Conclusions: It is unusual to succeed in including a substantial amount of cis and trans women in surveys predominantly recruiting MSM. Women in the survey showed high levels of awareness and understanding about the MPXV outbreak, and high vaccine acceptance.

Late Breakers/Hot Topics

O42

Virological failure and HIV RNA re-suppression rates in four randomised trials of dolutegravir, efavirenz or protease inhibitor-based treatment in 3116 participants

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Introduction: WHO guidelines currently recommend switches in treatment for patients with HIV RNA persistently above 1000 copies/mL despite adherence counselling. Ongoing viraemia could increase the chance of drug resistance. However, patients can show re-suppression of HIV RNA after adherence counselling, with no change in treatment. We compared rates of virological failure (VF) and re-suppression in four randomised trials of dolutegravir (DTG), efavirenz (EFV) and protease inhibitors (PI/r).
Methods: Data were analysed from four randomised trials: DolPHIN-2, ADVANCE, NAMSAL and VISEND. VF was defined as HIV RNA >1000 copies/mL after week 24. HIV RNA re-suppression was defined as HIV RNA <50 copies/mL at the next visit in DolPHIN-2, ADVANCE and VISEND, or <200 in NAMSAL. 'Sustained viraemia' was then subdivided into HIV RNA 50 to 99 or >1000 copies/mL at next visit. The percentage of participants with VF and HIV RNA re-suppression was then compared between treatment classes in a meta-analysis.
Results: DolPHIN-2 was conducted in South Africa and Uganda, ADVANCE in South Africa, NAMSAL in Cameroon and VISEND in Zambia. Rates of VF were not significantly different between DTG and EFV in ADVANCE (DTG 12%, EFV 9%), DOLPHIN-2 (DTG 33%, EFV 30%), and NAMSAL trials (DTG 16%, EFV 15%) (Table 1). In VISEND, VF was significantly lower for DTG versus PI/r (DTG 16%, PI/r 24%, $p = 0.0048$). Following VF, HIV RNA re-suppression rates were significantly higher for DTG in ADVANCE (DTG 57%, EFV 23%) and NAMSAL (DTG 60%, EFV 29%), but not in DOLPHIN-2 (DTG 34%, EFV 34%). In the meta-analysis, overall re-suppression rates were significantly higher for DTG versus EFV ($p = 0.04$). In VISEND, HIV RNA re-suppression was significantly more common for DTG versus PI/r (DTG 38%, PI/r 19%, $p = 0.0094$).
Discussion: In this analysis of 3116 patients in four randomised trials, episodes of viraemia >1000 copies/mL were seen for a range of treatments. However, HIV RNA re-suppression after initial viraemia

Abstract O42 – Table 1. Analysis results. Note: VISEND: Arm A, HIV RNA <1000 at screening; Arm B, HIV RNA >1000 at screening.

Trial	Arm	Viral failure	Re-suppression (<50/<200)	Sustained viraemia (>1000)	Sustained viraemia (50 to 999)	Lost to follow-up
ADVANCE	TAF/FTC/DTG	40/351 (11%)	22/40 (55%)	11/40 (27%)	1/40 (2%)	6/40 (15%)
ADVANCE	TDF/FTC/DTG	43/351 (12%)	25/43 (58%)	6/43 (14%)	5/43 (12%)	7/43 (16%)
ADVANCE	TDF/FTC/EFV	31/351 (9%)	7/31 (23%)	16/31 (52%)	4/31 (13%)	4/31 (13%)
DOLPHIN-2	TDF/3TC/DTG	41/124 (33%)	14/41 (34%)	10/41 (24%)	8/41 (19%)	9/41 (22%)
DOLPHIN-2	TDF/3TC/EFV	38/125 (30%)	13/38 (34%)	4/38 (10%)	8/38 (21%)	13/38 (34%)
NAMSAL	TDF/3TC/DTG	48/307 (16%)	29/48 (60%)	10/48 (21%)	3/48 (6%)	6/48 (12%)
NAMSAL	TDF/3TC/EFV	45/306 (15%)	13/45 (29%)	21/45 (47%)	5/45 (11%)	6/45 (13%)
VISEND	TDF/FTC/DTG (A)	10/209 (5%)	5/10 (50%)	2/10 (20%)	1/10 (10%)	2/10 (20%)
VISEND	TAF/FTC/DTG (A)	13/209 (6%)	4/13 (31%)	3/13 (23%)	5/13 (38%)	1/13 (8%)
VISEND	TDF/FTC/DTG (B)	39/208 (19%)	16/39 (41%)	11/39 (28%)	7/39 (18%)	5/39 (13%)
VISEND	TAF/FTC/DTG (B)	26/211 (12%)	9/26 (35%)	8/26 (31%)	3/26 (11%)	6/26 (23%)
VISEND	ZDV/3TC/LPV/r (B)	46/167 (27%)	9/46 (20%)	18/46 (39%)	7/46 (15%)	12/46 (26%)
VISEND	ZDV/3TC/ATV/r (B)	40/197 (20%)	7/40 (17%)	19/40 (47%)	8/40 (20%)	6/40 (15%)

was significantly more likely for participants taking DTG-based treatment, compared with either EFV- or PI-based treatment. For patients with VF on DTG, the benefits of switching to new drug classes are unclear, versus remaining long term on DTG with adherence counselling.

O43

Six-month outcomes of every 2-months long-acting cabotegravir and rilpivirine in a real-world setting: effectiveness, adherence to injections and patient-reported outcomes from PLWHIV in the German CARLOS cohort

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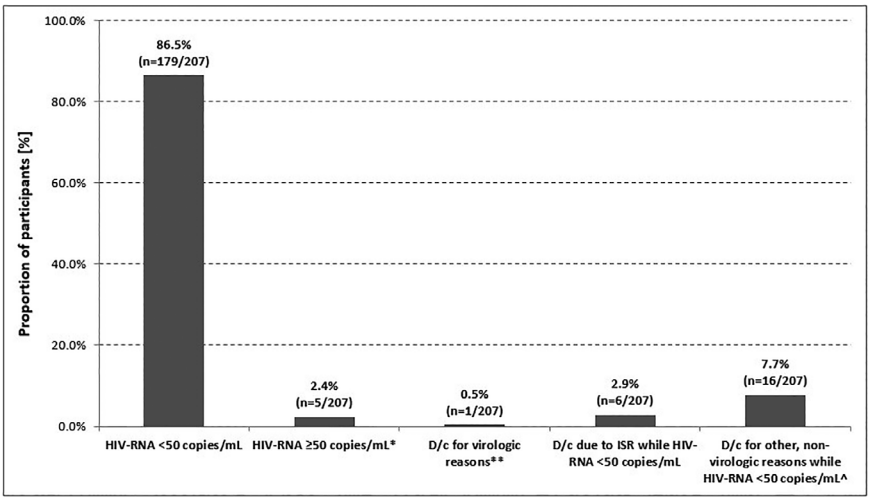
Background: The long-acting (LA) regimen of cabotegravir (CAB) and rilpivirine (RPV) offers an alternative mode of drug administration with less frequent dosing than daily oral antiretroviral therapy (ART). The prospective CARLOS cohort has been initiated to generate the first real-world evidence on effectiveness, adherence and patient experience of individuals choosing CAB+RPV LA in routine clinical care in Germany. Here we describe interim outcomes at 6 months.

Abstract O43 – Table 1. Baseline characteristics.

Baseline characteristics	Total	Observed data
Sex, male, % (n)	95.3% (225)	236
Age, years, median (IQR)	43 (36 to 50)	236
Age categories <50; 50 to 65; >65, % (n)	74.6% (176); 25.0% (59); 0.4% (1)	236
BMI ≥30 kg/m^2, % (n)	12.2% (23)	189
CD4 T-cell count, cells/μL, median (IQR)	721 (542 to 991)	232
History of AIDS (CDC C), % (n)	8.5% (20)	236
Time on ART, years (median, IQR)	8.0 (4.9 to 11.6)	210
≥3 previous ART regimens, % (n)	53.8% (106)	197
Most common regimens (>10%) prior to switch to CAB+RPV LA	B/F/TAF: 24.0% (n = 55); DTG/3TC: 18.8% (n = 43)	229
Reason for switch to CAB+RPV LA (HCP perspective)		236
Patient wish	91.9% (n = 217)	
Adherence concerns under oral ART	5.5% (n = 13)	
Medical need for parent	1.7% (n = 4)	
Other	0.8% (n = 2)	
Resistance test available at/before switch to CAB+RPV LA	60.6% (n = 143)	236
HIV-1 subtype		236
A	0.8% (n = 2)	
A1	1.3% (n = 3)	
A2	2.1% (n = 5)	
B	50.4% (n = 119)	
Other	5.1% (n = 12)	
Unknown subtype	40.3% (n = 95)	

B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DTG/3TC, dolutegravir/lamivudine; IQR, interquartile range.



Abstract O43 – Figure 1. Virological outcomes at injection 4/month 6 (missing=excluded: no viral data in window (n = 25), loss to follow-up (n = 4)). * Incl. n = 1 virological failure (confirmed HIV-RNA ≥200 copies/mL or single HIV-RNA ≥200 copies/mL followed by treatment d/c): HIV-1 subtype B, BMI 23 kg/m^2, no history of NNRTI resistance-associated mutations (RAMs) (INSTI resistance test not performed), injections in window, emergent NNRTI RAM (Y181C) and INSTI RAMs (L74I, T97A, E138K, Q148R, N155H) detected [BW1]); n = 2 with single HIV-RNA >200 copies/mL and n = 2 with 50 copies/mL; ** virologic failure; HIV-1 subtype C, BMI 20 kg/m^2, no history of NNRTI or INSTI RAMs, injections in window, emergent NNRTI RAMs (K101E, Y181C, G190A) detected; ^ incl. n = 7 participants preferring oral ART. D/c, discontinuation.

Materials and methods: CARLOS is a non-interventional, 3-year multi-centre cohort study including people living with HIV (PLWHIV) on suppressive daily oral ART switched to every 2-months CAB+RPV LA in accordance with the label. Interim outcomes at time of injection 4/month 6 (M6) include effectiveness, adherence to injection window and patient-reported outcomes including change in treatment satisfaction using the HIV Treatment Satisfaction Questionnaire [status version; HIV-TSQs].

Results: Two hundred and thirty-six PLWHIV reached the target window for 4th injection and were included in the analysis population at M6. Baseline characteristics and reasons for switch to CAB+RPV LA are shown in Table 1. The majority (84.7%; n = 200/236) started with oral lead-in (OLI). 90.7% (n = 574/633) of CAB+RPV LA injections were administered within the +/-7 day injection window, 6.5% occurred early and 2.8% occurred late. Oral bridging was documented for six individuals. At M6 86.5% (n = 179/207) maintained virological suppression and 2.9% (6/207) discontinued due to injection site reactions (ISRs). There were two virological failures (2/207; 1.0%). Full virological outcomes are shown in Figure 1. For PLWHIV completing the HIV-TSQs at baseline (mean score = 55.3) and at M6 (mean score = 60.6), a statistically significant treatment satisfaction score increase was observed (mean change = +5.4; p < 0.001; n = 157).

Conclusion: In this real-world cohort, switch to CAB+RPV LA is primarily patient driven, with low rates of PLWHIV discontinuing due to ISRs and the vast majority of injections being administered within the window or early. CAB+RPV LA shows high rates of maintenance of viral suppression, with low rates of treatment failure in the first 6 months following switch. Despite already high scores on oral ART, the treatment satisfaction score increased statistically significantly on long-acting ART in patients mostly self-selecting CAB+RPV LA.

O44

Expanded multivariable models to assist patient selection for long-acting cabotegravir+rilpivirine treatment: clinical utility of a combination of patient, drug concentration, and viral factors associated with virological failure over 152 weeks

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Abstract O44 – Table 1. Virological outcomes by the presence of key baseline and post-baseline factors.

Three baseline factors: RPV RAMs,[b] subtype A6/A1,[c] and BMI ≥30 kg/m^2			Two baseline factors + CAB and RPV PK[a]: RPV RAMs,[b] subtype A6/A1,[c] low initial CAB trough,[a] and low initial RPV trough[a]		
Baseline factors (number)	**Virological suppression, n (%)[d]**	**CVF, n (%)[e]**	**Factors (number)**	**Virological suppression, n (%)[d]**	**CVF, n (%)[e]**
0	844/970 (87.0)	4/970 (0.4)[f]	0	584/664 (88.0)	0/664 (0)[i]
1	343/404 (84.9)	8/404 (2.0)[g]	1	339/396 (85.6)	5/396 (1.3)[j]
≥2	44/57 (77.2)	11/57 (19.3)[h]	≥2	190/232 (81.9)	17/232 (7.3)
Total (95% CI)	1231/1431 (86.0) (84.1% to 87.8%)	23/1431 (1.6) (1.0% to 2.4%)	≥3	28/39 (71.8)	8/39 (20.5)[k]
		18/1224 (1.47)[l]	Total (95% CI)	1113/1292 (86.1) (84.1% to 88.0%)	22/1292 (1.7) (1.1% to 2.6%)

BMI, body mass index; CAB, cabotegravir; CVF, confirmed virological failure; FDA, Food and Drug Administration; NPV, negative predictive value; PK, pharmacokinetic; PPV, positive predictive value; RAM, resistance-associated mutation; RPV, rilpivirine.
[a]Below first quartile; [b]screening plasma samples were used for reverse transcriptase genotype analysis for participants in the FLAIR study. Baseline genotyping of participant samples from the ATLAS and ATLAS-2M studies was carried out retrospectively in peripheral blood mononuclear cell (PBMC) samples (pro-viral DNA); [c]HIV-1 subtype A1 or A6 classification based on Los Alamos National Library panel from HIV Sequence database (June 2020); [d]based on the FDA Snapshot algorithm of HIV-1 RNA <50 copies/mL at week 48 for ATLAS, week 124 for FLAIR, and week 152 for ATLAS-2M; [e]defined as two consecutive measurements of HIV-1 RNA ≥200 copies/mL; [f]PPV 0.4%; NPV 95.9%; sensitivity 17.4%; specificity 31.4%; [g]PPV 2.0%; NPV 98.5%; sensitivity 34.8%; specificity 71.9%; [h]PPV 19.3%; NPV 99.1%; sensitivity 47.8%; specificity 96.7%; [i]PPV 0%; NPV 96.5%; sensitivity 0%; specificity 47.7%; [j]PPV 1.3%; NPV 98.1%; sensitivity 22.7%; specificity 69.2%; [k]PPV 20.5%; NPV 98.9%; sensitivity 36.4%; specificity 97.6%; [l]analysis dataset for the multivariable modelling.

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Background: Confirmed virological failure (CVF) on long-acting cabotegravir (CAB) and rilpivirine (RPV) therapy occurred in 1% of participants in clinical trials through 48 weeks with few cases thereafter. Post hoc multivariable analyses exploring predictors of CVF were expanded to include data beyond week 48, and to incorporate additional factors/participants.
Materials and methods: Pooled data from 1651 participants (n = 1431 complete records) examined the influence of baseline viral, participant, and dosing regimen factors on CVF. These factors were evaluated in additional models that included predicted CAB/RPV trough concentrations (after 4 and 44 weeks of injections) in participants with no prior CAB+RPV exposure (n = 1292). Using Poisson regression modelling with variable selection procedures, retained factors were evaluated to understand their contribution to CVF (when present alone or in combination).
Results: After 4291 person-years (pys), the unadjusted CVF incidence rate was 0.54 per 100 pys (Q4W, 0.42; Q8W, 0.85; Q4W switch to Q8W, 0.54). 1.6% (n = 23/1431) of participants had CVF (n = 4/23 occurred after week 48) and 86% (n = 1231/1431) maintained virological suppression. Baseline RPV resistance-associated mutations (RAMs), HIV-1 subtype A6/A1, and BMI ≥30 kg/m^2 were predictive of CVF ($p < 0.05$ adjusted incidence rate ratio), with ≥2 baseline factors (BLFs) conferring higher risk (19.3%; NPV 99.1%) versus no BLFs (0.4%; NPV 95.9%) (Table 1). Virological suppression rates were 87%, 85%, and 77% in participants with 0, 1, or ≥2 key BLFs, respectively. Low predicted CAB/RPV troughs (≤1st quartile), but not BMI, were additional predictive factors in models including post-baseline pharmacokinetic variables. Regimen (Q8W/Q4W), gender, and CAB/other INSTI RAMs had no significant association with CVF.
Conclusions: The presence of ≥2 BLFs (RPV RAMs, A6/A1 subtype, and/or BMI ≥30 kg/m^2; 4% of population analysed), or ≥3 factors (when predicted trough pharmacokinetic data are included; 3% of population analysed), was associated with a higher CVF risk after up to 3 years of long-acting therapy. In absence of baseline and/or pharmacokinetic factor combinations (e.g. <2 or 3), CVF rates were low (NPV 99%), adding to the understanding of appropriate use of this long-acting treatment option.

O45

Modeling and simulation to optimize islatravir once daily (QD) doses in HIV treatment naïve and virologically suppressed populations

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Background: Islatravir (ISL) is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) being studied for HIV-1 treatment and prevention. Exposure-related decreases in total lymphocytes and CD4+ T-cell counts were observed across ISL clinical trials, with higher frequencies and magnitude of changes observed in ISL higher-dose regimens (20 mg once weekly; 60 and 120 mg once monthly). Data from the long term ISL treatment and PrEP trials were used to develop models that describe the changes in lymphocytes and CD4+ T-cells over time in relationship to intracellular ISL-TP concentrations. Optimized doses were identified to achieve efficacy thresholds and similar CD4+ T cell and lymphocyte dynamics compared to standard ART.
Methods: A two-step model building approach was taken. First, the ISL population pharmacokinetic (POPPK) model was used to generate individual posthoc estimates for the PK model parameters and were included in the lymphocyte and CD4+ cell dataset. Then, the CD4+ T cell and lymphocyte models were developed using the individual PK parameters and observed cell changes over time from long term ISL studies. CD4+ T cell changes were summarized across approved ART regimens for the virologically suppressed population to compare to PK/PD model predictions. The CD4+ T cell and lymphocyte models were then used to predict changes at different ISL dose levels. To predict the efficacy of a regimen, the POPPK model

was simulated to assess achievement of PK thresholds. The efficacy and CD4+ T cell and lymphocyte predictions were compared to inform on a new recommended QD dose regimen.
Results: 0.25 mg QD is predicted to achieve efficacy thresholds for all individuals for wild type virus and M184I/V variant. The CD4+ T cell and lymphocyte models adequately capture the dynamics for standard of care arms and ISL treatment arms for the Phase 2 and 3 treatment and Phase 2 PrEP trials. ISL 0.25 mg QD is predicted to result in similar CD4+ T cells and lymphocyte changes as standard antiretroviral therapy. Additionally, the predicted results fall within the range of CD4+ T cell changes observed in other virologically suppressed trials for approved ART regimens.
Conclusions: ISL 0.25 mg QD in combination with DOR 100 mg is predicted to achieve efficacious exposures for wild-type and M184I/V HIV-1 variants and have similar CD4+ T cell and lymphocyte changes as standard ART for treatment naïve and virologically suppressed populations.

O46

Total lymphocyte and CD4+ T-cell count changes in participants receiving islatravir (0.25, 0.75 and 2.25 mg QD) and doravirine +/- lamivudine: post-hoc analysis from a phase 2b dose- ranging study (P011)

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Background: Islatravir (ISL) is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) being studied for HIV-1 treatment and prevention. Exposure-related decreases in total lymphocyte and/or CD4+ T-cell counts were observed across ISL clinical trials, with higher frequencies and magnitude of changes observed in ISL higher-dose programs (20 mg weekly; 60 and 120 mg monthly). We conducted post-hoc analyses of changes in total lymphocyte and lymphocyte subset counts in the phase 2b dose-ranging study (P011) of ISL with doravirine (DOR) +/- lamivudine (3TC).
Methods: P011 (NCT03272347) was a 4-part, randomized, dose-ranging study; participants initially received ISL (0.25, 0.75, or 2.25 mg) with DOR (100 mg) and 3TC (300 mg) or the fixed-dose combination DOR/3TC/tenofovir disoproxil fumarate (TDF) once daily (Part 1). Participants receiving ISL+DOR+3TC and achieving HIV-1 RNA <50 copies/mL at week 20 or later stopped 3TC and continued their assigned initial ISL dose (blinded) with DOR (Part 2). Participants randomized to ISL switched to the 0.75 mg dose between weeks 60 and 84 and continued through week 144 (Part 3). Participants in the comparator arm continued DOR/3TC/TDF through week 144. Post-hoc analyses were conducted evaluating ISL effects on total lymphocyte and lymphocyte subset counts in Parts 1 and 2 through week 72 (prior to dose conversion). Participants who switched to ISL 0.75 mg before week 72 were censored from the week 72 analysis but included in all time points prior to switch. Incidence of infections and assessment of hematology parameters were also examined.
Results: Changes from baseline in total lymphocyte counts were comparable for participants in the ISL 0.25 mg and DOR/3TC/TDF groups and were more favorable than changes in the ISL 0.75 mg and 2.25 mg groups (Table 1). Increases from baseline in CD4+ T-cell counts were similar for the ISL 0.25 mg and DOR/3TC/TDF groups (Table 1). The incidence of infections was comparable across all treatment groups. No effects on other hematology parameters were observed.
Conclusions: Participants receiving ISL 0.25 mg + DOR (+/- 3TC) and those receiving DOR/3TC/TDF had comparable changes in total lymphocyte counts, with robust increases in CD4+ T-cell counts. These results support further evaluation of ISL 0.25 mg with DOR in treatment-naïve and virologically suppressed people living with HIV-1.

Abstract O46 – Table 1. Change in total lymphocyte counts and CD4+ T-cell counts in treatment-naïve participants with HIV-1, MK-8591-011 parts 1 and 2 (through week 72).

Total lymphocyte counts (10^9 cells/L)		
Treatment group	N	Mean % change from baseline (95% CI)[a]
DOR/3TC/TDF	22	15.9 (2.0, 29.9)
ISL 0.25 mg + DOR 100 mg (+/- 3TC)	19	20.5 (4.3, 36.6)
ISL 0.75 mg + DOR 100 mg (+/- 3TC)	19	-0.4 (-14.9, 14.1)
ISL 2.25 mg + DOR 100 mg (+/- 3TC)	16	-15.9 (-31.9, 0.1)
CD4+ T-cell counts (cells/mm^3)		
Treatment group	N	Mean % change from baseline (95% CI)[a]
DOR/3TC/TDF	22	60.1 (40.2, 80.0)
ISL 0.25 mg + DOR 100 mg (+/- 3TC)	19	79.8 (50.0, 109.6)
ISL 0.75 mg + DOR 100 mg (+/- 3TC)	18	47.1 (26.1, 68.2)
ISL 2.25 mg + DOR 100 mg (+/- 3TC)	16	24.0 (4.7, 43.4)

[a]The within-group 95% CIs were calculated based on the t-distribution.