State of the HIV Prevention Evidence Base for Pregnant and Breastfeeding Populations

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Overview

• Review quick background
• Review selected highlights from the current evidence base for HIV prevention options for pregnant and breastfeeding populations (PBFP)
  › Oral PrEP
  › Dapivirine vaginal ring
  › Cabotegravir long-acting injectable
• Review ongoing and upcoming research

26 April 2022
Background

26 April 2022
Prevention can’t exclude pregnant and breastfeeding people

<table>
<thead>
<tr>
<th>Country</th>
<th>TFR (births/woman)</th>
<th>% Infants ever breastfed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malawi</td>
<td>5.1</td>
<td>97.7</td>
</tr>
<tr>
<td>South Africa</td>
<td>2.4</td>
<td>87.4</td>
</tr>
<tr>
<td>Uganda</td>
<td>5.8</td>
<td>98.2</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>3.9</td>
<td>98.1</td>
</tr>
</tbody>
</table>

- **HIV transmission probability**
  - 1.05/1,000 sex acts (non-pregnant)
  - 2.19 in early pregnancy
  - 2.97 in late pregnancy
  - 4.18 in postpartum women

- **Risk higher vs. non-pregnant time**
  - Late pregnancy (aRR 2.82, p=0.01)
  - Postpartum (aRR 3.97, p=0.01)

TFR, World Bank, 2014; Malawi, 2015-6 DHS; South Africa, 1998 DHS; Uganda, 2011 DHS; Zimbabwe, 2015 DHS

Are breastfeeding studies really needed? Yes!

- Many studies exclude breastfeeding
- Breastfeeding impacts medication use, but very little data
- WHO recommends exclusive breastfeeding for 6 months, then 2+ years
- ↑ risk HIV acquisition
- High total fertility rates and long breastfeeding in areas with ↑HIV incidence
- FDA recommends breastfeeding studies

http://www.who.int/topics/breastfeeding/en/.


Oral PrEP

26 April 2022
Emerging evidence from a systematic review of safety of pre-exposure prophylaxis for pregnant and postpartum women: where are we now and where are we heading?

<table>
<thead>
<tr>
<th>Study</th>
<th>Design &amp; Population</th>
<th>PrEP-exposed pregnancies; time exposed</th>
<th>Pregnancy outcomes</th>
<th>Infant outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Partners PrEP Study; Kenya and Uganda; Mugo; 2014</strong></td>
<td>RCT in serodiscordant couples</td>
<td>Gestation at time of pregnancy detection= 37 days for TDF and 35 days for TDF/FTC</td>
<td>No differences</td>
<td>No differences</td>
</tr>
<tr>
<td><strong>FEM-PrEP: Kenya, South Africa; Callahan; 2015</strong></td>
<td>Randomized, placebo-controlled trial</td>
<td>n=69; Pregnancy tests were performed monthly and, if positive, study product was withheld</td>
<td>No difference by study arm</td>
<td>None reported</td>
</tr>
<tr>
<td><strong>VOICE; Uganda, South Africa, &amp; Zimbabwe; Bunge; 2015</strong></td>
<td>RCT</td>
<td>n=263; Pregnancy tests were performed monthly and, if positive, study product was withheld</td>
<td>No differences</td>
<td>None reported</td>
</tr>
<tr>
<td><strong>Partners Demonstration: Kenya &amp; Uganda Heffron; 2018</strong></td>
<td>Demonstration project in serodifferent couples; 126 pregnancies</td>
<td>n=30; Women were dispensed PrEP a median of 6 months (IQR 4–8) during pregnancy; 52% of women took at least 80% of expected doses</td>
<td>No differences</td>
<td>PrEP exposed infants lower z-score for length at 1-mo; no difference at 1-yr</td>
</tr>
<tr>
<td><strong>PrIYA Program; Kenya Dettinger; 2018</strong></td>
<td>Implementation program; 4680 pregnancies included in safety evaluation</td>
<td>n=246; 47% initiated PrEP in the second trimester, and 41% reported using PrEP for 1-3 months during pregnancy</td>
<td>No differences</td>
<td>No differences</td>
</tr>
</tbody>
</table>

**Slide credit:** Dvora Joseph Davey
Early data on PrEP safety in pre- and peri-conception periods came from unplanned exposures.
Safety of peri-conception daily oral PrEP use among HIV seronegative women

• Few studies have examined oral PrEP safety during peri-conception period
• Available data do not suggest adverse effects of using PrEP during peri-conception on pregnancy outcomes or infant growth
• Additional research needed
  › Adherence to oral PrEP as a peri-conception strategy
  › Potential additive benefit of PrEP use when HIV-seropositive partner is using antiretroviral therapy and virally suppressed
  › Identifying those who would most benefit from peri-conception PrEP use

Next generation of studies (2018-ongoing): Focus on implementation science and effective use or oral PrEP

- Increasing *geographic representation*
- Focusing *beyond individual level determinants* and strategies for PrEP implementation
- Delivering PrEP with an emphasis on *personal choice*, involving feedback from pregnant people in program design
- Increasing studies that *test strategies for improving provider delivered PrEP* to enhance PrEP reach, adoption, implementation, and maintenance during pregnancy


Figure 1. Key implementation science research opportunities to address evidence gaps of PrEP delivery for pregnant and postpartum women organized by the RE-AIM framework

Slide credit: Dvora Joseph Davey
Early pre-exposure prophylaxis (PrEP) initiation and continuation among pregnant and postpartum women in antenatal care in Cape Town, South Africa

Dvora Leah Joseph Davey¹,²,³,⁵, Rufaro Mvududu², Nyiko Mashele², Maia Lesosky², Nehaa Khadka¹, Linda-Gail Bekker³,⁶, Pamina Gorbach¹, Thomas J. Coates⁴ and Landon Myer²
PrEP initiation high in PrEP-PP Study

• Pregnant, HIV-negative ≥16 years at first ANC, follow-up to 12 months postpartum
  › HIV prevention counselling and offered PrEP, socio-demographic and behavioral data at each visit
• 1,201 participants (median gestation 21 weeks; age 26 years)
  › 84% initiated PrEP at first ANC visit (n = 1014)
  › 66% of those on PrEP returned for prescription at 1 month; 58% returned at 3 months
• Almost half on PrEP reported a side effect at 1 month, mostly nausea/vomiting (and side effects mattered to participants!)
• First, second trimesters: higher odds side effects (aOR 2.61; 95% CI 1.17–5.84) compared to postpartum

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- PrEP-PP clinic remained open and operational during COVID-19 lockdown
- 414 (91%) of 455 women opted to start PrEP at their first antenatal visit
- Preventing infant HIV (90%), unknown or positive partner serostatus (10%) were most common reasons
- During nationwide lockdown, missed PrEP visits increased significantly
- Suggests substantial impact of COVID-19 response on HIV prevention efforts
  - Fear of COVID-19 and contact with health facility were common barriers
- Community-based PrEP, phone contacts needed to address barriers

Perinatal outcomes following maternal pre-exposure prophylaxis (PrEP) use during pregnancy: results from a large PrEP implementation program in Kenya

Julia C Dettinger, John Kinuthia, Jillian Pintye, Felix Abuna, Emily Begnel, Kenneth Mugwanya, Joseph Sila, Harison Lagat, Jared M Baeten and Grace John-Stewart
PrEP Implementation in Young Women and Adolescents (PrIYA)

- PrEP services integrated in maternal and child health clinics at 16 sites in Western Kenya
  - 206 with prenatal PrEP use, 1324 without
- PrEP users more likely to report risks, e.g., violence, STI, partner w/ + or unknown HIV status
- Most initiated PrEP during second trimester (57%), used PrEP >1 month (58%)
- No major differences between PrEP-exposed and unexposed infants for preterm birth, LBW
- No malformations in PrEP-exposed, five in unexposed group, infants similar growth at 6 wks
- No differences in infant outcomes found by duration PrEP exposure, trimester of PrEP initiation, subset of women 15 to 24 years old or in multivariate analyses

IMPAACT 2009 Pharmacokinetic Component

- Observational cohort in South Africa, Malawi, Zimbabwe, and Uganda
  - Feasibility, acceptability, safety of PrEP in pregnant and postpartum AGYW

- First phase characterized PK of tenofovir during pregnancy and postpartum, established tenofovir-diphosphate (TFV-DP) benchmarks for adherence monitoring in second phase

- Forty AGYW, ~half of participants pregnant at 14-24 weeks, ~half 6-12 weeks postpartum

- Daily FTC/TDF administered under direct observation for 12 weeks

- TFV-DP from weekly dried blood spot, levels ~1/3 lower in those pregnant vs. postpartum

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New WHO postnatal care recommendations include oral PrEP!

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A.3 Preventive measures

17. Other maternal infections

Oral pre-exposure prophylaxis (PrEP)

Oral pre-exposure prophylaxis (PrEP) containing tenofovir disoproxil fumarate (TDF) should be started or continued as an additional prevention choice for postpartum and/or lactating women at substantial risk of HIV infection as part of combination HIV prevention approaches.
Dapivirine vaginal ring
HIV-1 Prevention During Pregnancy and Breastfeeding: A Portfolio of MTN Studies

MTN-042B & Systematic Literature Review

MTN-042 Deliver

MTN-043 B-PROTECTED

MTN-041 MAMMA

MTN-016

MTN-002

MTN-008

MTN-029

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MTN-016: EMBRACE

- Prevention Agent Pregnancy Exposure Registry
- Prospective observational cohort study
  - Fell pregnant during trials, or planned exposures in safety studies
- 460 women and 413 infants enrolled across 17 sites

“Women who become pregnant during the trial should be followed in a pregnancy exposure registry such as the Microbicide Trials Network Registry MTN-016.”
- 2014 Guidance for Industry

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MTN-016 outcomes of interest

- Adverse pregnancy outcomes
- Growth parameters of infants during first year of life
- Prevalence of major malformations in infants during first year of life
- Prevalence and persistence of HIV drug resistance mutations in plasma among HIV-infected infants
- MTN-016 unique design allowed for capture of outcomes among those randomized to placebo as well
MTN-016 (ASPIRE DATA)

• 2,629 women enrolled
• 169 women pregnant during follow up
• 179 incident pregnancies and 181 pregnancy outcomes

• Dapivirine use in periconception period does not appear to be associated with adverse effects on pregnancy or infant outcomes

MTN-029/IPM 039

- Same 25 mg DPV VR used in Phase 3 studies x 14 days of use
- 16 women at two US sites
  - 18+ y.o., HIV-, >6 weeks post-delivery
  - Lactating but weaning completed
- Pharmacokinetic (PK) – plasma, milk, cervicovaginal fluid
- Results
  - 100% retention
  - Safe – very few adverse events
  - Extremely low drug transfer to milk

MTN-041: Microbicide/PrEP Acceptability among Mothers and Male Partners in Africa (MAMMA)

• Primary Objectives
  › Attitudes about vaginal ring (VR) or oral PrEP during pregnancy (P) and breastfeeding (BF), incl. willingness to use

• Secondary Objectives
  › Potential preference for VR or oral PrEP during P/BF
  › Attitudes and perceptions re sexual activity during P/BF
  › Perceptions of HIV risk, community beliefs and practices

• Study completed – findings used to inform study tools, recruitment, retention and community activities, counseling program, and participant engagement plans

• 128 participants, 65 women, 63 men

MTN-041/MAMMA Findings

• Most important influencers of PBFP were partners
  › Health decisions made jointly (e.g., medication use, ante/postnatal and baby care)

• PBFP perceived to be at high risk for HIV, primarily because of partner's infidelities
  › New prevention options were welcomed

• Participants valued multiple options, personal preference key to product choice

• Theoretical concerns about products: miscarriage, infant development, complications during delivery, breastmilk supply and taste
  › Also concerns about potential vaginal discomfort, difficulty inserting/removing (ring)
  › Nausea/vomiting exacerbated during pregnancy (pill)

• Health care providers' (HCPs) knowledge and approval of product use needed to mitigate anticipated fears

• Participants recommended involving partners, HCPs in sensitization for future trials

MTN-042/MTN-043: Assessing safety of dapivirine VR and oral PrEP in pregnancy and beyond

<table>
<thead>
<tr>
<th>Time Period</th>
<th>MTN-042</th>
<th>MTN-043</th>
</tr>
</thead>
<tbody>
<tr>
<td>~6 weeks</td>
<td>MTN-042 assessing safety of DPV ring and PrEP at different time points in pregnancy</td>
<td>MTN-043 assessing safety of DPV ring and PrEP at different time points in postpartum mothers and breastfeeding infants</td>
</tr>
<tr>
<td>12 weeks – delivery</td>
<td>No difference in maternal or infant outcomes</td>
<td>Time period not currently being assessed</td>
</tr>
<tr>
<td>6 weeks pp</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;6 weeks pp</td>
<td></td>
<td></td>
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</tbody>
</table>
MTN-042/Deliver study design

• Participants randomly assigned to use either monthly ring or daily PrEP until delivery
  – For every one participant assigned to use PrEP, two use the ring
• Conducted in a stepwise fashion starting with group late in pregnancy
• Interim reviews conducted before beginning enrollment in next group
  • Seven members from various countries in Africa and North America
  • Experts in pediatrics, obs/gynecology, nursing, public health, statistics, ethics
• Pregnancy complications and outcomes, gestational age at delivery, mode of delivery, birth weight
• After each cohort, IRP looks at frequency of outcomes compared to what is expected locally, using data from MTN-042B
Deliver design modified to provide key results sooner

**Original Design**
4 groups, 750 women total. In all groups, twice as many use the ring as PrEP.

- **Group 1**
  - 36+ weeks (9-9 months)
  - 4-6 weeks
  - 150

- **Group 2**
  - 30-35 weeks (7-8 months)
  - 7-12 weeks
  - 150

- **Group 3**
  - 20-29 weeks (5-7 months)
  - 13-22 weeks
  - 150

- **Group 4**
  - 12-18 weeks (3-5 months)
  - up to 30 weeks
  - 300

**Modified Design**

- **Group 1**
  - no change

- **Group 2**
  - no change

- **Group 3**
  - 250 women
  - 13-30 weeks
  - 4 times as many use the ring

3 groups, 550 women total

26 April 2022
MTN-042 status

• Began in February 2020, completed follow-up of Group 1 (n=150) in May 2021
  › Group 1 data reviewed by Interim Review Committee
• No safety concerns and proceeded to second cohort
  › Completed enrollment in March 2022 (n=157)
• Provided there are no safety concerns, will proceed to Group 3, (n=250, 13-30 weeks)
• DELIVER expected to be completed in 2023

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MTN-042B: Assessing baseline pregnancy outcomes in Malawi, South Africa, Uganda, and Zimbabwe

- **Study Design**: Multi-site, chart review, cross sectional study
- **Study Population**: All women delivering or receiving immediate postpartum care (within one week of delivery) at one or two facilities affiliated with each of the 4 sites, a primary care facility and a referral facility
- **Sample Size**: Approximately 11,000 (8 weeks of deliveries at 4 sites)
- **Objectives**
  - Primary: To determine frequency of key pregnancy outcomes
  - Secondary: To determine frequency of pregnancy and infant complications, method of delivery, birth weight, and proportion of low birth weight (<2500g)

MTN-042B results

• All those delivering at designated facilities or admitted within seven days of delivery

• 10,138 records across four sites
  › 10,426 pregnancy outcomes
  › Preterm birth 13%, stillbirth 4.1%, gestational hypertension 4.4%, low birthweight 15.5%, neonatal death 2.0%
  › Suspected congenital anomalies 1.2%

• Systematically collected data on background rates of pregnancy outcomes, pregnancy complications, neonatal outcomes
  › Can be used as reference in support of ongoing HIV prevention studies

• Important background data for future studies of investigational products evaluated in pregnancy in these urban settings

Long-acting injectable cabotegravir

- Antiretroviral drug developed by ViiV Healthcare
- INSTI – inhibits HIV viral DNA from integrating with human DNA
- Formulated to be given every two months as injectable PrEP
- Previously approved in US and Canada for treatment, in combination with rilpivirine
- As of December 2021, additionally approved by US for use as prevention option
- Superior to daily oral PrEP in reducing HIV risk in populations at high risk of HIV acquisition
- More research needed on safety of CAB-LA use by PBFP

No adverse effects associated with CAB-LA exposure were noted in HPTN 084!

BUT – this study was not designed to address safety for PBFP.

26 April 2022
What about neural tube defects?

• Early concerns regarding dolutegravir and neural tube defects have diminished with accumulating safety data

• Current evidence suggests risk similar to other antiretrovirals used around time of conception

• No infants born to those taking CAB LA during HPTN 084 had a neural tube defect or other birth defect
  › Small number of deliveries during trial period

• Currently no findings to suggest that CAB LA exposure during pregnancy is associated with neural tube defects or other birth defects

26 April 2022
Limited data

• Insufficient human data on use of cabotegravir during pregnancy

• Risks we can’t assess yet
  › Birth defects, including neural tube defects
  › Miscarriage, impact on other pregnancy outcomes

• Unknown impact during breastfeeding

• Still need to learn
  › Whether cabotegravir is present in human breast milk – posited that may persist in milk for a year or longer after injection
  › Impact, if any, on milk production
  › Potential effects on breastfed infant

26 April 2022
Pregnancy outcomes and PK in Pregnant Participants Living with HIV Exposed to Long-Acting Cabotegravir and Rilpivirine

- Exposures ≥ 1 dose of CAB+RPV (oral/LA) from ViiV-sponsored Phase 2/3/3b treatment studies, compassionate use program
- Continued quarterly PK sampling for 52 weeks post last injection
- As of March 2021, 26/325 became pregnant while exposed to CAB+RPV (5 oral, 21 LA]
- 11 live births (1 oral, 10 LA), of which 10 had no congenital abnormalities and 1 had reported ptosis
  - 9 elective terminations and 6 miscarriages (5 in first 9 weeks of gestation)
- Pregnancy outcomes in those exposed to CAB+RPV at conception consistent with earlier findings
- CAB and RPV PK tail in pregnancy within expected range for non-pregnant
- Ongoing monitoring of birth defects within anti-retroviral pregnancy registry and pregnancy surveillance within treatment program

More evidence coming soon!

26 April 2022
HPTN 084 Open Label Extension (OLE)

• HPTN 084 showed that long-acting injectable cabotegravir (CAB LA) was superior to TDF/FTC for PrEP in study population

• OLE amendment undertaken to look at additional objectives
  › Acceptability (uptake, continuation, discontinuation) of open-label CAB LA
  › Safety of open-label CAB LA with and without oral PrEP lead-in
  › Pregnancy incidence among participants during OLE period
  › Safety and infant outcomes among pregnant participants
  › HIV incidence among participants who use CAB LA, combining participants from all three steps of HPTN 084

26 April 2022
In HPTN 084 OLE, contraception will be optional. Those who become pregnant on CAB LA permitted to stay on CAB LA or switch to oral TDF/FTC. Option of joining mother-infant sub-study with follow-up for about a year after birth.

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Priority questions for PBFP in HPTN 084

• Do pregnant participants metabolize CAB LA differently than non-pregnant?
• Do pregnant participants experience side-effects at the same rate as non-pregnant?
• Is CAB LA transferred to the infant?
**Study Design:** Phase 3B, randomized, open-label, multi-site, mother-infant pair safety and drug detection study, with 12 weeks of planned study product exposure to either DPV VR (25 mg) or oral Truvada® tablet (200 mg FTC/300 mg TDF)

**Study Population:** Healthy, HIV-uninfected breastfeeding participants and their healthy infants between 6 and 12 weeks old (inclusive) at the time of enrollment

**Sample size:** Approximately 200 mother-infant pairs
CATALYST: Catalyzing access to new prevention products to stop HIV

• To assess feasibility, acceptability, uptake, and patterns of use with a service delivery package providing choice of oral PrEP, PrEP ring, and CAB PrEP
  › Inclusive of individuals assigned female at birth of any gender identity or individuals assigned male at birth who identify as women
  › Especially adolescent girls and young women (AGYW)

• PEPFAR USAID delivery sites
  › Kenya, Lesotho, South Africa, Uganda, and Zimbabwe

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Study Population

- AGYW ages 15-24 – depending on national minimum age for consent, which differs across the five included countries
- Female sex workers (FSW) and those engaging in transactional sex
- Women aged 25 years and above
- Transgender women and gender diverse persons assigned female at birth
- Pregnant and breastfeeding populations – depending on national guidelines for the use of each PrEP product during pregnancy and breastfeeding

*Presumed HIV-negative based on results from the national testing algorithm.*
Guiding principles for inclusion of PBFP in CATALYST

1. **Ethical inclusion** of PBFP (no specific exclusion criterion for PBFP)
   We may not see many PBFP seeking enrollment, but they will appear during follow-up

2. **Make the protocol safe for PBFP**, but don’t design a *clinical safety study*

3. Informed **consent and counseling** are key

4. Adapt CATALYST procedures to **emerging safety data** from other studies
   Key safety analyses for PBFP will continue in HPTN 084 OLE, MTN-042 (DELIVER), etc.

5. Work with the **local standard of care**, e.g., antenatal care settings, for clinical management (build positive, informed relationships)

6. **Collect pregnancy outcomes**, but outsource analysis, if feasible

7. **Link to a registry**, if feasible, to follow outcomes beyond scope of CATALYST

26 April 2022
# State of the HIV prevention evidence base for PBFP: Safety

<table>
<thead>
<tr>
<th></th>
<th>Peri-conception</th>
<th>First trimester</th>
<th>Second trimester</th>
<th>Third trimester</th>
<th>Early postnatal (&lt;6 weeks)</th>
<th>Later postnatal: BF user</th>
<th>Later postnatal: infant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral FTC/TDF</td>
<td>Appears safe, no evidence of adverse impact on pregnancy complications, pregnancy outcomes, gestational age at birth, mode of delivery. Data continue to accumulate!</td>
<td></td>
<td></td>
<td></td>
<td>Most data from HIV treatment context, but no evidence of harm.</td>
<td>Appears safe, no evidence of adverse impact on maternal/infant outcomes, growth.</td>
<td></td>
</tr>
<tr>
<td>Dapivirine vaginal ring</td>
<td>Appears safe, no evidence of adverse impact.</td>
<td>Limited data, no evidence of adverse impact.</td>
<td>More data expected from MTN-042.</td>
<td>Emerging evidence from MTN-042.</td>
<td>No data</td>
<td>MTN-029 suggests safety profile similar to non-PBFP.</td>
<td>Data expected from MTN-043.</td>
</tr>
<tr>
<td>CAB LA</td>
<td>Very limited data during pregnancy and postpartum period. More data expected from HPTN 084 OLE and other ongoing/upcoming research.</td>
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A few highlights from the evidence

• Fortunately, no major safety signals noted to date
• Daily adherence to oral PrEP for pregnant AGYW appears particularly important
• Haven’t yet cracked the code on continuation – still a challenge for PBFP
• Side effects matter and appear to impact continuation
• Starting to understand correlates of use and continuation
• Partners are important influencers for prevention choices
• Integration of oral PrEP into MNH service delivery appears feasible but more research is needed
• Choices are important – PBFP need safe options and to understand the safety of options!

26 April 2022
The landscape has changed and momentum is building...

Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

Prescription Drug Labeling Sections 8.1 – 8.3 USE IN SPECIFIC POPULATIONS

**CURRENT LABELING**

- **8.1** Pregnancy
- **8.2** Labor and Delivery
- **8.3** Nursing Mothers

**NEW LABELING**

- **8.1** Pregnancy includes Labor and Delivery
- **8.2** Lactation includes Nursing Mothers
- **NEW** **8.3** Females and Males of Reproductive Potential

26 April 2022
Dr. Bonus Makanani (1965-2021)
Beloved advocate for ethical inclusion of PBFP in PrEP research
Thank you!

Community Members
Sharon Hillier
Lisa Rossi
Kristine Torjesen
Dvora Joseph Davey
ADDITIONAL REFERENCES


26 April 2022


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Breastfeeding is the norm, and most commonly used drugs are safe in breastfeeding, but many drugs have no breastfeeding safety data!
An ongoing dialogue!

- 2010: Next Steps for Microbicide and PrEP Research in Pregnancy
- US NIH, Bethesda, MD, USA
- Included clinical (infectious disease and maternal-newborn health), ethical, research, regulatory perspectives
- Set the stage for continued study of candidate HIV prevention products in pregnancy and breastfeeding

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Factors associated with continuation/discontinuation

- Those with side effects continued PrEP less vs. those without
- Less likely to continue
  - ≥1 prior pregnancy or postpartum vs. primigravid or pregnant
- More likely to continue
  - HIV+ partner or high risk perception
Systematic Literature Review: Objectives

Provide estimates of the frequency of adverse pregnancy outcomes conducted in the countries of participating in MTN-042

Compare these estimates with the frequency of adverse pregnancy outcomes observed among women who became pregnant in MTN trials (MTN-003, MTN-020, MTN-025)