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The potential benefits of long-acting injectable cabotegravir in pregnant and breastfeeding women and their infants

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Background: Pregnant and breastfeeding women (PBW) in sub-Saharan Africa have high HIV incidence rates and associated risk of vertical transmission to their infants. Oral preexposure prophylaxis (PrEP) and injectable PrEP (long-acting cabotegravir, or CAB-LA) can potentially reduce this HIV transmission, but population-level impacts are uncertain.

Methods: We extended a previously developed model of HIV and PrEP in South Africa to allow for variable PrEP duration and preference in PBW. We considered three potential scenarios for PrEP provision to PBW: oral PrEP only, CAB-LA only, and allowing oral/CAB-LA choice, with uptake and retention assumptions informed by South African data, each compared with a 'base' scenario without PrEP for PBW.

Results: Without PrEP for PBW, the model estimates 1.31 million new infections will occur between 2025 and 2035 in South African adults and children, including 100 000 in PBW, 16 800 in infants at/before birth, and 35 200 in children through breastmilk. In the oral PrEP-only scenario, these numbers would reduce by 1.2% (95% CI: 0.7–1.7%), 8.6% (4.8–12.9%), 4.0% (2.1–5.8%), and 5.3% (3.0–8.2%) respectively. In the CAB-LA-only scenario, the corresponding reductions would be 6.1% (2.9–9.6%), 41.2% (19.8–65.0%), 12.6% (6.0–19.4%), and 29.5% (13.9–46.8%), respectively, and in the oral/CAB-LA choice scenario, similar reductions would be achieved [5.6% (3.4–8.0%), 39% (23.4–55.9%), 12.4% (7.4–16.8%) and 27.6% (16.5–39.9%) respectively].

Conclusion: CAB-LA has the potential to be substantially more effective than oral PrEP in preventing HIV acquisition in PBW and vertical transmission, and can also modestly reduce HIV incidence at a population level.

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Keywords: breastfeeding, HIV, mathematical model, preexposure prophylaxis, pregnant women

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Introduction

Pregnant and breastfeeding women (PBW) in African countries have a relatively high HIV incidence [1], and are, therefore, an obvious group in which to promote the use of preexposure prophylaxis (PrEP). In addition, PBW who acquire HIV have a high risk of transmitting HIV to their infants, and preventing incident HIV during pregnancy/breastfeeding is, therefore, particularly important in reducing vertical transmission of HIV [1,2]. In view of this, WHO guidelines recommend oral PrEP in PBW in populations with high HIV incidence, noting that there is strong evidence of the safety of tenofovir and emtricitabine (the most commonly used oral PrEP drugs) during pregnancy and breastfeeding periods [3].

However, oral PrEP persistence and adherence are challenging for PBW in African settings. Although many women report initiating oral PrEP, few continue PrEP after the first month [4,5], and even fewer are found to have detectable levels of tenofovir consistent with moderate adherence [6,7]. Our previous modelling analyses suggested that oral PrEP could substantially reduce maternal HIV acquisition and vertical transmission in the South African setting [8], but this was based on the optimistic assumption that women would continue on PrEP throughout pregnancy and until the end of breastfeeding. These model estimates need to be revised in light of the poor persistence and adherence observed in cohorts of pregnant women initiating oral PrEP [4,7].

Long-acting injectable cabotegravir (CAB-LA) is a novel form of PrEP, which is substantially more effective than oral PrEP in preventing HIV acquisition in cis-gender women [9]. Because injections are only administered every 2 months, and there may be protection against HIV even when dosing is delayed [10], adherence is likely to be less of an impediment in achieving protective levels of drug. Our model of HIV and PrEP in South Africa has recently been extended to include CAB-LA, and we have shown CAB-LA could potentially reduce HIV incidence substantially [11]. However, in this previous analysis, we did not include scenarios with CAB-LA in pregnancy, (a) because of lack of data on safety and pharmacokinetics of CAB-LA in PBW, and (b) because South African guidelines were only recently extended to recommend oral PrEP in PBW [12]. Although safety data remain limited, preliminary results do not suggest there are likely to be required CAB-LA dose adjustments or safety concerns in PBW [13].

In the absence of PrEP for PBW, vertical transmission rates in South Africa are projected to decline to 450 per 100 000 births by 2030, well above the elimination target of less than 50 per 100 000 births [14]. This study aims to compare the predicted impact of a policy of promoting CAB-LA in South African PBW against the existing policy of offering oral PrEP to PBW, using a model that is calibrated to data from a South African cohort study of PrEP in PBW [15].

Methods

We adapted the Thembisa model, which has previously been used to model the impact of PrEP in South Africa [8,11,16]. Briefly, Thembisa is a compartmental, deterministic model of HIV, developed for South Africa. The model represents heterogeneity in HIV acquisition risk between 'high-risk' and 'low-risk' individuals (defined in terms of propensity for concurrent partners and commercial sex) as well as heterogeneity by age, sex, marital status, male circumcision status, and 'key population' status (with men who have sex with men [MSM] and female sex workers [FSWs] defined as separate risk groups). The simulated epidemic begins in 1985, and the numbers of HIV-positive individuals are updated at monthly time steps, allowing for HIV acquisition and disease progression. The model allows for women to transmit HIV to their infants either at/before birth or postnatally (through breastmilk), with both transmission risks depending on the mother's stage of HIV infection (highest during the 3-month acute phase that follows HIV acquisition) and mother's receipt of antiretroviral treatment (ART). A full description of the Thembisa model is provided elsewhere [17], and sections 1 and 2 of the Supplemental Digital Content, http://links.lww.com/QAD/D57 describe the modelling of sexual and vertical transmission of HIV.

In the 'base' scenario, the model makes provision for oral PrEP in MSM, FSWs, adolescent girls and young women (ages <25) and the balance of the sexually active population, though PrEP uptake is assumed to be much lower in the latter group (and proportional to the expected annual number of partners living with HIV). The model is parameterized using routinely reported numbers of people starting PrEP in each year [17]. For the purpose of quantifying PrEP impacts, the base scenario is defined as one in which there is no uptake of CAB-LA and no uptake of PrEP (oral or injectable) in PBW.

The model was extended to allow for differences in PrEP duration and choice of PrEP method between PBW and other women. Table 1 summarizes three possible scenarios for the promotion of PrEP to PBW: oral PrEP only, CAB-LA only, and offering women a choice of oral

Table 1. Assumed preexposure prophylaxis uptake, duration and efficacy, in pregnant and breastfeeding women.

	Scenario 1	Scenario 2	Scenario 3		Sources/notes
			PrEP choice		
	Oral only	CAB-LA Only	Oral	CAB-LA	
PrEP uptake[a]	41% (12%)	54% (20%)	20% (7%)	45% (17%)	[5] for oral PrEP, [18] for CAB-LA preference
OR for PrEP uptake in low-risk, relative to high-risk[a]	0.32 (0.15)	0.32 (0.15)	0.32 (0.15)	0.32 (0.15)	[15], based on frequency of sex with HIV-positive partners
Average PrEP duration (months)[a]	6.0 (2.0)	22.0 (5.9)	8.5 (4.2)	24.0 (6.0)	[5] for oral realistic, [19–21] for CAB-LA
Average duration of 'tail' protection (months)	1	3	1	3	Same assumption as before [11], based on [34]
Average PrEP protection (months)[a]	7.0 (2.0)	25.0 (5.9)	9.5 (4.2)	27.0 (6.0)	Sum of two previous rows
PrEP efficacy[a]	55% (10%)	95% (4%)	74% (12%)	97% (3%)	Based on 50% adherence for oral PrEP [7,35], higher efficacy for CAB-LA [9,36]
Reduction in condom use if using PrEP[a]	10% (8%)	10% (8%)	10% (8%)	10% (8%)	[37]

CAB-LA, cabotegravir (long-acting); OR, odds ratio; PrEP, preexposure prophylaxis; RR, risk ratio.
[a]For parameter values that are varied in the uncertainty analysis, the first value is the mean parameter value and the second (in brackets) is the standard deviation; a full explanation for the choice of distribution is provided in section 3 of the Supplemental Digital Content, http://links.lww.com/QAD/D57.

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PrEP or CAB-LA. Uptake assumptions are based on a South African cohort study [15] in the first scenario, and on local data regarding CAB-LA preferences in the latter two scenarios [18]. Probability distributions are specified to represent uncertainty around key PrEP parameters. As studies of CAB-LA in PBW are ongoing and unpublished, assumptions about the average duration of CAB-LA use are informed by a range of South African estimates of the average duration of injectable contraceptive use [19–21]. In the 'choice' scenario, women are assumed to be more motivated to remain on and adhere to their preferred prevention method. As assumed previously, average durations of PrEP use are extended by a 'tail period' (1 month for oral PrEP, 3 months for CAB-LA) to determine the average duration of protection [11].

The model was run 1000 times in the base scenario and each of the scenarios outlined in Table 1, each time using a different combination of parameters sampled from the distributions in Table 1, combined with a randomly sampled combination of parameters from the posterior distribution of Thembisa parameters generated previously [17]. The promotion of PrEP to pregnant women is assumed to begin from mid-2025, and we calculate the reduction in HIV incidence (relative to the base scenario) over the period from mid-2025 to mid-2035. We report the mean and 95% confidence interval (CI) based on the set of 1000 model projections.

Results

In the base scenario, our model predicts that between 2025 and 2035, there will be 1.31 million (95% CI: 1.19–1.43 million) new infections in adults and children, including 100 000 (89 000–111 000) in women who are attending antenatal clinics or breastfeeding, 16 800 (15 200–18 500) cases of vertical transmission at/before birth and 35 200 (31 400–39 600) cases of vertical transmission during breastfeeding. Table S2, http://links.lww.com/QAD/D57 and Fig. 1 summarize the main model results.

In the oral PrEP-only scenario, an 8.6% (4.8–12.9%) reduction in HIV incidence is expected in PBW, relative to the base scenario. Smaller reductions are expected in the number of postnatal vertical transmissions [5.3% (3.0–8.2%)], transmissions at/before birth [4.0% (2.1–5.8)] and population-level HIV incidence [1.2% (0.7–1.7%)]. Most of the variation in impact is attributed to uncertainty in PrEP uptake ($r = 0.38$) and relative odds of PrEP uptake in low-risk women ($r = -0.34$) (Figure S4, http://links.lww.com/QAD/D57). In the CAB-LA-only scenario, greater reductions in HIV incidence are expected: 41.2% (19.8–65%) in PBW, 29.5% (13.9–46.8%) in postnatal vertical transmission, 12.6% (6.0–19.4%) in transmission at/before birth, and 6.1% (2.9–9.6%) in total HIV incidence. Most of the variation in impact is attributed to uncertainty in CAB-LA uptake and the duration of CAB-LA use (Figures S1, http://links.lww.com/QAD/D57 and S2, http://links.lww.com/QAD/D57).

In the oral PrEP/CAB-LA choice scenario, reductions in HIV incidence are similar to those in the CAB-LA only scenario: a 39% (23.4–55.9%) reduction in HIV incidence among PBW, a 26.5% (16.5–39.9%) reduction in postnatal vertical transmission, a 12.4% (7.4–16.8%) reduction in transmission at/before birth, and a 5.6%

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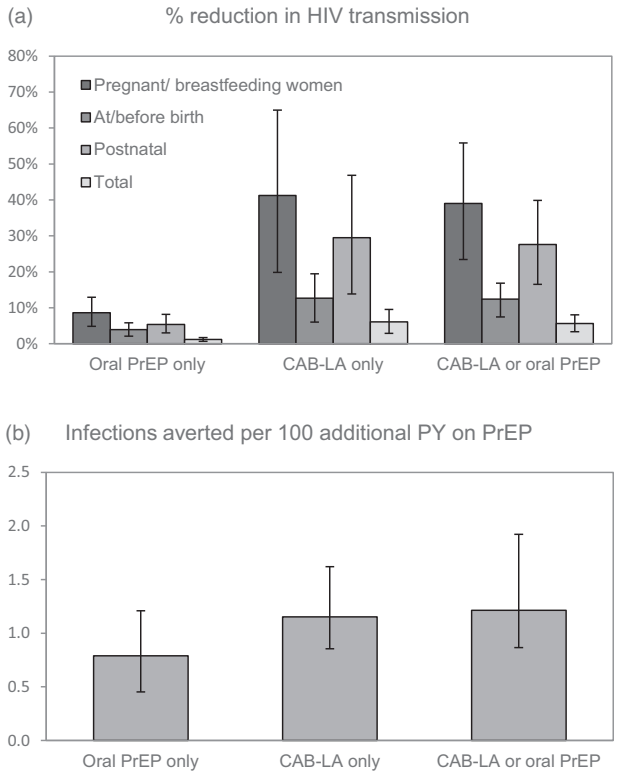


Fig. 1. Impact and efficiency of promoting preexposure prophylaxis to pregnant and breastfeeding women. Bars represent the average from 1000 simulations; error bars represent the 2.5th and 97.5th percentiles of the model estimates. CAB-LA, cabotegravir (long-acting); PrEP, preexposure prophylaxis; PY, person-years.

(3.4–8.0%) reduction in total transmission. These are equivalent to 38 900 (22 500–56 300) infections averted in PBW, 9700 (5600–14 400) infections averted through breastfeeding, 2100 (1200–2900) infections averted at/before birth and 73 600 (42 900–106 700) infections averted in total.

The number of HIV infections averted per 100 additional person years of PrEP (relative to the base scenario) was greatest in the oral/CAB-LA choice scenario [1.21 (0.87–1.92)] and lowest in the oral PrEP-only scenario [0.79 (0.45–1.21)]. The most significant source of variation in this measure of efficiency is the uncertainty in the relative odds of PrEP uptake in low-risk women ($r = -0.77$; Figure S5, http://links.lww.com/QAD/D57).

Discussion

Although our previous modelling suggested that providing oral PrEP to PBW could reduce vertical transmission in South Africa by as much as 40%, as well as substantially reduce HIV incidence in women of reproductive age [8], our updated estimates suggest a more limited impact is likely. Our updated model has been parameterized using recent data from a PrEP cohort study conducted among pregnant and postpartum women in South Africa, which shows reasonable oral PrEP uptake but limited adherence and continuation [5,7,15]. In this context, CAB-LA could potentially be very important, reducing HIV incidence in PBW by around 40%, and reducing vertical transmission by around 24% – a reflection of both greater acceptability of injectable prevention methods [22–24] and superior efficacy [9]. Offering a choice of CAB-LA and oral PrEP would lead to the greatest PrEP uptake (consistent with the effect of choice in family planning [25]), but the impact on HIV transmission would not differ materially from offering CAB-LA alone.

Randomized controlled trials of PrEP have mostly excluded pregnant women, making it difficult to assess safety in this population [26]. Data on the safety of CAB-LA in PBW are being collected in the open-label extension of HPTN 084 [9], and early data show promise in terms of safety and pharmacology [13]. While we wait for CAB-LA to be provided as 'standard of care', consideration should be given to other strategies to boost oral PrEP adherence, for example, through real-time adherence feedback [6,27], SMS communication [28], and addressing mental health barriers to adherence [29].

Another concern about the rollout of CAB-LA is the potential for drug resistance. Breakthrough infections in individuals receiving CAB-LA might develop resistance to integrase strand transfer inhibitors (INSTIs), which would limit the effectiveness of dolutegravir, another INSTI widely used in HIV treatment. Although our model does not simulate INSTI resistance, other modelling studies suggest the benefits of CAB-LA (in terms of reducing AIDS mortality) are likely to far outweigh the risks, even if there is a substantial resistance risk [30].

Our estimates of population-level impact may underestimate impacts in other African settings, where fertility rates and breastfeeding durations are greater [31,32], or may over-estimate impacts in settings with relatively poor coverage of antenatal care [33]. Nevertheless, these results point to the importance of expanding PrEP options beyond the currently available oral PrEP, and of achieving better PrEP persistence and adherence, if HIV prevention benefits to women and their infants are to be maximized.

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D.J.D., L.M., and L.F.J. conceived the study. L.F.J. and L.J. developed the model and led the model parameterization. D.J.D. and S.D.M. contributed data and advised on parameterization. L.F.J. ran all analyses and drafted the article. All authors critically reviewed the manuscript and contributed to editing the article.

Conflicts of interest

There are no conflicts of interest.

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