TDF vs EVG/COBI/FTC/TAF p<0.001 | |

**Abstract P121-Figure 1. Reduced GSS to at least one drug in STRs.**

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**Background:** STRs combine a full antiretroviral regimen in one tablet taken once daily potentially improving adherence, treatment satisfaction and virological outcome.
**Materials and methods:** We selected from ARCA database treatment-naïve (TN), treatment-experienced aviraemic (TE-A) and viraemic (TE-V) HIV-1 infected patients genotyped from 2015 to 2020 for protease/reverse transcriptase and integrase (when available). Genotypic susceptibility score (GSS) was labelled as reduced when decreased susceptibility to at least one drug of the regimen was detected. GSS was computed by Stanford HIVdb v.8.9-1 for the following STRs: RPV/FTC/TAF, DOR/3TC/TDF, DRV/COBI/FTC/TAF, EVG/COBI/FTC/TAF, DTG/ABC/3TC, BIC/FTC/TAF, DTG/RPV and DTG/3TC. Differences in the prevalence of resistance to the different STRs were assessed by $\chi$-square test and logistic regression was employed to detect predictors of resistance.
**Results:** We included 1959 cases (IN genotype: 998): 69% carried a B subtype, 71% were males, median age was 46 (IQR 35 to 54), HIV-1 RNA 4.1 log10 copies/mL (2.5 to 5.0). The prevalence of at least any RAM was 28.7% (NRTI 23.2%, NNRTI 12.1%, PI 5.7%, INSTI 7.4%) (Table 1). Reduced GSS was detected for EVG/COBI/FTC/TAF in 18.0%, DTG/ABC/3TC in 14.8%, BIC/FTC/TAF in 14.7%, DTG/3TC in 13.7%, RPV/FTC/TAF in 12.8%, DOR/3TC/TDF in 11.9%, DRV/COBI/FTC/TAF in 11.6% and DTG/RPV in 6.5% (Figure 1). Reduced GSS to STR was infrequent in TN (0.3% to 2.3%) and not predicted by any variable. At multivariate analyses, in TE-A a longer ART exposure predicted a reduced GSS for all STRs except for DTG/RPV. In TE-V, a lower risk of reduced GSS was predicted by more recent calendar year of genotype for most STRs except for DTG/RPV, RPV/FTC/TAF and DRV/COBI/TAF/FTC, by NNRTI- or INSTI-based last previous three-drug regimen (3DR) (vs 2NRTI+PI) for DOR/3TC/TDF, by NNRTI-based 3DR or PI + 3TC as last previous regimen (vs 2NRTI+PI) for DRV/COBI/TAF/FTC, by a higher number of past ART lines for RPV/FTC/TAF and by longer ART exposure for EVG/COBI/FTC/TAF, DTG/ABC/3TC and BIC/FTC/TAF. A reduced GSS for DTG/RPV was predicted by a higher number of previous ART lines in TE-A and TE-V and by NNRTI-based last previous regimen in TE-V.
**Conclusions:** RAMs circulate in a proportion of HIV-1 patients in Italy, depending on past ART history, and have the potential to affect currently available STRs.

# P122

## Impact of genetic variation of the APOBEC3G gene on HIV RNA, T-cell counts, markers of inflammation and clinical events

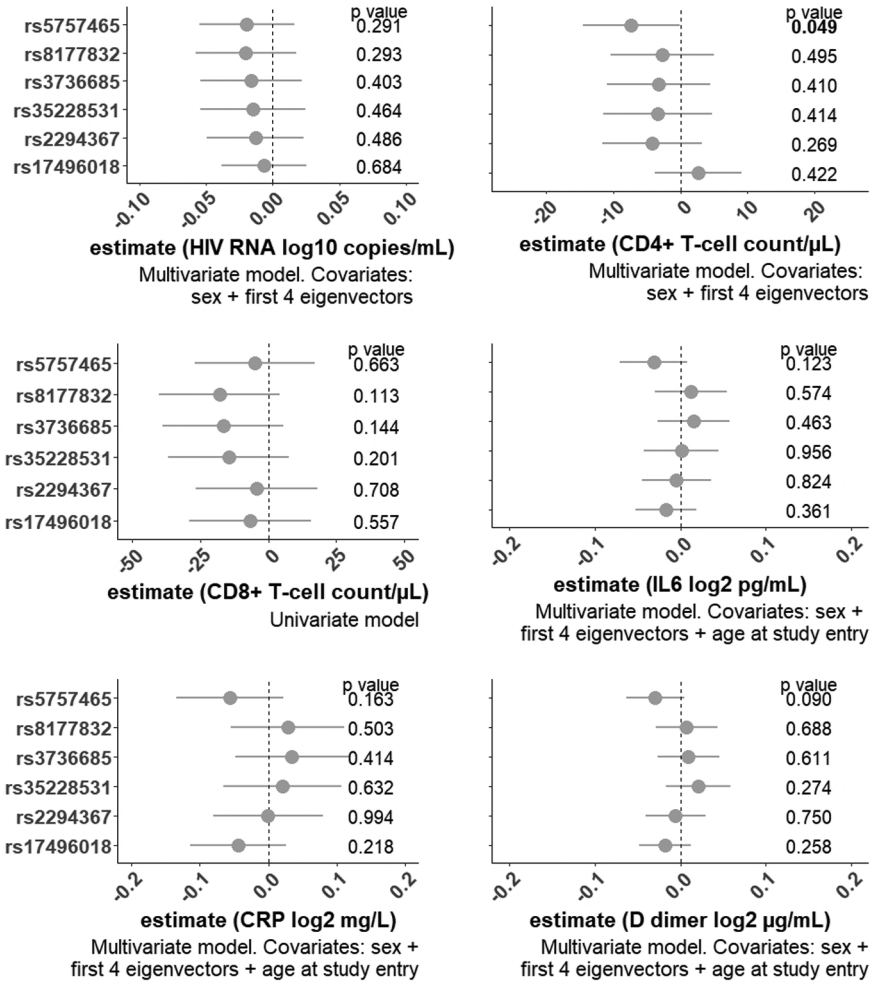
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**Background:** APOBEC3G protein interferes with HIV-1 replication by promoting deamination of cytidine-residues to uracil-residues in newly synthesised HIV-DNA. Single nucleotide polymorphisms (SNPs) in this gene have been associated with pathogenesis and clinical outcomes in PLWH in some cohorts but not in others. We aimed to validate these associations in a larger and more diverse cohort of PLWH.

**Materials and methods:** Clinical and genetic data were collected from participants of the START trial (NCT00867048). Six SNPs were selected based on previous literature associations (rs5757465, rs8177832, rs3736685, rs35228531, rs2294367, rs17496018). Effect sizes between the individual SNPs and laboratory parameters at study entry (HIV-RNA, CD4 + and CD8 + T-cell counts, interleukin-6, D-dimer and C-reactive-protein) were estimated by generalised linear models. Cox proportional hazards models explored the association of SNPs with time to AIDS onset, death and, in the deferred-treatment arm, treatment initiation. Multivariate analyses were run when the univariate approach showed $p < 0.05$. Covariates included sex assigned at birth and the first four eigenvectors (calculated using EIGENSTRAT to control for population structure). Age at study entry was also added for interleukin-6, D-dimer and C-reactive-protein multivariate models.

**Results:** A total of 2546 PLWH were included: 79.9% male, 22.7% Black and 55.1% White population, median age of 36.0 years (IQR 29.0 to 45.0). Median HIV-RNA was 4.2 $\log_{10}$ copies/mL (IQR 3.5 to 4.7) and median CD4 + T-cell count 651.0/µL (IQR 585.0 to 758.4). Univariate analyses revealed significant associations between all SNPs (except rs17496018) and all laboratory parameters (except CD8 + T-cell count). Most of those associations were no longer significant after adjustment (Figure 1). This loss of effect was primarily driven by population stratification (particularly, by the first eigenvector). Only rs5757465 remained significantly associated with CD4 + T-cell count,




**Abstract P122-Figure 1. Generalised linear models for association between APOBEC3G SNPs and HIV pathogenesis biomarkers among participants of the START trial (estimated effect sizes including 95% confidence intervals).**

**Abstract P122-Table 1. Cox proportional hazards models for association between APOBEC3G SNPs and clinical outcomes among participants of the START trial**

| APOBEC3G SNP | n who initiate ART/ n who do not initiate ART among participants allocated to the deferred arm Event distribution across genotypes | Risk of ART initiation - multivariate analysis (covariates: sex + first 4 eigenvectors) HR (95% CI) | n with AIDS events/ n without AIDS events among all participants Event distribution across genotypes | Risk of AIDS events - univariate analysis HR (95% CI) | n who die/ n who do not die among all participants Event distribution across genotypes | Risk of death - univariate analysis HR (95% CI) |
|---|---|---|---|---|---|---|
| rs5757465 (T>C) | [T/T: 319/309] [T/C: 288/203] [C/C: 103/62] | 0.97 (0.87 to 1.09) | [T/T: 21/1231] [T/C: 17/957] [C/C: 7/313] | 1.08 (0.72 to 1.64) | [T/T: 8/1244] [T/C: 8/966] [C/C: 1/319] | 0.89 (0.44 to 1.80) |
| rs8177832 (A>G) | [A/A: 590/418] [A/G: 107/126] [G/G: 13/30] | 0.95 (0.78 to 1.15) | [A/A: 34/1938] [A/G: 9/479] [G/G: 2/84] | 1.16 (0.67 to 2.00) | [A/A: 13/1959] [A/G: 3/485] [G/G: 1/85] | 1.16 (0.48 to 2.79) |
| rs3736685 (T>C) | [T/T: 590/417] [T/C: 106/124] [C/C: 13/30] | 0.95 (0.78 to 1.15) | [T/T: 34/1933] [T/C: 9/473] [C/C: 2/84] | 1.17 (0.68 to 2.01) | [T/T: 13/1954] [T/C: 3/479] [C/C: 1/85] | 1.16 (0.48 to 2.79) |
| rs35228531 (C>T) | [C/C: 643/475] [C/T: 48/67] [T/T: 7/11] | 0.99 (0.75 to 1.31) | [C/C: 39/2158] [C/T: 3/247] [T/T: 1/31] | 0.96 (0.41 to 2.23) | [C/C: 13/2184] [C/T: 3/247] [T/T: 0/32] | 1.47 (0.50 to 4.35) |
| rs2294367 (C>G) | [C/C: 219/200] [C/G: 298/246] [G/G: 184/119] | 0.98 (0.87 to 1.09) | [C/C: 17/811] [C/G: 17/1039] [G/G: 11/613] | 0.89 (0.60 to 1.31) | [C/C: 7/821] [C/G: 7/1049] [G/G: 3/621] | 0.75 (0.39 to 1.43) |
| rs17496018 (C>T) | [C/C: 608/507] [C/T: 93/62] [T/T: 5/3] | 1.03 (0.85 to 1.26) | [C/C: 38/2164] [C/T: 7/307] [T/T: 0/16] | 1.17 (0.55 to 2.49) | [C/C: 15/2187] [C/T: 2/312] [T/T: 0/16] | 0.87 (0.21 to 3.56) |

though with a small effect (estimate −10.5 cells/μL, $p = 0.049$). Overall, there were 45 AIDS events and 17 deaths. Of 1284 participants allocated to the deferred arm, 710 initiated antiretroviral therapy. No significant associations were observed (Table 1).

**Conclusions:** Variation in previously identified APOBEC3G SNPs was not significantly associated with pathogenesis biomarkers or clinical events in this large, diverse cohort of PLWH. High sensitivity of multivariate estimates to the first eigenvector indicates clinical differences are largely driven by population structure rather than by genetic diversity in APOBEC3G.

# P123

## Sustained viral suppression after switch to bictegravir/ emtricitabine/tenofovir alafenamide among clinical trial participants with preexisting M184V/I

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**Background:** Preexisting resistance can affect antiretroviral therapy efficacy in PLWH. One of the most common treatment-emergent resistance substitutions is M184V or, to a lesser extent, M184I. This substitution can be transmitted, archived in the viral reservoir, and

**Abstract P123-Table 1. Pooled analysis of preexisting M184V/I among virologically suppressed clinical trial participants who switched to B/F/TAF**

| | Pooled B/F/TAF | Study 1844 | Study 1878 | Study 4030 | Study 4580 | Study 4449 | Study 1474 |
|---|---|---|---|---|---|---|---|
| Prior regimen | — | DTG/ABC/3TC | Boosted DRV or ATV + either FTC/TDF or ABC/3TC | DTG + either FTC/TDF or FTC/TAF | Any 3rd agent + 2 NRTIs | EVG/COBI/ FTC/TAF or any 3rd agent + F/TDF | Any 3rd agent + 2 NRTIs |
| Total number of participants switched to B/F/TAF, n | 2034 | 545 | 532 | 283 | 489 | 85 | 100 |
| Median B/F/TAF treatment duration, weeks | 48 | 96 | 101 | 48 | 48 | 48 | 48 |
| HIV-1 RNA < 50 copies/mL at last visit, % (n/N) | 99% (2012/2034) | 98% (535/545) | 99% (525/532) | >99% (282/283) | 99% (486/489) | 100% (85/85) | 99% (99/100) |
| Baseline genotype available, % (n/N) | 90% (1824/2034) | 96% (522/545) | 94% (498/532) | 84% (237/283) | 98% (468/489) | 96% (82/85) | 17% (17/100) |
| Baseline M184V/I, % (n/N) | 10% (182/1824) | 3% (17/522) | 12% (62/498) | 20% (47/237) | 11% (50/468) | 4% (3/82) | 18% (3/17) |
| M184V/I HIV-1 RNA < 50 copies/mL at last visit, % (n/N) | 98% (179/182) | 100% (17/17) | 95% (59/62) | 100% (47/47) | 100% (50/50) | 100% (3/3) | 100% (3/3) |
| Treatment-emergent resistance, n | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

reactivated, even after reversion to wild-type virus in plasma. Studies 1844, 1878, 4030, 4580, 4449, and 1474 demonstrated the safety and efficacy of switching stably suppressed PLWH to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF). In this pooled analysis, we investigated the prevalence of preexisting M184V/I and impact on virologic outcomes.

**Methods:** Participants enrolled were aged ≥18 years (studies 1844, 1878, 4030, and 4580), ≥65 years (study 4449), or 6 to <18 years (study 1474). Preexisting drug resistance was assessed by historical genotypes (obtained from ~50%) and/or retrospective proviral DNA genotyping (obtained from > 90%; GenoSure Archive® assay, Monogram Biosciences). Virologic outcomes were based on last available on-treatment HIV-1 RNA, where early discontinuation with HIV-1 RNA < 50 copies/mL was considered suppressed.

**Results:** Altogether, 2034 participants switched to B/F/TAF, and cumulative baseline genotypic data were available for 90% (1824/2034). Preexisting M184V/I was detected in 10% (182/1824): by proviral genotyping only (79% [144/182]), historical genotype only (10% [18/182]), or both (11% [20/182]). Of those with M184V/I, 89% (162/182) had the V substitution only, 6% (11/182) had the I substitution only, and 5% (9/182) had both V and I. In 20% (37/182), M184V/I was the only resistance substitution detected, while in 80% (145/182), other primary resistance substitutions were detected in addition to M184V/I. At last study visit (24 to 156 weeks after B/F/TAF switch), 98% (179/182) of participants with preexisting M184V/I had HIV-1 RNA < 50 copies/mL compared to 99% (1623/1642) of those with wild-type M184 and 99% (2012/2034) of the overall B/F/TAF study population. No B/F/TAF-treated participant developed new drug resistance (Table 1).

**Conclusions:** Preexisting M184V/I was detected in 10% of suppressed participants' baseline genotypes, the majority of which was previously undocumented. High rates of virologic suppression in participants who switched to B/F/TAF, and the absence of treatment-emergent resistance, indicate B/F/TAF may be an effective and durable treatment for virologically suppressed PLWH with documented M184V/I.

## P124

### Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) shows high efficacy in clinical study participants infected with HIV-1 subtype F

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**Background:** HIV-1 subtype F accounts for less than 1% of infections worldwide but has been spreading among European MSM. Recent reports showed a significant delay in viral suppression using multiple integrase strand transfer inhibitor (INSTI)-based regimens for subtype F when compared to subtype B. Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a potent, once-daily single-tablet regimen for treatment of HIV-1 infection, with in vitro activity against all B and non-B subtypes, including subtype F. Here, we present an analysis of B/F/TAF efficacy against HIV-1 subtype F in treatment-naïve and virologically suppressed switch study participants.

**Methods:** Participants from five phase III B/F/TAF studies (GS-US-380-1489 and GS-US-380-1490 [treatment-naïve], and GS-US-380-1844, GS-US-380-1878, and GS-US-380-4449 [virologically suppressed switch]) were included. HIV-1 subtype and genotype were determined at baseline for all naïve study participants and for a subset in the switch studies by historical or proviral DNA archive genotyping. Treatment response was assessed by last on-treatment observation carried forward (LOCF) at the latest endpoints of each study.

**Results:** In total, 12 participants with HIV-1 subtype F (six from treatment-naïve and six from suppressed switch studies) were treated with B/F/TAF. Participants' baseline characteristics were: 75% male, 83% white, median age 43 (range: 26 to 74), 83% with CD4 count ≥500 cells/μl, and from Italy, Spain, Germany, France, and the UK. In the naïve studies, five of six participants on B/F/TAF suppressed by Week 4 (one with baseline HIV-1 RNA 888 000 copies/mL suppressed by Week 24), and all maintained HIV-1 RNA < 50 copies/mL through Week 144. Results were similar in eight participants in the treatment-naïve studies treated with dolutegravir plus two NRTIs. In the switch studies, all six B/F/TAF participants maintained suppression through the latest endpoints of each study (Weeks 48 to 156). None of the subtype F participants had virologic failure or qualified for resistance analysis.

**Conclusions:** In this study, there was no evidence of lower virologic response rates to INSTI-containing regimens, although the sample size was small. B/F/TAF showed high efficacy in participants infected with HIV-1 subtype F in treatment-naïve and switch studies. No participant with subtype F experienced virologic failure or developed resistance to B/F/TAF.

## P125

### Development of integrase inhibitor resistance under first-line treatment with bictegravir

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**Background:** Based on various clinical trials with thousands of patients, it has been shown that HIV-1 resistance against "second-generation" integrase inhibitors dolutegravir and bictegravir does not develop under therapy in vivo. However, there have been isolated clinical cases, where resistance development occurred due to failing DTG-containing treatment. To our knowledge, this is the first case report showing resistance development in vivo under first-line regimen with bictegravir.

**Methods:** Genotypic resistance analysis was performed before start of first-line treatment with a bictegravir-containing regimen in a 48-year-old female patient with a baseline viral load of 2 million copies/mL. The patient was hospitalised 06/2019 at the Medizinische Hochschule Hannover, Germany with a CD4 cell count of 57 cells/μL and severe comorbidities. For resistance estimation, a next-generation sequencing approach was realised on the Illumina Iseq 100 followed by interpretation according to the HIV-GRADE v11/2019 rules.

**Results:** At start of therapy 06/2019, the virus correlated to an HIV-1 subtype C wild-type virus harbouring the M50I polymorphism but no further resistance-associated substitutions in integrase, protease and reverse transcriptase. In 08/2019, the viral load declined to 200 copies/mL but never reached <50 copies/mL. In 10/2019, the viral load increased to 700 copies/mL and remained constant on that level with 1000 copies/mL in 01/2020, seven months after initial start of treatment. At that time point the patient already harboured a two-class resistant virus with M184V (65%) and M184I (34%) in the reverse transcriptase and the R263K (33%) and the H51Y mutation as minor variant (4%) within the integrase. The CD4 count recovered to 300 cells/μL and the patient switched to a darunavir-containing regimen in 01/2020.

**Discussion:** Although this report describes an isolated case, it shows that HIV resistance can develop under first-line treatment with second-generation integrase inhibitors. Despite the development of the mutations R263K+H51Y and M184V/I, the virus seemed to retain its capability to replicate. The role of severe immune deficiency, high initial viral load and potential non-adherence remains speculative in this context.

## P126

### Barriers for participation in HIV vaccine trials among general population in Argentina: first interim survey

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**Background:** Despite the availability of a wide range of effective HIV prevention tools in recent years, the rate of new infections in adults worldwide has not shown a notable decrease. There is a consensus on the need for a safe and effective vaccine to control the epidemic. Among the myriad factors related to HIV vaccine research, one key aspect in conducting clinical trials is finding potential candidates that are willing to participate [1-3]. HIV vaccine acceptability studies have been conducted in the US and developing countries. This topic has not yet been evaluated in Argentina.
**Materials and methods:** An anonymous online survey was administered from September to December 2019 among individuals (ages 18 to 60) who sought HIV testing services at a referral HIV clinic in Buenos Aires, Argentina, or who looked up information on its website and/or social networks. The survey captured attitudes towards a potential HIV vaccine as well as willingness to participate in an HIV vaccine trial. For this study, we performed a cross-sectional analysis.
**Results:** Eight hundred and thirty-eight participants completed the online survey (self-reported gender: cis-male 56.6%, cis-female 38.1%, non-binary 3%, transgender 2.4%). Among cisgender-men, 81.22% self-reported as MSM (n = 385). Median age was 29 (IQR 24 to 36) years, and 83.6% referred living in Buenos Aires and surrounding areas. Regarding participation in an HIV vaccine trial, 60.6% reported they would agree to join a study, 29% would consider it and 10.4% would refuse. The main barriers for participation were fear of being infected by the HIV vaccine candidate (40.6%) and lack of time to participate in a trial (20.4%); 37.6% of the participants referred no obstacle for potential participation.
**Conclusions:** This is the first survey conducted in Argentina to assess attitudes towards HIV vaccine trials. Although survey information specified that the vaccine candidate was not infective, main barrier to participation was fear of acquiring HIV due to the vaccine itself. Our study reflects the importance of education and the correct explanation of research protocols to potential participants. Since the study was carried out among individuals seeking health services information, selection bias may apply. This report provides initial data to continue exploring an area of recent interest in our country.

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# Late Presenters

## P127

### Improving the HIV testing cascade: adequate identification of patients with HIV indicator conditions in hospitals by electronic registration systems

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**Background:** Many patients visit physicians for HIV-related medical reasons in the years prior to their HIV diagnosis. These HIV indicator conditions (HIV-IC) provide an opportunity to test for HIV. The #AWARE.hiv project aims to improve HIV-IC driven testing. One of the key challenges is adequate identification of patients with possible indicator conditions in hospitals as the first step in the HIV testing cascade.
**Materials and methods:** Single centre prospective implementation project at Erasmus University Medical Center (MC) Rotterdam, The Netherlands. An extensive list was constructed of all ICD-10 codes related to HIV-IC. We created a two-step approach to identify possible indicator conditions by first screening for related registered ICD-10 codes in the electronic patient files and cross-compared these with standardised health insurance codes mandatory used by physicians in the Netherlands (DBC). Data were collected on all patients ≥18 years who entered care in the Erasmus MC in- and outpatient clinic between 1 January 2020 and 1 June 2020. By reviewing all ICD-10/DBC codes, we evaluated the feasibility and sensitivity of the screening method by ICD-10 and the HIV test rate in patients with HIV-IC.
**Results:** Identifying patients with possible HIV-IC using electronic registrations within existing institutional ICT infrastructures was possible. Out of 34 332 newly registered diagnoses 2700 (7.9%) were flagged by ICD-10 of which 387 (14.3%) were identified as HIV-IC. DBC screening yielded an additional 412 flagged diagnoses containing 15 HIV-IC. Of the 402 confirmed HIV-IC 166 (41%) had been tested for HIV and one person (0.6%) was found positive for HIV (Table 1). ICD-10 screening for HIV-IC had a 96.3% sensitivity (95% CI 93.9% to 97.9%), 93.2% specificity (95% CI 92.9% to 93.5%), 14.3% PPV (95% CI 13.8% to 14.9%) and > 99% NPV (95% CI 99.9% to 100%).

**Abstract P127-Table 1. Top 10 HIV indicator conditions**

| HIV indicator condition | N (%) | HIV test (%) |
|---|---|---|
| Hepatitis A + B + C | 45 (11%) | 36 (21.7%) |
| Lymphoma | 42 (10%) | 31 (18.7%) |
| Cervical cancer | 39 (10%) | 0 |
| Cervical dysplasia | 33 (8%) | 2 (1.2%) |
| Sexually transmitted infections | 26 (6%) | 8 (4.8%) |
| Peripheral neuropathy | 22 (5%) | 1 (0.6%) |
| Unexplained chronic renal impairment | 18 (4%) | 11 (6.6%) |
| Lymphocytic meningitis | 16 (4%) | 11 (6.6%) |
| Seborrheic dermatitis/exanthema | 14 (3%) | 1 (0.6%) |
| Unexplained chronic diarrhoea | 14 (3%) | 1 (0.6%) |

**Conclusions:** Screening of ICD-10 codes, if mandatory registered, helps to identify patients with HIV-IC in hospitals using electronic patient files, as widely used in high income settings. Our data confirm the gap between the presence of HIV-IC and the lack of HIV testing among a broad range of medical specialties in a low HIV prevalence setting. Future studies should focus on improving this gap by targeted interventions.

## P128

### Routine, automated and clinician independent universal screening of HIV infection in an emergency department: reducing late presentation by overcoming barriers to testing

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**Background:** Global efforts aim at tackling HIV/AIDS disease by stopping its transmission. However, late presentation of HIV infection, thought to be the main driver of onward transmission, is still a major local, national and European problem. Screening and testing awareness campaigns have not had an impact in lowering late presentation numbers and there seems to be generalised insufficient HIV testing in different healthcare settings. We describe the project of a universal, automated and clinician independent HIV screening in a general emergency department (ED).
**Material and methods:** For patients 18 to 65 years of age entering the ED the electronic medical record (EMR) automatically generates a request for HIV antibody test provided the patient: has a blood test as part of routine ED care; is not identified in the EMR as being HIV infected; does not have record of an HIV test in the EMR in the previous 365 days. Nursing staff receive a visual warning of patient eligibility and offer the screening; the 'opt-out' strategy is applied. Physicians can independently order an HIV test (based on clinical suspicion) in which case the patient is not considered for screening. Healthcare workers in the ED received specific training for this project. Linkage to care was guaranteed by a specialised nurse.
**Results:** In the first 16 months of project implementation 21 487 individuals were eligible for screening, of which 18 072 were tested (opt-out rate 6.3%); 44 patients were newly diagnosed with HIV (prevalence rate 0.24%). Late stage diagnosis (baseline CD4 counts <350) in the ED dropped from 90% in the 16 months prior to study implementation to 42%; average CD4 + count at diagnosis went from 198 cells/mm³ to 388 cells/mm³. Linkage to care was achieved in 93.1% of patients (41/44).
**Conclusions:** Our screening project in the ED shows encouraging results that point to a significant reduction in HIV late presentation. The strongest aspect of this project lies in EMR modifications that integrate HIV testing in normal clinical flow in the ED, make it clinician independent and bypass commonly identified barriers to testing: lack of time, staff concerns over test offering, issues with confidentiality and privacy.

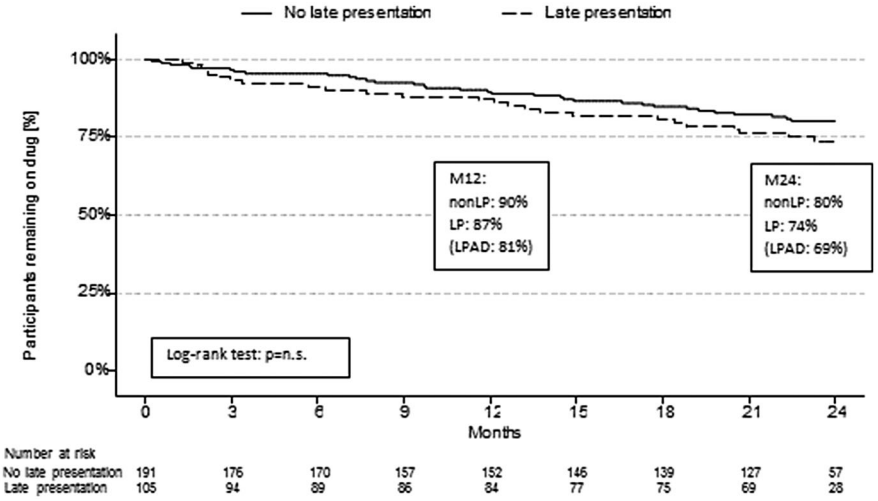
## P129

### Effectiveness and persistence of F/TAF-containing regimens (E/C/F/TAF, R/F/TAF or F/TAF + 3rd agent) in late and very late presenters: final 24-month results from the German TAFNES cohort study

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**Background:** The prospective TAFNES cohort was initiated to provide real-world data on effectiveness and safety of F/TAF-based regimens in routine clinical care in Germany. Here we present the final 24-month (M24) outcomes in ART-naïve PLWH comparing late presenters (LP; CD4 < 350/μL and/or history of AIDS) (including the subgroup of LP with advanced HIV disease [LPAD; CD4 < 200/μL and/or AIDS]) with PLWH in earlier disease stages (non-LP).
**Materials and methods:** M24 evaluation of treatment with either E/C/F/TAF, R/F/TAF or F/TAF + 3rd agent: Effectiveness outcomes comprise viral response (HIV-RNA < 50 copies/mL; discontinuation=failure, loss-to-follow-up/missing=excluded) and study/study drug




**Abstract P129-Figure 1. Study/study drug persistence (Kaplan-Meier estimates; event=discontinuation of the study and/or F/TAF-based study medication i.e. F/TAF-based single-tablet regimen or fixed-dose combination F/TAF, missing/loss-to-follow-up censored).**

**Abstract P129-Table 1. Reasons for discontinuation of the study and/or study medication, documented ADRs/SADRs and changes in HRQL (in the subgroup with baseline [BL] and Month 24 [M24] data)**

| n (%) | Overall | LP | Subgroup of LP: LPAD (n = 56) | non-LP |
|---|---|---|---|---|
| Discontinuations by Month 24, n (%) | 101 (34) | 38 (36) | 24 (43) | 63 (33) |
| Due to | | | | |
| Therapy simplification | 13 (4.4) | 8 (7.6) | 5 (8.9) | 5 (2.6) |
| ADRs | 11 (3.7) | 6 (5.7) | 4 (7.1) | 5 (2.6) |
| Virological failure | 4 (1.4) | 0 (0.0) | 0 (0.0) | 4 (2.1) |
| Lost to follow-up | 41 (13.9) | 13 (12.4) | 8 (14.3) | 28 (14.7) |
| Documented ADRs,[a] events/patients (% of patients) | 19/14 (4.7) | 10/8 (7.6) | 3/3 (5.4) | 9/6 (3.1) |
| Documented serious ADRs (SADRs), events/patients (% of patients) | 0/0 (0) | 0/0 (0) | 0/0 (0) | 0/0 (0) |
| Change HIV-SI[b] from BL until M24, mean (+/-SD) [n] | −3.5 (11.0) [126] | −4.4 (11.4) [44] | −5.9 (12.1) [20] | −3.0 (10.9) [82] |
| Change SF-36[c] physical component score from BL until M24, mean (+/-SD) [n] | +2.0 (9.1) [127] | +3.4 (8.8) [43] | +7.4 (9.6) [19] | +1.2 (9.2) [84] |
| Change SF-36[c] mental component score from BL until M24, mean (+/-SD) [n] | +3.5 (12.3) [127] | +6.6 (12.4) [43] | +6.7 (8.7) [19] | +1.8 (12.0) [84] |

[a]In another 4 patients (3 non-LP and 1 LPAD) ADRs were not documented as ADR in eCRF, but documented as reason for discontinuation;
[b]range 0 to 80, higher scores indicate more bothering symptoms;
[c]norm based scoring, higher scores indicate higher HRQL.

persistence (Kaplan-Meier estimates). Differences in viral response were tested for significance applying logistic regression adjusting for gender, age, HIV-RNA level, treatment group. Other outcomes included: non-serious/serious adverse drug reactions (ADRs/SADRs) and health-related quality of life (HRQL) using validated questionnaires (SF-36, HIV Symptom Index [HIV-SI]).

**Results:** N = 296 ART-naive PLWH were eligible for M24 analysis at study completion on 30 March 2020 (94% men, 9% CDC C, median age 37 years), 105 of whom were LP (35%; 56 LPAD [19%]), 191 nonLP; 156 patients received E/C/F/TAF (30% LP), 41 received R/F/TAF (22% LP) and 99 received F/TAF + 3rd agent (49% LP). At M24, overall virological response rate was 73% (n = 177/241), with no significant difference between LP (69%, n = 62/90; LPAD 60%, n = 28/47) and nonLP (76%, n = 115/151) in univariate analysis and adjusted for covariables. Study/study drug persistence through M24 in LP and nonLP was 74% (LPAD 69%) and 80%, respectively (Figure 1). Discontinuations and documented ADRs are shown in Table 1 with low rates of discontinuation due to ADRs or virological failure of 6% and 0% in LP (7% and 0% in LPAD) and 3% and 2% in nonLP, respectively. Changes in HRQL scores reflect improvements within all subgroups for HIV-SI and in LP and LPAD for SF-36 (Table 1).

**Conclusions:** In the German TAFNES cohort on initial F/TAF-based ART, late presenters had similar high retention and virological response rates as non-late presenters at M24. Discontinuations due to virological failure or ADRs were infrequent in both groups. Improvements in HRQL were observed in late presenters, particularly in those with advanced disease.

# P130

## Late presenters of HIV infection during COVID-19 pandemic

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**Background:** In December 2019 a novel coronavirus was identified in China [1]. The virus was named as severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) and the epidemic disease as coronavirus disease 2019 (COVID-19) [2]. The most vulnerable populations are patients with comorbidities such as chronic cardiovascular disease, chronic lung disease and chronic renal failure [3]. PLHIV were included among patients at increased risk from COVID-19 [4]. Although the number of cases of SARS-CoV-2 and HIV coinfection are limited based on published literature, during COVID-19 pandemic it seems difficult to maintain the HIV care continuum positive outcomes [5].

**Material and methods:** The aim of the present study is to highlight the impact of COVID-19 pandemic on HIV care and clinical monitoring. A retrospective study was conducted in HIV Unit of Alexandroupolis comparing data of outpatient visits of PLHIV, new diagnoses of HIV infection and percentages of late presenters between the first semester of 2019 and 2020.

**Results:** The number of PLHIV examined in HIV Clinic of Alexandroupolis during the first semester of 2019 was 245. The corresponding number in 2020 was 139. Especially during the period of lockdown in Greece (March–April 2020) outpatients visits were dramatically decreased to 28, while in March and April of 2020 were 68. After the lockdown period in May and June 54 PLHIV examined in our clinic. The number remained lower than the corresponding period in 2019 (146 outpatient visits). A significant increase was observed after the lockdown in new HIV diagnoses. Thirteen patients were diagnosed with HIV infection the first semester of 2020 mainly after the lockdown period, while six in 2019. Late presenters were the 46.2% of newly diagnosed individuals the first semester of 2020 and 33.3% in 2019.

**Conclusions:** The outpatient visits of PLHIV during COVID-19 pandemic are significantly reduced. However, the number of new HIV diagnoses and late presenters seems to be significantly increased after the lockdown period. It is vital to find ways to continue the clinical monitoring and care of PLHIV especially for newly diagnosed, non-virally suppressed and with HIV-defining diseases individuals in order to maintain the HIV care continuum positive outcomes.

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# COVID-19

## P131

### Resilience and frailty in people living with HIV during the lockdown experience in Italy in March-May 2020: are they two complementary constructs?

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**Background:** The construct of resilience is defined as an individual's "positive adaptation within the context of significant adversity". Therefore, we tried to assess the impact of the lockdown experience in Italy caused by the first COVID-19 epidemic wave in March–May 2020 in PLWH through a validated resilience score in relation to frailty.
**Methods:** In May 2020, all PLWH attending Modena HIV Metabolic Clinic at least once from 1 January 2019 were offered to complete an electronic questionnaire including health-related questions and the resilience score questionnaire (CD-RISC-10, short version [1]). A subset of these patients had a frailty evaluation within the previous year, assessed using 1) a 72-item Frailty Index (FI) that evaluated multiple health domains, 2) a 10-item HIV Index (HIVI) scoring the most significant HIV variables and 3) a 10-item Protective Index (PI) including socio-behavioural domains [2].
**Results:** Out of 1100 PLWH reached via mail, 506 (50%) completed the questionnaire. Median age was 54 (IQR 49 to 59), HIV duration >20 years was present in 63%. According to our cross-sectional survey, only 9% of PLWH worsened the general health status. The same proportion reported difficulties in reaching physicians and having access to HIV drugs. PLWH resilient to the lockdown event were 329 (73.13%). In a multivariable logistic regression these individuals were more likely to be in the age category > 60 (OR 0.43, 95% CI 0.22 to 0.85) and having a partner (OR 2.25, 95% CI 1.48 to 3.42), after correction for gender, working status and HIV variables. In the subset of 235 of PLWH who were assessed for frailty, CD-RISC-10 median score was −0.87 (±3.14) in frail and 0.08 (±2.29) in non-frail individuals ($p = 0.02$). In logistic regression analysis, resilience was not associated with FI, HIVI and PI.
**Conclusions:** Intervention to relieve social isolation and loneliness in PLWH are urgently needed to cope with the challenge of COVID-19 crisis. Resilience and frailty constructs may represent two complementary constructs of vulnerability in PLWH and they should be addressed simultaneously.

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## P132

### Impact of COVID pandemic among men who have sex with men living with HIV during COVID lockdown in Argentina

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**Background:** The Argentinean government established an early enforced lockdown to mitigate the spread of COVID-19 [1]. The risk for severe illness from COVID-19 among PLWH has not been established yet [2,3]. However, it is known they are at increased risk for mental health complications [4]. This cohort study examines the impact of COVID-related stress and enforced lockdown on treatment adherence among men who have sex with men living with HIV (MSMLWH) in Argentina.
**Methods:** Participants were people with HIV enrolled in a private/social security clinic network, the largest provider for HIV healthcare in Argentina. Participants completed an anonymous online survey assessing adherence to HIV treatment, COVID-19 prevention behaviour, disruptions to resources, psychosocial factors and substance use. For this analysis, we focused on MSMLWH outcomes.
**Results:** A total of 1336 participants (892 men and 444 women), aged between 18 and 82 years, residing mostly in Buenos Aires Metropolitan Area (94.1%), completed the online survey. Among men, 596 participants self-reported as men who have sex with men with a median age of 44 years (35 to 52). MSMLWH reported high adherence to lockdown (96.8%), loss of employment in their household (55.4%), difficulty in obtaining basic necessities such as food or clothing (36.6%) and 27.2% reported challenges to access internet-delivered medical services. Disruption in obtaining non-HIV medication was reported by 7.7% of the subjects, and 4.9% in the case of HIV medication; 29.9% reported suboptimal adherence. Mental health challenges were frequent: depression (14.1%), loneliness (15.6%) and anxiety (20.2%). Abuse (sexual, emotional or physical) was reported by 6.5%. 13.1% reported an increase in their alcohol consumption.
**Conclusions:** High adherence to prevention measures was reported among MSMLWH at the beginning of the lockdown. However, it challenged the access to health services and may have impacted on medication adherence. COVID-19 pandemic has significantly deteriorated the country's economy, and our study shows its impact on MSMLWH access to resources. Lockdown and COVID-stress have also affected MSMLWH's emotional health. Our study highlights the importance of strengthening HIV healthcare services to promote treatment adherence and mental health support during COVID pandemic, especially in lockdown periods.

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## P133

### COVIDApp: a health application as an innovative strategy for the management of the COVID-19 pandemic in long-term care facilities

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**Background:** The COVID-19 pandemic has caused an unprecedented worldwide public health crisis that requires new approaches. COVIDApp is a mobile application for the management of institutionalised individuals in long-term care facilities (LTCF).
**Methods:** COVIDApp was implemented in 196 care centres in collaboration with 64 primary care teams. Objectives: early detection; self-isolation of suspected cases and rapid diagnosis; remote treatment and monitoring of mild cases; and real-time monitoring of the progression of the infection. The following parameters of COVID-19 were reported daily: signs/symptoms; diagnosis by polymerase chain reaction; absence of symptoms for ≥14 days; total deaths; and healthcare workers isolated with suspected COVID-19. The number of centres at risk was also described.
**Results:** Data were recorded from ≥10 000 institutionalised individuals and up to 4000 healthcare workers between 1 and 30 April 2020. A rapid increase in suspected cases was seen until Day 6 but decreased during the 2 last weeks (from 1084 to 282 cases). Confirmed cases increased from 419 cases (Day 6) to 1293 cases (Day 22), remaining stable during the last week. Around 49.2% remained asymptomatic ≥14 days. A total of 854 (8%) deaths were reported (383 in suspected/confirmed cases). The number of isolated healthcare workers remained high over the 30 days; suspected cases decreased during the last 2 weeks. The number of high-risk LTCF decreased from 9.5% to 1.5% (Figure 1).
**Conclusions:** COVIDApp could help clinicians to rapidly detect and remotely monitor suspected and confirmed cases of COVID-19 among institutionalised individuals, thus limiting the risk of spreading the virus. The platform shows the progression of infection in real time and can help us to design new monitoring strategies.

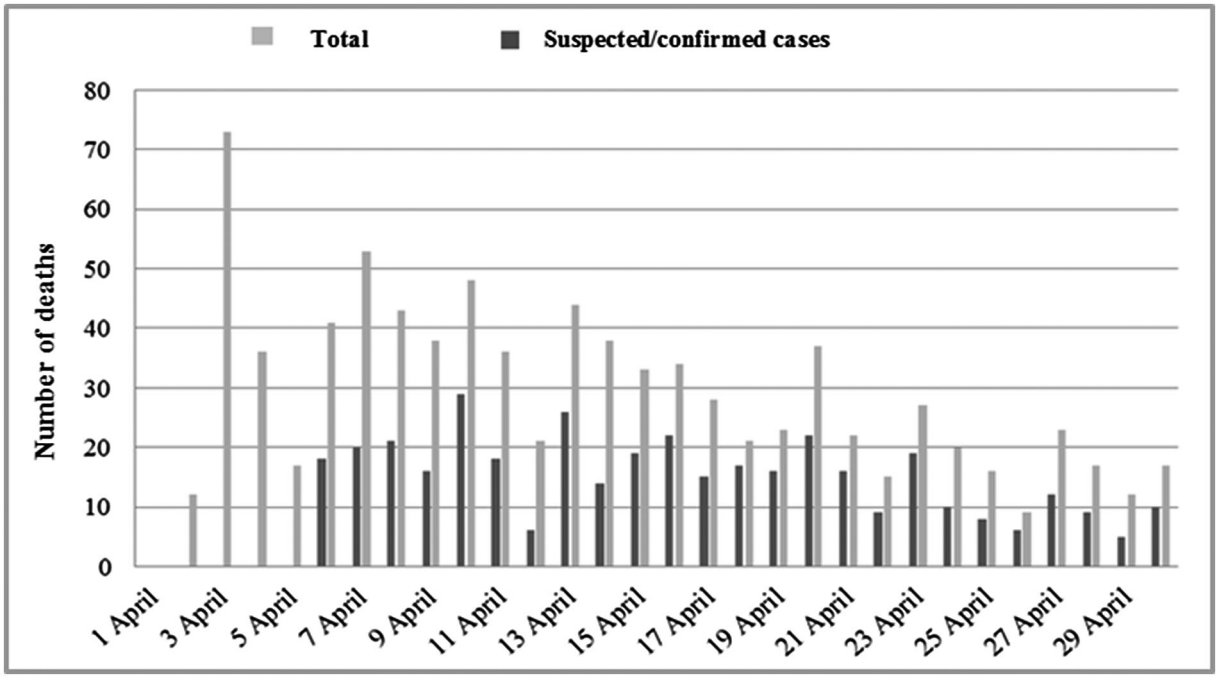
## P134

### SARS-CoV2 pandemic: SARS-CoV2 seroprevalence and impact on HIV suppression in PLWH

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**Background:** Lockdown, as a strategy to control SARS-CoV2 pandemic, has been implemented in several countries including Italy. Modena HIV Clinic shut down from 24 February to 4 May 2020. The aim of the present study was to assess the prevalence of SARS-CoV2 positive serology among PLWH and to investigate the impact of the pandemic on HIV virological control in this population.
**Materials and methods:** SARS-CoV2 serological assays were performed in PLWH attending Modena HIV Clinic after 4 May 2020, as




**Abstract P133-Figure 1. Total number of deaths and deaths in suspected/confirmed cases among residents, as reported by long-term care facilities healthcare staff over 30 days.**

part of HIV follow-up which includes HIV viral load and CD4 + assessment as well. HIV virological blips were defined as HIV RNA > 40 copies/mL after two consecutive undetectable HIV RNA in previous assays. Serological tests of the general population were obtained from local hospital laboratory. A descriptive analysis was done to address differences between groups: continuous variables were compared using non-parametric analysis (Mann–Whitney), while categorical variables were compared using chi-square test. The level of statistical significance was set for *p*-value less than 0.05. Multivariate analysis was performed using stepwise logistic regression method.

**Results:** Until 17 June 2020 a total of 52 072 serological assays were obtained from 30 286 people. Four hundred and ninety-six (1.6%) were performed in PLWH, thus the 28.7% (496/1733) of the whole Modena HIV cohort was tested. SARS-CoV2 serological tests were positive in 1577 people (5.2%), 17 (3.4%) in PLWH and 1560 (5.2%) in HIV-negative people, respectively ($p = 0.072$; chi-square test). Regarding logistic multivariate analysis, age (OR 1.007; 95% CI 1.004 to 1.010; $p < 0.001$) and foreign nationality (OR 1.070; 95% CI 1.181 to 1.591; $p < 0.001$) were the only determinants for being SARS-CoV2 seropositive, while HIV serological status was not associated (OR 0.627, 95% CI 0.385 to 1.021; $p = 0.061$). Virological blips were observed in 3.7% (15/406) of patients in cART. One patient stopped treatment and the remaining had virological blips < 1000 copies/mL (range 41 to 225 copies/mL); none of them was SARS-CoV2 positive.

**Conclusions:** Our data show no statistically significant difference in SARS-CoV2 seroprevalence between HIV-positive and HIV-negative people. Still, the increase in viral blips is worrisome, as it may reflect decreased adherence to cART or difficult drug supplying due to lockdown.

## P135

### Prevalence of respiratory virus infections during a SARS-CoV2 epidemic

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**Background:** On 10 March 2020, the World Health Organization declared a global pandemic due to widespread infection of the novel coronavirus SARS-CoV-2. This epidemic struck while the winter epidemics of respiratory viruses were not yet finished. In order to better understand the aetiologies of influenza-like syndromes in the COVID-19 period, we analysed the samples taken in a hospital screening centre in Paris, France at the very beginning of the epidemic.

**Materials and methods:** We collected nasopharyngeal swabs from persons attending the outpatient testing unit of St-Antoine University Hospital in Paris from 28 February to 27 March 2020. Real-time polymerase chain reaction (RT-PCR) was performed for SARS-CoV-2 and for the most common respiratory pathogens. Patient characteristics, symptoms at presentation and risk factors were collected. Data were analysed for normality and descriptive statistics were presented as a number (%) for categorical variables and median (interquartile range [IQR]) for continuous variables. Chi-square test was used for categorical variables.

**Results:** Overall, 707 patients sought medical care. According to the former testing strategy 468 patients (66.2%) qualified for testing by RT-PCR and were included in final analysis. The median (IQR) age was 37 (29 to 50) years and 139 patients (29.7%) were male. The prevalence of SARS-CoV2 was 37.4% and 37 patients (7.9%) were positive for other pathogens, mainly influenza. Two hundred and fifty six patients (54.7%) had negative results. Symptoms such as anosmia, fever and headache were more frequently seen in patients with SARS-CoV2 compared to other pathogens (respectively 26.3% vs 2.7%, $p < 0.00001$; 78.9% vs 64.9%, $p < 0.02$; 45.1% vs 29.7%, $p < 0.002$), while nasopharyngitis was more common in patients with other viruses (24.3% vs 10.39%, $p < 0.003$). Over the study period, the prevalence of respiratory viruses other than SARS-CoV2 decreased (Week 1: 26.4%, Week 2: 7.3%, Week 3: 1.8%) until it became zero on the fourth week (Table 1).

**Abstract P135-Table 1. Viral and bacterial agents detected in patients tested for SARS-CoV-2 infection, Paris, France, 28 February to 27 March 2020 (n = 468)**

| Pathogens | Patients with pathogen detected, n (%) |
|---|---|
| SARS-CoV-2 | 175 (37.4) |
| Influenza A | 6 (1.3) |
| Influenza B | 7 (1.5) |
| Metapneumovirus | 5 (1.1) |
| Rhinovirus/enterovirus | 8 (1.7) |
| Coronavirus HKU1 | 3 (0.6) |
| Adenovirus | 2 (0.4) |
| M. pneumoniae | 1 (0.2) |
| Respiratory syncytial | 1 (0.2) |
| Mixed infections (excluding SARS-CoV-2) | 4 (0.9) |

**Conclusions:** Over the period of March 2020 seasonal respiratory viruses quickly disappeared while COVID-19 affected more than a third of people consulting for an influenza-like illness in a hospital screening centre in Paris. The anosmia-fever-headache triad has been found much more frequently in association with SARS-CoV2 than with other respiratory viruses and could be a warning sign in case of a new epidemic.

## P136

### Prophylactic dose of low-molecular-weight heparin (LMWH) might not be sufficient to mitigate the clinical scenario in patients with COVID-19 and severe pneumonia

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**Background:** Coronavirus disease 2019 (COVID-19) is commonly complicated with coagulopathy and prophylactic daily low-molecular-weight heparins (LMWHs) are currently recommended in patients hospitalised with COVID-19 pneumonia in order to reduce the incidence to venous thromboembolism (VTE). Aims of the study were to assess the role of LMWH at prophylactic dose on the clinical

progression and on the evolution of inflammation parameters in patients with COVID-19 pneumonia compared with those who did not receive prophylactic LMWH.

**Materials and methods:** Patients ≥18 years with SARS-CoV-2 infection diagnosed by means of RT-PCR positive on nasopharyngeal swab (at least once) and/or serology, with a radiologically confirmed pneumonia were included. Primary endpoint: time from hospital admission (baseline [BL]) to invasive mechanical ventilation/orotracheal intubation/death (IV/IOT/death). Secondary endpoint: to compare the mean changes of inflammation parameters and to compare them between patients receiving LMWH at prophylactic dose and those not receiving LMWH. In order to control for measured confounders, a marginal Cox regression model with inverse probability weights was used.

**Results:** Three hundred and seventy-four patients: 36% female, median (interquartile range [IQR]) age of 61 (IQR, 51 to 75) years, a median of eight days from onset of symptoms (5 to 11) to start LMWH. Overall, we observed 62% of patients with >1 comorbidity and 10% of IOT and/or death; median BL PaO2/FiO2 was 339 mmHg (275 to 409). The estimated probability of IV/IOT/death at 15 days from admission, for patients receiving prophylactic LMWH was 22.1% (95% CI 15.6 to 30.8) and for those who did not receive LMWH was 5.0% (95% CI 2.3 to 10.8). The risk of IV/IOT/death in the two groups appeared to vary by PAO2/FiO2 (Table 1). Only a significant decrease of D-dimer was observed with the use of prophylactic LMWH (Table 2).

**Abstract P136-Table 1. HR of invasive ventilation/IOT/death from fitting a marginal Cox regression model**

| | Unadjusted and adjusted marginal relative hazards of invasive mechanical ventilation/IOT/death[a] | | | |
|---|---|---|---|---|
| | Unadjusted HR (95% CI) | *p*-value | Adjusted[b] HR (95% CI) | *p*-value |
| All patients | | | | |
| No prophylactic LMWH | 1.00 | | 1.00 | |
| Prophylactic LMWH | 1.83 (0.78, 4.33) | 0.166 | 1.30 (0.53, 3.23) | 0.568 |
| Baseline $PaO^2/FiO^2 \leq 300$ mmHg | | | | |
| No prophylactic LMWH | 1.00 | | 1.00 | |
| Prophylactic LMWH | 2.80 (1.02, 7.71) | 0.046 | 2.54 (0.85, 7.61) | 0.096 |
| Baseline $PaO^2/FiO^2 > 300$ mmHg | | | | |
| No prophylactic LMWH | 1.00 | | 1.00 | |
| Prophylactic LMWH | 0.26 (0.04, 1.69) | 0.159 | 0.38 (0.01, 9.70) | 0.555 |

[a]Initiation of invasive mechanical ventilation or death. P at interaction test between LMWH use and baseline PaO2/FiO2 level = 0.059;
[b]adjusted for age, gender, number of comorbidities, PAO2/FiO2 at admission, time-varying use of immune-therapy, azithromycin and censoring using IPW.

**Abstract P136-Table 2. Mean changes per day of hyperinflammation parameters**

| | Parameters | At admission | Last observation | Change/day, mean | *p*-value |
|---|---|---|---|---|---|
| LMWH | Lymphocytes, cells/mmc | 1340 | 1604 | 12.3 | 0.642 |
| No LMWH | | 1346 | 1597 | 17.5 | |
| LMWH | D-dimer, ng/mL | 2204 | 1411 | −59.9 | 0.007 |
| No LMWH | | 1010 | 1127 | 18.4 | |
| LMWH | CRP, mg/dL | 6.4 | 3.3 | −0.28 | 0.308 |
| No LMWH | | 4.6 | 2.5 | −0.13 | |
| LMWH | Ferritin, pg/mL | 638 | 766 | 15.4 | 0.029 |
| No LMWH | | 407 | 515 | −5.8 | |
| LMWH | LDH, U/L | 279 | 249 | −1.2 | 0.612 |
| No LMWH | | 256 | 232 | 2 | |

CRP, C reactive protein; LDH, lactic dehydrogenase; LMWH, low-molecular-weight heparin.

**Conclusions:** Our results highlight that standard doses of prophylactic LMWH did not add any clinical advantage in COVID-19 pneumonia and more specifically in critically ill patients, even though some differences have been observed on the efficacy of heparin derivatives as anti-inflammatory agents. These findings support the feeling that prophylactic doses of anticoagulation might not be sufficient to contrast the hypercoagulable and hyper-inflamed state established in many COVID-19 patients.

## P137

### Symptoms of viral infection and polymerase chain reaction (PCR) positivity rates of SARS-CoV2 in healthcare professionals in Paris, France

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**Introduction:** On 10 March 2020, the World Health Organization declared a global pandemic due to widespread infection of the novel coronavirus SARS-CoV-2 [1]. In France, the testing policy in the beginning of the pandemic suggested a restriction to symptomatic persons with risk factors or health care workers (HCWs) [2]. We report the results of prevalence testing for SARS-CoV-2 and the associated symptoms in HCWs presented with influenza-like illness during the first month at St-Antoine Hospital in Paris.

**Patients and methods:** We prospectively collected nasopharyngeal swabs from persons attending the outpatient testing unit of St-Antoine University Hospital in Paris from 28 February to 31 March 2020. Real-time polymerase chain reaction (RT-PCR) was performed for SARS-CoV-2 and for the most common respiratory pathogens. Patient characteristics, symptoms at presentation, occupation and risk factors were collected. Data were analysed for normality and descriptive statistics were presented as a number (%) for categorical variables and median (interquartile range [IQR]) for continuous variables. Chi-square test was used for categorical variables.

**Results:** Overall, 823 patients sought medical care during the study period. According to the former testing strategy 623 (74.9%) qualified for testing for SARS-CoV-2, among whom 481 (77.2%) were HCWs. The median (IQR) age was 37 (29 to 50) years and 181 patients (29.1%) were male. The overall prevalence of SARS-CoV2 was 28.1%. Among patients with negative SAS-CoV2 PCR, 37 (4.5%) were carriers of another respiratory virus, mainly influenza virus (35%). Compared

to other patients, HCWs had higher prevalence of SARS-CoV2 (30.1% vs 21.1%, $p < 0.04$). The median (IQR) onset of symptoms before the test was 3 (2 to 4) days in patients with COVID-19. Fever and cough were noted in 138 (78.9%) and 124 (70.9%) patients respectively while anosmia, fever, myalgia and headache were significantly more common in patients with SARS-CoV2 infection (26.3% vs 6.7%, 78.9% vs 56.7%, 46.9% vs 31.5% and 45.1% vs 31.7% respectively).
**Conclusions:** At the very beginning of the COVID-19 epidemic in France, the overall prevalence of SARS-CoV2 positivity in a hospital screening centre in Paris was 30.1% among HCWs who sought medical care for influenza-like illness, which highlights the importance of screening of health care professionals for SARS-CoV2 during an epidemic period.

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# P138

## Understanding how HIV testing has been affected by the COVID-19 response

F Greenhalgh; A Von Lingen; B Cigan; G Barbareschi; F Amort; M Cascio; A Schneider and I Hodgson

European AIDS Treatment Group, Brussels, Belgium

**Background:** In response to COVID-19 being declared a pandemic, concerns were raised about the impact on PLHIV, different communities affected by HIV and healthcare systems. EATG collected several data reporting the disruptions and solutions found at community level. As the first rapid assessment (RA) indicated changes to testing practices, EATG expanded the questions on testing in the second RA to understand how testing appointments and follow-up to testing were being affected and the community centres' response to this.
**Methods:** EATG conducted an online survey-based RA with a data collection period from 27 March to 3 April 2020. The questionnaire included quantitative and qualitative questions in English. It was disseminated through the networks of EATG and AIDS Action Europe. The results of the first survey informed the questions of the second RA which was also available in Russian and was broadly disseminated for response from 27 April to 4 May 2020. The survey was addressed to PLHIV and communities most affected by HIV who are affiliated to organisations or as individuals.
**Results:** In the first survey, 16/47 respondents reported that HIV testing in healthcare settings was available only in emergencies, 11/47 as postponed and 17/47 reported no change. Several reported disruption to HIV testing activities from community centres, with suspension of testing activities or appointment-only testing. Three respondents reported exploring self-testing programmes. In the second survey, respondents noted that self-testing kits were available through the following means: NGOs (25/29), pharmacies (16/29), online (15/29), vending machines (3/29) (Figure 1). While 6/29 people reported kits were unavailable due to shortages, 16/29 respondents noted they were never available in their location. Examples of community interventions to assist and encourage self-testing were provided from several countries.
**Conclusions:** There appears to have been limitations in access to HIV testing overall. However, community organisations have developed innovative approaches to maintain a counselling and testing service, including self-testing and online assistance/counselling and linkage to care support. Financial and regulatory barriers to self-testing remain in many locations, meaning this was not a viable alternative everywhere.

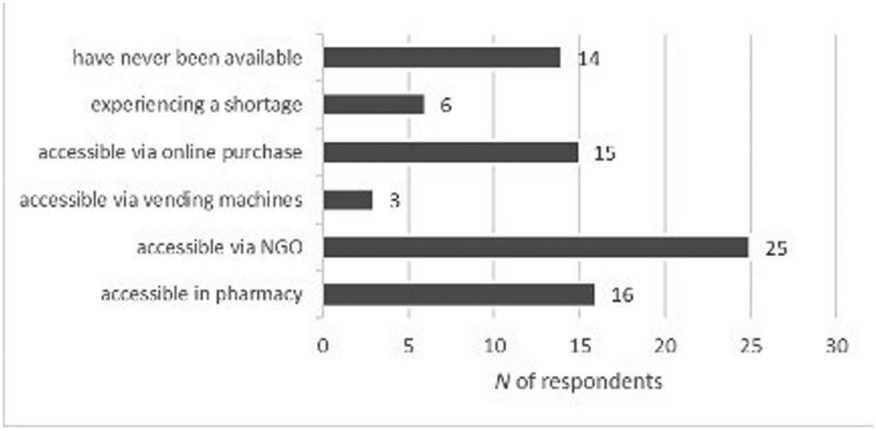
# P139

## Cross-border movement restrictions during Covid-19 and foreign nationals' access to healthcare and medicines

F Greenhalgh; A Von Lingen; B Cigan; G Barbareschi; F Amort; M Cascio; A Schneider and I Hodgson

European AIDS Treatment Group, Brussels, Belgium

**Background:** In response to COVID-19 being declared a pandemic, concerns were raised about the various implications for PLHIV, different communities affected by HIV and healthcare systems. EATG collected several data using two rapid assessments (RAs) reporting the disruptions and solutions found by community organisations for PLHIV or communities affected by HIV. With the closure of borders, some PLHIV were unable to return to their countries of origin or residence. This represented a risk for continuity in treatment and care. The RAs explored this challenge and community-level responses.
**Methods:** EATG conducted an online survey-based RA with a data collection period from 27 March to 3 April 2020. The questionnaire included quantitative and qualitative questions in English. The survey was addressed to PLHIV and communities most affected by HIV who are affiliated to organisations or individuals. It was disseminated




**Abstract P138-Figure 1. Do you have information regarding access to HIV self-tests?**

through EATG and AIDS Action Europe networks. The results informed the questions of the second RA, also available in Russian, which was disseminated from 27 April to 4 May 2020. It included an open question about other impacts of COVID-19 and practical community-level solutions.

**Results:** Where PLHIV were unable to return to their countries of origin/residence due to closed national borders, respondents from Italy, Cyprus, Lithuania, Malta, Poland, Russia and Serbia reported helping them to obtain needed ARVs when personal stock ran out. These persons could not access needed ARVs due to legal restrictions on who can access national healthcare systems. This included a number of migrants without residency status. Alternative solutions included: PLHIV paying for medications themselves; PLHIV switching to cheaper ARV combinations or "stretching" their therapy; pharmaceutical companies donating relevant medications (sometimes at the demand of community organisations); one Portuguese respondent reported a significant legislative change that ensured temporary universal access to healthcare until 30 June.

**Conclusions:** Responses to the RA indicate gaps in continuity of care for PLHIV stranded outside of their residential/origin country and demonstrate that community organisations have provided support for these PLHIV to trouble-shoot personal ARV shortages and bridge gaps in universal healthcare. Public health emergencies preparedness and respect for human rights warrants legislative change towards access to universal healthcare.

## P140

### The impact of COVID-19 epidemic on HIV care in Croatia

N Bogdanic[1]; S Zekan[2]; V Romih Pintar[1]; D Lukas[2] and J Begovac[2]

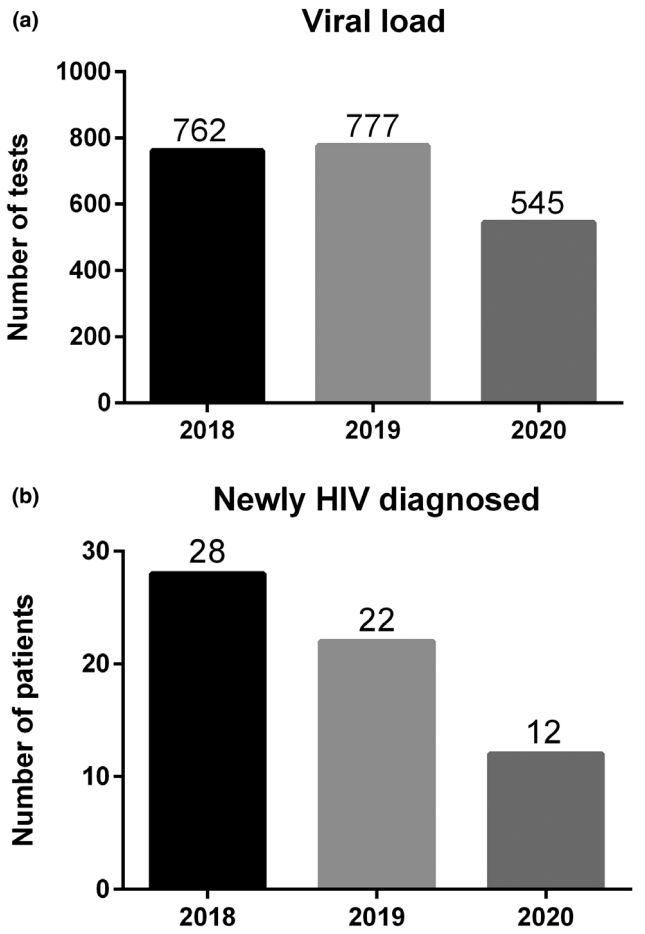
[1]University Hospital for Infectious Diseases, Outpatient HIV Department, Zagreb, Croatia. [2]University Hospital for Infectious Diseases, University of Zagreb School of Medicine, Department of Infectious Diseases, Zagreb, Croatia

**Background:** HIV care in Croatia is centralised and all PLWHIV are treated at the University Hospital for Infectious Diseases (UHID) in Zagreb; the hospital pharmacy also dispenses ART. In response to the initial phase of the COVID-19 pandemic a lockdown has been imposed between 16 March and 27 April 2020. UHID became the central hospital for treatment of COVID-19 in the Zagreb area. We aim to quantify the impact of COVID-19 epidemic on HIV care at UHID.

**Materials and methods:** We reviewed data from all interactions of PLWHIV with the HIV treatment centre from 3 February till 28 June 2020. The following was analysed: phone interactions, office visits, number of viral load (VL) tests performed and interactions that resulted in dispensing ART. Data on HIV care was extracted from the local database and periods March–June 2018, 2019 and 2020 were compared.

**Results:** The COVID-19 epidemic in Croatia started on 25 February. The major increase in confirmed COVID-19 cases happened from 16 to 22 March when 205 cases were confirmed and the peak of outbreak was recorded from 30 May to 5 April when the number of cases was 469. HIV care office visits declined for >50% in March compared to February (average 46 vs 22.5 per week, respectively). An average of 8.5 shipments of ART per week were made in February and 31 shipments per week in March. The maximum number of ART shipments (N = 45) and phone consultations (N = 415) were made in a week of epidemic acceleration (16 to 22 March). There were fewer viral load measurements in March–June 2020 compared to 2019 and 2018 and fewer newly HIV-diagnosed persons entered care in 2020 (Figure 1); the median CD4 count/mm$^3$ was 410.5 (2018), 339.5 (2019) and 120 (2020).

**Conclusions:** During the first phase of COVID-19 outbreak a transition from face-to-face communication to mainly telephone consultations was observed. Fewer VL measurements were done. The observed drop in newly diagnosed persons entering care is probably due to the interruption of the work of community-based and other voluntary counselling and testing centres in Croatia.




**Abstract P140-Figure 1. Number of viral load measurements (a) and persons newly diagnosed with HIV (b) in the period March–June 2018, 2019 and 2020.**

## P141

### Cancer, transplantation, and other immunocompromising conditions were not significantly associated with severe COVID-19 or death in hospitalized COVID-19 patients in Chicago

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**Background:** Cancer, transplant, and other immunocompromising conditions have been associated with severe COVID-19 illness [1,2]. On 15 May 2020, Cook County had the highest COVID-19 county incidence in the US with 58 457 cumulative cases, 1500 new infections, and 50 deaths daily, and University of Chicago Hospitals (UCH) had identified 1969 COVID-19 patients.

**Methods:** We determined the incidence of severe COVID-19 illness in the first 401 patients at UCH from 13 March 2020 to 18 April 2020 with a structured chart review and the UCH clinical data warehouse and its association with symptoms, comorbidities, and COVID

**Abstract P141-Table 1. Comorbidities in COVID-19 patients at the University of Chicago by severity of illness**

| | All patients | | | Moderate illness | | | Severe illness | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 401 | | | 233 | | | 168 | | | |
| N | Mean/N | SD/% | N missing | Mean/N | SD/% | N missing | Mean/N | SD/% | N missing | *p*-value |
| HTN | 276 | 69% | 1 | 147 | 63% | 0 | 129 | 77% | 1 | 0.004 |
| DM | 152 | 38% | 3 | 76 | 33% | 3 | 76 | 45% | 0 | 0.02 |
| Obese (30 <BMI <40) | 133 | 34% | 4 | 75 | 33% | 3 | 58 | 35% | 1 | 0.74 |
| Morbid obese (BMI > 40) | 69 | 17% | 4 | 41 | 18% | 3 | 28 | 17% | 1 | 0.89 |
| CKD | 96 | 24% | 1 | 43 | 18% | 0 | 53 | 32% | 1 | 0.003 |
| COPD | 90 | 23% | 3 | 50 | 22% | 1 | 40 | 24% | 2 | 0.63 |
| CHF | 65 | 16% | 1 | 30 | 13% | 0 | 35 | 21% | 1 | 0.04 |
| Cancer | 56 | 14% | 2 | 31 | 13% | 1 | 25 | 15% | 1 | 0.76 |
| CAD | 53 | 13% | 3 | 27 | 12% | 2 | 26 | 16% | 1 | 0.33 |
| Hgh Dx | 5 | 1% | 1 | 3 | 1% | 0 | 2 | 1% | 1 | 1 |
| Liver Dx | 16 | 4% | 2 | 10 | 4% | 1 | 6 | 4% | 1 | 0.92 |
| Autoimmune | 27 | 7% | 1 | 15 | 6% | 0 | 12 | 7% | 1 | 0.93 |
| Immuno supp. | 21 | 5% | 1 | 11 | 5% | 0 | 10 | 6% | 1 | 0.74 |
| Steroid | 17 | 4% | 1 | 7 | 3% | 0 | 10 | 6% | 1 | 0.23 |
| Chemo (for cancer patients only) | 13 | 24% | 1 | 7 | 23% | 1 | 6 | 24% | 0 | 1 |
| Solid organ transplant | 9 | 2% | 1 | 3 | 1% | 0 | 6 | 4% | 1 | 0.17 |
| HIV | 8 | 2% | 2 | 7 | 3% | 1 | 1 | 1% | 1 | 0.15 |
| Stem cell Tx | 4 | 1% | 1 | 2 | 1% | 0 | 2 | 1% | 1 | 1 |
| Immunocompromised (row 15 to 21) | 55 | 14% | 2 | 31 | 13% | 1 | 24 | 14% | 1 | 0.89 |

clinical syndromes. Severe COVID-19 was defined as: use of high flow 02, CPAP, or helmet; mechanical ventilation; ECMO; or death.

**Results:** Of 401 patients, 90% were black, 2% Latinx, 6% white, and 2% other, 52% were women, and ages were >80 years 14%, 70 to 79 17%, 60 to 69 23%, 50 to 59 21%, 40 to 49 12%, and < 40 14%. Seventy-five percent of patients were South Side residents. Mean time from symptoms to presentation was six days, and median/mean length of stay was 6/10 days. Treatments included hydroxychloroquine +/- lopinavir/r (136/33.9%), remdesivir (122/31%), and tocilizumab (83/21%). One hundred and sixty-four (41%) patients had severe COVID illness. One hundred and two (26%) were ICU admits and 67 (17%) were intubated. Fifty-one (13%) patients died within 30 days of discharge, including four (7.8% of deaths) with moderate illness clinically. Fifty-six patients had current or past cancer diagnoses (CA), and 55 patients had organ transplantation, autoimmune disease, HIV, or immunosuppressive therapy (IC). In univariate analysis, age >60, HTN, CKD, DM, and CHF were associated with severe illness. COPD, CAD, CA, and IC were not associated with a greater risk of severe illness (Table 1). In multivariate analysis, age >60 years was the strongest predictor of severe illness, and CA and IC were not associated with severe illness. Incident ARDS, acute kidney injury, PE, DVT, high D-dimer, MI, arrhythmia, uncontrolled DM, DKA, cytokine release syndrome, altered mental status, co-infection, and hepatitis also were associated with severe illness or death.

**Conclusions:** In a predominately African American population of hospitalized patients with COVID-19 on the South Side of Chicago, cancer, organ transplantation, HIV, autoimmune disease, and immunosuppressive therapy were not significantly associated with severe COVID-19 illness or death.

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# P142

## Effect of first three months of COVID pandemic on HIV services in Greece: a short survey among HIV physicians

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**Background/purpose:** The first wave of the COVID-19 pandemic was successfully contained in Greece with a low infection attack rate. Strict lockdown measures were implemented from March to May 2020. ID physicians were amongst the frontline healthcare workers. The purpose of this survey was to assess the operational effect of COVID-19 on HIV clinics in Greece.

**Materials/methods:** Information was gathered in June 2020, after the lockdown lift, via an anonymous questionnaire distributed to an expert panel of HIV/ID physicians (n = 9).

**Results:** Participants' clinics provided care in total for 4335 PLWHIV. Of the nine panelists, 80% worked in a COVID-19 reference hospital, 90% had direct involvement in COVID-19 patient care, devoting an average of 90% of their working time on COVID-19. Four COVID-19 cases in PLWHIV were reported (approx. 0.1%); one was hospitalised and all recovered without complications. During lockdown all clinics had to cancel scheduled visits (25% completely, 50% covering only emergencies and prescriptions). All centres stopped routine checks for cardiovascular and other comorbidities and 75% also stopped routine laboratory testing as well as mental health services. Overall there was an 82% drop in routine

appointments during lockdown compared to Jan–Feb. Significantly fewer PEP cases were recorded, and there was an approximate 50% drop in new HIV cases (34% were late presenters) compared to the monthly average of Jan–Feb. For 62.5% of the panel there was no concern about poorer adherence to ART or higher risk sexual behaviour for their patients during lockdown; however, all were concerned either moderately (87.5%) or seriously (12.5%) about an increase in substance use. After the first wave some centres limited scheduled appointments to avoid overcrowded clinics, while others considered adding extra ones to compensate for lost visits. Policy was also dictated by the local epidemic situation.

**Conclusions:** This short survey demonstrates that in Greece, in the context of a successful early containment of the COVID-19 pandemic, there was a major disruption in HIV services, mainly due to the low number of HIV/ID physicians having to cover multiple roles (including HIV care) and the healthcare system's insufficient capacity to deal with routine care under pressure.

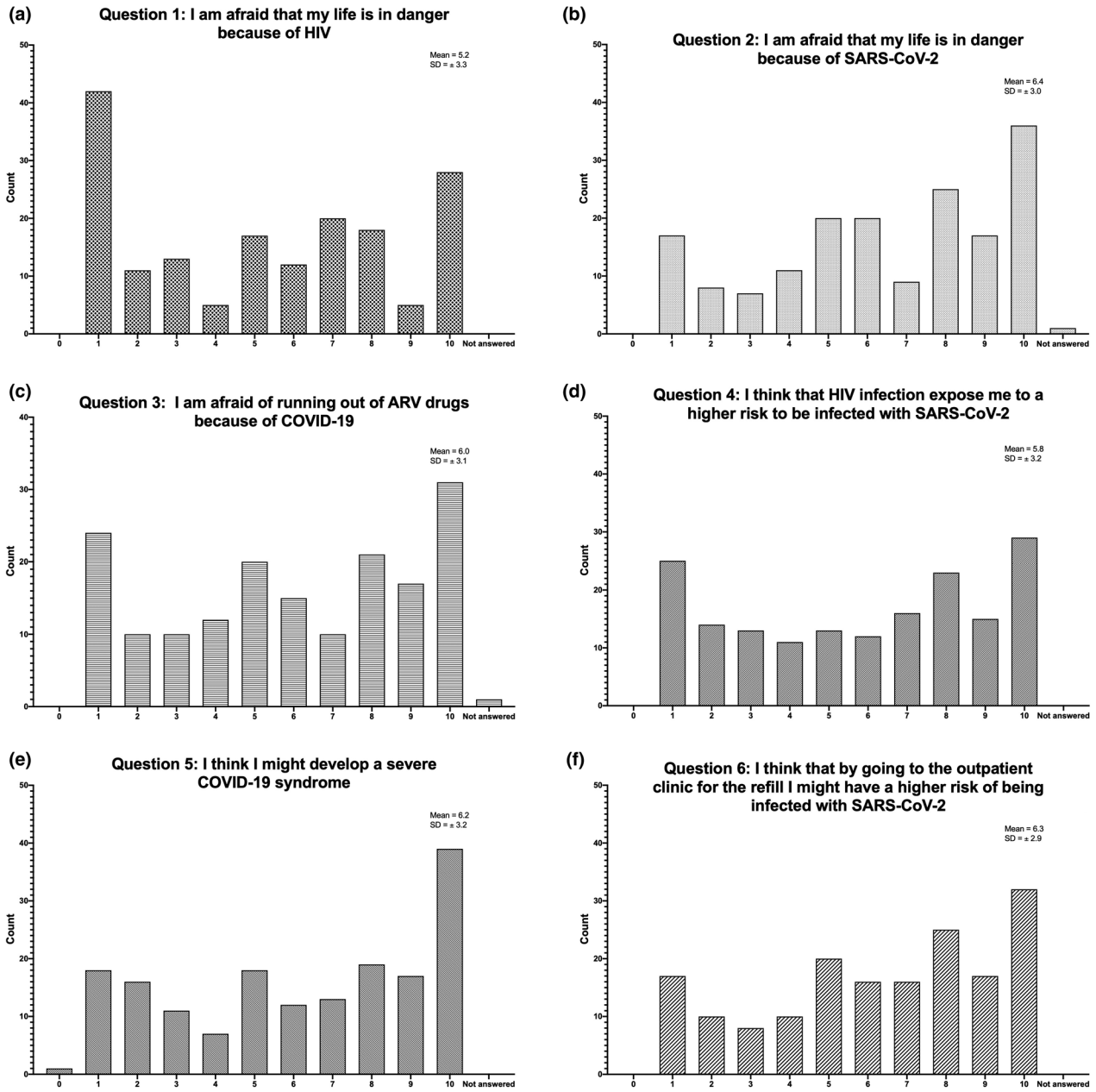
## P143

### Fears and perception of the risk of infection with SARS-CoV-2 in a cohort of HIV+ subjects on antiretroviral treatment in an outpatient clinic in Sicily

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[1]University of Catania, Department of Clinical and Experimental Medicine, Catania, Italy. [2]ARNAS Garibaldi, PO Nesima, Unit of Infectious Diseases, Catania, Italy

**Background:** On 24 March 2020, World Health Organization (WHO) released a Question and Answer (Q&A) on COVID-19 and HIV and antiretroviral drugs, aiming to give some answer to the more frequent




**Abstract P143-Figure 1. Bar graphs, a–f, show the count of PLWHA scoring each question and the score they attributed to each parameter. In each figure mean values and standard deviation are also shown.**

question that in these days everywhere were formulated from people living with HIV/AIDS (PLWHA).
**Materials and methods:** During the lockdown, from 18 March to 17 April 2020, we briefly interviewed the patients in follow-up at our outpatient clinic. The aim of the questionnaire proposed to the patient was to ascertain if they were more afraid for their own health because of HIV or because of SARS-CoV-2, attributing a score from 1 to 10 to several parameters (Figure 1, a–f). We also analysed several parameters related to the HIV infection (CD4 + count, plasma HIV-RNA). Statistical analysis was performed with SPSS for Windows v.26.0.
**Results:** We collected data from 171 patients, 28 females (16.4%), 140 males (81.9%) and three male to female transgenders (1.8%). Mean age was 48.4 years (standard deviation [SD] ±11.6 years). Forty-two patients (24.6%) were interviewed by phone, while 129 (75.4%) were interviewed live. Ninety-six patients (56.1%) came from out of Catania, while 75 (43.9%) lived in Catania. Figure 1 shows the results of the interview. Mean result for question 1 was 5.2 (SD ± 3.3), while mean result for question 2 was 6.4 (SD ± 3.0). The difference between the two results is statistically significant ($p = 0.0005$), meaning that during lockdown PLWHA were more afraid because of COVID-19 than because of HIV.
**Conclusions:** Lockdown came with a lot of consequences. Among them, decreased access to cure for everyone except those suffering from COVID-19 and other emergencies. This led to an increased fear for someone's health. In particular, PLWHA were more afraid for their own health because of the consequences of the lockdown or a potential SARS-CoV-2 infection than because of HIV infection. On the bright side, this means that PLWHA trust their ARV therapies and attending infectious diseases doctors.

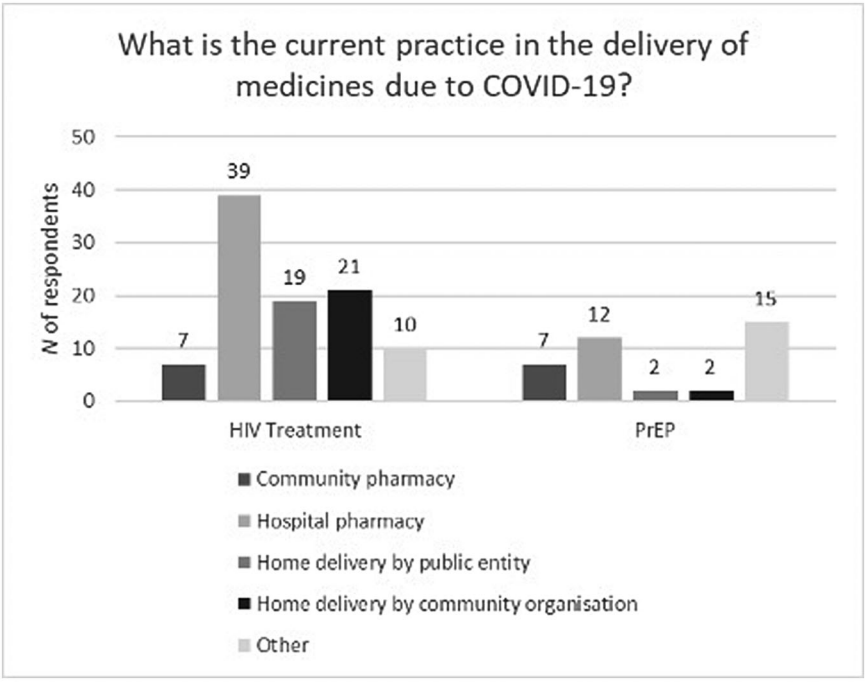
## P144

### How has the COVID-19 response changed medicine deliveries for people living with or at risk of HIV?

F Greenhalgh; A Von Lingen; B Cigan; P Varasi; F Amort; M Cascio; A Schneider and I Hodgson

European AIDS Treatment Group, Brussels, Belgium

**Background:** In response to COVID-19 being declared a pandemic, concerns were raised about the various implications for PLHIV, different communities affected by HIV and healthcare systems. EATG collected several data using two rapid assessments (RAs) reporting the disruptions and solutions found at community level. Given sanitary emergency measures, a question was included on how medicines were accessed by PLHIV safely and easily, to document medicines delivery practices in different locations.
**Methods:** EATG conducted an online survey-based RA with a data collection period from 27 March to 3 April 2020. The survey was addressed to PLHIV and communities most affected by HIV who are affiliated to or not to local organisations. It included quantitative and qualitative questions in English. It was disseminated through EATG and AIDS Action Europe networks. The results of the first survey informed the questions of the second RA which was also available in Russian and was disseminated for response from 27 April to 4 May 2020.
**Results:** In total, 39/51 respondents reported that HIV treatment was being delivered at hospital pharmacies and 11/51 reported that medicines could be accessed at local pharmacies (Figure 1). Public entities (19/51) and community organisations (21/51) have been organising home delivery. In Serbia, patients can choose to collect their medicines at dedicated pharmacies or, in some cases, delivery by community organisations. In Ukraine, most respondents report home delivery is possible. Respondents noted that PrEP, where available, is delivered at hospital pharmacies (7/22), at community/local pharmacies (8/22), public entity (1/22) and 1/22 as part of a clinical study (Slovenia). Several respondents reported a lack of availability of PrEP (Romania, Greece, Albania, Kazakhstan and Abakan (Russia)).
**Conclusions:** Community organisations can be seen to be playing a crucial part in HIV treatment through assisting with delivery of medicines. The possibility to receive treatment via local pharmacies and/or delivery rather than attending hospitals is an intervention that could be considered to improve the quality of life of PLHIV by reducing the amount of times they would need to visit a hospital/hospital pharmacy and increase safety in times of sanitary crisis.




**Abstract P144-Figure 1. What is the current practice in the delivery of medicines due to COVID-19?**

# P145

## Characterisation of PLWH with COVID-19 in a tertiary care reference centre for emerging infectious diseases in Portugal

C Nunes Silva[1]; J Caldas[1]; A Martins[1]; S Policarpo[1]; R Rocha[1]; F Freitas[1]; M Mesquita[2]; I Abreu[1]; L Graca[1]; P Palma Martins[1]; F Ceia[1]; C Pineiro[1]; N Neves[1]; S Silva[1]; M Tavares[1]; R Serrão[1] and A Sarmento[1]
[1]Centro Hospitalar de São João, Infectious Diseases Department, Porto, Portugal. [2]Centro Hospitalar de São João, Immuno-Allergology Department, Porto, Portugal

**Background:** In the current COVID-19 pandemic, some risk factors for severe disease and death have been identified, including age, male gender, diabetes mellitus, cardiovascular and lung diseases, chronic kidney disease and cancer. Although still scarce, current data does not support an increased risk for severe COVID-19 on PLWH [1,2]. Our aim was to describe clinical characteristics and outcomes of PLWH with COVID-19 followed in our hospital, a reference centre for emerging infectious diseases in Portugal.
**Materials and methods:** Retrospective analysis on cases of PLWH with a confirmed COVID-19 diagnosis between 2 March and 14 July 2020. The data showcased in Table 1 was collected from patient records. Proven COVID-19 required a positive SARS-CoV-2 nucleic acid amplification test on respiratory samples.
**Results:** We followed 2092 patients with COVID-19, eight of whom were PLWH (six males, mean age 48 ± 15 years) on ART at the time of diagnosis, which included protease inhibitors (PI) in two and tenofovir alafenamide in two. Median CD4 + T cell count was 626 (range 14 to 1337) cells/mm$^3$. Seven were virally suppressed and had a CD4 + T cell count ≥350 cells/mm$^3$, and six had at least one comorbidity other than HIV. Two patients received treatment with hydroxychloroquine, both of whom were hospitalised: one with concomitant ankylosing spondylitis on methotrexate and the other diagnosed with SARS-CoV-2 pneumonia while hospitalised for candidaemia. The latter was a 67-year-old HIV-2 infected patient on a failing ART regimen without immune recovery and with detectable HIV viraemia, and the only casualty in our cohort. He had multiple comorbid conditions and required treatment with supplemental oxygen therapy. Seven patients were classified as having mild disease, six of whom currently considered fully recovered with a median 40.5 days (range 21 to 74 days) until two consecutive negative SARS-CoV-2 PCR tests.
**Conclusions:** PLWH accounted for < 0.4% of patients with COVID-19 in our centre. PLWH may still get infected during PI- and/or tenofovir-based ART. A severe clinical picture among those with viral suppression on ART was not seen thereby adding to the growing body of evidence supporting the notion that adequately controlled HIV does not by itself place one at increased risk for severe disease or excess mortality.

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**Abstract P145-Table 1. PLWH with COVID-19**

| | Age | Sex | Years since HIV diagnosis | ART | Years of ART | CD4 T cell count (/mm$^3$) | CD4/CD8 T cell ratio | HIV RNA (copies/mL) | Other comorbidities | COVID-19 symptoms | COVID-19 classification | Hospital admission | Supplemental oxygen | Hydroxychloroquine | Outcome | Time from symptom onset to offset | Days from diagnosis to cure[a] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 27 | Male | 8 | TAF/FTC/RPV | 5 | 592 | 0.71 | <20 | No | Cough, chest pain | Mild | No | No | No | Recovery | 12 | 55 |
| 2 | 31 | Male | 7 | ABC/3TC+RPV | 7 | 433 | 0.76 | <20 | Epilepsy | Cough, nasal congestion, odynophagia, headage, myalgias, anosmia, dysgeusia | Mild | No | No | No | Recovery | 13 | 24 |
| 3 | 38 | Male | 5 | ABC/3TC/DTG | 5 | 810 | 0.76 | <20 | Ankylosing spondylitis | Fever, myalgias, headache, odynophagia | Mild | Yes | No | Yes | Recovery | 15 | 74 |
| 4 | 43 | Female | 11 | ABC/3TC+RAL | 9 | 1337 | 2.38 | <20 | No | Nausea, vomiting, myalgias, anosmia, dysgeusia | Mild | No | No | No | Recovery | 41 | 67 |
| 5 | 54 | Female | 20 | DRV/r+DTG | 15 | 424 | 0.38 | <20 | Dyslipidaemia, COPD | Back pain | Mild | No | No | No | Recovery | 10 | 21 |
| 6 | 55 | Male | 17 | ABC/3TC | 17 | 784 | 1.59 | <20 | Dyslipidaemia, benign prostatic hyperplasia | Fever, odynophagia | Mild | No | No | No | Follow-up | 20 | NA |
| 7 | 67 | Male | 17 | TAF/FTC+ DRV/r+ DTG+MVC | 17 | 14 | 0.03 | 6870 | Dyslipidaemia, diabetes mellitus, CVD, COPD, active cancer | Fever, dyspnoea | Severe | Yes | Yes | Yes | Death | 12 | NA |
| 8 | 67 | Male | 12 | ABC/3TC+NVP | 13 | 660 | 0.46 | <20 | Dyslipidaemia, benign prostatic hyperplasia | Malaise, cough | Mild | No | No | No | Recovery | 15 | 26 |

3TC, lamivudine; ABC, abacavir; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; DRV, darunavir; DTG, dolutegravir; FTC, emtricitabine; MVC, maraviroc; NA, not applicable; NVP, nevirapine; r, ritonavir; TAF, tenofovir alafenamide. COVID-19 was classified as severe if one of the following present: dyspnoea, respiratory rate > 30/min, blood oxygen saturation < 94% and/or lung infiltrates > 50% within 24 to 48 hours. [a]Cure: resolution of signs and symptoms and two consecutive negative PCR tests for SARS-CoV-2 collected at least 24 hours apart.

# P146

## Assessing the mental health of people living with HIV in Scotland during COVID-19

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**Background:** There are 6122 PLHIV in Scotland today. Despite advances in treatment, living with HIV can exacerbate vulnerability to mental health conditions such as depression, anxiety and suicidal ideations. Social distancing measures in response to COVID-19 pandemic has prompted a need to understand the factors that produce and reinforce psychosocial distress. Given the higher prevalence of mental ill-health among PLHIV, this research comes at a critical time where targeted interventions are required to ensure that PLHIV can develop strategies to cope with an ongoing COVID-19 crisis.
**Methods:** An online cross-sectional survey assessing mental wellbeing among PLHIV in Scotland during COVID-19 lockdown between April and May 2020.
**Results:** The survey reached 49 PLHIV across eight Scottish health boards. Seventy-eight percent identified as male, 10% female, 10% did not disclose and 2% identified as other. Age ranged between 20 and 68 (μ: 46). Top concerns during COVID-19 are: COVID-19 infection (67%), financial implications (64%), Scotland's ability to care for COVID-19 patients (61%), self-isolation (39%) and food/supplies shortages (36%). When asked how often respondents felt nervous/anxious in the past two weeks, 12% stated 'everyday', 9% 'nearly every day' and 39% 'several days'. When asked how often respondents felt down, depressed or hopeless in the past two weeks, 15% stated 'very often', 3% 'often', 18% 'somewhat often' and 33% 'sometimes'. Of those, within the last two weeks, 22% had thoughts of self-harm and 39% felt they "would be better off dead". Thirty percent did not know who to turn to when depressed; 45% felt isolated from others. Only 17% accessed a mental health service. Seventy-two percent have an existing mental health condition.
**Conclusions:** COVID-19 is putting a significant strain on the mental health of PLHIV across Scotland. The research suggests that the burden of mental ill-health is borne disproportionately by PLHIV during the ongoing COVID-19 pandemic and is further exacerbated by existing mental health conditions, financial stress, and social isolation and lack of support. Unless action is taken to strengthen the resilience of PLHIV in times of change and uncertainty, mental health disparities are likely to continue as COVID-19 persists.

# P147

## Characteristics and outcomes of inpatient COVID-19 infections in people living with HIV

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**Background:** There is a paucity of data in the clinical characteristics and outcomes of PLWHIV diagnosed with COVID-19 infections. This case series describes our experience of PLWHIV diagnosed with COVID-19 who received inpatient care from an HIV service in Manchester, UK.
**Methods:** Characteristics including demographics, duration of admission, symptoms, relevant investigations, use of antibiotics and outcome were recorded from March to July 2020 of patients with suspected or confirmed COVID-19. Data was retrospectively collected from electronic patient records (Table 1).
**Results:** Sixteen PLWHIV were diagnosed with COVID-19 as an inpatient between March and July 2020. Twelve (75%) were admitted with COVID symptoms. Four (25%) likely had hospital acquired infection, one of these was asymptomatic. Twelve of 16 (75%) were Black Asian Minority Ethnic (BAME) group. Comparatively, 31% of PLWHIV across the service are of BAME ethnicity.

**Abstract P147-Table 1. Demographics characteristics and outcomes**

| | | Range |
|---|---|---|
| Gender | | |
| Male (inc trans male) | 13 (81.3%) | |
| Female (inc trans female) | 3 (18.75%) | |
| Age | 56.2 | 46 to 68 |
| Years since diagnosis | 14.5 | 1 to 28 |
| Established on ARVs | 16 (100%) | |
| Median CD4 pre COVID | 603 | 83 to 1236 |
| Median CD4 during COVID | 393 | 177 to 901 |
| HIV viral load pre COVID | All < 200 | |
| Median length of stay (days) | 6.9 | 1 to 22 |
| **Admission** | **Yes** | **Notes** |
| Common symptoms | | |
| Cough | 9 (56.3%) | |
| Fever | 8 (50%) | |
| Short of breath | 6 (37.5%) | |
| Confusion | 2 (12.5%) | |
| COVID-19 swab positive | 13 (81.3%) | |
| Received antibiotics | 13 (81.3%) | 2 (12.5%) unknown |
| New renal impairment | 7 (43.8%) | 1 (6.2%) unknown |
| COVID-19 trial | 3 (18.75%) | |
| ICU admission | 2 (12.5%)<br>1 required intubation | |
| Death | 4 (25%)<br>2 of which non COVID related | |
| **Comorbidities** | | |
| Diabetes mellitus | 5 (31.3%) | |
| Hypertension | 7 (43.8%) | |
| Cardiovascular disease | 5 (31.3%) | |
| Pre-existing renal disease | 4 (25%) | |
| BMI > 30 | 7 (43.6%) | |

**Conclusions:** Twelve of 16 (75%) individuals, who all had well-controlled HIV (viral load < 200) at the time of COVID-19 diagnosis, recovered. With age widely regarded as the greatest risk factor for adverse outcomes in those diagnosed with COVID-19, it is interesting that the COVID-related deaths were in individuals in their 50s. Both were in men, one of black African and one white British ethnicity. Both had a history of hypertension and presented with fever, shortness of breath and cough. The two other deaths were in individuals in the terminal phases of cryptococcal meningitis and metastatic cancer. In our cohort, black ethnicity, male gender, hypertension, raised BMI, cardiovascular disease and pre-existing renal disease were common. As in the general population, black individuals were disproportionately affected. The causes of this are multifactorial and require further exploration. Over 43% of individuals experienced new renal impairment. One patient had to switch ARVs (from FTC/TAF/DTG to DOR/3TC/DTG). PLWHIV are already at risk of adverse renal outcomes and it is important to follow these individuals up to establish the long-term sequelae. Limited conclusions can be drawn due to the small size of the data pool, but this case series suggests that those with well-controlled HIV have similar outcomes to the general population.

## P148

### SARS-CoV-2 infection in HIV patients: we anticipated a worse scenario

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**Background:** The immune suppression and deregulation associated with HIV infection anticipated a clinical and prognostic outcome facing SARS-CoV-2 co-infection. According to the current literature, is still uncertain whether patients with HIV infection have greater morbidity or mortality in the course of COVID-19.
**Materials and methods:** Demographic, epidemiological, clinical, laboratorial and therapeutic data was collected, regarding the HIV-infected population, diagnosed with SARS-CoV-2 infection, a hospital centre in Lisbon, Portugal, during the period between 16 March 2020 and 1 July 2020. Statistical analysis was performed in order to describe and analyse the different groups.
**Results:** During the study period, 18 436 RT-PCR SARS-CoV-2 tests were performed at our hospital laboratory. After excluding duplications, the tests revealed a positivity rate of 6.7% (n = 815) and a hospital admission rate of 33.8% (n = 276). Considering the tested population, 132 (1.08%) patients were HIV infected: 14 (1.72%) tested positive for SARS-CoV-2 infection and the remaining 118 (1.04%) showing a negative result. Regarding HIV patients with SARS-CoV-2 diagnosis (n = 14), only four (28.6%) meet hospitalisation criteria. The HIV co-infected SARS-CoV-2 positive group showed a male predominance (64.29%) and a mean age of 53.14 years. All of them were on antiretroviral therapy with undetectable plasma HIV RNA and a mean TCD4 + count of 664.9 cells/mm$^3$. HIV patients with SARS-CoV-2 infection that required hospital admission had a mean age of 61.5 years versus 49.8 years of those who were managed on an ambulatory basis. The immunological state between the two groups was similar. Regarding the four HIV patients hospitalised, three patients (75%) presented with severe pneumonia and were admitted in the intensive care unit. The average hospitalisation length in these patients was 51.7 days, the mean time to achieve RT-PCR SARS-CoV-2 negative tests was 28 days and none of them died (mortality rate 0%).
**Conclusions:** In our population, there was no evidence of a higher incidence of SARS-CoV-2 infection related to HIV infection. The evolution of SARS-CoV-2 infection in HIV chronic infected patients was similar to non-HIV patients.

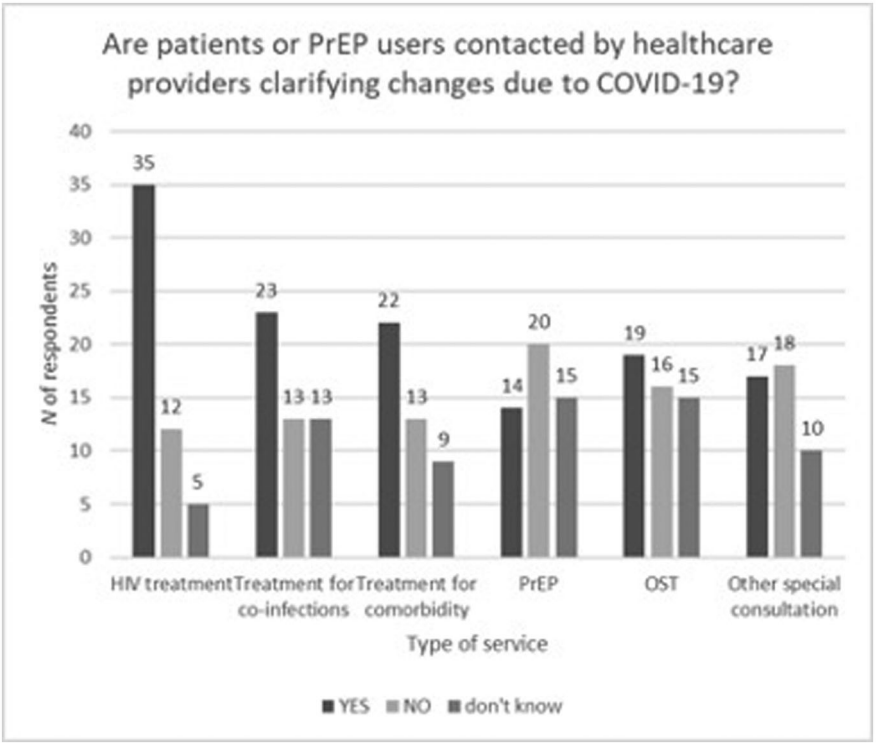
## P149

### Understanding how the COVID-19 response affects the quality of care services for people living with HIV and communities affected by HIV

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**Background:** In response to COVID-19 being declared a pandemic, concerns were raised about impacts on PLHIV, different communities affected by HIV and healthcare systems. EATG collected several data reporting the disruptions but also responses at the level of community services. To understand how quality of care was impacted, one question asked how appointments as part of HIV care were being dealt with and the other asked about communication between healthcare




**Abstract P149-Figure 1. Are patients or PrEP users contacted by healthcare providers clarifying changes due to COVID-19?**

providers and HIV patients/PrEP users during the first months of the pandemic.

**Materials/method:** EATG conducted an online survey-based rapid assessment (RA) with a data collection period from 27 March to 3 April 2020. The questionnaire included quantitative and qualitative questions in English. It was disseminated through EATG and AIDS Action Europe networks. The results of the first survey informed the questions of the second RA which was also available in Russian and was disseminated from 27 April to 4 May 2020. The survey was addressed to PLHIV and communities most affected by HIV who are affiliated to organisations or as individuals.

**Results:** In the first RA, 14/27 survey respondents to the question reported their scheduled appointments with health services were cancelled/postponed, 11/18 had their future visits cancelled/postponed. Disruption in HIV care was also observed in the second RA where 13/30 respondents reported healthcare provider-initiated contact about visits. Disruptions to follow-up care were also confirmed. While 35/52 respondents reported some communication with HIV healthcare providers, several (12/52) reported no interaction and 5/52 reported having no information about it (Figure 1). Regarding delayed routine testing, there is not always clear information on how and when viral load, CD4 count and blood tests will be rescheduled.

**Conclusions:** Several healthcare facilities have tried to maintain a link with their patients using telemedicine tools, as appointments were reportedly moved online, demonstrating innovative approaches used in place of regular practices. With consultations cancelled, rather than postponed, appointments may be lost entirely, meaning people could be left behind or lost from follow-up at crucial points of treatment and care unless patients are proactive and knowledgeable about their needs.

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