



UNIVERSITY OF ZIMBABWE
COLLEGE OF HEALTH SCIENCES CLINICAL TRIALS RESEARCH CENTRE

Saving Lives Through Innovative Research Strategies

What we have learned from MTN-041 (MAMMA)

Views about pregnant and breastfeeding women using PrEP and the Dapivirine vaginal ring

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Ensuring the HIV Prevention Needs of Pregnant and Breastfeeding Women

Harare – 28 January 2020

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 want 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?

- A conversation about a particular topic involving 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



Focus group discussions were conducted with three different groups of people

- 1. Pregnant and Breastfeeding Women :** HIV-negative-women, ages 18-40, currently pregnant or breastfeeding or had been within the previous two years
 - 2 Focus groups: 10 women, 7 women, median age 25
- 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: 9 men, 7 men, median age 25
- 3. Grandmothers:** With a daughter/daughter-in-law currently pregnant or breastfeeding or had been within the previous two years
 - 2 focus groups: 9 grandmothers, 8 grandmothers
 - Median age: 45



What is an in-depth interview?

- 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



In-Depth Interviews were conducted with “Key Informants”

- Key informants are people who have a broad perspective about what is going on in the community
- At Zengeza:
 - 10 in-depth interviews were conducted
 - 2 nurses
 - 2 religious leaders
 - 2 traditional care providers
 - 2 social service provider
 - 1 community health worker
 - 1 community leader
 - 8 Female, 2 male
 - Median age was 52





What we learned from MAMMA

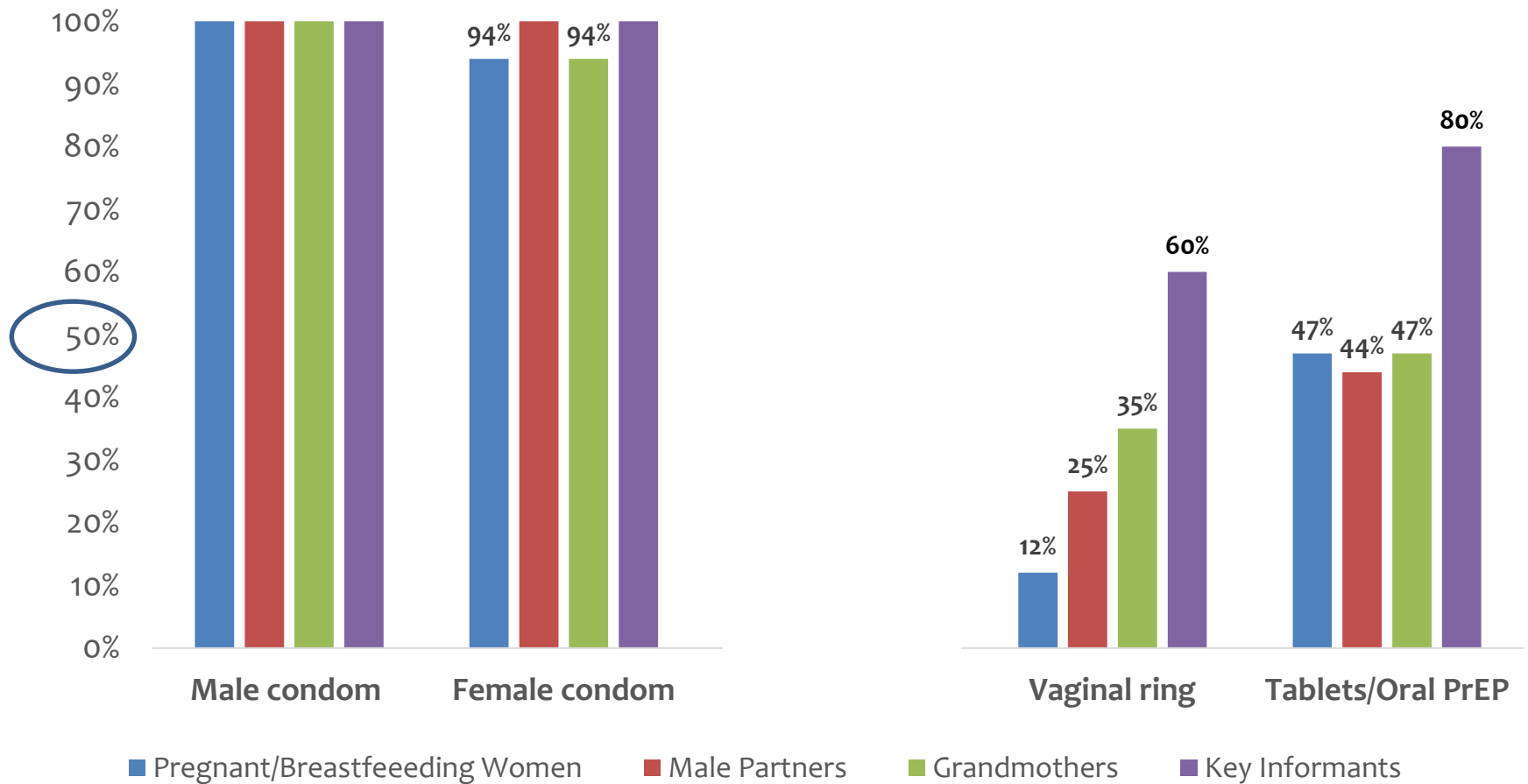
(based on participant responses)

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:
 - Decreased desire for sex in women
 - Men's lack of desire for sex with pregnant partner
 - Breastfeeding women give more attention to babies than men
 - Men dislike using condoms with married/pregnant partners
 - Male partner refusal to test for HIV (assumes same status as female partner)
 - Women's use of recreational drugs and alcohol while pregnant

Awareness of HIV Prevention Methods



Pregnant & Breastfeeding Women (N=17)

- When asked about their previous use of HIV prevention methods:
 - More than half had used male condoms (59%)
 - None had ever used female condom, vaginal ring, or oral PrEP pills

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

Antenatal care and HIV testing

- 41% of the pregnant and breastfeeding women said they make these decisions together with their partner
 - 53% said that a woman decides for herself
- 63% of men thought these decisions were made jointly
 - 19% of men said that a woman decides for herself, and another 19% said that men make these decisions

Medication and vitamin use

- 50% of pregnant and breastfeeding women and male partners said the woman herself makes decisions
- 32% said that decisions are made jointly

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

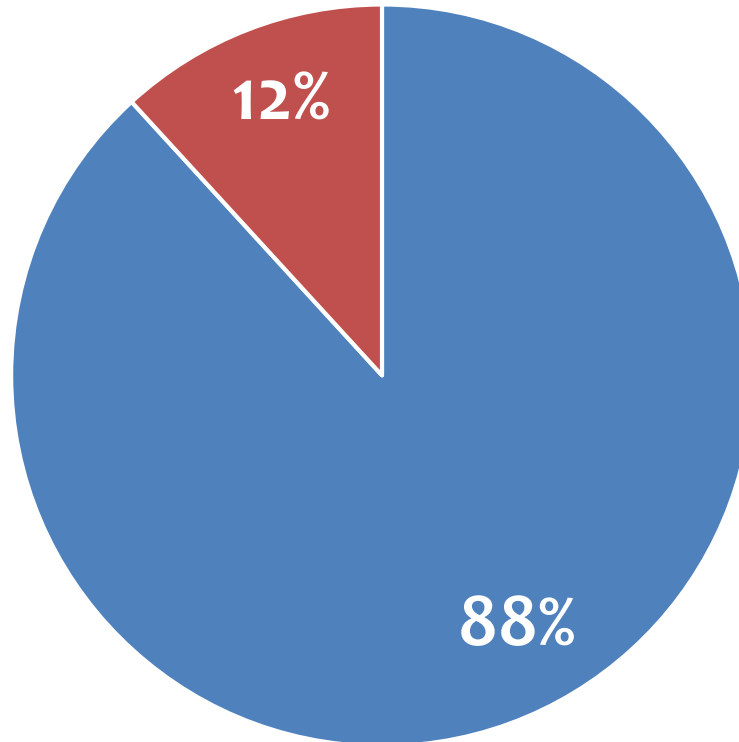
- Their male partners
 - Differing opinions among pregnant and breastfeeding women about how involved a male partner should be in decision making
 - Men desire involvement
- Important voices in the community
 - Health care providers
 - Religious leaders (e.g. pastors)
- Other trusted voices in the community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





Who women listen to most during pregnancy?

Pregnant & Breastfeeding Women said:

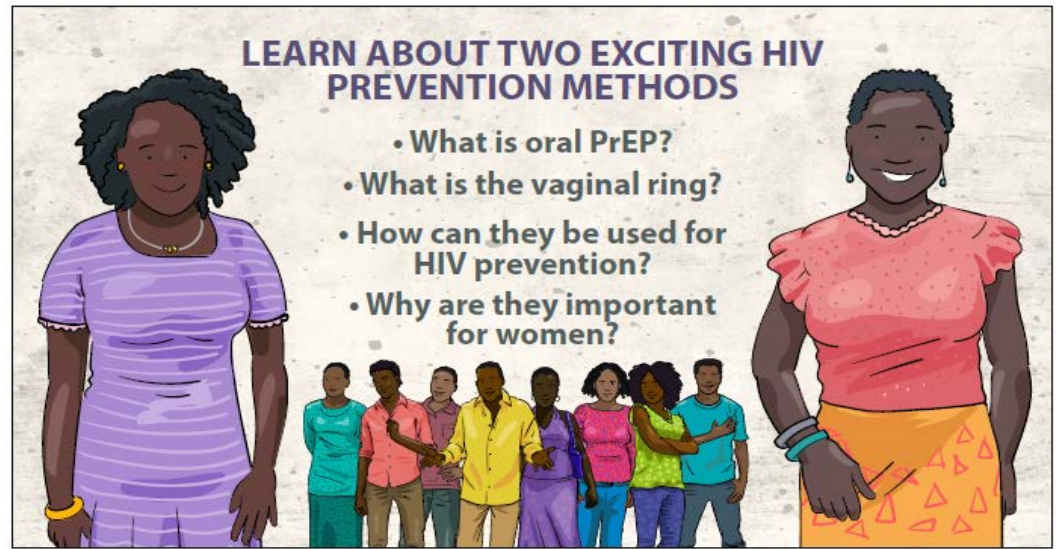


■ The father of their baby

■ Their doctor

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)





What did groups say they liked about PrEP that might help in using it?

- Familiarity and comfort with daily pills
- Whole body protection vs. vaginal protection
- 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 just think that I will have peace of mind because I will be knowing that I am on the safe side.”
(Jane, Female)



What did they say could be potential barriers to using oral PrEP?

- 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.)



What about PrEP itself was seen as a potential barrier to 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

“These pills are tricky, if your family members start to see you taking these pills every day they will not understand you. Even when you try explaining that it is to prevent HIV some of our parents might take long to understand or might even think that you are on ART”

(Tsitsi, Female)



What about using oral PrEP during pregnancy?

Concerns 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)

“As a pregnant mother, what first comes into my mind is the issue of side effects to me and the baby, because just like any other pill there are side effects. The other thing is, since my hormones are already tempered around with because of pregnancy, will the PrEP pill go down well with me?”

(Tanya, Female)



What did groups say they liked about the ring that might help in using it?

- **Monthly dosing regimen**
 - Peace of mind (low stress)
 - Convenient (will not interfere with daily life)
 - Discreetness
 - Avoid gossip/rumors
- Local (vaginal) exposure
- **Endorsement by health care providers would be important**

“So the ring is discreet. No man will be able to tamper around with it. It is only you who knows that, “I must now go and change the ring”.”

(Mbuya, Grandmother)



What did they say could be potential barriers to using the vaginal ring?

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

*“Already as I progress in pregnancy the vagina will be enlarging and with this [Ring] now, what will the sex partners say? They will not enjoy sex.”
(Jane, Female)*



What about the ring itself was seen as a potential barrier to 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 inserted for one month
 - Not hygienic
 - 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



What about using the ring during pregnancy?

- 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



Would women use these products during pregnancy ?

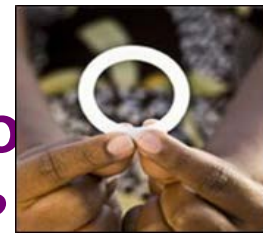


Across all groups, pregnancy was perceived as a high-risk period and participants were willing to use/recommend use of products **if:**

- 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



What might help to motivate women to use PrEP or the ring during pregnancy?



- **Protection of woman and baby**
 - Including healthy pregnancy outcome
- Emphasis on staying healthy as a person AND as a family
 - “... you will be able to protect your baby from HIV or even yourself during pregnancy when you are using the ring and the pill.”
(Tanatswa, Zengeza)
- Recognition in several focus group discussions that preference for pills vs. ring is a matter of **personal preference**



Practical Recommendations



- **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
 - Need to explain side effects (explicitly asked by participants)



Practical Recommendations



- **Dapivirine vaginal ring**
 - Need 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)

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