

Stakeholders Meeting: Day One Recap



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**Ensuring Safe HIV Prevention Methods for
Pregnant and Breastfeeding Women**

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The Need

- Pregnant and breastfeeding women deserve to be included in clinical trials of potentially beneficial drugs
 - Mothers benefit, infants benefit, clinicians benefit, science benefits
- Women may be pregnant or breastfeeding for a significant portion of their lives
- Pregnancy and breastfeeding represent periods of high HIV risk
- Preventing HIV infection in the mother protects her baby, too

Two HIV Prevention Methods



- PrEP is daily use of an ARV tablet (Truvada)
 - Approved in a number of African countries
 - Most information about safety during pregnancy and breastfeeding is from HIV-infected women taking Truvada as treatment.
 - WHO recommends PrEP during pregnancy and breastfeeding but guidelines on its use differ – some countries say more data is needed



- The dapivirine ring is used every month
 - Found to be well tolerated and to reduce HIV risk in two Phase III trials
 - ASPIRE and The Ring Study
 - We know less about the safety of the ring in pregnant and breastfeeding women (but information we do have is reassuring)
 - The International Partnership for Microbicides (IPM) is seeking its regulatory approval– would not be for pregnant/breastfeeding women

Regulators and national programs need information about the safety of a drug in pregnancy and breastfeeding before deciding about its use in these populations.

DELIVER and B-PROTECTED

- Are two studies that will evaluate the safety of PrEP and the ring in pregnant and breastfeeding women
 - DELIVER for pregnant women
 - B-PROTECTED in breastfeeding women

deliver



- Both will be conducted by the National Institutes of Health-funded Microbicide Trials Network at 4 sites in 4 countries



Uganda (Kampala)
MU-JHU Research Collaboration

Malawi (Blantyre)
College of Medicine-John Hopkins University Research Project

Zimbabwe (Harare)
University of Zimbabwe College of Health Sciences Clinical Trials Research Centre – Zengeza

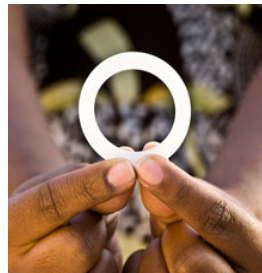
South Africa (Johannesburg)
Wits RHI Shandukani Research Centre (042/042B/043)
Wits RHI Hillbrow CRS (041)

What is similar about the two studies?

- Women in both studies use either the monthly ring or daily PrEP during the time that they are in the study
 - Which product women use will be determined by chance (randomization) – like flipping a coin



or



4 Groups of Women

- Will enroll 750 pregnant women at different times during pregnancy

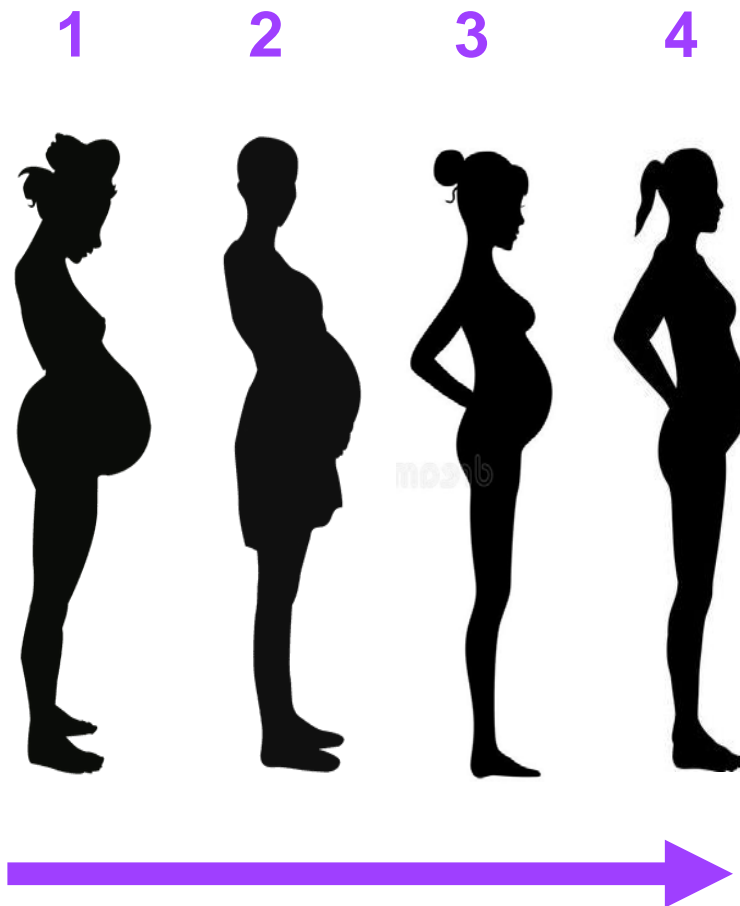
Group 1 – 36+ weeks pregnant (about 8-9 months)

Group 2 – 30-35 weeks pregnant (about 7-8 months)

Group 3 – 20-29 weeks pregnant (about 5-7 months)

Group 4 – 12-19 weeks pregnant (about 3-5 months)

Study Design at a Glance



- Will enroll one group at a time, beginning with women late in pregnancy
- Women will be randomly assigned to use either the monthly ring or daily PrEP until the time they deliver
 - Twice as many women will use the ring, because we need more safety data with the ring
- Interim reviews will be conducted before deciding to enroll the next group of women

Breastfeeding moms and their babies



- B-PROTECTED will enroll 200 HIV-uninfected mothers who are breastfeeding a baby between the ages of 6-12 weeks
 - Their babies will also be enrolled in the study
- Women must be HIV-uninfected and be planning to exclusively breastfeed for the duration of the study
- Women will use either the ring or PrEP for 3 months and both women and their babies will be followed for an additional two weeks

The Bottom Line

- Pregnant and breastfeeding women need HIV prevention tools that they know are safe for them and their babies
- Two products, PrEP and the dapivirine vaginal ring, are safe and can reduce the risk of HIV, but we need to know that they are safe to use by women during pregnancy and breastfeeding.
- Two studies—DELIVER and B-PROTECTED— will evaluate the safety of these drugs in pregnant and breastfeeding moms

In the end, it's about ensuring women can be protected against HIV with options they know are safe – safe for themselves, their pregnancies and for their babies.