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OAC0502

Estimation of the counterfactual HIV incidence in the PURPOSE trials

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Background: PURPOSE 1 (NCT04994509;P1) and PURPOSE 2 (NCT04925752;P2) evaluated twice-yearly lenacapavir for HIV pre-exposure prophylaxis. These trials employed a novel counterfactual HIV-incidence design comparing observed HIV incidence among participants receiving investigational agents to estimated background HIV incidence (bHIV) using a recent infection testing algorithm (RITA) in a pre-randomization cross-sectional cohort of screened participants. We report bHIV in P1/2, estimated by a RITA, with varying parameters and additional counterfactual estimates.

Methods: Samples from participants diagnosed with HIV during screening underwent testing for recent infection; bHIV was calculated using a RITA with recency assay parameters reported in Kassanjee 2016 (mean duration of recent infection and false recent rate based on weighted average of included subtypes; T = 2 years). Multiple counterfactual estimates of HIV incidence were also considered: observed and RITA-estimated incidence in the ECHO trial, predicted HIV incidence using modified VOICE score among participants (P1) and predicted HIV incidence calculated using emtricitabine-tenofovir disoproxil fumarate (F/TDF) efficacy-adherence relationship and correlation with rectal gonorrhoea incidence (P2). Additionally, bHIV was compared using varying recency assay parameters.

Results: Estimated bHIV in P1 was 2.41/100 person-years (py; 95% confidence interval 1.82,3.19) and 2.37/100py (1.65,3.42) in P2 (Figure 1). Predicted HIV incidence in P1 using modified VOICE score was 9.35/100 py (8.11, 11.09); observed HIV incidence in ECHO was 4.77/100 py (4.24, 5.35). Predicted HIV incidence in P2 ranged from 2.87/100 py (1.09, 6.72) using the F/TDF efficacy-adherence relationship to 6.19 (3.53, 8.85) using rectal gonorrhoea incidence. Varying RITA parameters had minimal impact on the bHIV estimate.

Conclusions: RITA-based bHIV for P1/2 were consistent with conservative incidence estimates. Of additional counterfactual estimates evaluated, the F/TDF efficacy-adherence estimate was most similar to RITA-based bHIV. Modified VOICE score and rectal gonorrhoea correlation yielded higher HIV-incidence estimates, which may be explained by the calibration of these methods earlier in the HIV epidemic. These findings support RITA-based bHIV estimates as comparators in future HIV prevention trials.

OAC0503

Efficacy, safety and pharmacokinetics of twice-yearly subcutaneous lenacapavir for PrEP among adolescents and young people in the phase 3 trials PURPOSE 1 and PURPOSE 2

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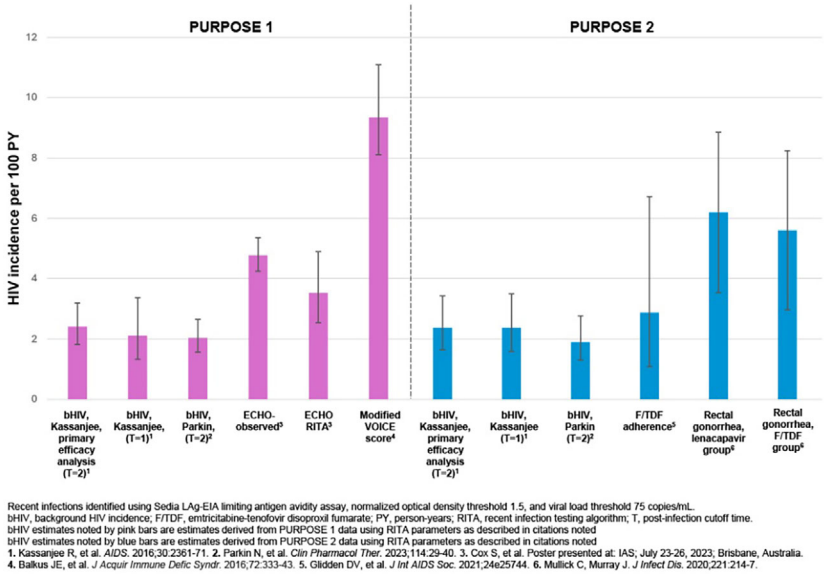

Recent infections identified using Sedia LAg-EIA limiting antigen avidity assay, normalized optical density threshold 1.5, and viral load threshold 75 copies/mL.
bHIV, background HIV incidence; F/TDF, emtricitabine-tenofovir disoproxil fumarate; PY, person-years; RITA, recent infection testing algorithm; T, post-infection cutoff time.
bHIV estimates noted by pink bars are estimates derived from PURPOSE 1 data using RITA parameters as described in citations noted
bHIV estimates noted by blue bars are estimates derived from PURPOSE 2 data using RITA parameters as described in citations noted
1. Kassanjee R, et al. *AIDS*. 2016;30:2361-71. **2.** Parkin N, et al. *Clin Pharmacol Ther*. 2023;114:29-40. **3.** Cox S, et al. Poster presented at: IAS; July 23-26, 2023; Brisbane, Australia. **4.** Balkus JE, et al. *J Acquir Immune Defic Syndr*. 2016;72:333-43. **5.** Glidden DV, et al. *J Int AIDS Soc*. 2021;24e25744. **6.** Mullick C, Murray J. *J Infect Dis*. 2020;221:214-7.

Figure 1. OAC0502: Comparison of estimated background HIV incidence and 95% CI using RITA and alternative counterfactual estimates in PURPOSE 1 and PURPOSE 2.