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Modelling the potential impact of providing pre-exposure prophylaxis (PrEP) in pregnant and breastfeeding women in South Africa

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Abstract

Objective: HIV-uninfected pregnant and breastfeeding women are at high risk of HIV acquisition, contributing to vertical transmission. Pre-exposure prophylaxis (PrEP) is safe in pregnancy, but PrEP in pregnancy is not policy in many countries including South Africa (SA). We evaluated the potential impact of providing PrEP for pregnant/breastfeeding women using a HIV model for SA.

Methods: Our model considers two scenarios: a conservative scenario that matches the experience reported in the Kenyan PrEP programme for pregnant women (probability of uptake=32% and 11% in high-risk and low-risk women, respectively); and an optimistic scenario with PrEP initiated by 80% of all pregnant women. We compared this with PrEP for female sex workers (FSWs), men who have sex with men (MSM), and adolescent girls/young women (AGYW). Women are assumed to remain on PrEP throughout pregnancy and breastfeeding, and an equivalent average PrEP duration (2 years) is assumed in other scenarios.

Results: Between 2020–2030, if PrEP is provided to pregnant/breastfeeding mothers, we project a 2.5% reduction in total HIV transmission (95%CI:2.4–2.6%) in the conservative scenario and 7.2% (95%CI:6.8–7.5%) in the optimistic scenario, which is similar to that in the FSW and MSM PrEP scenarios (1.9% and 3.0% respectively). Without PrEP, 76,000 (95%CI: 64,000–90,000) new cases of vertical transmission are expected; PrEP provision may reduce these infections by 13% (95%CI:13–14%) in the conservative scenario and 41% (95%CI:39–44%) in the optimistic scenario.

Conclusion: High levels of uptake of and adherence to PrEP among pregnant/breastfeeding women could substantially reduce maternal and infant HIV acquisition in SA.

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Keywords

PMTCT; pregnant women; breastfeeding women; South Africa; pre-exposure prophylaxis; PrEP

Background:

Pregnant and breastfeeding women are at high risk of HIV acquisition [1–6] due to a combination of increased biological and behavioral risks [2, 5, 7]. Pre-exposure prophylaxis (PrEP) is one of the few female-controlled HIV prevention methods that could contribute to the elimination of HIV incidence in this group [8–10]. The WHO released guidelines in July 2017 supporting the delivery of PrEP to prevent HIV in pregnant/breastfeeding women [11]. There are limited data on the potential impact of PrEP initiation, retention, and adherence on HIV prevention in women and vertical transmission in high HIV incidence communities [8, 9]. Pregnant women are ineligible to start PrEP in most countries, with most national policies limiting eligibility to female sex workers (FSWs), adolescent girls and young women (AGYW) and men who have sex with men (MSM). In South Africa (SA), which is one of the countries most affected by HIV, the 2016 PrEP policy does not include pregnant/breastfeeding women. To help understand the potential impact of PrEP in SA, we used a mathematical model to estimate the potential impact of providing PrEP to pregnant/breastfeeding women on HIV incidence in women and infants. We compared the impact of PrEP in pregnancy with providing PrEP to AGYW, FSWs and MSM in SA.

Methods

We used the Thembisa model (version-4.1 [16]), a demographic and HIV model developed for SA, to estimate the potential impact of introducing PrEP for pregnant/breastfeeding women. The model was used previously to estimate the potential impact of targeting PrEP to sex workers [17] and youth [18] in SA. A detailed description of the model structure and assumptions is provided elsewhere [16]. The model stratifies the SA population by individual age, sex, risk group, marital status, sexual experience and uptake of PrEP, simulating the change in the SA population profile using assumptions about sexual behavior patterns, HIV transmission and HIV disease progression to estimate the numbers of individuals moving between the different model compartments over each time step. Vertical transmission is modelled based on assumptions about rates of perinatal and postnatal transmission, which depend on maternal HIV disease stage and the form of antiretroviral treatment/prophylaxis received by the mother-child pair. Perinatal and postnatal transmission both depend on the rate of maternal HIV acquisition during pregnancy/breastfeeding, with high transmission risk assumed during acute maternal HIV infection [5, 16].

We consider two possible scenarios for modelling PrEP uptake during pregnancy/breastfeeding. In the ‘conservative’ scenario, we set the model assumptions to match the experience reported in the Kenyan PrEP program for pregnant women [19] where 16% of all HIV-negative women initiated PrEP during pregnancy, and the odds of PrEP initiation in women who had been diagnosed with a sexually transmitted infection (STI) in the last 6-months was 4-times that in women without an STI diagnosis. Based on these data, we

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assume a probability of PrEP uptake during pregnancy of 32.3% and 10.6% among high-risk and low-risk women respectively (see supplementary material for details). In the second 'optimistic' scenario, we consider the potential impact if PrEP is initiated by 80% of all pregnant women (high and low-risk). In both scenarios, women are assumed to remain on PrEP for an average duration of 2-years (average time from the first antenatal visit to delivery, 0.4-years [20], plus the average duration of breastfeeding, 1.4-years [21]). PrEP use is conservatively assumed to be associated with a 10% reduction in condom use [7, 25]. Women who take PrEP are assumed to be at a 65% lower risk of HIV acquisition per act of condomless sex [26]. Perfect use of PrEP would be associated with a higher reduction in risk of HIV acquisition, but prior studies in women have shown low adherence and imperfect use [27–30]. Women receiving PrEP are assumed to be tested for HIV at regular intervals, and pregnant women are assumed to be offered HIV testing at their first antenatal visit, at 34-weeks gestation and at 6-weeks postpartum [31]. Women who acquire HIV while on PrEP are assumed to be diagnosed on average 3-months after HIV acquisition. In both scenarios, we consider the impact of providing PrEP over the period from 2020 to 2030 in SA.

We compared the effectiveness of PrEP in pregnant/breastfeeding women with three alternative PrEP promotion scenarios: PrEP for FSWs, MSM and AGYW. For the sake of consistency, the same average duration of PrEP (2 years) is assumed in all scenarios. The same PrEP efficacy and reduction in condom use is assumed in all scenarios, except for the MSM scenario, where a higher efficacy (85%) is assumed [32]. In all alternative scenarios, the annual rate of PrEP uptake in the target population is set such that a PrEP coverage of 50% is achieved in the target group, except in the AGYW scenario, where the 50% coverage applies only to sexually active high-risk women aged 15–24 (the annual rate of PrEP uptake in low-risk women is assumed to be 0.329 times that in high-risk women, to be consistent with the assumptions made in the 'conservative' PrEP scenario for pregnant/breastfeeding women). Sensitivity analyses were conducted to assess the effect of assuming lower PrEP efficacy and different average PrEP durations (see supplementary material for details).

Scenarios are compared in terms of reduction in total HIV incidence, and reduction in vertical transmission, relative to a baseline scenario in which there is minimal PrEP uptake by FSWs and MSM [16]. Scenarios are also compared in terms of the numbers of HIV infections averted per 100-person years of PrEP provision, as a measure of PrEP efficiency. All outputs are calculated for the period from 2020 to 2030. Means and 95% credibility intervals (CI) are calculated from 1000 different model simulations, each with a different set of assumptions about HIV transmission probabilities, HIV testing and disease progression; these parameter combinations are sampled from the distributions that give the best model fits to SA HIV prevalence, mortality and HIV testing data [16].

Results:

In the absence of PrEP, 1.90 million new HIV infections (95%CI: 1.76–2.06 million) are expected over the 2020–2030 period. The projected total number of HIV infections averted in SA as a result of providing PrEP during pregnancy/breastfeeding is 48,000 (95%CI: 43,000–52,000) in the conservative scenario and 136,000 (95%CI: 124,000–149,000) in the optimistic scenario. This is equivalent to 2.5% (95%CI: 2.4–2.6%) and 7.2% (95%CI: 6.8–

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7.5%) reductions respectively in the total projected number of HIV infections over the 2020–2030 period (Figure-1a). Without PrEP, 76,000 (95%CI: 64,000–90,000) new cases of vertical transmission are expected over the 2020–2030 period. This total is expected to be reduced by 13.2% (95%CI: 12.5–14.0%) in the conservative scenario and 41.4% (95%CI: 39.1–43.8%) in the optimistic scenario (Figure-1b). The reduction in HIV incidence in the conservative scenario is similar to the FSW and MSM PrEP scenarios, but the reduction in vertical transmission is greater in the conservative PrEP in pregnancy scenario (Figure-1). Under the optimistic scenario PrEP would have a proportionally greater impact on breastfeeding transmission (47% reduction;95%CI:44–49%) vs. in utero and intrapartum transmission (23% reduction;95%CI:18–27%). The reduction in HIV incidence in the optimistic scenario is projected to be less than in the AGYW scenario, but the reduction in vertical transmission is projected to be greater in the former scenario.

The scenarios differ in terms of efficiency of PrEP provision. The number of HIV infections averted per 100-person years of PrEP is expected to be greatest in the case of PrEP promoted to FSWs (7.0, 95%CI: 5.3–8.6) and MSM (4.4, 95%CI: 2.9–6.6), though credibility intervals are wide due to the scarcity of HIV prevalence data for these populations (Figure-2). The number of infections averted per 100-person years of PrEP is expected to be similar in the AGYW scenario (2.4, 95%CI: 2.1–2.7) and the conservative scenario in which PrEP is promoted to pregnant/breastfeeding women (2.3, 95%CI: 2.0–2.5). If PrEP uptake is high in both high- and low-risk pregnant/breastfeeding women, in the optimistic scenario, PrEP efficiency is expected to be almost half of that in the conservative scenario (1.2, 95%CI: 1.1–1.4). In the sensitivity analysis in which lower PrEP efficacy was assumed, PrEP impact and efficiency were estimated to be substantially lower than in the main analysis, although the relative ranking of different targeting strategies remained unaltered (Figures-S4 and S5). Setting PrEP retention assumptions for key populations to be more consistent with recent SA data led to lower estimates of PrEP impact for FSWs and AGYW but marginally higher estimates of PrEP impact for MSM (Figure-S6), as the latter group appears to have relatively high PrEP adherence.

Discussion:

This analysis demonstrates that PrEP to pregnant/breastfeeding women in SA may have significant impact on prevention of HIV acquisition and vertical transmission. The greatest impact of PrEP in pregnancy is in vertical HIV transmission, with projected reductions between 13% in the conservative scenario and 41% in the optimistic scenario. The reduction in total new infections with PrEP to pregnant/breastfeeding women is similarly high in the optimistic PrEP scenario, with more infections averted compared to scenarios providing PrEP to either FSWs or MSM.

The effectiveness of PrEP in pregnancy is heavily dependent on the proportion of pregnant women who take PrEP, their risk factors for HIV acquisition, and adherence to PrEP during pregnancy/breastfeeding periods. There is a dearth of data on PrEP uptake and adherence in pregnant/breastfeeding women [9, 19]. A recent study in pregnant and postpartum SA women found that there was a high potential interest in PrEP during pregnancy, though baseline knowledge was low [36].

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Although the efficiency of promoting PrEP to pregnant/breastfeeding women is not as great as the efficiency of promoting PrEP to MSM and FSWs, this does not necessarily mean that promoting PrEP to these groups is significantly less cost-effective. There are significant demand creation and outreach costs associated with reaching high-risk groups [35]. Further, the number of life-years saved per infant HIV infection averted is likely to be greater than the number of life-years saved per adult HIV infection averted, given the longer life expectancy of infants compared to adults. Considering our findings, we recommend that PrEP policies be updated to include pregnant/breastfeeding women, especially high-risk pregnant women, which was one of the most efficient strategies in our analysis.

A limitation of our model is the assumption that women who initiate PrEP during pregnancy remain on PrEP throughout the pregnancy/breastfeeding period. Although we lack data on retention rates when PrEP is initiated during pregnancy, early data from the PrEP program in FSWs show a worryingly low rate of retention [33], suggesting that our assumptions about retention in pregnant/breastfeeding women may be optimistic. Interventions to support PrEP retention and adherence in this population are essential.

Conclusion:

High levels of uptake of and adherence to PrEP among pregnant/breastfeeding women could fundamentally alter maternal and infant HIV acquisition in SA. There is an urgent need for implementation research to identify interventions that will facilitate PrEP use during pregnancy/breastfeeding in SA.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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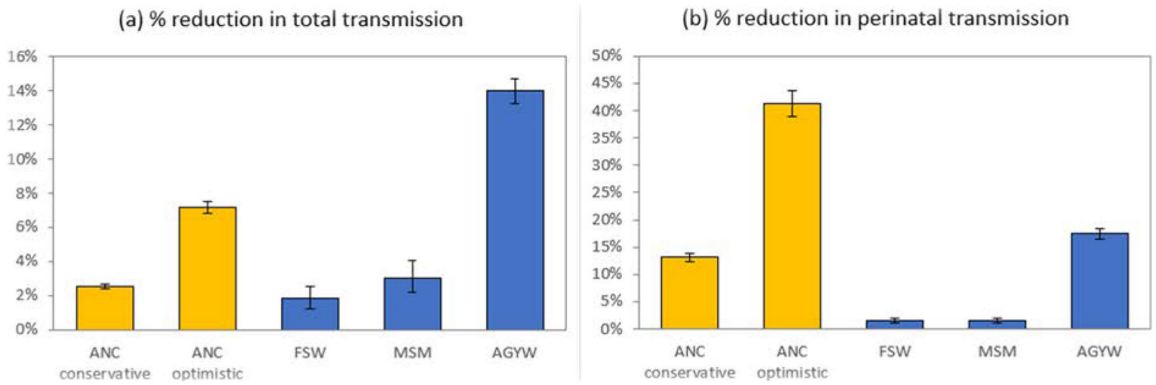

Figure 1:

Expected reductions in HIV incidence due to PrEP, 2020–2030, under different enhanced PrEP promotion scenarios

AGYW = adolescent girls and young women (sexually active, aged 15–24); ANC = antenatal care (includes breastfeeding women); FSW = female sex worker; MSM = men who have sex with men.

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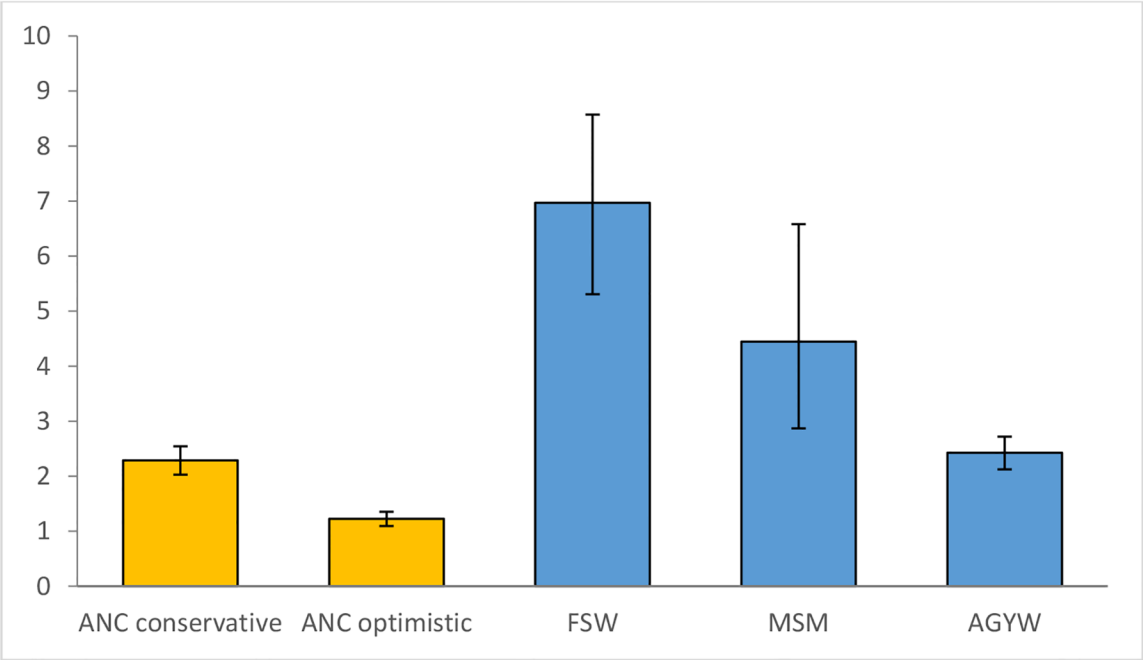

Figure 2:

HIV infections averted per 100-person years of PrEP, 2020–2030

AGYW = adolescent girls and young women (sexually active, aged 15–24). ANC = antenatal care (includes breastfeeding women). FSW = female sex worker. MSM = men who have sex with men.