Mini Oral Session

MO41

Durable efficacy of switching from a three-/four-drug tenofovir alafenamide (TAF)-based regimen to the two-drug regimen dolutegravir/lamivudine (DTG/3TC) in the TANGO study through week 196

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Background: Switching to DTG/3TC has demonstrated durable and non-inferior efficacy versus continuing three-/four-drug regimens for maintaining virologic suppression in people living with HIV-1 through week (W) 48 in SALSA and W144 in TANGO. Efficacy and safety at W196 from TANGO, for those who were virologically suppressed on TAF-based regimens at baseline and switched to DTG/3TC at W148 and for those who switched to DTG/3TC at day 1, are presented.

Abstract MO41 – Table 1. Summary of TANGO study outcomes at week 196.

	ES DTG/3TC (N = 369)		LS DTG/3TC (N = 298)	
Parameter, n (%)	**Day 1 to week 48**	**Day 1 to week 144**	**Day 1 to week 196**	**Week 148 to week 196**
Efficacy outcomes (Snapshot, ITT-E population)				
HIV-1 RNA <50 copies/mL	344 (93)	317 (86)	306 (83)	278 (93)
HIV-1 RNA ≥50 copies/mL	1 (<1)	1 (<1)	3 (<1)	0 (0)
No virologic data	24 (7)	51 (14)	60 (16)	20 (7)
Key safety outcomes (safety population)				
Any AE	295 (80)	336 (91)	347 (94)	239 (80)
AEs leading to withdrawal	13 (4)	23 (6)	25 (7)	9 (3)
Drug-related grade 2 to 5 AEs	17 (5)	21 (6)	23 (6)	11 (4)
SAEs	21 (6)	57 (15)	65 (18)	15 (5)
Fatal AEs	1 (<1)	3 (<1)	4 (1)	0 (0)
Confirmed virologic withdrawals (all screened participants)	0 (0)	0 (0)	1 (<1)[a]	0 (0)

AE, adverse event; DTG/3TC, dolutegravir/lamivudine; ES, Early-Switch; LS, Late-Switch; SAE, serious AE.
[a]No resistance-associated mutations were observed.

Materials and methods: TANGO evaluated efficacy and safety of switching to DTG/3TC from stable TAF-based regimens in virologically suppressed adults (HIV-1 RNA <50 copies/mL for >6 months) with no prior virologic failure. Participants were stratified by baseline third agent class and randomized 1:1 to switch to DTG/3TC at day 1 (Early-Switch [ES] group) or continue TAF-based regimens for 144 weeks. Those continuing TAF-based regimens and maintaining virologic suppression at W144 switched to DTG/3TC at W148 (Late-Switch [LS] group). Efficacy through W196 was analyzed via Snapshot algorithm (ITT-E population). Clinical safety and laboratory toxicity were also evaluated.
Results: Overall, 369 participants switched to DTG/3TC at day 1 (ES) and 298 switched to DTG/3TC at W148 (LS). A high proportion of the ES group maintained virologic suppression through year 4, with few new safety events between W144 and W196 (Table 1). After 48 weeks of DTG/3TC, the LS group at W196 and the ES group at W48 had comparable proportions of participants with virologic suppression and similar safety profiles (Table 1). Through W144, no DTG/3TC participants met confirmed virologic withdrawal (CVW) criteria versus three TAF-based regimen participants. Post-W144, no LS group participants and one ES group participant met CVW criteria at W196. No resistance-associated mutations were observed for any CVW.
Conclusions: Switching from three-/four-drug TAF-based regimens to the two-drug regimen DTG/3TC showed durable efficacy, high barrier to resistance, and good tolerability through 4 years, with few new safety events between years 3 and 4. W196 efficacy and safety in the LS group were consistent with W48 data in the ES group. These results support DTG/3TC as a robust and well-tolerated treatment alternative to three-/four-drug TAF-based regimens with fewer antiretroviral agents for maintaining virologic suppression.

MO42

Impact of switch towards 3TC/dolutegravir on the intact and total viral reservoir in the Rumba study

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Background: Dual therapy with 3TC/dolutegravir (Dovato®) has been thoroughly evaluated in several switch clinical trials using plasma viral load as a primary endpoint (50c/mL threshold) showing non-inferiority to 3-drug regimen and is now part of the EACS and other global guidelines as first-line regimen for antiretroviral therapy (ART)-naïve and ART-experienced adults with HIV. We report the week 48 results of Rumba, the first randomized clinical trial evaluating the impact on the viral reservoir of switch from a 2nd generation integrase inhibitor (INI)-based triple ART regimen towards Dovato® versus Biktarvy®.
Materials and methods: One hundred and thirty-four people living with HIV were included at the Ghent HIV reference centre, with HIV-1 RNA <50 copies/mL plasma and at least 3 months on any stable second-generation INI-based triple ART. Participants were randomised 2:1 to switch to Dovato® (N = 89) or to switch or stay on Biktarvy® (N = 45). After blood collection at baseline and W48, CD4+ T cells were isolated from peripheral blood mononuclear cells (EasySep Human CD4+ T cell isolation kit, Stemcell), followed by DNA extraction (DNeasy Blood&Tissue kit, Qiagen). Total and intact

Abstract MO42 – Table 1. Patient characteristics.

Baseline	Total N = 134	Dovato® N = 89	Biktarvy® N = 45
Dropouts after randomisation	13/134	9/89	5/45
Sex (M/F)	118/12	79/8	39/4
Age (year), median (IQR)	46 (37 to 54) n = 128	46 (36 to 53) n = 86	45 (40 to 56) n = 42
CD4 at screening (cells/μL), median (IQR)	689 (550.5 to 929.5) n = 125	691 (558 to 933) n = 83	676.5 (526.75 to 871.75) n = 42
CD4 nadir (cells/μL), median (IQR)	289 (168 to 424) n = 123	296.5 (165.75 to 449) n = 84	273 (194 to 385) n = 39
Peak viral load (copies/mL plasma), median (IQR)	97 646.5 (26 736.73 to 323 510.5) n = 114	122 563 (32 291.7 to 405 526.8) n = 76	62 447.85 (12 097.4 to 192 502.3) n = 38
Time on ART (year), median (IQR)	7.2 (4.6 to 10.8) n = 123	8.1 (4.75 to 11.15) n = 82	6 (4.35 to 8.95) n = 41
Time from start ART to undetectable viral load (year), median (IQR)	0.3 (0.2 to 0.4) n = 117	0.3 (0.2 to 0.4) n = 78	0.3 (0.1 to 0.7) n = 39
Total HIV-1 DNA copies/10^6 CD4+ T cells, median (IQR)	651.83 (267.47 to 1322.92) n = 112	772.75 (419.53 to 1387.88) n = 75	511.41 (282.84 to 1482.83) n = 37
Intact proviral HIV-1 DNA copies/10^6 CD4+ T cells, median (IQR)	21.21 (1.9 to 58.48) n = 87[a]	21.21 (2.07 to 41.56) n = 61	26.01 (0 to 108.68) n = 26
Week 48			
Total HIV-1 DNA copies/10^6 CD4+ T cells, median (IQR)	439.37 (189.14 to 1185.35) n = 108	503.87 (233.49 to 1246.49) n = 73	324.57 (140.95 to 1123.68) n = 35
Intact proviral HIV-1 DNA copies/10^6 CD4+ T cells, median (IQR)	12.03 (2.55 to 41.68) n = 87	8.7 (0 to 37.37) n = 61	28.06 (4.75 to 63.45) n = 26
Delta week 48-baseline			
Total HIV-1 DNA copies/10^6 CD4+ T cells, median (IQR)	-122.67 (-330.98 to 57.03) n = 108	-131.26 (-397.41 to -93.83) n = 73	-112.18 (-219.06 to 42.78) n = 35
Intact proviral HIV-1 DNA copies/10^6 CD4+ T cells, median (IQR)	-5.05 (-28.57 to 14.56) n = 87	-6.47 (-30.00 to 15.87) n = 61	-4.65 (-18.67 to 14.94) n = 26

[a]Dataset (n = 112) further refined: only participants with quantifiable results at baseline were included.

proviral HIV-1 DNA copies were quantified in triplicate using a digital PCR assay combining the cross-subtype intact proviral DNA assay [1] and the total HIV-1 DNA assay [2] (Qiacuity, Qiagen). *RPP30* was measured for normalisation based on cell input. Data analysis was performed with the ddpcrRquant algorithm.

Results: Of the 134 patients randomised in the study, 120 reached the W48 primary endpoint (Dovato® N = 80, Biktarvy® N = 40). Patient dropouts due to non-virological reasons were similar between the two study arms. Baseline levels of total and intact HIV-1 DNA are presented in Table 1. At 48 weeks, a similar decline of 131.26 (-397.41 to -93.83) and 112.18 (-219.06 to 42.78) total HIV-1 DNA copies/million CD4+ T cells and of 6.47 (-30.00 to 15.87) and 4.65 (-18.67 to 14.94) intact HIV-1 DNA copies/million CD4+ T cells was observed in the Dovato® and Biktarvy® group respectively.

Conclusions: Preliminary investigations of this first head-to-head study suggest that HIV-1 reservoir dynamics are similar between Dovato® and Biktarvy® and that switch towards 3TC/dolutegravir does not increase the total or intact HIV-1 viral reservoir. Adjusted analyses are on-going and will be presented.

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MO43

Prevalence, risk factors and the impact of antiretroviral treatment in SARS-CoV-2 infection in people with HIV: a cross-sectional study

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Abstract MO43 – Table 1. Independent risk factors of SARS-CoV2 infection in PLHIV.

Variable	Variable	Adjusted prevalence rate ratio	(95% confidence interval)	p-value
Age*Sex	18-34 Men	1		0.0004
Age*Sex	18-34 Women	1.719	(1.109; 2.664)	0.0004
Age*Sex	35-49 Men	0.837	(0.705; 0.993)	0.0004
Age*Sex	35-49 Women	0.953	(0.669; 1.357)	0.0004
Age*Sex	50-64 Men	0.651	(0.520; 0.814)	0.0004
Age*Sex	50-64 Women	0.887	(0.619; 1.270)	0.0004
Age*Sex	≥65 Men	0.648	(0.432; 0.972)	0.0004
Age*Sex	≥65 Women	0.660	(0.299; 1.454)	0.0004
Origin: Continent	Europe	1		<0.0001
Origin: Continent	Americas	1.659	(1.428; 1.928)	<0.0001
Origin: Continent	Others	1.601	(1.129; 2.269)	<0.0001
Origin: Continent	*Missing*	0.943	(0.714; 1.245)	<0.0001
MSM (or Bisexual)	No	1		0.0024
MSM (or Bisexual)	Yes	1.378	(1.120; 1.694)	0.0024
Transexual	No	1		0.6871
Transexual	Yes	0.937	(0.682; 1.287)	0.6871
AIDS-defining disease	No	1		0.7953
AIDS-defining disease	Yes	1.028	(0.835; 1.265)	0.7953
Plasma HIV viral load	Detectable	1		0.5664
Plasma HIV viral load	<50 copies/mL	1.078	(0.834; 1.392)	0.5664
CD4 T-cell count[a]	CD4 T-cell count[a]	0.995	(0.984; 1.007)	0.4156
CD8 T-cell count[a]	CD8 T-cell count[a]	0.994	(0.986; 1.003)	0.2044
Active syphilis	No	1		0.0001
Active syphilis	Yes	1.507	(1.227; 1.850)	0.0001
on ART	No	1		0.2299
on ART	Yes	0.724	(0.427; 1.227)	0.2299
Type of ART (3rd drug)	InSTI	1		0.2725
Type of ART (3rd drug)	NNRTI	1.160	(0.961; 1.399)	0.2725
Type of ART (3rd drug)	IP	1.085	(0.900; 1.308)	0.2725
NRTI backbone	TAF/FTC	1		0.6372
NRTI backbone	TDF/FTC	1.067	(0.785; 1.448)	0.6372
NRTI backbone	ABC/3TC	1.091	(0.904; 1.317)	0.6372
NRTI backbone	Other	1.169	(0.944; 1.448)	0.6372
NRTI backbone	No NRTI	1.033	(0.783; 1.363)	0.6372

[a]Adjusted prevalence rate ratio per 50 units increase.

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Background: The risk factors for SARS-CoV-2 infection in people living with HIV (PLHIV) are not well known. The protective role of antiretroviral treatment (ART), and in particular of tenofovir disoproxil fumarate (TDF), is controversial, being confirmed by some cohort studies [1] but not others [2]. The objective of this study is to know the prevalence and risk factors of SARS-CoV-2 infection and the role of ART in the cohort of 5476 PLHIV at the Hospital Clinic of Barcelona.
Methods: Cross-sectional study of all consecutive PLHIV attending the HIV Unit between November 2020 and May 2021. We determined total antibodies, IgG (Atellica Solution IM analyzer from Siemens Healthiness), IgM and IgA (Luminex) antibodies in plasma against the receptor binding domain (RBD) of the spike glycoprotein of SARS-CoV-2. Multivariable Poisson regression with robust standard errors was used to identify predictors of SARS-CoV-2 infection (StataCorp, 2021).
Results: Of the 5476 patients, 1076 were excluded due to lack of plasma samples (n = 639), previous vaccination (n = 431) or absence of informed consent (n = 6). Four thousand, four hundred patients were included in the study. Overall, median (IQR) age was 48 (39 to 56) years, 84% were male, 68% were men who have sex with men (MSM), 57% were European, 44% had university education, 17% had previous AIDS-defining diseases, 98% were taking ART, and 92% had an undetectable plasma HIV RNA viral load (<50 copies/mL) with median (IQR) CD4 of 673 (496 to 886.5) and CD8 of 782 (580 to 1068). Sixty-one percent were on an InSTI-based ART, 57% on TAF/FTC and 5% on TDF/FTC. Five percent of patients had syphilis during the study period. One thousand, one hundred and eighty had total antibodies against SARS-COV-2, but only 780 (18%; 95% CI 17 to 19) had positive IgG (n = 553, 13%), IgA (n = 444, 10%) and/or IgM (n = 483, 11%). Being young and female, MSM, non-European origin, and infected with syphilis were independently associated with SARS-COV-2 infection (Table 1). Neither ART nor the use of tenofovir (TDF or TAF) protected against SARS-CoV-2 infection.
Conclusions: Nearly a fifth of PLHIV were infected with SARS-CoV-2, being infection associated with non-European young MSM or women, and syphilis. Neither ART nor the use of tenofovir was protective.

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MO44

Prevalence, outcomes, and factors associated with testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among people living with HIV across Europe in the multinational EuroSIDA cohort

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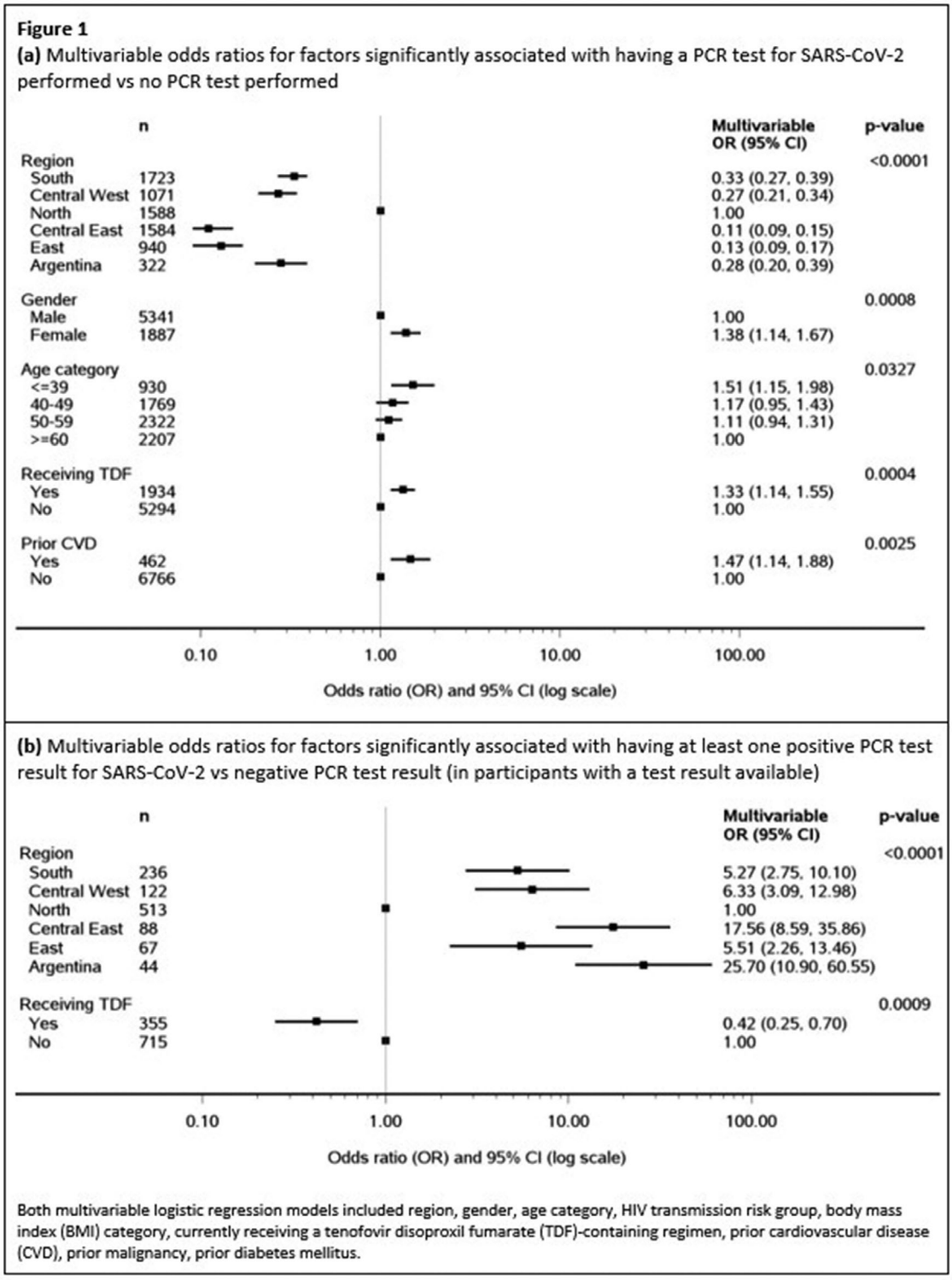
Abstract MO44 – Table 1. Prevalence of SARS-CoV-2 PCR tests, results, and hospitalisations in the EuroSIDA regions in 2020.

SARS-CoV-2 PCR testing and results	Total (N = 7228)	Southern Europe (N = 1723)	Central Western Europe (N = 1071)	Northern Europe (N = 1588)	Central Eastern Europe (N = 1584)	Eastern Europe (N = 940)	Argentina (N = 322)
Tested, N	1070	236	122	513	88	67	44
Tested, % (95% CI)	14.8 (14.0 to 15.6)	13.7 (12.1 to 15.4)	11.4 (9.6 to 13.5)	32.3 (30.0 to 34.7)	5.6 (4.5 to 6.8)	7.1 (5.6 to 9.0)	13.7 (10.1 to 17.9)
Positive, N	140	39	23	15	33	12	18
Positive, % (95% CI)	1.9 (1.6 to 2.3)	2.3 (1.6 to 3.1)	2.1 (1.4 to 3.2)	0.9 (0.5 to 1.6)	2.1 (1.4 to 2.9)	1.3 (0.7 to 2.2)	5.6 (3.4 to 8.7)
Negative, N	930	197	99	498	55	55	26
Negative, % (95% CI)	12.9 (12.1 to 13.7)	11.4 (10.0 to 13.0)	9.2 (7.6 to 11.1)	31.4 (29.1 to 33.7)	3.5 (2.6 to 4.5)	5.9 (4.4 to 7.6)	8.1 (5.3 to 11.6)
Hospitalised due to SARS-CoV-2, N	28	8	5	4	5	5	1
Hospitalised due to SARS-CoV-2, % (95% CI)	0.4 (0.3 to 0.6)	0.5 (0.2 to 0.9)	0.5 (0.2 to 1.1)	0.3 (0.1 to 0.6)	0.3 (0.1 to 0.7)	0.5 (0.2 to 1.2)	0.3 (0.0 to 1.7)



Abstract MO44 – Figure 1. Multivariable odds ratios for factors significantly associated with having a PCR test for SARS-CoV-2 (a) and having at least one positive PCR test result for SARS-CoV-2 (b).

Background: With the increasing age and growing burden of comorbidities the population of people living with HIV (PLWHIV) [1,2] might be at higher risk of symptomatic COVID-19 and worse outcomes [3,4]. We aim to describe SARS-CoV-2 testing in a large cohort of PLWHIV and assess factors associated with PCR testing as well as with positive test results.
Materials and methods: PLWHIV from the EuroSIDA cohort under prospective follow-up on 1 January 2020 were included from the sites that provided any testing data. Proportions of PCR testing, positive test results, and hospitalisations reported up to 1 January 2021 were compared across five European regions plus Argentina. Multivariable logistic regression was used to determine factors from a pre-specified set of potential predictors associated ($p < 0.05$) with being tested for SARS-CoV-2 (vs untested) and with at least one positive test result (vs negative).
Results: Of 7228 participants, 1070 (14.8%, 95% CI 14.0 to 15.6) had a SARS-CoV-2 test reported during 2020. The proportion ranged from 32.3% in Northern Europe to 5.6% in Central-Eastern and 7.1% in Eastern Europe (Table 1). These differences between regions remained significant after adjustment. Likewise, women, people under 40 years, those with prior CVD, and those receiving TDF-containing regimen were significantly more likely to have been tested (Figure 1a). Overall, 140 PLWHIV (1.9%, 95% CI 1.6 to 2.3) tested positive, ranging from 0.9% in Northern Europe to 5.6% in Argentina. The adjusted odds of testing positive were the highest in Argentina and Central-Eastern Europe compared to the North, and lower in PLWHIV receiving TDF (Figure 1b). No other factors reached significance threshold. Twenty-eight people were hospitalised due to COVID-19 (0.4% of the study population, 95% CI 0.3 to 0.6), ranging from 0.3% to 0.5% across regions. Of these, five received life support, and six died.
Conclusions: We observed large heterogeneity in SARS-CoV-2 testing in PLWHIV across EuroSIDA regions, reflecting differences in testing policies and data availability. All regions except North reported a proportion tested below 15% and a high fraction of positive results. TDF was associated both with testing and a negative test result, requiring further investigation. The proportion of hospitalisations was consistent across regions, with a low observed proportion of COVID-related deaths.

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MO45

The stability and predictors of change in clinically relevant multimorbidity clusters over time among people with HIV in the Pharmacokinetic and clinical Observations in PeoPle over fifty (POPPY) study

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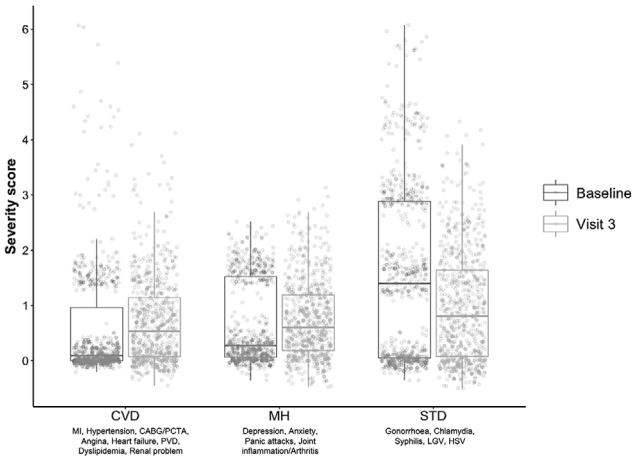
Background: The prevalence of multimorbidity is increasing among people with HIV (PWHIV). Although multimorbidity clusters have been defined using cross-sectional data, their trajectories have not been well studied. We examine the stability of clusters and factors associated with any changes over a 3- to 5-year period in PWHIV participating in the POPPY study.
Materials and methods: Common comorbidity patterns in PWHIV were identified using principal component analysis (PCA), based on Somers' D statistic, at study entry and after 3 to 5 years. Three patterns were extracted based on biological relevance (cardiovascular diseases (CVD), sexually transmitted diseases (STDs) and mental health (MH)) and severity scores for each participant/pattern were determined using PCA coefficients (higher severity scores represent the presence of a greater number of comorbidities). The distribution (median, interquartile range [IQR]) of severity scores were described over time. Predictors (age, gender, ethnicity, sexual orientation, current smoker, body mass index $\geq$30 kg/m^2) of changes in the severity scores were assessed using linear regression.
Results: The 694 included participants had a median age of 52 [IQR 46 to 59] years, 83.7% were white, 86.6% male, 76.5% MSM, 97.4% on antiretroviral therapy; 90.6% with undetectable HIV viral load. The median [IQR] CVD severity score increased from 0.12 [0.00 to 1.29] at baseline to 0.54 [0.07 to 1.14] at visit 3, with that for MH increasing from 0.29 [0.08 to 1.54] to 0.60 [1.18 to 1.19] over the same period. In contrast, the median STD severity score decreased from 1.35 [0.03 to 2.88] to 0.80 [0.07 to 1.64]. White ethnicity was associated with an increase in severity scores for CVD (0.52 [0.11 to 0.92], $p = 0.01$) whereas male gender was associated with an increase in MH severity score (0.35 [0.04 to 0.66], $p = 0.03$). Additionally, MSM was associated with an increase in severity scores for both STDs and MH (1.51 [0.95 to 2.06], $p < 0.0001$ and 0.52 [0.19 to 0.85], $p = 0.002$, respectively) (Figure 1).



Abstract MO45 – Figure 1. Patterns of comorbidities and distribution of their severity scores over a 3- to 5-year period in people with HIV (PWHIV) participating in the POPPY study (n = 694). * Severity scores were determined using participants principal component analysis (PCA) coefficients for each cluster. A higher severity score denotes a participant having a greater number of comorbidities within that cluster.

Conclusion: The burden of patterns of comorbidities, especially CVD and MH, have increased over time. Changes in severity scores across patterns appear to be attributable to different demographic/lifestyle factors, suggesting that development of targeted interventions are crucial for PWHIV exhibiting distinct patterns of multimorbidity.

MO46

Trends in maternal characteristics and pregnancy outcomes among women living with HIV in the UK: 2014 to 2019

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Background: The vertical transmission rate in the UK has remained <0.3% since 2012. We describe recent trends in characteristics and outcomes of pregnancies in women living with HIV (WLWH) in the UK in 2014 to 2019.

Materials and methods: The Integrated Screening Outcomes Surveillance Service (ISOSS), part of the NHS Infectious Diseases in Pregnancy Screening Programme, commissioned by NHSE, conducts population-based surveillance of pregnancies in WLWH. Analyses covered pregnancies in WLWH diagnosed before delivery with estimated date of delivery (EDD) 2014 to 2019, reported by 31/12/2021.

Results: There were 5858 pregnancies among 3353 women, with annual numbers decreasing from ~1100 in 2014 to 2015 to 800 to 900 in 2018 to 2019. The median age at EDD was 34 years (IQR 30 to 38) with the proportion of pregnancies in women aged ≥40 years increasing from 12.5% (278/2224) in 2014 to 2015 to 19.1% (316/1655) in 2018 to 2019, p < 0.001. Pregnancies in women born in sub-Saharan Africa declined, from 72.0% (1575/2187) in 2014 to 2015 to 64.1% (1052/1642) in 2018 to 2019, while those among women born in Eastern Europe increased from 4.3% (95/2187) to 6.9% (114/1642), p < 0.001. Proportion of pregnancies in women with vertically-acquired HIV increased from 1.7% (35/2055) in 2014 to 2015 to 3.7% (55/1500) in 2018 to 2019, p < 0.01. By 2018 to 2019, 90.6% (1500/1655) of pregnancies were in women diagnosed before pregnancy, an increase from 86.8% (1925/2219) in 2014 to 2015 (p < 0.001). The proportion of women on ART at conception increased from 67.2% (1453/2162) to 81.0% (1321/1630) (p < 0.001). Among women with antenatal diagnosis, there was earlier median start of ART (19 weeks [IQR 16 to 23] in 2014 to 2015, 16 weeks [14 to 20] in 2018 to 2019). Proportion of women with first antenatal CD4 count >500 increased from 51.2% in 2014 to 2015 to 58.5% in 2018 to 2019 (p = 0.001). Over the period, >90% of delivery viral loads were undetectable (<50 copies/mL) (91.3% in 2014 to 2015, 93.1% in 2018 to 2019), p = 0.278. Vaginal deliveries increased from 44.3% to 47.4% in 2014 to 2019 (p = 0.018); the preterm delivery rate remained ~12%. Supported breastfeeding cases increased from 1.5% (24/1595) in 2014 to 2015 to 5.8% (72/1240) in 2018 to 2019, p < 0.001.

Conclusion: Changes in the population of WLWH accessing antenatal care in the UK have implications for service provision and require monitoring. Clinical outcomes are reassuring and ISOSS will continue to monitor emerging areas of interest including infant feeding and health inequalities.