MTN-041: Protocol Overview

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Introduction

Qualitative Assessment of Acceptability of Vaginal Ring (VR) and Oral Pre-exposure Prophylaxis (PrEP) Use during Pregnancy and Breastfeeding (P&B)

Working “fun” title:

Microbicide Acceptability among Mothers and Male Partners in Africa (MAMMA)
Sample & Study Population

• ≤200 men and women
  – Pregnant or breastfeeding women, aged 18-40 recruited from the community
  – Male partners, aged 18 and over, of pregnant or breastfeeding women

• ~24-40 key informants (KI)
  – Recruited in the community, including health care providers (HCP)
Study Sites

- Uganda
  - Kampala (MU-JHU)
- Malawi
  - Blantyre
- Zimbabwe
  - Harare (Zengeza)
- South Africa
  - Johannesburg (Wits RHI - Shandukani)
Study Design

- Exploratory acceptability study that will utilize focus group discussions (FGDs) and in-depth interviews (IDIs)
Study Objectives

Primary:
1. To explore attitudes about use of a vaginal ring (VR) during Pregnancy & Breastfeeding (P&B),
2. To explore attitudes about use of oral PrEP during P&B

Secondary: During P&B…
1. Potential preference between VR and PrEP
2. Perception of sexual activity
3. Perception of HIV risk
4. Communities practices and taboos affecting product use
Lit Review: Key Pregnancy Social Actors/Influences

• **Family members/friends;** especially older women (mothers, grandmothers, aunts).

• **Male partners**

• **Traditional healers** more socially and physically accessible than health care professionals (HCPs).
  – E.g. in Uganda, doctor/patient ratio is 1:1,800, traditional healer/patient ratio is 1:150.
  – Traditional Birth Attendants (TBAs) also consulted during pregnancy.
Lit Review: Biomedical vs. Traditional Healing

- HCPs against the use of traditional healing
- Pregnant women and traditional healers assert traditional health practices address pregnancy needs and ailments that biomedicine does not.
  - Ex: isihlambezo (Zulu herbal remedy) used for general maternal health & to help facilitate a quick and painless delivery.
    - Helps urban women to cope with the urban lifestyle, changing environment, and preserves spiritual purity (Varga and Veale, 1997).
Lit Review: Common Practices During Pregnancy

• Herbal remedies: the use of various herbal remedies is noted in all four countries.
  – SA: described among various ethnic groups.
  -- Uganda: consuming emumbwa, a clay soil mixed with herbs, aids delivery process (greater flexibility of pelvic bones).
• Return to parental home during final trimester (Zimbabwe).
• Placenta burial rites: traditional in Uganda.
Lit Review: Pregnancy Taboos

• **Witchcraft:** a fear for pregnant women as bewitchment could cause preterm birth/miscarriage.
  – Zimbabwe: early pregnancy kept secret to avoid bewitchment. Blood screening may be avoided.
  – Malawi: quarreling with people creates opportunity for bewitchment.

• **Vaginal practices:** unacceptable to insert things into the vagina when pregnant (SA)

• **Impurity:** caused by sexual activity, vaginal bleeding, or recent death in the household (Malawi).

• **Medicine:** a woman should not take “bitter” medicine while pregnant (ex: ‘capsules’ or anti-malarials) (Malawi).
Lit Review: Key Breastfeeding Social Actors/Influences

- **Infant caretakers and senior female relatives** (esp. for mothers living in households with extended family)

- **Governmental/health organizations**
  - Example: Since 2011, SA promotes and supports exclusive breastfeeding and stopped supplying free formula milk at public facilities.

- **Breast-milk substitute (BMS) marketing**:
  - influences social norms around infant feeding, promoted the idea that BMS is superior to breast milk.

- **High rates of HIV/AIDS in SSA**:
  - impacts recommendations around exclusive formula feeding, exclusive breast-feeding, or mixed feeding.
Lit Review: Breastfeeding
Common Practices

• Mixed feeding (breast-feeding and other foods/fluids before 6 mos.) is extremely common in SSA.
Lit Review: Breastfeeding Taboos

• **Abstinence while breastfeeding**: Sex is seen as “heating” the woman’s body, which changes the quality of her milk. Semen can make the breastmilk impure.
  – For men, abstinence is only required for a few months. For women, it is for full breastfeeding period.
  – Men seek out other sexual partners due to longer period of abstinence for female partners.

• **Pregnant women cannot breastfeed**: based on the notion that when a woman is pregnant, her breastmilk belongs to the infant in utero. It is said that this milk can make the baby sick.
  – Becoming pregnant while breastfeeding is also a sign that the woman has not adhered to the abstinence requirement, so she may face social stigma (Tanzania, Zimbabwe).
MTN stakeholders survey summary

- 39 participants completed the survey (18-Sept-17)
  - Average age: 41 (range 24 – 65)
  - 87% female
  - 92% have children
  - Half (50%) with last child more than 5 years ago

Gender

- 87%
- 10%
- 3%

Male  Female  Unknown (no response)
Participants

- Clinician: 28%
- Nurse: 28%
- Study/clinic coordinator: 10%
- Pharmacist: 8%
- Outreach worker: 8%
- Interviewer: 5%
- Other: 13%

Geographical distribution:
- South Africa: 23%
- Zimbabwe: 5%
- Uganda: 5%
- Malawi: 2%

Total: 39
Have you ever worked with pregnant and/or breastfeeding women?

Yes, 95%
Average length of time that local women breastfeed

- 16.8 months (range: 4 – 42 months)
- 81% of participants said women breastfeed for at least 12 months
Products or medications for pregnancy

- 72% had ever prescribed/recommended medications or products for use during pregnancy
Products/medications for breastfeeding

• 51% have prescribed or recommended medications or products
Pregnancy “dos”

- Prepare birth canal
  - Bath in, chew, or drink herbs
    - “Bathing herbs or taking herbs to soften the bones for easy delivery” - Uganda
  - Chew or eat clay (Uganda)
  - Vaginal stretching
    - “inserting a fist lubricated with Vaseline” - Zimbabwe
- Stay healthy
- Get plenty of rest, stay active
Pregnancy “don’ts”

- Dietary restrictions
  - Certain fruits: no oranges, pineapple, mango (South Africa)
  - No eggs
- No sex (during various points in pregnancy)
- Avoid funerals and graveyards
- Do not wait until showing to announce pregnancy
- No breastfeeding during pregnancy
- Do not stand in doorway (South Africa)
Breastfeeding “dos”

• Frequency
  – Every two hours… *from alternating breasts* -South Africa
  – “On demand”, from anywhere at any time

• Drink lots of fluids
  – Ginger beer (South Africa)
  – Increases milk supply

• Dietary
  – Eat lots of berries
  – High salt diet, eat salty nuts (Zimbabwe)

• Use breast milk to treat eye infections
Breastfeeding “don’ts”

• Dietary restrictions
  – No spicy food

• Don’t breastfeed...
  – In public
  – While sleeping
  – If pregnant
Diet and pregnancy

• Recommendations
  – Healthy diet, vegetables
  – Iron-rich food

• Restrictions
  – Seafood
  – Eggs
  – Certain fruits (bananas, oranges)
  – Potatoes
Diet and breastfeeding

- **Recommendations**
  - Well balanced diet
  - Porridge
  - Lots of fluids

- **Restrictions**
  - Alcohol
  - Caffeine
  - Spicy foods
How often women use BOTH traditional & biomedical medicine?

- Not often: 16%
- Somewhat often: 53%
- Very often: 32%
Influence baby’s gender

Do people in your community do anything to influence the baby’s gender while attempting to conceive or during pregnancy?

Yes
32%
How gender is influenced

• Sex positions
  – “Changing sex positions...” - Zimbabwe
  – “If a woman looks at her partner all the time then she will have a boy” - Uganda

• Traditional healers

• Use of herbs / herbal medications
What do women insert into the vagina to prepare for delivery?

• Herbs
• Soap
• Fist / fingers (Zimbabwe)
• Nothing (South Africa)
Changes in sex practices

• Abstinence
  – During last trimester / late in pregnancy
  – After birth
    • From one to six months
    • While breastfeeding
Who influences decisions during pregnancy?

- Mother: 89%
- Mother-in-law: 22%
- Doctor: 76%
- Pregnant woman: 25%
- Pregnant woman’s husband or partner: 20%
- Other family members: 40%
- Religious leader: 0%
- Traditional healer: 20%
- Friends: 0%
- Other, please specify: 0%

Most Influential
Influential
Who influences decisions during breastfeeding?

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<thead>
<tr>
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<th>Most Influential</th>
<th>Influential</th>
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<tbody>
<tr>
<td>Pregnant woman</td>
<td>42%</td>
<td>71%</td>
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<tr>
<td>Mother-in-law</td>
<td>23%</td>
<td>69%</td>
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<tr>
<td>Doctor</td>
<td>23%</td>
<td>46%</td>
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<tr>
<td>Mother</td>
<td>23%</td>
<td>71%</td>
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<tr>
<td>Pregnant woman’s husband or partner</td>
<td>0%</td>
<td>71%</td>
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<tr>
<td>Friends</td>
<td>23%</td>
<td>42%</td>
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<tr>
<td>Religious leader</td>
<td>0%</td>
<td>1%</td>
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<tr>
<td>Other family members</td>
<td>0%</td>
<td>18%</td>
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<tr>
<td>Traditional healer</td>
<td>0%</td>
<td>14%</td>
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<tr>
<td>Other, please specify:</td>
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Discussion

• Consider traditional and biomedical practices

• Social actors/ KI in 041:
  – consider adding mothers/ in-laws
  – TBA and traditional healer

• Do’s relevant practices/behaviors:
  – Ingestion: herbs etc., vitamins/supplements
  – some vaginal preparation (late pregnancy)

• Don’t ; taboos
  – Witchcraft (not evoked in survey)
  – Dietary restrictions
  – Sexual abstinence (differential in F and M)
Acknowledgements

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Extra slides for thursday
Primary Objectives

• To explore attitudes about use of a vaginal ring (VR) during pregnancy and breastfeeding, including participants’ 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 participants’ willingness to use or recommend/support use of oral PrEP during pregnancy and breastfeeding
Secondary Objectives

• To explore potential preference for a VR or oral PrEP during pregnancy and breastfeeding
• To explore participants’ attitudes about and perceptions of sexual activity during pregnancy and breastfeeding, including how a VR or oral PrEP might affect sexual activity
Secondary Objectives cont.

• To explore participants’ 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