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Delivering PrEP to pregnant and breastfeeding women in sub-Saharan Africa: The Implementation Science Frontier

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Abstract

HIV acquisition during pregnancy and postpartum periods remains high despite increased access to and initiation of antiretroviral therapy in sub-Saharan Africa. Moreover, maternal seroconversion during pregnancy and breastfeeding remains a source of significant paediatric HIV infection in the region. In order to curb vertical HIV transmission, HIV acquisition during pregnancy and lactation must significantly decline. Biological and behavioural factors contribute to high HIV incidence, including hormonal changes that alter genital mucosal surfaces, and frequent condomless sex with HIV-infected partners or partners of unknown serostatus. Pregnant and breastfeeding women who are at risk of HIV acquisition during pregnancy and lactation require female controlled interventions such as pre-exposure prophylaxis (PrEP) to prevent HIV acquisition during those particularly vulnerable periods. Before PrEP scale up for pregnant and lactating women, there is an urgent need for operations research to evaluate how best to provide PrEP to pregnant and breastfeeding women in settings of high HIV incidence. This should include how to: (1) integrate PrEP delivery and counselling into antenatal and postnatal care, (2) ensure optimal adherence during at-risk periods, and (3) target PrEP for maximum impact, including reaching pregnant and breastfeeding young women. In light of current knowledge on the safety of PrEP in pregnancy and breastfeeding, next steps are needed to ensure barriers to PrEP effectiveness are addressed.

Introduction

HIV acquisition during pregnancy and postpartum periods remains high despite increased access to and initiation of antiretroviral therapy (ART) in sub-Saharan Africa [1–5]. There

are biological and behavioural factors that drive high HIV incidence during pregnancy and breastfeeding periods such as hormonal changes that alter genital mucosal surfaces, and frequent condomless sex with HIV-infected partners or partners of unknown serostatus [3, 6–9]. Maternal seroconversion during pregnancy and breastfeeding contributes significantly toward paediatric HIV infections in sub-Saharan Africa [3, 10].

Oral pre-exposure prophylaxis (PrEP) efficacy in preventing HIV acquisition has been demonstrated in four randomized control trials among heterosexual men, women, serodiscordant couples, injecting drug users, and men who have sex with men when PrEP is used as directed [11–14]. Currently pre-exposure prophylaxis (PrEP) is one of the only female controlled methods that is effective for preventing HIV acquisition. However, PrEP trials excluded pregnant women from enrolment, and those who fell pregnant during these studies were discontinued from PrEP [11, 14]. A recent systematic review demonstrated that PrEP was not associated with increased pregnancy-related adverse events, and no studies have found adverse effects among infants exposed to tenofovir disoproxil fumarate (TDF) as part of treatment for HIV-infected women during pregnancy [15, 19–21] or breastfeeding [16, 22, 23]. In addition, our studies in South Africa demonstrated that the use of tenofovir during pregnancy was not associated with adverse events among infants [20, 21].

PrEP adherence has been low during clinical trials of women. In the FEM-PrEP and VOICE trials, PrEP was not effective at preventing HIV acquisition among women in eastern and southern Africa because of low drug exposure (tenofovir was detected in plasma in fewer than one-third of participants) [31, 32]. Pregnant and breastfeeding women may have improved initiation and adherence to PrEP because of the desire to prevent vertical HIV transmission. However, future studies need to consider how best to increase adherence.

Part of the difficulty in preventing perinatal and postpartum HIV acquisition is that pregnant and breastfeeding women are oftentimes at risk of other health problems in addition to HIV. Prior studies have shown that over half of pregnancies in African women may be unplanned [2, 4]. This combined with multiple partners, condomless sex, transactional sex, substance use, gender based violence and rape, all compound the challenges of addressing the need for effective female-controlled interventions to prevent HIV, but also to address the complexities of adherence and retention in the face of such clusters of risk.

In our view, PrEP is a public health priority in settings of high HIV incidence. This is especially true during peri-conception, pregnancy and breastfeeding in South Africa where HIV incidence is high and the probability of vertical transmission is highest when women seroconvert and are viremic. There is an urgent need for operations research to evaluate how best to provide PrEP to pregnant and breastfeeding women in settings of high HIV incidence, including how to ensure optimal adherence. We advocate that the field move beyond clinical trials to focus on operations research to evaluate how best to operationalize PrEP delivery in pregnancy and breastfeeding adolescent girls and women, recognising the high risk nature of this group. We review the operational issues that need to be addressed and evaluated to ensure that PrEP delivery is effective at preventing HIV acquisition during pregnancy and lactation in high HIV incidence communities.

Integrating PrEP delivery and counselling into antenatal and postnatal care

Prior PrEP studies have not included pregnant women; thus, we do not know about how to integrate PrEP delivery and counselling into antenatal and postnatal care. Similar to operational research that helped optimize delivery of ART to pregnant and breastfeeding women [36, 37], we need additional studies that operationalize how best to (1) deliver PrEP (e.g. through pharmacies, in community pick up points, or within clinical visits), (2) monitor PrEP adherence, and (3) counsel pregnant and breastfeeding women to optimize PrEP initiation, retention and effective use during periods of condomless sex with HIV-infected partners or partners of unknown serostatus. Notably, prevention within serodiscordant couples in an era of multi-component prevention requires attention to both partners, and development of synergies between ART initiation and retention for HIV-infected partners and PrEP for HIV-negative partners to avoid missing prevention opportunities. Further, integrating PrEP into postnatal care may be more complex, because of the different care providers and locations. For example, postnatal care, well baby visits and immunization visits may all be separate providers in different locations from antenatal care providers. Operations research studies are urgently required to understand the role of peer-educators, counsellors, nurses and doctors in promoting PrEP use, and ensuring adherence through vulnerable periods of pregnancy and lactation.

We hypothesize that mothers' risk perceptions, risk behaviors and concerns of protecting her child during and after pregnancy may be powerful drivers of PrEP initiation and adherence, similar to what we have found in PMTCT programs [27]. However, the ongoing concern about taking medication during pregnancy, and beliefs about side effects among infants, may supersede women's concern about HIV acquisition. In this context, operations research is needed to determine how best to operationalize PrEP delivery to women who need it. Specifically, what cadre of providers should be trained to provide PrEP to pregnant women. Table 1 lists some of the essential operations research questions for optimal PrEP efficacy to prevent maternal HIV acquisition.

Optimal PrEP adherence during peri-conception, pregnancy and postpartum periods

PrEP efficacy requires adherence during periods of sexual activity and adherence requires PrEP access, awareness and counselling. Currently, a major obstacle in the PrEP field is effective use, especially among women during at risk periods before periods of sexual activity [25, 30–33]. Little is known about how to successfully engage and retain women trying to conceive, as well as pregnant and breastfeeding women living in high burden settings in PrEP care, nor how to effectively support adherence and persistence to PrEP in this population. PrEP adherence in this population must be understood within the context of highly variable risk for HIV infection during pregnancy and breastfeeding [25].

Prevention of mother to child transmission may also make women taking PrEP more acceptable to their partner(s), family, as well as health providers. Prior studies demonstrated an association between having perceived HIV risk and improved PrEP adherence [36]. Improving knowledge about the increased risk of HIV acquisition during pregnancy and

breastfeeding could possibly contribute to improved PrEP initiation and adherence. Furthermore, provider barriers may include perceptions that PrEP will lead to more risk or more condomless sex. More research is needed on what kinds of messages, to whom and from whom, to ensure optimal PrEP adherence in peri-conception, pregnant and breastfeeding women. Novel approaches are needed to understand and evaluate provider and patient level barriers to the PrEP cascade in peri-conception, pregnancy and lactation periods in high HIV incidence countries.

Targeting PrEP to at-risk women in peri-conception, pregnancy and postpartum periods

Not all HIV-uninfected African pregnant and lactating women will benefit from taking PrEP. The World Health Organization (WHO) set the threshold of ensuring PrEP availability where HIV incidence is 3 or more per 1000 person years (PY) [29]. In communities where HIV incidence is lower than 3 per 1000 PY, it may make sense to target PrEP delivery to those at highest risk. A recent study developed a risk score to predict maternal HIV acquisition in Kenya [30]. Risk scores are one method for reaching pregnant women at high risk of HIV acquisition, but, there is a need to identify other ways to reach target populations. For example, a risk score that is dependent on self-reported measures of behaviour may underestimate the true HIV acquisition risk, and not all women have insight into their partners' risk taking behaviours. The generalizability of risk prediction methods requires careful consideration as part of future operations research to understand the role of targeting PrEP in different contexts [38].

PrEP for adolescent girls and young women at high risk of HIV acquisition

In sub-Saharan Africa, an estimated 7000 new HIV infections are occurring weekly in adolescent girls and young women [28]. Further, adolescent girls have high pregnancy rates in South Africa. Approximately 1.6% of 15-year-old, 3.7% of 16-year-old, and 7% of 17-year-old girls were pregnant in 2013 [28]. Prior studies have demonstrated significant challenges providing PrEP to adolescent girls and young women and the issues around providing PrEP to pregnant and postpartum women are unknown, which makes pregnant and postpartum adolescents and young women a particularly vulnerable group [32, 34]. Operations research should include adolescent pregnant girls to evaluate predictors of PrEP initiation, retention and adherence among this particular population which may differ from adult pregnant and breastfeeding women [2]. Including adolescent girls will increase the validity and generalizability of those interventions. Finally, it would be unethical to not provide pregnant and breastfeeding adolescent girls and young women with PrEP and include them in PrEP studies [2].

Conclusion

In light on current knowledge on the safety of PrEP in pregnancy and breastfeeding, and the persistent high HIV incidence during these vulnerable periods, PrEP in pregnancy and breastfeeding is critical to the elimination of maternal to child HIV transmission. There is an urgent need for operations research to evaluate how best to provide PrEP to pregnant and

breastfeeding women in settings of high HIV incidence. Specifically, pilots and operations research should focus on evaluating how best to deliver PrEP in peri-conception, antenatal and postnatal care, who should be targeted for PrEP delivery (including how best to reach and manage adolescent girls and young women), and how to address the barriers to PrEP effectiveness, and promote optimal adherence given the multifactorial challenges these women face in staying HIV negative. Such studies are required to ensure that when PrEP in pregnancy and breastfeeding programs are rolled out, they are utilizing and adapting the best of current knowledge in the field to ensure optimal impact.

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Table 1

Key operations research questions for optimal PrEP efficacy to prevent maternal HIV acquisition

Issue	Key questions
Clusters of risk factors and their effect on PrEP initiation and adherence	What are the various clusters of risk factors that may affect pregnant and breastfeeding women's HIV risk, and young women especially? How does such clusters of risk affect PrEP access, initiation and adherence? What are interventions to address these barriers?
Health care provision for PrEP in pregnant women	Can midwives, nurse practitioners or doctors prescribe PrEP? Who can provide PrEP prescription refills? At what frequency? Follow-up labs and clinical monitoring?
Health care provision for PrEP in postpartum women	Who is able to prescribe PrEP in post-partum care? What kind of provider is in the best place to do so? What frequency are labs and clinical monitoring needed in the postpartum period? What are the strengths and limitations of PrEP integration into family planning counselling and serve provision versus into postpartum or routine child health care?
Partner or partners involvement in PrEP care	Does the father of the child, or sex partner(s) need to be involved in PrEP decision making and counselling? If so, when do partners become facilitators to HIV prevention intervention such as PrEP, and when are they barriers? What is the role of the father of the child (and other sex partners) in preventing HIV acquisition and transmission?
Role of peer support	What is the impact of peer counselling from peers, including other mothers on PrEP, on PrEP initiation and adherence?

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