

Stakeholder Attitudes and Beliefs About Use of HIV Prevention Products during Pregnancy

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Overview

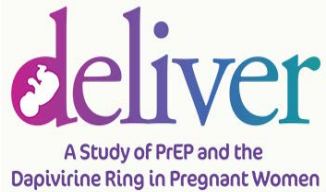
- MTN-041/MAMMA: Overview and Methods
- Perceived HIV risk
- Key influencers for women
- Product concerns by trimester
- Perspectives on study product use
- Practical recommendations for stakeholders and MTN-042 study team
- Informing the DELIVER and B-PROTECTED studies

MTN-041/MAMMA

- MAMMA: **M**icrobicide/PrEP **A**cceptability among **M**others and **M**ale Partners in **A**frica
- Exploratory acceptability study that utilized focus group discussions (FGDs) and in-depth interviews (IDIs)



Why MAMMA?



- Two HIV prevention products to be evaluated for safety in future phase IIIb trials



Truvada for daily oral PrEP

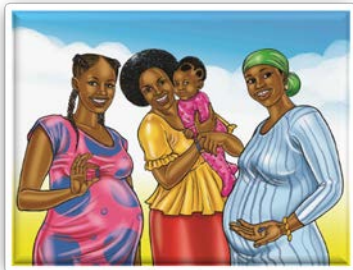


Monthly DPV vaginal ring

Why MAMMA?

- **End-users and other stakeholders** might have different attitudes and views about using these prevention products during pregnancy and breastfeeding
- These perspectives could influence whether or not pregnant or breastfeeding women will use PrEP or the ring during this time
- **Groups included:**

P/BF Women



Male Partners



Grandmothers



Key Informants



Main Research Questions:

- 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
- Provide insights and recommendations to inform protocol and trial implementation



Sample Size and Sites (N=232)



-  **Chitungwiza, Zimbabwe (N=60)**
-  **Johannesburg, South Africa (N=53)**
-  **Blantyre, Malawi (N=51)**
-  **Kampala, Uganda (N=68)**

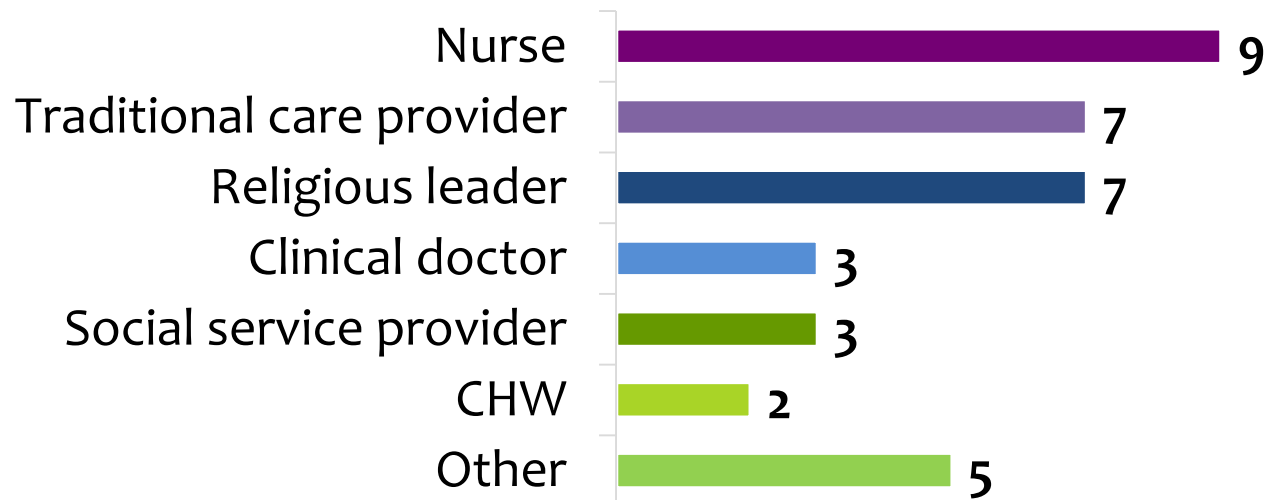
Key Characteristics of P/BF Women & Male Partners

	Women	Men
Total	N=65	N=63
Mean age (range), years	27 (19-40)	31 (19-54)
Secondary education completed	51%	56%
Married or living with partner	77%	81%
Living with parents	19%	18%
Living with child	68%	56%
Currently pregnant/Partner pregnant	50%	32%
Median number of live births/ children fathered	2 (0-6)	1 (0-8)
Ever breastfed (parous women, N=53)	91%	NA

Key Characteristics of Grandmothers & Key Informants

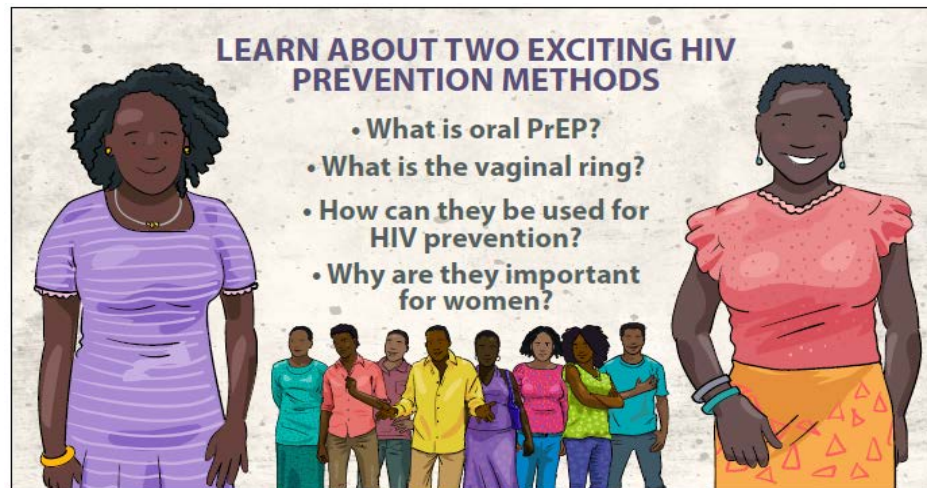
	Grandmothers	Key Informants
Total	N=68	N=36
Mean age (range), years	51 (36-69)	50 (25-79)
Secondary education completed	30%	78%
Female	100%	69%
Living with child	81%	58%

Number of KI in Profession/Role



Methods

- We conducted 23 FGDs and 36 IDIs across the 4 countries
- Participants were recruited from various community settings
- During the interview/FGD Participants watched a 6-minute video which described the two HIV prevention products
- Participants handled sample placebo products (PrEP pills and ring)



Groups of Participants

Groups	N	FGDs/Site	IDIs/site
Pregnant & Breastfeeding Women	65	2	--
Male Partners	63	2	--
Grandmothers	68	1-2	--
Key Informants	36	--	6-10
TOTAL	232	23	36

Results



Are pregnant women seen as being at high risk for HIV? **YES**

Across all groups, pregnant women are seen as being at a period of high risk

- Bicultural

*I think when we are pregnant like this sex is limited so the husband will go out there to find it ...nurses encourage us to give men sex, even when you do not feel like it to avoid him from going out
(Tsitsi, Zimbabwe)*

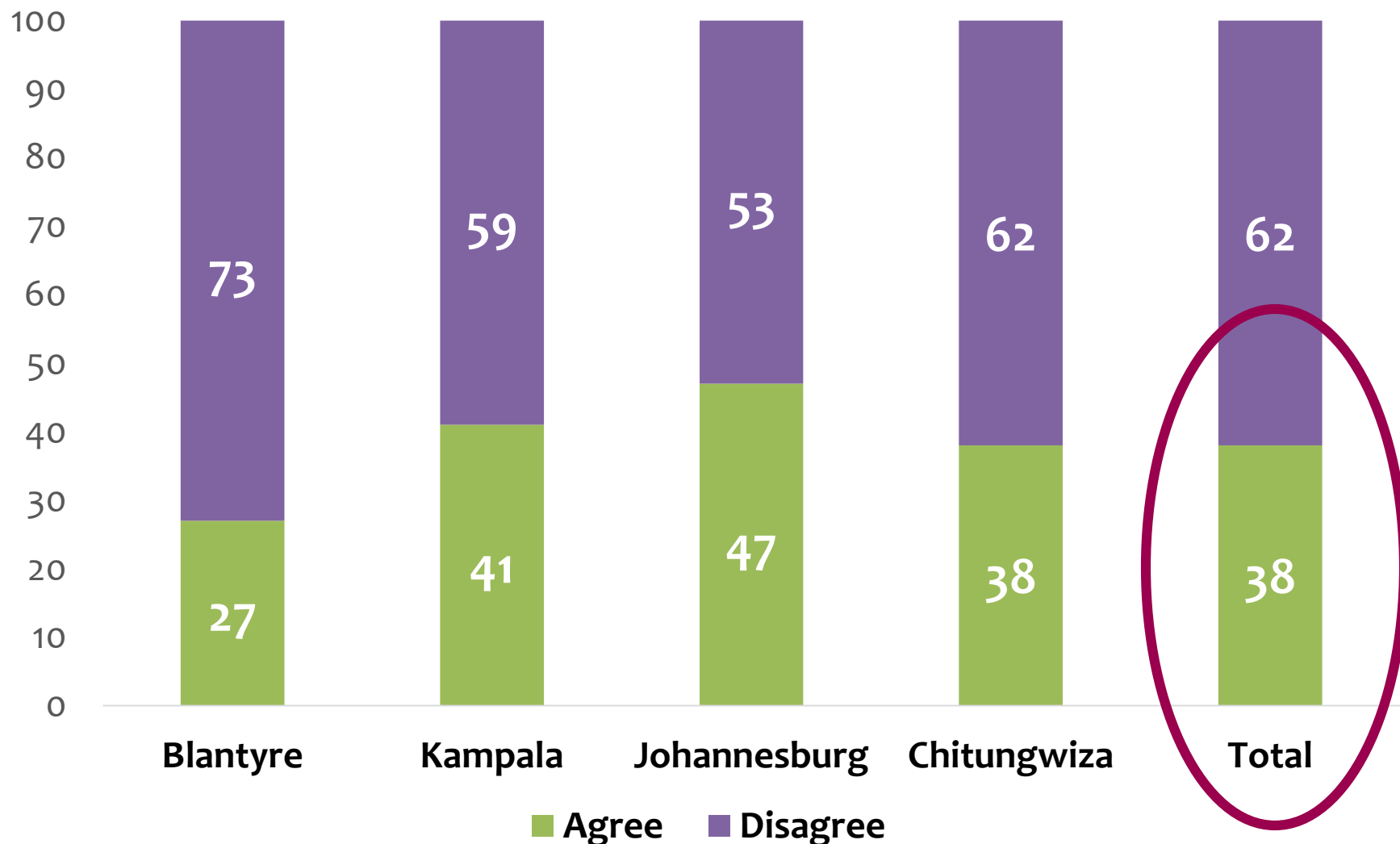
as

females

- Women at risk

- Women's use of recreational drugs & alcohol while pregnant

PBF Women (N=65): “My partner might be having sex with someone else” (%)



Key Influencers for Pregnant Women

- Women were asked, “besides you, who has the most influence over your decisions during pregnancy?”
 - At all sites except Johannesburg, **male partners** were identified by women as having the most influence over decisions during pregnancy (60-88% of women)
 - In Johannesburg, **grandmothers** were most influential (43% of women)
 - A minority of women identified their doctor, aunt or sister as most influential to decision making

Socio Ecological Framework

DYAD: HIV Protection

Efficacy

Health

Woman:

- No future impact on fertility
- No stigmatization
- No relationship disruption

Pregnancy:

- No complication, easy delivery

Lactation:

- No effect on quality/quantity of milk

Baby:

- Term, healthy, normal growth

Oral PrEP Concerns by Trimester (All)

Maternal stages:



- **Adverse pregnancy outcomes**
 - Belief that fetus is particularly vulnerable early on)
 - Risk of miscarriage
- **Symptom related concerns**
 - **Exacerbate nausea & other symptoms**
- **Increases appetite**
- **Drug interaction / compatibility concerns:**
 - Interference with pregnancy hormones
 - Incompatibility with traditional herbs & other medications

- Potent drug may **disable** baby

Oral PrEP: Concerns are concentrated early in pregnancy

Vaginal Ring Concerns by Trimester (All)

Maternal stages:



- **Vaginal products proscribed (taboo)**
- Misperceived as **abortion tool**
- **Exacerbates physical discomfort of pregnancy**



- **Concerns at time of delivery**
 - Baby entangled/injured
 - Clinician unaware of ring
- **Vaginal route concerns**
 - Vagina “too busy”
 - Vagina enlarged, fragile
- **Skill concerns**
 - Ability to insert/remove ring when heavily pregnant

Vaginal Ring: Concerns are concentrated later in pregnancy



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:

- Proven safe and effective for the dyad (woman and baby)
- Recommended, prescribed and endorsed by Health care providers
- Thorough education is provided NOT just to pregnant and breastfeeding women but also to key stakeholders:
 - Male partners
 - Family and Community members
 - Religious leaders
 - Traditional birth attendants, healers, and practitioners



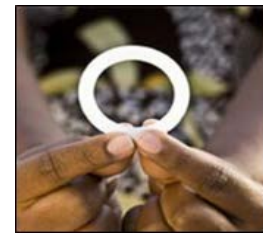
Practical Recommendations (1)



- **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 women
- **Male Partners**
 - Education efforts targeted to male partners
 - Men willing to 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 circumstances)



Practical Recommendations (2)



- **Oral PrEP**
 - Consider strategies to address community-level HIV stigma
 - Explanation of side effects (explicitly asked by participants)
- **Dapivirine Vaginal Ring**
 - Need for more product information (unfamiliarity of the route)
 - 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)

Stakeholder Meetings at Each Location

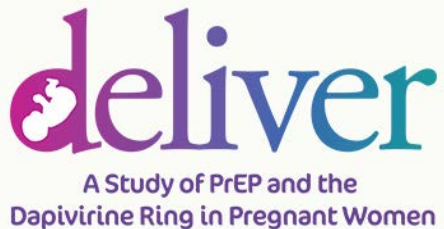
- In-country stakeholder meetings focused on the DELIVER and B-PROTECTED studies were conducted in each country
 - ~ 60 people at each meeting, including former MTN-041 participants
 - Each meeting included a session called **Different Views about Pregnant Women Using PrEP and the Ring: What we have learned from MTN-041** that was followed by a panel and group discussion



MAMMA Informing DELIVER & B-PROTECTED	Examples
<p>External providers are a target for outreach efforts</p>	<ul style="list-style-type: none"> • Provider Guides developed to use during outreach efforts • Training of providers in catchment area • Continuous updates to stakeholders
<p>Participants will receive explicit safety information on product use during P/BF & from trusted sources</p>	<ul style="list-style-type: none"> • Product factsheets incl. “what is known & knowledge gaps” • Testimonials, product ambassadors etc..
<p>Importance of male partner engagement/influence</p>	<ul style="list-style-type: none"> • Pre-Enrollment Decision tool • Make clinic conducive to MP visits • Engage MP from antenatal clinic visits
<p>New topic areas of interest emerged</p>	<ul style="list-style-type: none"> • Data collection tools include further questioning around: <ul style="list-style-type: none"> • Birth preparation practices • Key influencers for decision making

In Conclusion

The MAMMA study collected important scientific data and key information to prepare the communities and the clinical teams to successfully implement



Aknowledgements

- **Study Participants!!!!**
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