

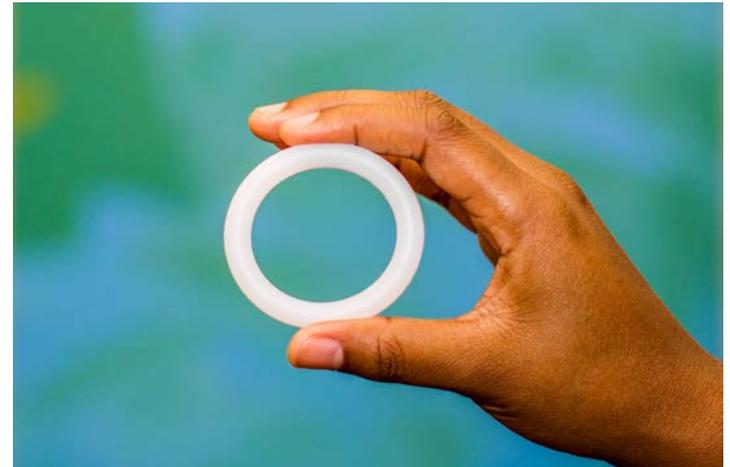


Negative rumours and misconceptions about a vaginal ring for HIV-1 prevention in sub-Saharan Africa

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Outline

- Background
 - ASPIRE trial
 - Rationale for this analysis
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 - Defining rumours
- Results
 - Effect of rumors
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The MTN-020 ASPIRE TRIAL

- MTN-020/ASPIRE assessed safety and effectiveness of the dapivirine vaginal ring among HIV negative women in Africa
- ASPIRE qualitative component explored socio-contextual factors that influenced study participation and ring adherence
- Using qualitative methods, this analysis explored rumours and misconceptions that circulated during the ASPIRE study

ASPIRE Qualitative study sites



- MU-JHU (Kampala, Uganda)
- UNC-Lilongwe (Lilongwe, Malawi)
- Spilhaus (Harare, Zimbabwe)
- South Africa:
 - Wits RHI (Johannesburg)
 - DTHF (Cape Town)
 - MRC/Isipingo (Durban)

Rationale for this analysis

- There is need to address rumours during study implementation because rumours have the potential to adversely affect study product acceptance and adherence.



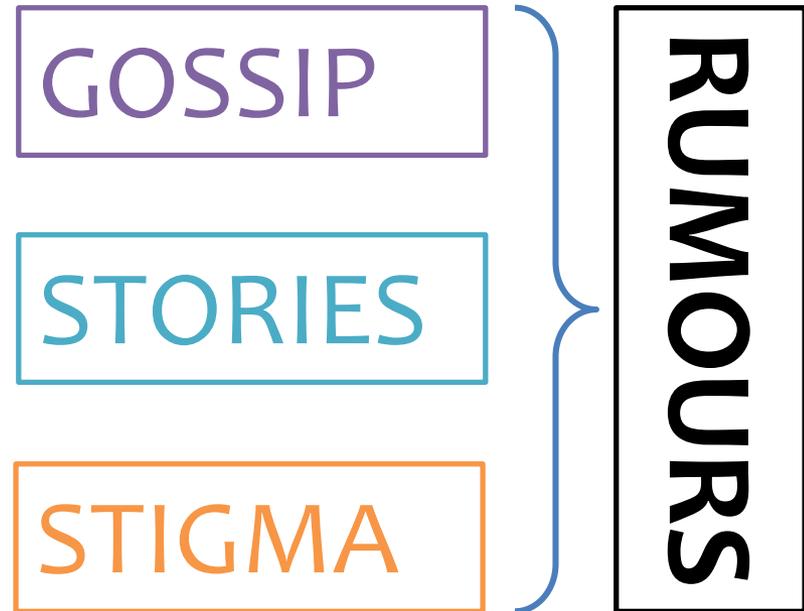
Methods

Qualitative methods used to explore behavioural and contextual experiences.

- Serial IDIs (n=80) & single IDIs (n=34), these elicited personal experiences of using vaginal ring and study participation experience
- FGDs (n =100) explored the broader community context and social dynamics relevant to the study

Contextualizing rumours in the ASPIRE Qualitative Component

- Audio recordings of the interviews were translated/transcribed into English then coded in NVivo 11
- The ‘rumours’ code was applied to any text relating to **gossip**, **stories**, or **stigma** in the community about the research in general, antiretroviral drugs (ARVs), HIV transmission, the ring or the ASPIRE trial.



Defining rumors

- “Rumours” are neither true nor false and their authenticity does not need to be proven beyond merely being discussed ^{1,2}
- Rumours that have been cited in other trials or medical contexts include ^{1, 3}:
 - Researchers deliberately infecting people with HIV
 - Clinical trials being a form of planned genocide of black communities
 - Researchers stealing blood and body parts for resale



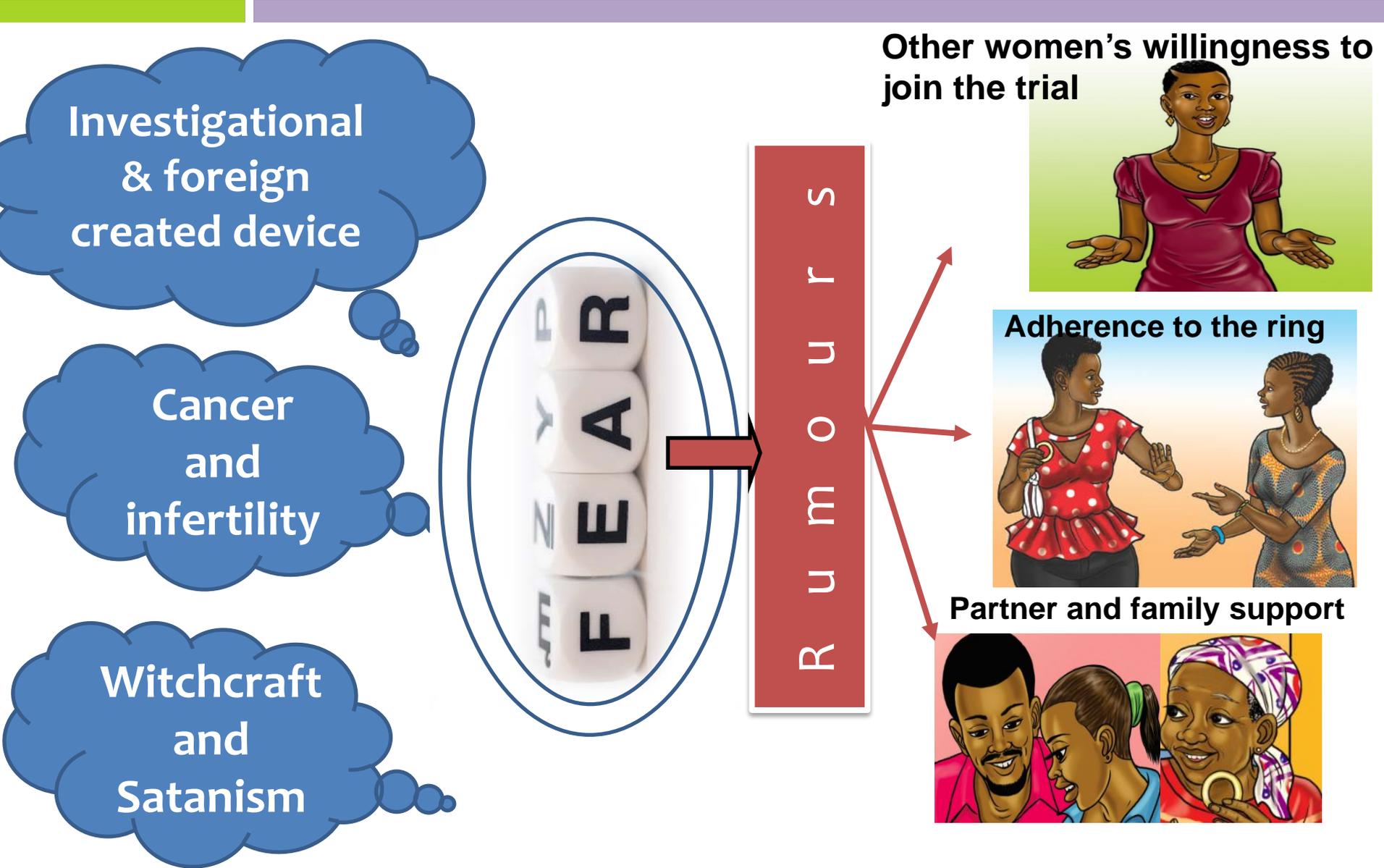
Results outline

1. Sample characteristics
2. Schematic of Key findings
3. Ways used to address rumors
4. Negative rumours and vaginal ring acceptance

1. Study sample characteristics (N=214)

- Mean age was 26 years
- 45% were married
- 73% completed secondary school.
- At baseline:
 - 72% had disclosed study participation to their primary partners
 - 59% had disclosed ring use
- 46% of the participants were from South Africa while Zimbabwe Malawi and Uganda each contributed 18 %

2 Schematic of key findings



VR use and Rumours of cervical cancer

The investigational and foreign nature of the ring linked to cervical cancer.

“I heard that it was a study, **this thing was not even licensed but rather they were researching it.** The neighbours said, “What research?! ...what type of ring is this? It will cause cancer. That ring is no good!” (22, Malawi, single IDI)

“Having something artificial in the body was likely to cause cancer.”
(26, Uganda, serial IDI)

VR use and Infertility

- Fear of alleged toxicity of the investigational drug and the vaginal administration of the ring influenced the emergence of rumours of infertility.

“The whites see that the population is high and so are devising means to see that this population does not increase, and women do not give birth again.”

(26, Uganda, serial IDI)

“People say that the ring has some toxic drugs that will make us infertile... because the ring is placed on the cervix.”

(19, Malawi, serial IDI)

VR use & women witchcrafting men

Women had concerns that male partners would perceive VR as witchcraft.

“As black people, black men believe that anything inserted in the vagina has to do with witchcraft. Men think that us as women want to keep them by inserting things in our vaginas.”
(20, Durban, South Africa)

“If he found out and asked about the ring he may think you are bewitching him... then he strangles you, and you die”
(26, Uganda, serial IDI).

“If you don't tell him about the ring, it can happen accidentally that the thing has fallen down [ring has moved in vagina]... he can think it is witchcraft.”
(24, Malawi, single IDI)

VR use and Rumours of with Satanism

- The ring was perceived as a Satanic object that sucks blood and energy of participants & partners:

“Some were saying that the study is Satanic... that our partners will have their blood sucked whenever we have sex with them. When we insert the ring it will be sucking blood from the uterus.”

(21, Malawi, serial IDI)

“They were saying rings with the drug drain husbands’ private parts so that they will not feel the desire for sex with women... he will be frail after having been used by Satanists.”

(22, Zimbabwe, FGD)

Effect of rumours on willingness to participate in the study

Rumours frightened some women from participating in the study:

“They did not participate in the study... they said, ‘If we go there [participate in the study], will we remain healthy? It may be that those things are going to kill us or cause us problems.’”

(27, Uganda, FGD)

“My neighbor ... told me that she cannot join because the ring sucks blood.”

(28, Malawi, serial IDI)

Effect of rumours on adherence

Rumours reportedly negatively influenced ring adherence.

“When we are sitting in the waiting area, people talk... about different experiences they had with the ring, and that scared me... then I decided to remove the ring, and I only inserted it when I was coming for my visit.”

(23, Durban, South Africa)

“For these women to reach the extent of removing the ring, it means they were listening to misconceptions from those who are not in the study. They [women not participating in the trial] were instigating fear in them.”

(28, Malawi, FGD)

Effect of rumours on social support

“Because of what other people were saying, that it was Satanic, they sell the blood that is collected from us, and that the ring will suck the partner’s blood; that is why he [partner] did not want to allow me to participate.”

(22, Malawi, single IDI)

3 Addressing Rumours

- ASPIRE sites implemented strategies to increase ring adherence and address the rumours circulating about the ring:
 - Participant engagement
 - Male partner engagement
 - Community engagement
- Engagement activities:
 - Disseminated accurate information about study
 - Was a “safe” forum where to discuss fears
 - Allayed ring and study related fears



Positive effect of engagement activities

“The adherence support meetings are helpful so we encourage one another[...]We are also able to refute other reports, if one friend is reporting something which doesn't happen here or has given a report which is not right regarding ring use.” (30, Malawi, serial ID1)



“If he [partner] comes here the study staff explain to him so he will be able to explain himself whenever there are rumors. His friends will also get a ‘sense’ of things and understand about the study.” (27, Zimbabwe, serial ID1)



The Laboratory Tour - Zimbabwe

- The laboratory tour was organized by three ASPIRE sites in Zimbabwe to address rumours of Satanism related to blood draws.

“It was good for us to know about it [blood handling procedures] from one of us we know from the study and to know where the bio-specimen are stored. We are just told that they are stored [specimen] but we won't know exactly where they are stored but one of us was shown where they are stored and even our rings, those used ones.”

(23, Zimbabwe, serial ID1)

4 Negative rumours and Vaginal ring acceptance

- Existence of negative rumours was not mutually exclusive of ring acceptability.
- Some participants were not affected about the negative rumours that circulated:

“People were saying this is a Satanic organization, so we just stopped telling them. I discuss with my friends who are in ASPIRE when we meet here because each one of us knows what happens and we don’t see it as strange.”

(30, Malawi, serial IDI)

Summary

- Rumors reflected the fear people had about ring use /study participation and the mistrust they had about research.
- Rumours may have impacted on ring adherence, willingness to participate in the study & partner/family support for study participants.
- Engagement activities helped address rumours, resulting in enhanced trust and rapport between staff and participants.

Conclusion

- Rumours are inevitable in a research context evaluating a novel health technology.
- Implementation of interventions including ongoing education and engagement activities in ASPIRE reportedly mitigated some rumours that otherwise could adversely affect the trial.
- Negative rumours co-existed with participants' acceptance of and adherence to the ring.

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