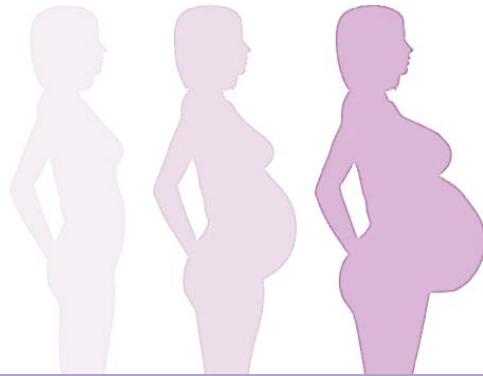


MTN-042: A Quick Review



Sharon Hillier, PhD

Two HIV prevention methods



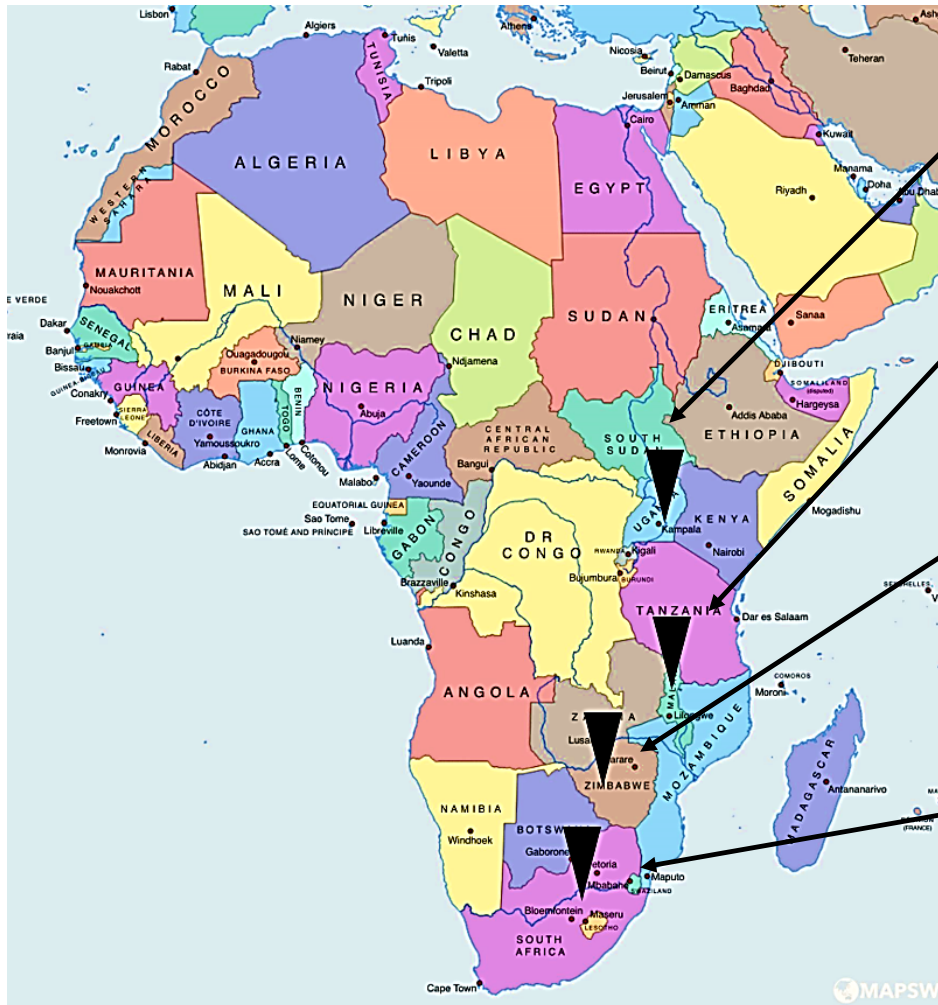
- PrEP is daily use of an ARV tablet (Truvada)
 - Approved in a number of African countries
 - Guidelines differ: Some say it's OK during pregnancy, others want more data



- The dapivirine ring is used every month
 - Found safe and to reduce HIV risk in two Phase III trials – ASPIRE and The Ring Study
 - The International Partnership for Microbicides (IPM) is seeking its regulatory approval– would not be for pregnant women

- Regulators and national programs need information about the safety of a drug in pregnancy before deciding about its use in pregnant women

Will enroll 750 women at 4 sites in 4 countries



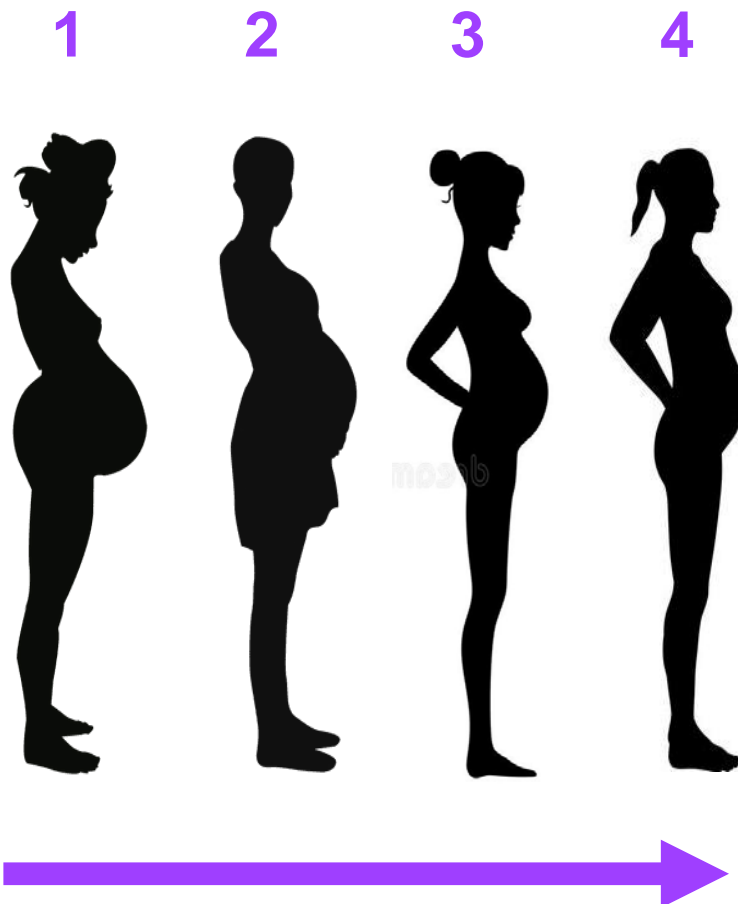
Uganda (Kampala)
MU-JHU Research Collaboration

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

Study design



- Women will be randomly assigned to use either the monthly ring or daily PrEP
 - For every one woman assigned to use PrEP, two will use the ring
- Will be conducted in a stepwise fashion starting with women late in pregnancy
- Interim reviews will be conducted before deciding to enroll the next group of women

Each group will use the ring or PrEP a longer time

	number	Ring or PrEP?	Approximately how long?
Group 1 36+ weeks 	150	100 will use the ring 50 will use PrEP	4-6 weeks
Group 2 30-35 weeks 	150	100 will use the ring 50 will use PrEP	7-12 weeks
Group 3 20-29 weeks 	150	100 will use the ring 50 will use PrEP	13-22 weeks
Group 4 12-19 weeks 	300	200 will use the ring 100 will use PrEP	Up to 30 weeks

The study's objectives

Primary Objective

- To describe the **maternal, peri-partum, and infant safety profile** associated with use of PrEP and the dapivirine ring during pregnancy

Secondary Objectives

- To describe **pregnancy outcomes** associated with use of PrEP and the dapivirine ring during pregnancy
- To describe **how the body takes up the active drug** (pharmacokinetics) in PrEP and the dapivirine ring during pregnancy
- To characterize **adherence** – how well women are able to use daily PrEP and the monthly dapivirine ring during pregnancy
- To characterize **acceptability** – do women find using PrEP and the ring acceptable during pregnancy?

Exploratory Objective

- To describe the **vaginal microbiome (good and bad bacteria in the vagina)** in participants using oral PrEP and the vaginal ring during pregnancy

Who may participate?

- Healthy, HIV-uninfected women 18-45 years old with an uncomplicated pregnancy
- Must be within the window of the particular gestational age being enrolled at that time
 - Group 1 – 36+ weeks pregnant
 - Group 2 – 30-35 weeks pregnant
 - Group 3 – 20-29 weeks pregnant
 - Group 4 – 12-19 weeks pregnant
- Must be will willing to be randomized to use either daily PrEP or the monthly vaginal ring during the study
- May not plan to access and/or use oral PrEP outside the study
- Must be planning to deliver her baby at a health center or hospital

A stepwise approach with interim reviews

