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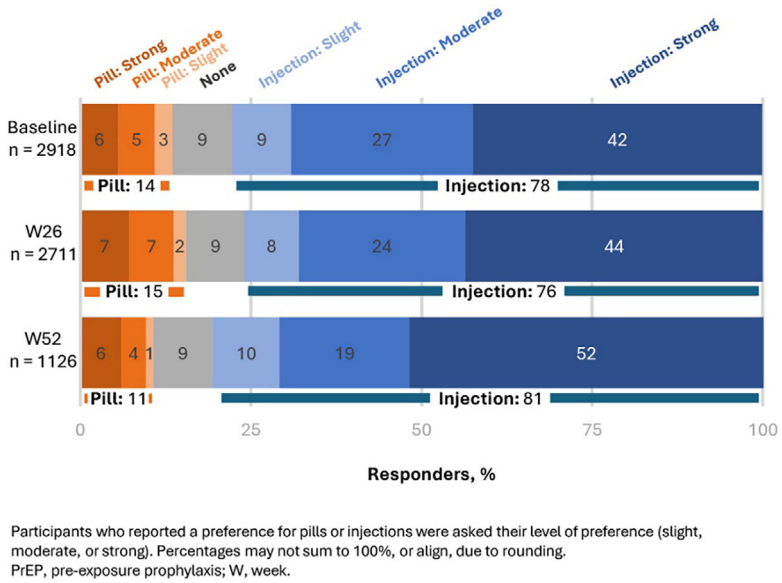

Figure 1. OAC0504: PrEP administration preferences (daily oral pills vs twice-yearly injections) among all participants in the PURPOSE 2 trial.

an alternative injection/tablet placebo. During injection visits, participants completed an electronic questionnaire about PrEP administration preference (twice-yearly injections or daily pills) and how administration type impacts HIV risk perception and PrEP adherence. Data were collected at baseline (prior to injection), Week (W) 26 and W52. Categorical responses were analysed descriptively.
Results: Of 3271 treated participants, 2918 and 1126 completed the questionnaire at baseline and W52 (primary analysis), respectively. Over 75% of participants preferred twice-yearly injections over daily pills; 11–15% preferred daily pills (Figure 1). Among those with a preference for injections, over half reported a strong preference. Most participants reported that they would feel more protected from HIV (baseline: 66%; W26: 66%; W52: 69%) and be more confident about not missing a dose (baseline: 76%; W26: 73%; W52: 77%) with twice-yearly injections versus daily pills. Results were generally consistent across geographies included in the trial.
Conclusions: Most participants preferred and felt more protected from HIV with twice-yearly injectable PrEP, although results highlighted the importance of choice. These data indicate twice-yearly lenacapavir could increase the uptake of, adherence to, and persistence with PrEP among men and gender-diverse people.

OAC0505

Inclusion of pregnant and lactating people in the PURPOSE 1 study: efficacy, safety and pharmacokinetics

L.-G. Bekker[1], D. Moodley[2], I. Harkoo[2], G. Kigozi[3], C.E. Louw[4], M. Malahleha[5], T. Palanee-Phillips[6], R. Panchia[7], N. Singh[8], D.D. Diallo[9], L. Mworeko[10], S. Puryear[11], P. Wong[11], P. Arora[11], M. Imperial[11], C. Deaton[12], A. Kintu[11], M. Das[11], F. Matovu Kiweewa[13]
[1]The Desmond Tutu HIV Centre, University of Cape Town, Cape Town, South Africa, [2]Centre for the AIDS Programme of Research in South Africa, University of KwaZulu-Natal, Durban, South Africa, [3]Africa Medical and Behavioral Sciences Organization, Kalisizo, Uganda, [4]Madibeng Centre for Research, Brits, South Africa, [5]Synergy Biomed Research Institute, East London, South Africa, [6]Wits RHI, University of the Witwatersrand, School of Public Health, Johannesburg, South Africa, [7]Perinatal HIV Research Unit, University of the Witwatersrand, Soweto, South Africa, [8]HIV and Other Infectious Diseases Research Unit, South African Medical Research Council, Durban, South Africa, [9]SisterLove, Inc., Atlanta, United States, [10]International Community of Women Living with HIV Eastern Africa, Kampala, Uganda, [11]Gilead Sciences, Inc., Foster City, United States, [12]Gilead Sciences, Cambridge, United Kingdom, [13]Makerere University-Johns Hopkins University Research Collaboration, Kampala, Uganda

Background: Pregnant and lactating people (PLP) are disproportionately vulnerable to HIV-1 acquisition but historically excluded from Phase 3 HIV trials. PURPOSE 1 (NCT04994509) was the first pre-exposure prophylaxis (PrEP) trial to intentionally include PLP to address their urgent unmet need for HIV prevention options.
Methods: We engaged community stakeholders, regulatory agencies, ethics committees and maternal/paediatric health experts to responsibly include PLP in PURPOSE 1. To respect autonomy and reproductive choice, contraception was offered but not required; participants who became pregnant could remain on study drug following additional informed consent. We describe pregnancy outcomes, adverse events (AEs) and HIV infections in PLP randomized to twice-yearly subcutaneous lenacapavir up to the primary analysis. Lenacapavir plasma concentrations in PLP during each trimester/postpartum were compared with non-PLP using a population pharmacokinetics (popPK) model. Lenacapavir concentrations in breastmilk and infant plasma were measured (smaller subset).
Results: Of 2140 participants receiving lenacapavir, 184 participants had 193 pregnancies, of which 88 (45.6%) were ongoing. The 105 pregnancies with outcomes included 52 live births (49.5%) and 53 losses (50.5%), including 30 induced/elective abortions (28.6%), 20 spontaneous abortions (19.0%) and 3 stillbirths (2.9%). Maternal pregnancy-associated AEs were uncommon, with gestational hypertension/pre-eclampsia (n = 4) and hyperemesis gravidarum (n = 3) most reported. No HIV infections occurred in PLP receiving lenacapavir. In the PopPK analysis, predicted lenacapavir exposure was not statistically significantly different by pregnancy trimester or postpartum status compared with non-PLP (Table 1). Lenacapavir was present in breastmilk (median milk-to-plasma ratio: 0.63 [n = 8 matched pairs]); however, lenacapavir exposure in infant

Table 1. OAC0505: Summary of model-predicted lenacapavir exposures stratified by pregnancy group[a].

	Did not become pregnant	Non-pregnant period	First trimester (EGA 1-84 days)	Second trimester (EGA 85-189 days)	Third trimester (EGA > 189 days)	Postpartum (within 13 weeks after pregnancy)[b]
	Mean (% CV) [N]	Mean (% CV) [N]	Mean (% CV) [N]	Mean (% CV) [N]	Mean (% CV) [N]	Mean (% CV) [N]
Day 1 to Week 26[c]						
C_{max}, ng/mL	73.7 (49) [245]	73.0 (46) [100]	74.6 (44) [49]	74.2 (61) [4]	85.2 (–) [1]	57.2 (34) [9]
C_{trough}, ng/mL	30.5 (45) [245]	30.2 (46) [66]	27.8 (41) [43]	29.5 (40) [38]	21.7 (69) [4]	30.3 (44) [12]
Week 26 to Week 52[d]						
C_{max}, ng/mL	83.5 (45) [205]	87.2 (32) [45]	82.5 (36) [29]	78.1 (32) [25]	93.4 (40) [8]	90.6 (39) [8]
C_{trough}, ng/mL	37.0 (46) [205]	33.2 (40) [30]	34.8 (53) [25]	34.3 (42) [33]	33.3 (42) [17]	42.4 (54) [10]

[a]Includes participants who had PK samples analyzed as part of the PopPK cutoff date (February 28, 2024).

[b]Following childbirth or pregnancy termination.

[c]Participants who took both oral lenacapavir 600 mg loading doses within 72 hours and had a lenacapavir 927 mg dose on Day 1 were included. C_{trough} = Week 26.

[d]Participants who took both oral lenacapavir 600 mg loading doses within 72 hours and had a lenacapavir 927 mg dose on Day 1, had an on-time SC lenacapavir 927 mg dose at Week 26 (26 weeks ± 2 weeks), and did not take the oral bridging regimen between Day 1 and Week 52, were included. C_{trough} = Week 52.

% CV, percentage coefficient of variation; C_{max}, maximum concentration; C_{trough}, trough concentration; EGA, estimated gestational age; pop(PK), (population) pharmacokinetics; SC, subcutaneous.

plasma was minimal (median breastfed-infant-to-mother plasma ratio: 0.05 [n = 11 matched pairs]).

Conclusions: Lenacapavir was efficacious, safe and well tolerated, with no clinically significant exposure differences in PLP and minimal exposure in breastfed infants. Proactive evaluation of lenacapavir efficacy, safety and PK data in PLP can support accelerated access to lenacapavir for PLP who need or want PrEP.

OAC0602

If funding falls short: projecting the impact of international HIV budget cuts across 26 countries

D. ten Brink[1], R. Martin-Hughes[1], A. Bowring[1], N. Wulan[1], S. Dalal[2], N. Scott[1]

[1]Burnet Institute, Melbourne, Australia, [2]World Health Organization, Geneva, Switzerland

Background: International funding for HIV has been critical in reducing new HIV transmissions and deaths. While treatment financing is commonly prioritized domestically, HIV prevention and testing, especially for key populations, remain more vulnerable to cuts in international funding. Reductions in international aid of 10%–70% (19% weighted average) have been announced commencing in 2026, in the five countries that account for over 90% of international HIV funding. We investigated the impact of these funding reductions on the HIV epidemic in 24 countries through mathematical modelling.

Methods: We used existing, country-validated Optima HIV models in 24 countries (Albania, Armenia, Azerbaijan, Belarus, Bhutan, Cambodia, Colombia, Cote d'Ivoire, Eswatini, Georgia, Kazakhstan, Kenya, Kyrgyzstan, Malawi, Malaysia, Moldova, Mongolia, Mozambique, South Africa, Sri Lanka, Tajikistan, Uganda, Uzbekistan, Zimbabwe). We compared a status quo scenario, with most recent HIV spending continued from 2024 to 2040, to scenarios with 18.8% cuts to international funding from 2026. Country-specific impacts of funding cuts on HIV prevention and testing programme coverage were derived based on the proportion of international funding, with lower bounds assuming equal spending reductions across all programmes and overheads and upper bounds assuming all spending reductions directly impacted service coverage. Treatment and facility-based testing were assumed to continue through domestic funding. We projected HIV incidence, HIV-related deaths and cascade outcomes to 2040.

Results: Across the 24 countries considered, a 19% reduction in international funding could lead to a 10–64% reduction in HIV prevention and testing programme coverage, a cumulative increase of 14–68% in new HIV transmissions and a 4–13% in HIV-related deaths across 2026–2040. In addition, there was a 4–21% increase in total people living with HIV and a 2–16% increase in people