

REVIEW

The use of oral human immunodeficiency virus pre-exposure prophylaxis in pregnant and lactating women in sub-Saharan Africa: considerations, barriers, and recommendations



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ABSTRACT

In sub-Saharan Africa (SSA), 63% of new human immunodeficiency virus (HIV) infections in 2021 were among women, particularly adolescent girls, and young women. There is a high incidence of HIV among pregnant and lactating women (PLW) in SSA. It is estimated that the risk of HIV-acquisition during pregnancy and the postpartum period more than doubles. In this article, we discuss the safety and effectiveness of drugs used for oral HIV pre-exposure prophylaxis (PrEP), considerations for initiating PrEP in PLW, the barriers to initiating and adhering to PrEP among them and suggest recommendations to address these barriers. Tenofovir/emtricitabine, the most widely used combination in SSA, is safe, clinically effective, and cost-effective among PLW. Any PLW who requests PrEP and has no medical contraindications should receive it. PrEP users who are pregnant or lactating may experience barriers to starting and adhering for a variety of reasons, including personal, pill-related, and healthcare facility-related issues. To address the barriers, we recommend an increased provision of information on PrEP to the women and the communities, increasing and/or facilitating access to PrEP among the PLW, and developing strategies to increase adherence.

1. Introduction

In sub-Saharan Africa (SSA), 63% of new infections in 2021 were among women.¹ Furthermore, adolescent girls and young women (AGYW) who are in the prime of their reproductive lives are more at risk of acquiring human immunodeficiency virus (HIV).² Several studies have reported a high incidence of HIV among pregnant and lactating women (PLW).^{3,4} One study estimated that the average incidence rate of HIV among pregnant and lactating women (PLW) was 3.6 per 100 person-years in 2020.⁴ There is evidence that the risk of HIV acquisition more than doubles during pregnancy and the postpartum period.⁵ Compared to women who contract HIV outside of these times, PLW are more likely to pass the infection on to their infants.³ Several behavioural and biological factors have been linked to an increased risk of HIV acquisition in PLW.⁵ Some of the behavioural aspects include transactional sex, having several sexual partners, and using condoms inconsistently with partners who are HIV-positive or whose status is unknown.⁶

Biomedical interventions to reduce the risk of HIV acquisition among at-risk individuals have resulted in the approval of pre-exposure prophylaxis (PrEP) among non-pregnant and non-lactating populations. These include heterosexual men and women, sero-discordant couples, injectable drug users, and men who have sex with men. The speed with which countries in SSA adopted the World Health Organization (WHO) oral PrEP recommendations into their national guidelines varied from country to country. In 2018, only South Africa, Kenya, and Zimbabwe had dedicated national PrEP campaigns.⁷ By February 2023, only three countries in SSA had not yet adopted the WHO oral PrEP recommendations, and these are Angola, Mauritania, and Sudan.⁸ The successful implementation studies conducted in Kenya and other demonstration projects of oral PrEP among PLW in other countries like South Africa, Malawi, Lesotho, and Zimbabwe are expected to motivate several countries in SSA to roll out oral PrEP among PLW.⁹ Furthermore, cost-effectiveness studies of oral PrEP among PLW in SSA revealed that it was cost-effective because the incremental cost-effectiveness ratio of

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oral PrEP among PLW was below the recommended regional threshold.¹⁰

Limited trials have looked at the use of oral PrEP in PLW. This is because most PrEP trials did not enrol any pregnant women and those who became pregnant while taking the drug were removed from the trials.⁹ However, studies indicate that taking oral PrEP is not linked to an increase in pregnancy-related adverse events, and several studies have reported no negative effects in infants exposed to tenofovir (TDF) as part of treatment for HIV-infected PLW.⁹ Despite the risks of contracting HIV and the documented effectiveness of PrEP, it continues to be underutilised, especially during pregnancy and lactation.¹¹ We, therefore, advocate for expanding access to PrEP during antenatal care (ANC) and postnatal care (PNC) in SSA. In this article, we discuss the safety and effectiveness of drugs used for oral PrEP, considerations for initiating PrEP in PLW, the barriers of initiating and adhering to PrEP in this population and suggest recommendations to address them.

2. Safety and effectiveness of oral PrEP

The most commonly used drug combination for PrEP in SSA includes TDF and emtricitabine (TDF/FTC). This combination is taken daily whilst the person is at substantial risk of HIV acquisition.¹² One modelling study conducted in South Africa revealed that widespread use of oral PrEP among PLW would reduce vertical transmission by 41% and overall HIV transmission by 2.5%.¹³ However, adherence is necessary for oral PrEP to be effective. Effective medication concentrations in the vaginal and cervical tissues are attained with good adherence in non-pregnant women.¹² As medication levels fall throughout the second and third trimesters of pregnancy due to an expanding volume of distribution and enhanced renal clearance, adherence may even be of greater significance. Under near-perfect adherence, TDF concentration was one-third lower in pregnancy compared to the postpartum period, according to a study done among pregnant and postpartum adolescents and young women using TDF for oral PrEP in SSA.¹⁴ According to one study, a pregnant woman who takes seven TDF doses per week will have TDF concentrations that are comparable to those of a non-pregnant woman who takes six doses per week. Accordingly, adherence among pregnant women may be more crucial for PrEP effectiveness than it is in non-pregnant women.¹⁵ In addition, it may take up to 20 days for maximum intracellular concentrations of TDF/FTC or TDF to reach cervicovaginal tissues, according to studies in non-pregnant women.¹⁶ Because maximum concentrations are reached in about three weeks, we encourage PLW to use other HIV prevention methods like condoms within this time. However, it should be noted that a decrease in condom use among people taking oral PrEP has been reported.¹⁷ To encourage PLW to use condoms even when using oral PrEP, there should be provision of education on the importance of condom use when initiating oral PrEP to both the women and their partners.

A systematic review conducted in 2017 involving TDF/FTC exposure during pregnancy did not identify any safety concerns that would restrict the use of PrEP during lactation or demand that women who become pregnant while still significantly at risk of contracting HIV stop using it.¹⁸ In terms of pregnancy incidence, stillbirths, preterm delivery, small for gestational age, birth defects, birth weight, maternal mortality, or infant mortality, there were no statistically significant differences between TDF and non-TDF regimens. The majority of studies reported normal infant linear growth.¹⁸ Another systematic review of the safety of PrEP for pregnant and postpartum women conducted in 2020 revealed that none of the completed studies found any differences in pregnancy and perinatal outcomes associated with PrEP exposure, including gestational age at birth, birth weight, birth length, and growth indicators at 6 weeks. Only one study reported that infants exposed to oral PrEP had shorter z-scores for length at one month than those who were not exposed. However, after a year, there was no longer a difference.⁹ One of the gaps identified by the systematic review was that few of the studies

examined long-term infant outcomes after prenatal PrEP exposure like bone growth beyond one year.⁹

3. Clinical considerations for initiating oral PrEP

Any PLW who requests PrEP should get it, provided there is no medical contraindication to its use, such as renal failure.¹⁹ PLW may be motivated to use PrEP for a variety of reasons. These include the need to prevent HIV infection for themselves and their babies, worry about a partner's risky behaviours, and worry about not knowing their partners' HIV status.²⁰ It is also specifically advised for PLW who have a history of sexually transmitted infections (STIs) such as *Neisseria gonorrhoeae* and *Chlamydia trachomatis*; infrequently use condoms with one or more partners whose HIV status is unknown; take non-occupational HIV post-exposure prophylaxis (nPEP); have taken multiple courses of nPEP; engage in transactional sex; have a substance use disorder; have an HIV-positive partner without a consistent virological suppression; have a history of experiencing intimate partner violence (IPV); or have a partner with any of the above factors.¹⁹ The WHO recommends that PrEP be continued in women taking PrEP who subsequently become pregnant and remain at substantial risk of HIV acquisition, women whose partners are HIV-positive but are not virally suppressed, and any woman at substantial risk of HIV acquisition.²¹ The WHO also recommends that PrEP in PLW should be combined with adherence counselling, safety monitoring and HIV retesting every three months, and other HIV prevention methods.²¹

When initiating PrEP, PLW should have baseline HIV testing.¹⁹ It has been reported that PrEP users experience delays in the detection of antibodies and antigens during acute infection. A study conducted among cisgender men and transgender women who have sex with men revealed that about 18% of the participants had delayed detection of incident infections.²² Since HIV-RNA testing is not readily available in SSA, we recommend that antigen/antibody combination immunoassays continue to be used to test for HIV among PrEP users. However, apart from testing clients at baseline, they should also be tested after one month of PrEP initiation, and every three months thereafter to pick up those who might initially have been in the window period.²³ When starting women on PrEP, hepatitis B surface antigen (HBsAg) testing should also be conducted. PLW who test positive for HBsAg should be started on PrEP and referred to a doctor for liver function monitoring and management of Hepatitis B infection. If a woman has a chronic HBV infection, she should be advised about the risk of flare-ups when TDF-based PrEP regimens are discontinued.¹⁹ Renal function tests are to be performed as well at the initiation and every 12 months. Women should not start taking PrEP if their creatinine clearance (CrCl) is less than 60 ml per minute. Moreover, PrEP should be stopped if a woman on TDF/FTC develops CrCl that is less than 50 ml per minute.¹⁹ Testing for renal function may be a challenge in many parts of SSA. However, since less than one percent of oral PrEP users younger than 30 years of age experience abnormal creatinine clearance,²¹ we suggest that renal function tests be removed as a condition for initiating oral PrEP in PLW younger than 30 years of age who do not have any comorbidities. Although the U. S. Center for Disease Control and Prevention recommends that all PLW starting PrEP should have baseline testing for gonorrhoea, chlamydia, and syphilis,¹⁹ aetiological testing of STIs is not done routinely in SSA. We, therefore, recommend the syndromic screening of STIs and syphilis testing at baseline for all PLW being initiated on PrEP.²³

4. Barriers to initiation and adherence to oral PrEP

Whilst self-reported PrEP adherence may be high among PLW, one study that performed drug levels found that few PLW had optimal adherence. The study, which was conducted in South Africa, reported a self-reported adherence of more than 75% at 30 days among PLW yet only 61% of them had detectable levels of TDF in the blood.²⁴ A few studies have been conducted to explore the barriers to initiation and

adherence to PrEP among PLW in SSA. The barriers can be divided into individual-level, pill-related, and healthcare facility-related. Several individual-level barriers were reported in studies conducted in SSA. Anticipated stigma was reported in studies conducted in South Africa and Malawi.^{20,25–28} Stigma may result in non-disclosure to partners and family members. A study conducted in South Africa revealed that several women were concerned that their partners would believe they were HIV positive and had been concealing this information from them, which might result in IPV.²⁵ Being away from home was identified as a challenge for initiation and adherence to PrEP care among PLW in South Africa,^{25,28} but a study conducted in Malawi did not report this.²⁰ Forgetfulness was also reported in South Africa while partner approval was reported in Zambia.^{25,29}

One of the pill-related barriers is fear of or experiencing side effects such as nausea, vomiting, and dizziness. This barrier was reported by several studies conducted in South Africa and Malawi.^{20,24–26} The side effects may also be exacerbated by pregnancy. Women taking other tablets for other diseases may stop PrEP if they develop side effects due to a lack of knowledge as to which tablets are causing the side effects.²⁰ In the PrEP-PP study, women who experienced side effects or were postpartum were less likely to continue on PrEP.²⁴ Studies in South Africa and Malawi also reported that some women do not initiate or adhere to PrEP because they dislike tablets, have problems committing to a daily pill, or have challenges taking PrEP in addition to other tablets such as vitamins for pregnancy or analgesics after delivery.^{20,25}

Several healthcare facility-related barriers were reported to be barriers to PrEP initiation and adherence. Limited access to healthcare facilities due to factors such as financial, logistic, distance, and transport was revealed in studies conducted in South Africa and Zambia.^{25,26,29} The COVID-19 pandemic and its related lockdowns were also identified as barriers to PrEP initiation and adherence by studies conducted in South Africa.^{25,28} Other healthcare facility-related barriers identified in Zambia include the negative attitude of healthcare providers and long waiting times at the clinics.²⁹ Additional barriers included a shortage of healthcare providers who have the training to prescribe and dispense oral PrEP among PLW and healthcare facilities running out of oral PrEP drugs.³⁰ Furthermore, some healthcare providers may not be comfortable prescribing oral PrEP among PLW since there are no national guidelines for this group in some countries.³⁰

5. Recommendations

Based on the barriers faced by PLW in initiating and adhering to PrEP, we came up with several recommendations that we grouped into three broad categories. These categories are an increased provision of information on PrEP to the women and the communities, access to PrEP among PLW, and developing strategies to increase PrEP adherence.

5.1. Increased provision of PrEP information

Misinformation about PrEP is associated with a low level of initiation and adherence to PrEP among PLW,²⁶ as well as stigma and discrimination.²⁷ To address this challenge, we recommend an increase in the provision of accurate information about the importance of PrEP to women and their babies, including its risks and benefits. This information should be made available at all healthcare facilities, including ANC and PNC clinics. We also recommend that healthcare providers offering ANC and PNC should always discuss with women about PrEP. The discussion should include an assessment of the barriers to PrEP adherence and address concerns about the safety of PrEP for women and their babies. Counselling about oral PrEP should also emphasize that the early side effects of oral PrEP are usually transient.²⁴ A study conducted in Malawi and Zambia among PLW revealed that most of the women had little information about oral PrEP. However, after receiving adequate information, they expressed willingness to be initiated on oral PrEP.³¹ Although we could not find studies on what facility-based

or community-based strategies are more effective for educating PLW about PrEP, several strategies have been used to increase awareness of other HIV services among women. The strategies include individualised counselling, group counselling, counselling via virtual platforms, integrated or sequential counselling, the use of virtual platforms, provision of facts, peer education with sharing of experiences, community education, and the use of mass media. A study conducted in South Africa among AGYW revealed that the use of a mass media communication intervention increased PrEP awareness and improved the demand for HIV prevention services.³² Motivational text messages have also shown promise for the uptake of HIV testing and HIV services among AGYW at high risk of HIV in low-to-middle-income countries (LMICs).³³ We advise that studies that compare the effectiveness of these methods among PLW be conducted.

5.2. Increasing access to PrEP

We recommend integrating PrEP with ANC and PNC clinics to increase PrEP coverage since there is a high attendance of these clinics in the region. In addition, almost all pregnant women are tested for HIV at these clinics. Since the infrastructure for HIV services is already available at these clinics, PrEP delivery through these clinics may be efficient and easy. However, this may mean that PLW will require more time with the healthcare providers, leading to an increase in the workload of healthcare providers.³⁰ To address the increase in workload, we recommend the implementation of task shifting. Task shifting would involve training of nurses and nurse assistants previously not involved in HIV care to provide oral PrEP to PLW. In the PrEP Implementation for Young Women and Adolescents (PrIYA) program conducted in Kenya, there was the successful integration of PrEP into ANC and PNC clinics.³⁴ In the PrIYA study, nurses screened HIV-uninfected PLW for their willingness to consider PrEP and their behavioural risk factors to inform PrEP counselling. All PrEP-specific services including dispensing PrEP drugs were delivered by nurses within the ANC or PNC clinics without an extra cost to the clients.³⁴ The integration resulted in several additional working hours for the nurses, which could be reduced by group or peer counselling.³⁴ A scoping review conducted for service delivery models that promote linkages to PrEP for AGYW in SSA revealed that PrEP delivery within family planning or maternal and child health clinics increased PrEP initiation among them.³⁵ We suggest that countries in the region learn from the implementation of Option B+ prevention of mother-to-child transmission (PMTCT), which resulted in a complete integration of ART and PMTCT services, as well as an increase in coverage of PLW.³⁶ We also recommend the establishment of national PrEP guidelines for PLW, as this was reported to motivate healthcare providers to provide PrEP to this target group.³⁰ In SSA where the prevalence of HIV is high, we recommend universal PrEP counselling for all PLW. A study conducted in Kenya revealed that universal PrEP counselling offers a simpler and more effective way of integrating PrEP services in maternal and child health care services as no screening is required to reach the same levels of appropriate PrEP use and HIV incidence as a risk-guided strategy.³⁷

5.3. Strategies to increase adherence

Several strategies have been studied to increase PrEP adherence among AGYW and PLW in LMICs. These strategies include short message service (SMS) reminders, drug-level feedback, peer group support, and conditional economic incentives.³³ A study conducted in Kenya among PLW on PrEP revealed that two-way text messages expanded support for PrEP and offered opportunities for dialogue between healthcare providers and PLW which went beyond the healthcare facilities. This enabled PLW to ask and receive answers regarding PrEP in real-time, which facilitated the adherence to and continuation of PrEP use among them.³⁸ The use of long-acting injectables like cabotegravir and

dapivirine vaginal ring, which have been shown to be effective, may address challenges associated with daily oral PrEP. However, studies are underway to confirm their safety in PLW.²⁴

6. Conclusion

Women who acquire HIV during pregnancy and lactation are more likely to transmit the virus to their infants compared to those who acquire it outside these periods. Several behavioural and biological factors contribute to the high incidence of HIV among PLW. It is therefore important to develop strategies such as the use of PrEP to reduce the chances of PLW of acquiring HIV. The most commonly used combination for PrEP in SSA of TDF/FTC, which has been shown to be efficacious in PLW. Considering the available evidence on PrEP among PLW, we recommend universal access to PrEP for PLW. Barriers to the initiation and continuation of PrEP among PLW can be divided into individual-related, pill-related, and healthcare facility-related challenges. To address these barriers, we recommend that strategies be devised to increase the provision of PrEP information, increase PrEP adherence, and PrEP access among PLW.

Competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Enos Moyo: Conceptualization, Writing – original draft. **Grant Murewanhema:** Writing – review & editing. **Perseverance Moyo:** Writing – review & editing. **Tafadzwa Dzinamarira:** Supervision, Writing – review & editing. **Andrew Ross:** Supervision, Writing – review & editing.

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