PrEP for Pregnant and Breastfeeding Women (PBFW):

Findings from Stakeholder Discussions in Seven African Countries
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## Webinar Agenda

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PrEP in Pregnant and Breastfeeding Women: Background and PEPFAR Approach

Jenny Albertini (SGAC) on behalf of PEPFAR’s PrEP Community of Practice
Why offer PrEP to pregnant and breastfeeding women?

- Pregnancy and breastfeeding are periods of heightened HIV risk.
  - Women are 2-4 times more likely to acquire HIV during pregnancy and breastfeeding.

- PrEP can prevent two individuals from getting HIV: the mother and the baby.
  - PrEP is an important strategy for reaching elimination of mother-to-child HIV transmission (EMTCT).

- The existing safety data support the use of PrEP in pregnant and breastfeeding women who are at substantial risk of HIV infection.
  - Women spend a significant proportion of their lives pregnant or breastfeeding, and there is no evidence of adverse pregnancy or perinatal outcomes with PrEP to preclude its use.
Heightened HIV acquisition risk during pregnancy and breastfeeding

**Biological Susceptibility**
- Elevated hormonal levels (progesterone dominated) associated with cervical inflammation (12)
- Untreated STIs associated with cervical inflammation (13,14,15)
- Changes in the vaginal microbiome associated with genital inflammation (16,17)
- Nutritional deficiency and lowered immunity

**Behavioural exposure**
- Behaviour changes in women and male partners during the pregnancy/postpartum period (10,18,19)
- Less condom use, intimate partner violence (20,21)

Source: Moodley D. 2017 (4)
New maternal HIV infections are a driver of vertical transmission

In this graph:
- Bars are number of new infant infections in each African region
- Red represents vertical transmission due to incident maternal infection

In southern Africa, approximately 30% of all new infections in children are attributed to mothers acquiring HIV during pregnancy and breastfeeding.

Safety of PrEP drugs during pregnancy and breastfeeding

Two systematic reviews:

(1) **Use of TDF in pregnant and breastfeeding women through 2016** (33 articles)


(2) **Completed, ongoing or planned PrEP in pregnancy projects or studies from 2014 to 2019**

(14 articles: 5 completed studies, 9 ongoing/planned studies)


Findings:

- None of the studies found significant differences in pregnancy or perinatal outcomes associated with tenofovir exposure.
- Nine ongoing studies, to be completed by 2022, will provide data on ~6200 additional PrEP-exposed pregnancies.
PrEP may be offered to HIV-negative pregnant and breastfeeding women, specifically:

- Woman taking PrEP who subsequently becomes pregnant and remain at substantial risk of HIV infection
- Pregnant or breastfeeding HIV- woman living in a setting with high HIV incidence who are at substantial risk of HIV acquisition
- Women with HIV+ partners but not virally suppressed, or status unknow for safer conception

PEPFAR Guidance on PrEP for PBFW

• Our Scientific Advisory Board (SAB) reviewed this topic in 2016 and determined:
  • PrEP should be offered as part of combination HIV prevention to women at substantial risk of HIV infection during pregnancy and breastfeeding.
  • PEPFAR should have country-specific discussions about the introduction of PrEP in pregnant women, including reference to local epidemiology, cost-effectiveness, affordability, the local regulatory environment including pharmacovigilance and whether there is a need for demonstration projects to fill remaining gaps.
• COP19 Guidance (developed in 2018) incorporated the first specific section on PrEP in PBFW (Section 9.2.1: PrEP Targeting and Programming for Women)
  • PrEP access must include comprehensive counseling to decrease risk, including limiting number of sexual partners, increasing condom use, and reduction of sexual violence. Countries with high HIV prevalence rates should consider this population a priority for PrEP scale up in order to achieve their goals of epidemic control and elimination of MTCT.
PEPFAR Guidance on PrEP for PBFW

- COP20 Guidance enhances language around PrEP as a minimum program requirement:
  - Direct and immediate assessment for and offer of prevention services, including pre-exposure prophylaxis (PrEP), to HIV-negative clients found through testing in populations at elevated risk of HIV acquisition (PBFW and AGYW in high HIV-burden areas etc...)

- PrEP activities for women are woven into key initiatives like DREAMS and programming for key populations, and we also focus attention in specific populations such as pregnant and breastfeeding women (PBFW) and discordant couples in highly endemic areas.

- Since January 2019 PEPFAR has convened an interagency Community of Practice (COOP) on PrEP Implementation. This allows us to keep PrEP highlighted as a key technical area within PEPFAR programming, and to ensure countries receive adequate technical support.
  - A sub-group within this COOP has focused on the specific issue of PrEP for PBFW, which led to the survey and landscape findings we will discuss today.
Scaling up PrEP for PBFW: What Comes Next

- In COP2020, PEPFAR is targeting 1 million people on PrEP
  - This is an ambitious goal; more than triple the target for new PrEP initiations from COP19.
  - PrEP is a core program requirement and recommended for all populations at high-risk of HIV acquisition, including pregnant and breastfeeding women in high-risk geographic areas or age groups.
  - While enabling policies for PrEP are in place in most countries, policy changes may be needed in some countries to allow PrEP in pregnancy and breastfeeding.
  - Maternal retesting in pregnancy and breastfeeding offers an opportunity to re-offer PrEP.
  - ANC is a key entry point for the DREAMS program and PrEP is one of its key interventions
Summary

• Pregnant and breastfeeding women represent a priority population for PrEP.

• Improving PrEP implementation in this population is a priority of PEPFAR’s PrEP Community of Practice.

• Understanding experiences, barriers and challenges when implementing PrEP among pregnant and breastfeeding women is needed for successful PrEP scale-up in this population.
PREP COOP
Sub-Task Team for PBFW

Nicole Flowers (CDC)
COOP subtask team and Country Survey

**PREP COOP Leadership**
Jennifer Albertini (SGAC), Robyn Eakle and Sangeeta Rana (USAID), Pragna Patel (CDC)

**The purpose of the PrEP COOP is to facilitate and drive accelerated PrEP scale-up across PEPFAR agencies and countries**

**PrEP and PBFW Sub-Task Team**
CDC- Michele Montandon, Nicole Flowers; Peace Corps- Liz Hawryluk; USAID- Anouk Amzel, Sheena Sharifi Abadan

**Part 1**
- Involved a high level survey to countries on PrEP and PBFW practices
- Received responses from 17 countries
- Focused on national guidelines, access to PrEP for this population, data collection and risk screening.
- Learned that the majority of country programs were amenable to offering PrEP to PBFW but were not doing it at substantial levels.
Part 2: Stakeholder Calls

Part 2

• Gather more in-depth information about the status of PrEP among PBFW in PEPFAR supported countries
• Host a series of stakeholder discussion calls with multiple countries

Project Facilitators/Hosts
ICAP team- Elaine Abrams, Julie Franks, Fatima Tsiouris and Jennifer Zech
Jhpiego team- Lisa Noguchi, Kate Brickson, Megan McAndrew, Repsina Chintalova-Dallas and Jason Reed

Project Objectives
- To determine the current status of PrEP implementation for PBFW;
- To identify barriers to PrEP introduction and scale-up among PBFW, and,
- To identify opportunities and interventions to increase access to PrEP for PBFW
Stakeholder Calls: The Process

Countries Engaged:

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<td>Mozambique</td>
<td>Tanzania</td>
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<td>Eswatini</td>
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- PEPFAR coordinators, CDC & USAID staff were asked to provide a list of PrEP stakeholders
- Invited stakeholders represented policy makers, civil society, implementing partners, clinicians, donors, and multilaterals
- 60-90 minute discussions were held between February 26-March 16
- Facilitated discussion focused around PrEP among PBFW:
  - Availability/access and supporting guidelines/tools
  - Implementation challenges, successes, opportunities
  - Future Scale-up
Virtual Calls

• The stakeholder discussions were recorded.
• ICAP and Jhpiego reviewed the recordings and compiled a summary of the findings.
• The remainder of this webinar is dedicated to sharing the findings.
PrEP for Pregnant and Breastfeeding Women: Landscaping Findings

Julie Franks, Senior Technical Advisor, ICAP at Columbia University
Lisa Noguchi, Director, Maternal Newborn Health, Jhpiego
Overarching Themes

- All seven countries have PEPFAR PrEP targets in FY2020
- Variability in progress to scale-up, specifically in MCH settings
  - Six countries report ongoing PrEP services
  - One remains in planning stages
- Agreement on importance of PrEP for PBFW, but implementation and integration are still suboptimal
  - Common challenges
  - Opportunities to push forward
Guidelines and Tools

- **National PrEP guidelines in place in most countries**
  - However, most guidelines not specific to PBFW
- **PrEP screening and monitoring tools available in most countries but not tailored to PBFW**
  - Some noted too many tools – suggested synthesizing and capturing data of the different priority populations
  - Tanzania: KP tools to be adapted for ANC, launch in June '20
- **Screening and identification primarily at facility level**
  - Via HTS or through risk assessments in MCH/ANC settings
  - Eligible PBFW identified through drop-in centers, DREAMS risk assessments, referred to HIV clinics or providers for PrEP
  - Lack of community-level engagement/awareness across countries
  - Malawi: no procedures for screening PBFW; guidelines in development
PrEP Monitoring and Reporting

• Variability reported across countries, electronic and paper-based approaches
• PEPFAR indicators reported by all six countries providing services
• Disaggregation for PBFW in targets and indicator reporting would motivate collection and evaluation of PBFW PrEP data
• Stand-alone PrEP registers in MCH may not be as helpful as single register for ANC and PrEP together
  • eSwatini has PrEP register available in ANC setting
• Monitoring PrEP continuity is complex and requires analysis beyond what may be required for indicators
PrEP Access for Pregnant and Breastfeeding Women

• In general, PBFW can access PrEP (Malawi is current exception)
  • About half are or planning integrated PrEP in MCH
  • Others screen for PrEP within MCH and refer to providers, typically ART providers

• Programs reaching key and vulnerable populations report seeing PBFW clients
  • Not due to specific demand creation activities or in-service settings tailored to PBFW needs
  • PBFW accessing PrEP through community-based PrEP services, not just facility-based

• Pathway to scale-up variable across countries
  • Some starting with research or demonstration projects
  • Data on breakdown of pregnant vs. breastfeeding vs. both not collected as part of this landscaping
PrEP Acceptability

- PBFW seem interested in PrEP once informed
  - May be more motivated to adhere
  - Regarded as promising priority population
  - Motivation appears higher in pregnancy than during breast feeding
  - Partner awareness and support is important, warranting specific messaging for communities

- PrEP acceptability research ongoing
  - South Africa and Mozambique, pending in Malawi
Common Concerns

- Conflation and co-location of ART and PrEP contribute to stigma
- Safety concerns (reported in about half of respondents)
- Influencers, including partners and parents unaware of PrEP use and purpose
- Side effects, pill burden/fatigue
- Competing demands, especially in postnatal period, when integrated ANC-PrEP services for PrEP are no longer available
Successes

- Good uptake among willing population that may be particularly motivated to use PrEP for HIV prevention
  - Better uptake if sensitized prior to clinic, pamphlet in waiting area can prepare women for questions
  - Women can identify risk, willing to use PrEP if needed

- Healthcare workers
  - Possible to train HCW to provide counseling and PrEP
  - Enthusiastic about having an intervention for HIV-women, especially those at high risk

- Integrating PrEP and ANC appears feasible in MCH settings, if appropriately resourced

- Coordination across MCH, HIV stakeholders
Challenges

- National Guidelines
- Implementation strategy
- Supply chain
- Facility level
- Community level
- Other challenges/remaining resource needs
Challenges: National Guidelines

• National guidelines lack clarity and full integration
  • Not always followed or implemented as intended; requires more integration

• Country examples
  • South Africa stakeholders emphasized need for clearer guidance on if/when PrEP can be offered; currently there is confusion
  • Lesotho emphasized need for clearer guidance on messaging on management of side effects
Challenges: Implementation Strategy

• **Resource constraints impact implementation**
  • Intensive training for HCW, issues with turnover
  • HCWs overburdened with activities making follow-up with clients challenging
  • Introducing PrEP at all service delivery points and expanding clients eligible for PrEP will lead to potential overburdening

• **Implementation dependent on priorities of partner supporting county or region**
Challenges: Supply Chain at National and Facility Levels

- Initial supply chain challenges, but most resolved
  - Where challenges remain, suboptimal reporting on commodities impacts whole supply chain
- Working with community organizations and facilities to improve reporting
- Careful forecasting helped avoid supply chain challenges in eSwatini
  - Use national targets and uptake data from demonstration projects to forecast scale-up supply
Challenges: Facility Level PrEP Delivery

- Human resources burden for training, implementation
- Some confusion at facility level inhibits PrEP uptake
  - Need to define ‘at risk‘ beyond sero-discordant couples
- Retention issues, especially for postnatal women
- Having one-stop shop model may be ideal, but requires restructuring of services
- Many tools in use - should be optimized for sites
  - Challenge to harmonize across distinct service sites
  - Differences on best way to implement, different entry points, infrastructure, conditions
  - Different M&E tools in use at some sites
Challenges: Community Level

- Need targeted messaging strategies (facility and community level)
- Limited community mobilization impacts demand
  - Community awareness/demand is lacking
- No country had a community strategy or messaging in place for PBFW before implementation
  - Identified this as a major gap
- Stigma: community view associates PrEP with HIV, or for those who are promiscuous
Remaining Gaps and Challenges

• Significant lack of formal normative/policy/clinical practice/implementation guidance for PBFW in MCH
  • Clinical guidelines specific to initiating/managing PrEP for PBFW

• Pharmacovigilance (setting up and maintaining pregnancy, birth outcome surveillance)

• Community-level sensitization that reaches influencers with information

• Increased resource demands if expanding to MCH
  • Human (both people and time), financial, material

• Training to increase capacity substantially

• Additional counseling messages for PrEP providers, e.g., related to starting and stopping PrEP by PBFW
Additional Resources, Interventions, and Program Components Needed

- Adaptation of data collection tools for both PrEP and MCH, especially registers
  - Adapt MCH registers to include PrEP
  - Alternatively: implement specialized register for MCH settings
- Disaggregation of PrEP indicators to include PBFW as population
- Adherence/continuation strategies specific to PBFW spanning multiple providers/locations
- Additional financial (and other) resources needed if broadly expanding to MCH
  - Accommodation for PEPFAR reporting requirements by MCH sites if supported to integrate PrEP
Models and Examples for PrEP Services for PBFW

- Greater expansion beyond facility-based services
- Mentor mothers model/peer support groups (previously studied)
- HIV self-testing to augment effort of MCH providers
- Community-based one-stop-shop service outlets for PBFW seeking ANC and PrEP
Next Steps to Scale-Up PrEP for PBFW

- Clarifications from governments, normative agencies, donors
  - Who should be screened?
  - Is the vision to train all MCH providers to screen all women?
  - Will there be a prioritization strategy, e.g., certain sub-national units, specific sub-populations of PBFW?

- Better outline of PrEP care pathway
  - Continuum involves multiple providers across multiple sites
  - Client-level monitoring across continuum
Recommendations for Other Countries

• Include PrEP as part of PMTCT strategy
• Be prepared with communications strategy and resources in advance
• Balance community and facility level engagement
  • Including early community engagement
  • Critical strategy to support getting to 95-95-95 and EMTCT
• Consider novel tools
  • Self-administered sensitization, integrated tracking and monitoring
Additional Considerations

- Differential access to and uptake of particular maternal child health services impact opportunities to reach potential PrEP clients
  - ANC attendance generally better than postnatal care
  - Recommended postnatal care contacts – short-term (<24 hours, 48-72 hours, 7-14 days, six weeks after birth)
  - PPFP settings may represent critical opportunity for multiple key services, including PrEP

- Differentiated service delivery options, e.g., community-based to support PrEP distribution among PBFW

- Additional PrEP research ongoing and planned for pregnant and breastfeeding populations
  - PrIYA, IMPAACT 2009, DELIVER, B-PROTECTED
THANK YOU!

The organizers gratefully acknowledge all participants in the landscaping.

Photo credits: Jhpiego
Panelist Q&A

Robyn Eakle, USAID
Julie Franks, ICAP
Lisa Noguchi, Jhpiego
Pragna Patel, CDC
Thank you!
Resources

- Slides and recording will be posted publicly and shared with all attendees