

### Different views about pregnant women using PrEP and the ring: What we have learned from MTN-041

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## Why MTN-041?

- Different groups of people might have different attitudes and views about using oral PrEP or the dapivirine ring during pregnancy and breastfeeding
- The perspectives of these groups could influence whether or not a woman will use PrEP or the ring during pregnancy and breastfeeding
- What kind of groups?
  - Pregnant and breastfeeding women
  - Male partners
  - Mothers or mothers-in-law (grandmothers of the babies)
  - Doctors, nurses, traditional leaders and others in the community
- We wanted to understand whether these groups would be willing to use or recommend these products during pregnancy and breastfeeding -- before conducting the DELIVER and B-PROTECTED studies

# Other questions we want to answer through MTN-041:

- 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?

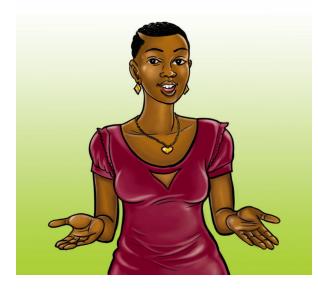
- Do they feel women are at risk of HIV during pregnancy or breastfeeding?
- What community beliefs or practices may be taboo or encouraged during pregnancy or breastfeeding? Do these affect use of the vaginal ring or oral PrEP?

## **Study Design**

 Each site conducted in-depth interviews and focus group discussions to try to answer these questions

## What is an in-depth interview?

- A face-to-face conversation between a researcher and a study participant
- Uses a "semi-structured questionnaire"
- Involves open-ended questions
  - The person answers in their own words (not a "yes" or "no")
- Is recorded with permission
- Length of interviews range
  - In Blantyre they were about an hour or
     1.5 hours



## Why do we do in-depth interviews?

- 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

# What is a focus group discussion?

 A conversation about a particular topic involving about 4-12 people who share certain characteristics

-such as women of a certain age

 1-2 facilitators lead the conversation, and there is a note-taker



- Discussions are recorded with permission
- Length of discussions in Blantyre ranged from 1-2 hours

### Why do we do focus group discussions?

- Group dialogue "triggers" the sharing of ideas
- Provides "expert" knowledge on a topic
- Useful for understanding if there is overall agreement (group consensus) on a topic or issue, or if views or opinions differ, and what these are
- Help get deep into topics to understand group norms
- Relatively low cost and efficient

# MTN-041 involved focus group discussions with three different groups of people

#### **Pregnant and Breastfeeding Women:**

• HIV-uninfected women, ages 18-40, who were currently pregnant or breastfeeding or had been within the previous two years

#### Male Partners:

• Men aged 18 or older with a partner who was currently pregnant or breastfeeding, or had been within the previous two years

#### Grandmothers:

• Grandmothers who had a daughter or daughter-in-law currently pregnant or breastfeeding, or within the previous two years

### In-Depth Interviews with "Key Informants"

- A key informant is someone who has first hand knowledge about what is going on in the community, and may include:
  - Clinicians (e.g., obstetrician, nurse, pharmacist, midwife)
  - Traditional care providers (e.g., traditional birth attendant, healer)
  - Social service providers (e.g., social worker, family planning counselor)
  - Community health workers
  - Community leaders (e.g., local chief, religious leader)

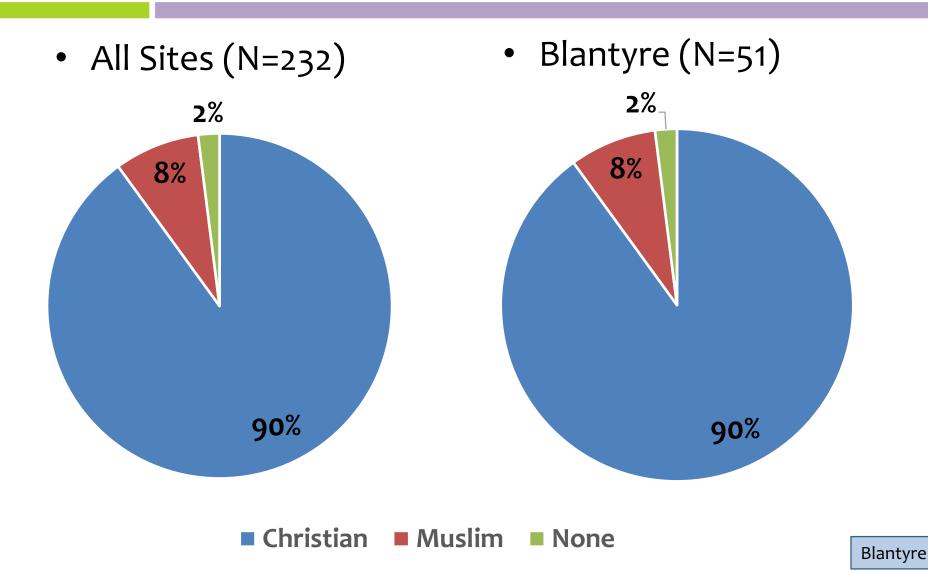
### **Overview of MTN 041 participants across** all 4 sites

- 232 participants took part across sites:
  - Blantyre, Malawi: 51
  - Kampala, Uganda: 68
  - Johannesburg, South Africa: 53
  - Zengeza, Zimbabwe: 60
- Study groups and interviews at each site:
  - Pregnant & Breastfeeding Women: 2 focus groups discussions
  - Male Partners: 2 focus group discussions
  - Grandmothers: 1-2 focus group discussion
  - Key Informants: 6-10 in-depth interviews

### **Overview of participants in Blantyre**

- Study groups and interviews in Blantyre
  - Pregnant & Breastfeeding Women: 2 focus groups discussions
  - Male Partners: 2 focus group discussions
  - Grandmothers: 1 focus group discussion
  - Key Informants: 10 in-depth interviews

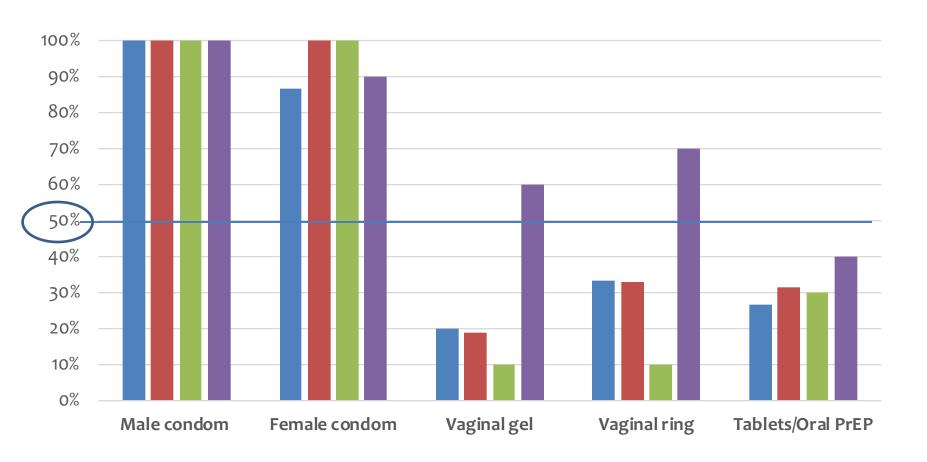
### **Religious distribution (%)**



• The information on the following slides is specific to Blantyre



### **Awareness of HIV Prevention Methods**



■ Pregnant/Breastfeeding ■ Male Partners ■ Grandmothers ■ Key Informants

Blantyre

### **Male Partner Focus Group Discussions**

- 2 focus groups were conducted, one with 6 men and one with 10 men
- Average age: 29
- Most men:
  - Were married or living with partner (94%)
  - Had partners who were not pregnant (79%)
  - Earned an income of their own (81%)
- All men had at least one child

### **Grandmother Focus Group Discussions**

- One focus group took place with 10 participants
- Median age: 48
- Most grandmothers:
  - Lived with their children (80%)
  - Earned an income of their own (80%)
  - Had not completed secondary education (90%)



### **Key Informant Interviews**

- 10 in-depth interviews were conducted
- Median age: 58
- 6 female, 4 male

- Number and Profession/Role
  - Nurse (2)
  - Religious leader (1)
  - Social service provider (1)
  - Traditional care provider (2)
  - Clinical doctor (1)
  - Community Health Worker (1)
  - Chief (1)
  - Pharmacist (1)

#### Pregnant & Breastfeeding Women Focus Group Discussions

- Two focus groups were conducted
- Median age: 26
- Most women:
  - Were Christian (93%)
  - Earned an income of their own (60%)
  - Had not completed secondary education (60%)
  - Lived in a household with a mobile telephone (73%)
- Of note:
  - About half of women were currently pregnant (53%)
  - More than half worried about not having enough food more than 3 times in past 4 weeks (27%)

### Pregnant & Breastfeeding Women

- When asked about their previous use of HIV prevention methods:
  - Most had used male condoms (73%)
  - None had ever used a female condom, oral PrEP, vaginal gel, or vaginal ring

# Who makes decisions about a woman's antenatal care and HIV testing?

- Majority of pregnant and breastfeeding women and male partners said they make joint decisions about a woman's antenatal care and HIV testing (about 60%)
- Less than half said that a woman makes this decision for herself (about 40%)

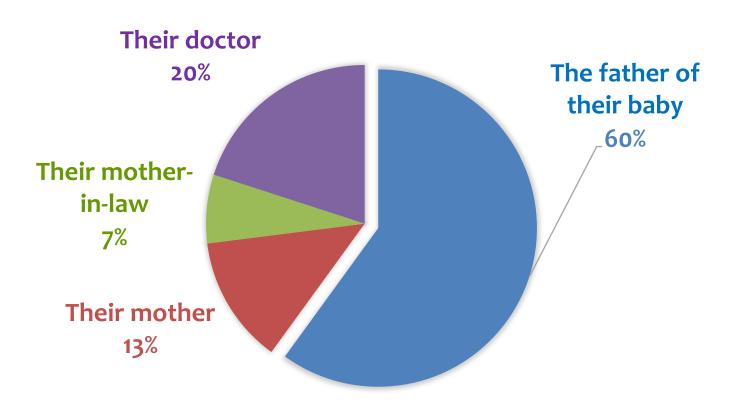
# Who makes decisions about a woman's medication and vitamin use during pregnancy?

- Over half of pregnant and breastfeeding women and male partners said the woman herself makes decisions around medication and vitamin use (53%)
- Less than half said that decisions are made jointly (40%)
- Few said that the male partner decides (6%)



# Who do women listen to most during pregnancy?

#### Pregnant & breastfeeding women said:



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

- Across all groups, it was recognized that pregnancy is a period of high risk
  - Biological factors:
    - Weak immune system
    - Faster blood flow (grandmother perspective)
  - Behavioral factors:
    - Women's increased or decreased desire for sex
    - Men dislike using condoms with married partners
    - Men's lack of desire for sex with pregnant partner
      - Lack of interest or attraction to women
      - Women's negative attitudes toward male partners due to hormonal changes
      - Concern about hurting baby (particularly later in pregnancy)
    - Periods of time without sex due to cultural beliefs (stopping sex around the 6<sup>th</sup> or 7<sup>th</sup> month of pregnancy)
  - These behavioral factors lead men to seek other sexual partners

### **Video about HIV Prevention Products**

- A 6-minute video describing the two products was shown to all participants in the middle of the interview/focus group discussion
- Participants were also shown samples of oral PrEP tablet and the vaginal ring at this time



 The following slides present findings from the discussion related to oral PrEP and the vaginal ring that took place after the video was played

### Motivations for Product Use: Perspectives from all study groups

- Protection of woman and baby

   Including healthy pregnancy outcome
- Emphasis on staying healthy as a person AND as a family
- Recognition in several focus group discussions that preference for pills vs. ring is a matter of personal preference

"I would speak like this...if the woman has made a choice to use the pill or the ring **you are protecting your life and also making your family healthy**." (Debora, Blantyre)



# What do people like about PrEP that would help in using it?

- Familiarity and comfort with daily pills
- Whole body protection vs. vaginal protection
- Alternative to condom use
- Taking it before bed (so it works while asleep)
- Protection of mother and baby
  - Peace of mind
- Perception that pills are:
  - "tested," "approved," "supported around the world," "have no side effects"
- Endorsement by chiefs and health care providers

"...discussion with the chiefs it is a good idea, because in the communities, chiefs are ones who put rules ...the chiefs have their own ways of reinforcing things to happen as they want their people to be prevented..." (Chikondi, Male)



# What are some potential barriers to oral PrEP use across all groups?

- Lack of male partner support
- Lack of education/not "understanding"
- Rumors in the community (lack of community support)
- Lack of leadership support (e.g. chiefs, traditional healers, family, friends, etc.)
- Religious beliefs/practices



# What are some product-specific barriers to oral PrEP use across all groups?

- Big size, bitter taste
- Dosing regimen related:
  - -Forgetfulness/stressful to remember
  - Impact on appetite
  - 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
- Association between pills and side effects in general: weight loss/gain, hunger patterns, bleeding

"The problem with the pill is being forgetful...I think for those that can remember they can take it but not for those that are forgetful like me...I can't try it...[giggling]...it is better I opt for the ring because I will just stay with it...[laughing]" (Triza, female)



#### What are some pregnancyspecific 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)

"...Taking these tablets to protect yourself from HIV while you are pregnant can be worrisome... you don't know how the drugs will work in your body while you are pregnant. They may come with so much strength that may lead to fatigue, or can even destroy the baby you are expecting. *So, yes it is good that the drugs will protect* from HIV, but they may bring some undesirable side effects while you are pregnant; as it is said that when one is pregnant, she should not be taking drugs." (Lucy, female)



# What do people like about the vaginal ring that would help in using it?

- Monthly dosing regimen and discreetness
  - Peace of mind (low stress)
  - Hidden from male partners and others
    - Avoid gossip/rumors
- Local (vaginal) exposure
- Male partner preference for vaginal ring over pills (discreet, useful in context of multiple concurrent partners)
- Endorsement by health care providers and chiefs is important

"And also this vaginal ring I feel is a good method because when you put it once, it means it is there for the whole month and you will be using that very same ring...once you insert it, you are done and you just have to remember the date to change it." (Favour, Male)



# What are some potential barriers to vaginal ring use across all groups?

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

"It is not allowed for a pregnant woman to be inserting the ring in the vagina because when a woman is pregnant there are many problems or I should say that so many happenings in the same vagina... I should say that she cannot be busy having time to take care of the ring..." (Chikondi, Male)





What are some potential product-specific barriers to vaginal ring use across all groups?

- Big, hard, "scary"
- Interference with sex:
  - Impact on sexual desire
  - Male partner may feel it
  - Penis may go through ring
- Interference with menstrual cycle
- Concern that ring will move out of place or get lost in body
- Concern about infection or dirtiness due to monthly dosage
- Belief that leaving the ring in place can lead to reproductive cancers



What are some 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 taboo 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

#### Who has the most 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 be in a decision to use either product
  - Men desire involvement
- Who are the most important voices in the community?
  - Health care providers
  - Religious leaders (e.g. pastors)
- Other trusted voices in the community?
  - Elders/grandmothers
  - Community leaders and village chiefs
  - Traditional counselors, traditional birth attendants, healers, and practitioners

# Would women use these products during pregnancy?







- Across all groups, pregnancy is perceived as a high-risk period and participants are willing to use/recommend use of products if:
  - They are safe for the woman and baby
  - Healthcare providers prescribed and endorsed them
  - Thorough education is provided NOT just to pregnant and breastfeeding women but also to:
    - Male partners
    - Community members/family
    - Religious leaders
    - Chiefs



## Practical Recommendations: Safety/Efficacy

#### • Product education:

- Explain what we know and don't know (e.g. safety for non-pregnant women, address "tested/approved" belief)
- Explain product mechanism of action, side effects

#### Product use ambassadors

- Power of testimonials from real users and pregnant and breastfeeding women
- Education and product use: discuss the context of research for MTN-042 vs. clinical practice

## Practical Recommendations: 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)



### Practical Recommendations about 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)

"What I see for me that men can understand but also become willing that their wives...can take part in the study, it is one way that you could have branches, small ones like in the areas. Just like we are here, one to an area, one to area so that he can be one who educate and campaign to men so that men can understand better. That is one way according to how I see."

(Chikondi, Male partner)

### Discussion

