

What we hope to learn in the MTN-041 qualitative study

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Study Rationale

 MTN-041 study is designed to identify individual, interpersonal, social and cultural factors that may affect uptake of two safe and effective methods; monthly dapivirine ring and daily oral PrEP in pregnant and breastfeeding women

 Pregnant and breastfeeding women are at high risk of HIV yet seldom –studied population

Study Population: Focus Group Discussions

- Pregnant and breastfeeding women-HIV uninfected, aged 18-40 currently or recently pregnant or breastfeeding
- Male partners- men aged 18 or older whose partners are currently pregnant or breastfeeding, or whose partners were pregnant or breastfeeding within the previous two years
- Grandmothers- maternal and paternal grandmothers whose daughters or daughters-inlaw are currently/recently pregnant or breastfeeding

Study Population: Key informant Indepth Interviews

- Individuals who:
 - Currently work as:
 - A clinician (e.g., obstetrician, nurse, pharmacist, etc.)
 - Traditional care provider (e.g., Traditional birth attendant, healer, midwife, etc.)
 - Social service provider (e.g., social worker, family planning counselor, etc.)
 - Community health worker in one of the study countries
 - Currently acts in a community leadership role
 (e.g., local chief, religious leader, etc.)

Study Objectives: Primary

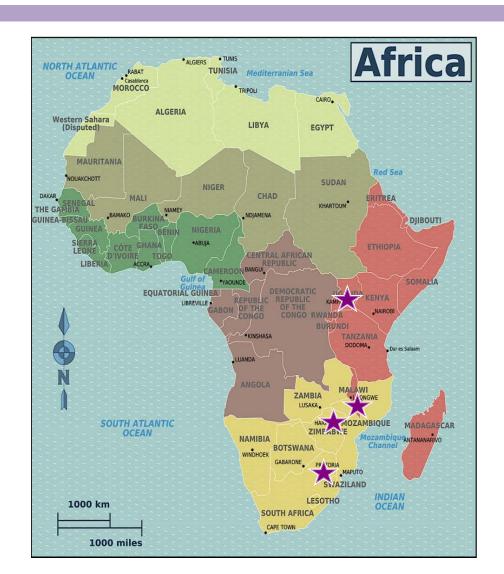
- To explore attitudes about use of a vaginal ring during pregnancy and breastfeeding, including willingness to use or recommend/support use of a VR during pregnancy and breastfeeding
- To explore attitudes about use of oral PrEP during pregnancy and breastfeeding, including willingness to use or recommend/support use of oral PrEP during pregnancy and breastfeeding

Study Objectives: Secondary

- To explore potential preference for a vaginal ring or oral PrEP during pregnancy and breastfeeding
- To explore attitudes about and perceptions of sexual activity during pregnancy and breastfeeding, including how a VR or oral PrEP might affect sexual activity
- To explore perceptions of HIV risk during pregnancy and breastfeeding
- To explore **community beliefs** and **practices** considered **taboo** (or encouraged) during pregnancy and breastfeeding that might affect VR and PrEP uptake and use during these periods, including use of oral medications and intravaginal products

Study Sites

- Uganda Kampala (MU-JHU)
- MalawiBlantyre (JHU-CTU)
- Zimbabwe
 Zengeza (UZCHS-CTRC)
- South Africa
 Johannesburg (Wits RHI)



Topic Areas

- Health, HIV worry, and decision making while pregnant/breastfeeding
- Sexual activity and vaginal practices while pregnant/breastfeeding
- Oral PrEP and vaginal ring acceptability
- Suggestions/recommendations to encourage product use in pregnancy/breastfeeding



Study Timeline

January 2018:

- IRB Submissions
 - -Engagement

April/May 2018:

- Activation
- Data Collection









February/March 2018:

- Approvals
 - Staffing
 - Training

April 9-10 2018:

042 Protocol Development Meeting

How & when will MTN-041 inform conduct of MTN-042

- Feed into MTN-042 protocol development meeting (depending on timing of activation and onset of data collection)
- Provide insight into possible concerns about/barriers to use of dapivirine vaginal ring and oral PrEP during pregnancy and breastfeeding and how they can be addressed eg FAQ
- Inform and guide MTN-042 recruitment efforts, informed consenting, participant retention and product adherence efforts



Acknowledgements

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- Study sites

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