Previously on PrEP, now pregnant – What to do??

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Introduction

• Pregnancies amongst adolescents and young women – 16% of all births
  - 19% will have repeat pregnancies before age 20

• Proportions HIV infections – 19% amongst adolescents (- 29.5% nationally 15 – 49yrs)

• HIV risk up to 6X higher in young women (15-24 years) compared to male peers

• AIDS is the 2\textsuperscript{nd} leading cause of death among adolescents (NCCEMD)

Seroconversion in pregnancy

- Women remain vulnerable to HIV during pregnancy and even more so postdelivery.

- Local studies have shown sero-conversion rates of 1.3% to 3.0% in pregnancy (2005-2009), and 3.3% (95% CI: 2.8%-3.8%) in 2011 – 2012 data.

- The pooled meta-analysis - HIV incidence was not significantly higher among pregnant or postpartum (3.9 per 100 person-years (4.7 during pregnancy and 2.9 postpartum) women vs nonpregnant/postpartum women,

- similar to that defined as “substantial risk” in nonpregnant individuals, (eg female sex workers)

- Recent analysis - risk per condomless coital act was significantly increased during pregnancy through 6 months’ postpartum - aRR 2.76; (95% CI, 1.6–4.8) compared to nonpregnant/nonpostpartum time and was highest during late pregnancy (aRR 2.82; 95% CI, 1.3–6.2) and postpartum (aRR 3.97; 95% CI, 1.5–10.5).

Moodley D, 2011 / Chetty V, 2012 / Mofenson L, 2018
Figure 2. Antenatal and Postnatal Seroconversion Rates by District in KwaZulu Natal January-December 2015.
Risk of MTCT

• Great efforts in reduction of MTCT, (4% at 4-8 weeks despite the 88% ARV prophylaxis coverage)

• 40 000 children are newly infected in SA annually

• Johnson et al modelled a 34% projected increase in MTCT from recently infected mothers in the absence of any intervention.
  - further cautions that MTCT from women who seroconvert during lactation will become the dominant mode of MTCT.

• Incident HIV infection during pregnancy and breastfeeding contributes to a significant proportion of infants with HIV in very high incidence settings,

  Johnson L, 2012
Case for PrEP

• PrEP could complement established HIV prevention strategies for pregnant and breastfeeding women as part of a comprehensive package to reduce HIV infections among women and transmission from mothers to infants in settings with high HIV incidence.

• In 2015, WHO recommended that oral PrEP containing TDF be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination HIV prevention approaches.

• Although there is limited experience with the use of PrEP in antenatal and postnatal care services, it is an important new HIV prevention method to consider, particularly for high-burden settings where women remain at significant HIV risk.

WHO 2017
Criteria for PrEP

3 scenarios for women who would most benefit most during pregnancy and breastfeeding:

• woman taking PrEP who subsequently becomes pregnant and remains at substantial risk of HIV infection;

• pregnant or breastfeeding HIV-negative woman living in a setting with high HIV incidence who is at substantial risk of HIV acquisition; or

• woman whose partner is HIV-positive but is not virally suppressed.

• PrEP combined with screening for acute infection, adherence counselling, safety monitoring and HIV retesting every three months, in addition to other existing HIV prevention options, including condoms, should be offered.

WHO Technical brief - PrEP, 2017
Figure 2. A suggested prioritization framework for offering PrEP to pregnant and breastfeeding women (4)

Antenatal registration
Provider-initiated HIV testing & counselling

HIV-positive
PMTCT, treatment, support, offer partner notification

HIV-negative
Standard HIV post-test guidance and counseling on prevention

Partner testing
Offer partner testing & conduct risk assessment

Partner HIV-negative

Partner not tested or HIV-positive
Offer partner:
1. HIV treatment (if HIV-positive)
2. Condom promotion
3. Risk reduction counselling

Risk assessment using tool

Woman at substantial risk of HIV acquisition
Provide comprehensive HIV prevention options:
1. STI screening and treatment (syndromic and syphilis)
2. Condom promotion
3. Risk reduction counselling
4. PrEP with emphasis on adherence
5. Emphasize importance of follow-up ANC visits

Woman not at substantial risk of HIV acquisition

Woman who chooses to initiate PrEP

1. Clinical and laboratory assessments
2. Adherence counselling
3. Emphasize importance of follow-up visits and repeat HIV testing

Reassess woman’s risk
Offer partner referral for VMMC
Risk assessment tool (Kenyan)

- No of lifetime partners
- Male partner’s HIV status (6 for unknown)
- RPR (5 for reactive)
- BV
- Candidiasis

Pintye J, et al, 2017
Safety of PrEP in pregnancy

- TDF, based PrEP is part of the WHO preferred first-line ART regimen recommended for adults, including pregnant women.
- The existing safety data support the use of PrEP in pregnant and breastfeeding women who are at continuing substantial risk of HIV infection.
- It is widely used with good tolerance and no increased reports of safety and adverse events.
- In PrEP trials, exposure to TDF-containing PrEP during the first trimester of pregnancy was not associated with adverse pregnancy or infant outcomes.
Ongoing surveillance

• There is no safety-related rationale for disallowing or discontinuing PrEP use during pregnancy and breastfeeding for HIV-negative women who are receiving PrEP and remain at risk of HIV acquisition

• - benefits of preventing HIV acquisition in the mother, and the accompanying reduced risk of mother-to-child HIV transmission outweigh any potential risks of PrEP, including any risks of fetal and infant exposure to TDF and FTC in PrEP regimens

WHO Technical brief, PrEP, 2017
Ongoing surveillance

3 areas to be monitored during PrEP use.

- **Maternal adverse outcomes**: monitoring treatment-limiting toxicities associated with ART in pregnant women, particularly mortality;
  - morbidity – renal impairment – creatinine / proteinuria as well as BMD (esp during breastfeeding, and does it reverse upon stopping)

- **Adverse birth outcomes**: monitoring toxicity in the fetus in utero, (SB / PTB / LBW and major congenital anomalies or early infant deaths).

- **Adverse infant and child outcomes**: monitoring health outcomes in infants and young children exposed to ARV drugs in utero or via breast milk, esp impact on growth and development.
Regular ANC

• At baseline
• Screen for creatinine as in PMTCT program;
• Hep B screen - if +ve regular LFT testing
• Watch for proteinuria / BP
• STI screen including BV
• Repeat HIV testing every 3 months
• Re-evaluate risk at regular visits,
Key messages

• PrEP is safe during pregnancy and breastfeeding.
• PrEP should be provided as part of a comprehensive package.
• Adherence matters.
• Disclosure can have benefits.
• Recognize “seasons of risk”.
• PrEP can be cost-effective.
• PrEP in not for everyone.
• Ongoing surveillance is necessary.
Thank you