What we have learned from MTN-041 (MAMMA) Views about pregnant women using PrEP and the Dapivirine vaginal ring

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Why MTN-041/MAMMA?

- Different groups of people might have different attitudes and views about using oral PrEP or the dapivirine vaginal ring during pregnancy and breastfeeding
- Groups include:

- These perspectives could influence whether or not a pregnant or breastfeeding women will use PrEP or the ring during this time

We wanted to understand whether these groups are willing to use or recommend use of these products during pregnancy and breastfeeding before conducting the DELIVER and B-PROTECTED studies at the same sites

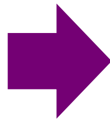
Other questions we wanted to answer through MAMMA:

- Do different groups prefer the vaginal ring or oral PrEP during pregnancy and breastfeeding?
- What do different groups think and feel about sexual activity during pregnancy or breastfeeding?
  - Would a vaginal ring or oral PrEP affect sexual activity?
- Do they feel women are at risk of HIV during pregnancy or breastfeeding?
- What community beliefs or practices may be taboo or encouraged during pregnancy or breastfeeding? Do these affect use of the vaginal ring or oral PrEP?

Study Design & Sites

Focus group discussions and in-depth interviews were conducted in order to understand or answer these questions

232 MAMMA participants



- Uganda - 68
  Kampala (MU-JHU)
- Malawi - 51
  Blantyre (JHU-CTU)
- Zimbabwe - 60
  Zengeza (UZCHS-CTRC)
- South Africa - 53
  Johannesburg (Wits RHI)

What is a focus group discussion and why do we do it?

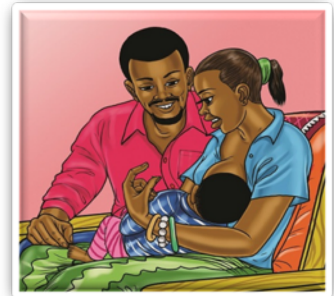
- A conversation about a particular topic involving about 4-12 people who share certain characteristics (ex: women of a certain age)
- A facilitator to lead the conversation and a note-taker
- Discussions are recorded with permission
- Length of discussion ranged from 2 hours and 25 min to 3 hours and 15 min

- We do it because:
  - Group dialogue triggers the sharing of ideas
  - Provides expert knowledge on a topic
  - Exposes diverse opinions and ideas as well as identifies where there is group consensus
  - Relatively low cost and efficient

Focus group discussions were conducted with three different groups of people

1. **Pregnant and Breastfeeding Women :** HIV-uninfected women, ages 18-40, currently pregnant or breastfeeding or had been within the previous two years
   - 2 Focus groups - 9 women, 6 women
   - Median age: 26

2. **Male Partners :** Aged 18 or older with a partner who was currently pregnant or breastfeeding or had been within the previous two years
   - 2 focus groups– 7 men, 5 men
   - Median age: 33



3. **Grandmothers:** With a daughter/daughter- in-law currently pregnant or breastfeeding or had been within the previous two years
   - 2 focus groups - 12 grandmothers, 8 grandmothers
   - Median age: 57

What is an in-depth interview and why do we do it?

- Face-to-face conversation between a researcher and a study participant
- Semi-structured guide (questions)
  - Open-ended questions
  - Participants answers in their own words (cannot be answered with "yes" or "no")
- Recorded with permission
- Length of interview ranged from 50 minutes to 2 hours and 14 min

- We conduct IDIs to:
  - To understand an individual's **feelings, opinions,** and **experiences** about a particular topic
  - To address sensitive topics that a person might not want to share in group settings

In-Depth Interviews were conducted with "Key Informants"

- Key informants are people who have first hand knowledge about what is going on in the community
- At Wits RHI:
  - 6 in-depth interviews were conducted
    - Nurse (2)
    - Religious leader (x1)
    - Traditional care provider (x1)
    - Clinical doctor (x1)
    - Study coordinator (x1)
  - 4 Female, 2 male, median age was 36

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What we learned from MAMMA
(based on participant responses)

Is there a belief that pregnant women are at risk for HIV?

YES

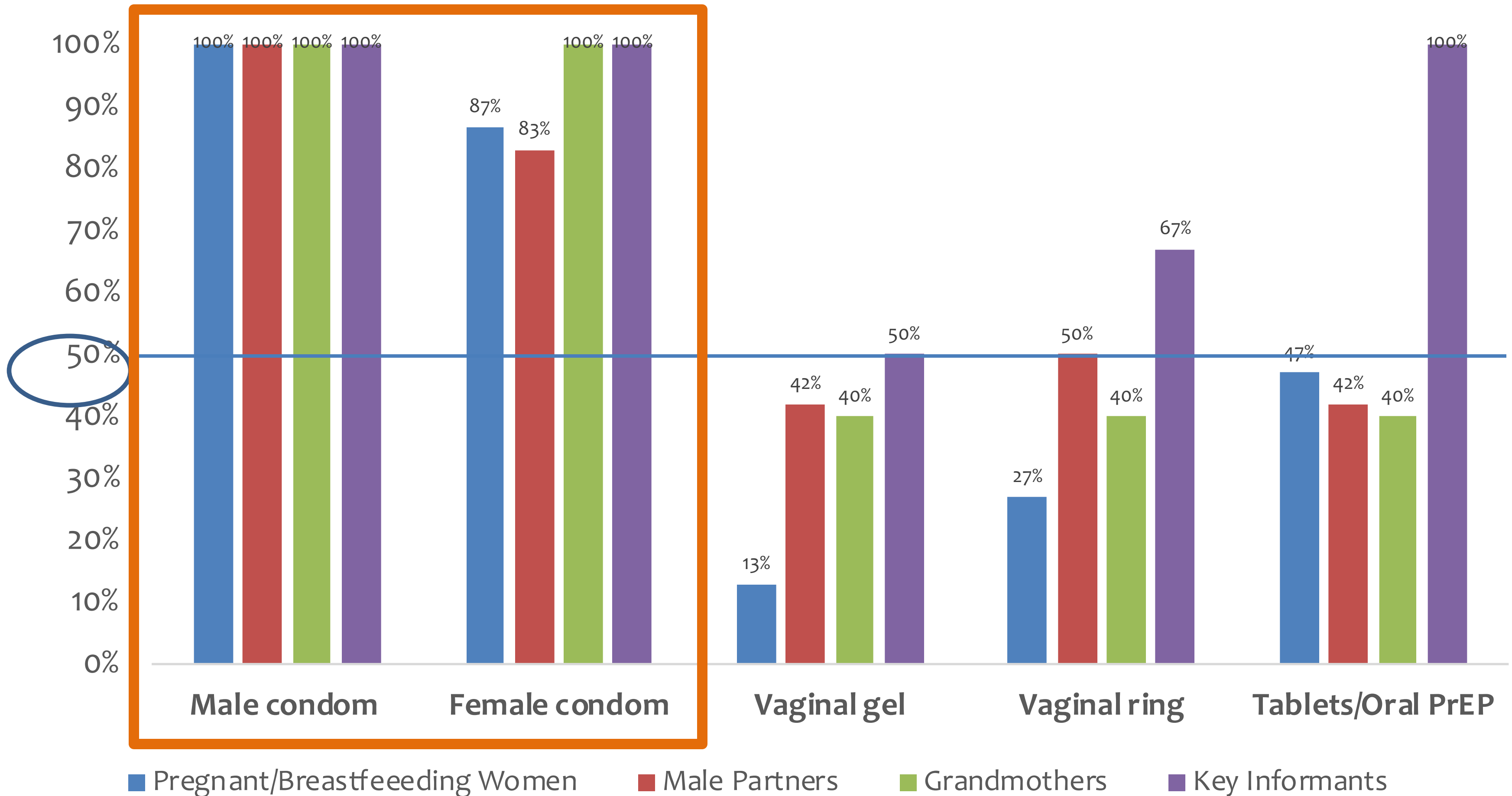
Across all groups, it was recognized and reported that pregnancy is a period of high risk for various reasons

- Biological factors:
  - Weak immune system
- Behavioral factors:
  - Increased/decreased desire for sex in women
  - Men dislike using condoms with married/pregnant partners (unnecessary since partner is already pregnant)
  - Male partner refusal to test for HIV (assumes same status as female partner)
  - Women at risk of rape
  - Women's use of recreational drugs and alcohol while pregnant

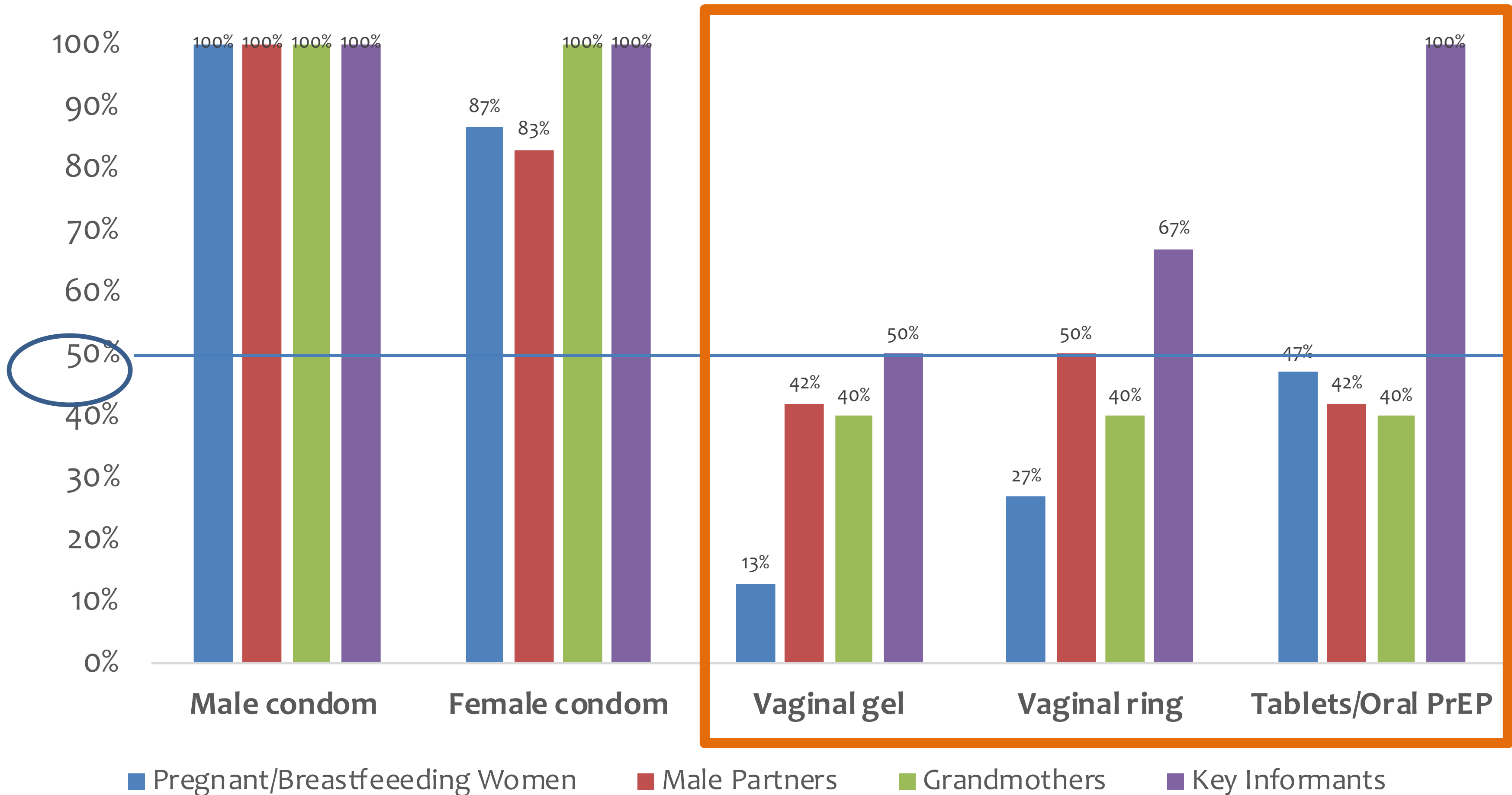
Is there a belief that pregnant women are at risk for HIV?

- Behavioral factors:
  - Pregnant women seen as attractive (“hot bodies”) - may lead them to have multiple sexual partners
  - Men’s lack of desire for sex with pregnant partner (leads them to seek other sexual partners)
    - Lack of interest or attraction
    - Women’s hormonal changes - Negative attitudes toward male partners
    - Concern about hurting baby (particularly later in pregnancy)

Awareness of HIV Prevention Methods



Awareness of HIV Prevention Methods



Pregnant & Breastfeeding Women

- When asked about their previous use of HIV prevention methods:
  - Most had used male condoms (93%)
  - Two had used female condoms (13%)
  - Three had used oral PrEP pills (20%)
  - None had ever used vaginal gel or vaginal ring

Who Influences Pregnant and Breastfeeding Women's Decisions (Participants perspectives)

Antenatal care and HIV testing

- 53% of the pregnant and breastfeeding women said they make these decisions together with their partner
  - 47% said that a woman decides for herself
- 25% of men thought these decisions were made jointly
  - 50% of men said that a woman decides for herself, and the other 25% said that men make these decisions

Medication and vitamin use

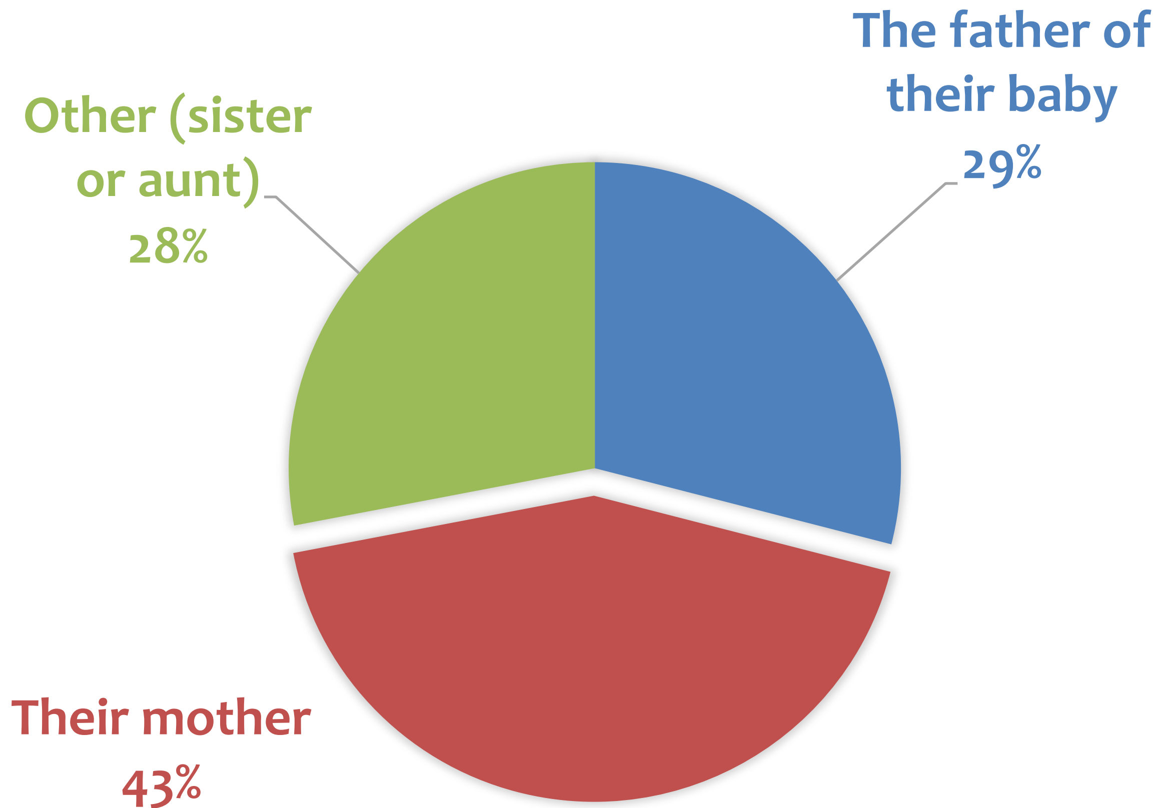
- 60% of pregnant and breastfeeding women and male partners said the woman herself makes decisions
- 40% said that decisions are made jointly

Who has influence on a woman's decisions during pregnancy? Perspectives from all groups

- Their male partners
  - Differing opinions among pregnant and breastfeeding women about how involved a male partner should be in decision making
  - Men desire involvement
- Important voices in the community
  - Health care providers
  - Religious leaders (e.g. pastors)
- Other trusted voices in the community
  - Elders/grandmothers
  - Community leaders
  - Traditional birth attendants, healers, and practitioners

Who women listen to most during pregnancy?

Pregnant & Breastfeeding Women said:



HIV Prevention Products

- A 6-minute video which described the two HIV prevention products was shown to the participants
- Participants were also shown sample products at this time (oral PrEP pills and vaginal ring)

Perspectives From Study Groups

What people would like about PrEP that could help in using it

- Familiarity and comfort with daily pills
- Whole body protection vs. vaginal protection
  - Boosts women's self-confidence
- Protection of mother and baby
  - Peace of mind
- Perception that pills are:
  - "tested", "approved", "supported around the world", "have no side effects"
- **Endorsement by health care providers is important**

> *"I think the pill is alright because it will protect the baby as well, during pregnancy… it will protect the baby because they developed it knowing what effect it will have."*
>
> **(Makhosi, Female)**

Perspectives From Study Groups

Potential barriers to oral PrEP use

- Lack of male partner support
- Taboo to take medicine while pregnant unless prescribed by a health care provider
- Lack of education/not "understanding"
- Rumors related to HIV stigma in the community
- Lack of leadership and peer support (e.g. Government, elders/family, friends, etc.)

Perspectives From Study Groups

Product-specific barriers to oral PrEP use

- Big size, bitter taste
- Dosing regimen related:
  - **Forgetfulness/stressful** to remember
    - Particularly for pregnant teenagers
  - Pill burden (e.g. tedious and demanding)
  - Interaction with other drugs (e.g. oral contraceptive pills)
- **Stigma**: packaging, color, similarities to ART
- Not familiar with using pills as a way to prevent HIV
- Potential for the pill to introduce mistrust in relationships

> *"I think packaging… will play a big role… if its packaging it's the same as the packaging for HIV pills and we get them from the clinic we queue with people… [People will say] "I have seen her at clinic carrying a blue packet of the tablets, it's those ones, it means she is like that," you know stigma"*
>
> **(Lisa, Female)**

Perspectives From Study Groups

Pregnancy-specific concerns about oral PrEP

- Concern about fetal health:
  - Association with miscarriage
- Adverse pregnancy outcomes (e.g. deformities)
  - Belief that fetus is particularly vulnerable “early on” (2-3 mo.)
- Worsening of pregnancy side effects (e.g. fatigue, vomiting, dizziness, headache)

“You might be worried that the pill will make the baby disabled. During pregnancy and after delivery. The baby may be disabled, so yeah”
(Pink, Female)

Perspectives From Study Groups

What people would like about the vaginal ring that could help in using it

- **Monthly dosing regimen and discreetness**
  - Peace of mind (low stress)
  - Convenient (will not interfere with daily life)
  - Hidden from male partners and others
    - Avoid gossip/rumors
- Local (vaginal) exposure
- **Endorsement by health care providers is important**

"…I prefer the ring because you cannot forget it you will be wearing it the whole month…so this is the safest one…With pills what if she goes out Saturday and Sunday, and you only see her on Monday, and she didn't take the pills…So, it's better the ring"

(Maki, Grandmother)

Perspectives From Study Groups

Potential barriers to vaginal ring use

- Lack of male partner support
- Lack of familiarity with method (vaginal insertion)
- Community level barriers:
  - Lack of education
- Belief that vaginal ring "promotes promiscuity"
- Potential for the ring to introduce mistrust in relationships

"…I doubt they would agree and want their partners to use it. For them it would be questionable, how do you use such a product knowing that it's just me and you… it would be like undermining their manhood because….it means… you can always go outside [cheat] with that ring as you are…protected."

(Mastermind, Male Partner)

Perspectives From Study Groups

Potential product-specific barriers to vaginal ring use

- Big, hard, “scary”
- Interference with sex:
  - Impact on sexual pleasure
  - Male partner may feel it
  - Penis may go through ring
- Interference with menstrual cycle
- Stays in situ for one month
  - Unhygienic
  - Associated with possible vaginal infection or reproductive cancer/damage to reproductive organs
- Concern that ring will move out of place or get lost in body

Perspectives From Study Groups

Pregnancy-specific concerns about vaginal ring use

- May add to the physical discomfort of pregnancy
  - Related to vaginal insertion process and placement of ring in the vagina
- Fear/taboo of inserting products vaginally during pregnancy
  - Vaginal insertion may lead to questions about attempted abortion
- Concern about the impact on head/brain development of baby
- Concern about delivery if vaginal ring is not removed
  - e.g. strangling, hurting or blocking the baby
  - Baby might come out holding the ring

Perspectives From Study Groups

Would women use these products during pregnancy?

Across all groups, pregnancy was perceived as a high-risk period and participants were willing to use/recommend use of products **if:**

- Guaranteed safe and effective for woman and baby
- Health care provider prescribed and endorsed
- Thorough education is provided NOT just to pregnant and breastfeeding women but also to:
  - Male partners
  - Community members/family
  - Religious leaders
  - Traditional birth attendants, healers, and practitioners

Perspectives From Study Groups

Motivations for Product Use

- **Protection of woman and baby**
  - **Including healthy pregnancy outcome**
- Emphasis on staying healthy as a person AND as a family
  - *"…the most important thing is the safety of both the mother and the foetus…and then the nice part about it is she will also be protecting you [the partner] from getting the virus as well."* (**Mastermind, Male partner**)
- Recognition in several focus group discussions that preference for pills vs. ring is a matter of **personal preference**

Practical Recommendations

- **General**
  - Product education:
    - Explain what we know and don't know (e.g. safety for non-pregnant women)
    - Explain product mechanism of action, side effects
  - Product use ambassadors
    - Power of testimonials from real users and pregnant and breastfeeding women
- **Oral Prep**
  - Consider strategies to address HIV stigma in the community
  - Explanation of side effects (explicitly asked by participants)

Practical Recommendations

- **Dapivirine vaginal ring**
  - Need for more product information
    - Pregnancy-specific anatomy education to address:
      - Insertion/removal process
      - Who can/will do it
    - Location of vaginal ring in body
  - Explanation of side effects (explicitly asked by participants)
- **Male Partners**
  - Education efforts targeted to male partners
  - Men offer support as long as they are fully informed and involved in decision making "from the beginning"
  - Counseling on male partner disclosure (tailored to participant circumstance)

Acknowledgments

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