HHS Public Access

Author manuscript

Cult Health Sex. Author manuscript; available in PMC 2020 November 01.

Published in final edited form as:

Cult Health Sex. 2019 November ; 21(11): 1209–1224. doi:10.1080/13691058.2018.1552989.

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

Miria Chitukuta[*,a], **Zoe Duby**[b], **Ariana Katz**[c], **Teopista Nakyanzi**[d], **Krishnaveni Reddy**[e], **Thesla Palanee-Phillips**[e], **Tchangani Tembo**[f], **Juliane Etima**[d], **Petina Musara**[a], **Nyaradzo M. Mgodi**[a], **Ariane van der Straten**[c] **MTN-020/ASPIRE Study Team**

[a]University of Zimbabwe College of Health Sciences-Clinical Trials Unit (UZCHS-CTRC), Harare, Zimbabwe [b]Division of Social and Behavioural Sciences, School of Public Health and Family Medicine, University of Cape Town, South Africa [c]Women's Global Health Imperative (WGHI) RTI International, San Francisco, CA, USA [d]Makerere University – Johns Hopkins University Research Collaboration, Kampala, Uganda [e]Wits Reproductive Health and HIV Institute (Wits RHI), South Africa [f]University of North Carolina Project, Lilongwe, Malawi

Abstract

Rumours may influence health-related behaviours, including uptake and adherence to HIV prevention products. This ASPIRE study assessed the safety and effectiveness of a vaginal ring delivering the antiretroviral dapivirine for HIV prevention in Africa. We explored negative rumours about study participation and the vaginal ring amongst study participants and their communities in Malawi, Uganda, South Africa and Zimbabwe. Two hundred and fourteen women participated in either single or serial in-depth interviews, or a focus group discussion. Three key findings emerged in the data. Firstly, rumours reflected fears concerning the ring and trial participation. Given the historical-political context of the countries in which the trial was conducted, the ring's investigational nature and its foreign origin, ring use was rumoured to cause negative health outcomes such as cancer and infertility and was also associated with practices such as witchcraft or Satanism; salience of these rumours varied by country. Secondly, rumours reportedly affected participants' adherence to the ring, and other women's willingness to participate in the study. Finally, participants reported that participant engagement activities helped address rumours, resulting in enhanced trust and rapport between staff and participants.

Keywords

adherence; HIV prevention; rumours; Satanism; vaginal ring; witchcraft

Background

In sub-Saharan Africa, HIV disproportionally affects women. Women comprise 56% of the people living with HIV (UNAIDS 2018). This gender disparity suggests an urgency for

[*]Corresponding Author: Miria Chitukuta Email: mchitukuta@uzchs-ctrc.org.

female initiated, user-controlled methods for HIV prevention, and the need to address barriers to women's ability to use such methods. Rumours, defined as "unverified and instrumentally relevant information statements in circulation that arise in the context of ambiguity and that function primarily to help people to make sense and manage threat." (Difonzo and Bordia 2007: 273) may be one such barrier to uptake of health interventions. Rumours are neither true nor false and their authenticity does not need to be proven beyond merely being discussed (Geissler and Pool 2006). Rumours relating to particular diseases can be viewed as a means through which a community seeks to make sense of and manage the realities of that disease, enabling people to feel a sense of control or power over the condition (Difonzo et al. 2012). In public health, understanding the genesis of rumours is critical given the potentially adverse effects rumours may have on health-related behaviours and medical decision-making (Difonzo et al. 2012). In clinical trial settings, rumours that gain acceptance can have serious implications for both study implementation and intervention outcomes (Stadler 2003; O'Neill et al. 2016). Fears and concerns about investigational products expressed as rumours by participants in the VOICE study and members of their communities, contributed to low uptake of and poor adherence to tenofovir gel, oral tenofovir and oral Truvada for HIV (van der Straten et al. 2014). Because rumours have the potential to undermine intervention research, it is critical that researchers attempt to understand collective concerns and narratives and to address them.

The emergence of rumours in medical research, particularly in studies conducted in resource-constrained settings, is not new. Rumours reported in the context of research trials, clinical practices or in public health institutions in sub-Saharan Africa and beyond, include the trade or theft of blood and body parts, as well as sterility caused by an intervention (Kaler 2009; Campion-Vincent 2002; White 2000). There have also been rumours of researchers deliberately infecting people with HIV, or clinical trials being a form of planned genocide of black communities by white scientists (Hooper 1999).

The monthly dapivirine vaginal ring may provide a solution to the need for a female-initiated HIV prevention method (Baeten et al. 2016; Nel et al. 2016). This drug delivery method may circumvent potential difficulties related to adherence that women experience in the use of daily or coitally-dependent regimens, and may also circumvent potential stigma, as it cannot be seen when worn. Primary results from the MTN-020/ASPIRE trial indicated moderate protection of the dapivirine vaginal ring against HIV-1, with higher effectiveness among women who had evidence of better adherence (Baeten et al. 2016). Earlier analysis of qualitative data from ASPIRE revealed that peers, partners and other people had an important influence on women's perceptions and use of the ring, and that participants' attitudes towards the ring were positive overall and had improved over time with increased familiarity (Montgomery et al. 2017). This is consistent with other clinical research suggesting that vaginal rings were acceptable in Africa (Nel et al. 2016; van der Straten 2012).

Nevertheless, given that the vaginal ring is a new technology in Africa, and the potentially negative impact that rumours may have on uptake and adherence to health products, we used qualitative methods to explore specific rumours about the vaginal ring and study participation that coexisted during the MTN-020/ASPIRE trial, and how they varied by

country. To our knowledge, this is the first report of rumours concerning the vaginal ring in the context of a large HIV prevention trial conducted in Africa.

Methods

Background to the ASPIRE study

The MTN-020/ASPIRE study was a phase 3, double-blind, randomized placebo-controlled trial, assessing the safety and effectiveness of the dapivirine vaginal ring[1] amongst healthy, sexually active, HIV-negative women in Africa. A total of 2,629 female participants were enrolled at 15 sites in Malawi, South Africa, Uganda and Zimbabwe. Participants were randomized 1:1 to receive either a vaginal ring containing 25mg of dapivirine or a placebo vaginal ring (International Partnership for Microbicides) every 4 weeks and were followed for up to 33 months between August 2012 and June 2015. From March 2013, an adherence monitoring system, as well as participant and male engagement activities were implemented across all fifteen study sites to enhance participant buy-in and product adherence within the trial setting, promote participant retention and facilitate social interactions between staff and study participants (Schwartz et al. 2014). These included group education activities such as adherence support clubs, social events (such as movie nights, games or sporting events), waiting room discussions and laboratory tours for participants. Adherence support clubs offered participants opportunity to share experiences including ring use, adherence and rumours in a small group setting.

ASPIRE qualitative component and procedures

The ASPIRE study qualitative component was conducted concurrently with the main trial from February 2013 to June 2015 at 6 sites, representing each trial country (in Harare, Zimbabwe; Lilongwe, Malawi, Kampala, Uganda) and 3 metropolitan areas of South Africa (Cape Town, Durban and Johannesburg). Multiple modes of data collection were used to address the qualitative component objective of exploring behavioural and contextual experiences. In-depth interviews (IDI) elicited participants' personal experiences of using the vaginal ring and study participation and focus group discussions (FGD) explored the broader community context and social dynamics relevant to the study. As shown in table 1, a total of 214 trial participants enrolled in one of 3 interview modalities: a single IDI (n=34), up to three serial IDIs (n=80), or an exit (FGD) (n=100). Participants who had completed a product use end visit and had used the ring in the 3 months prior to this visit were randomly selected for participation in FGD, while those who permanently discontinued product use (due to seroconversion or early study participation withdrawal) or had some adherence challenges, were purposively selected for a single IDIs. Participants for serial IDIs (conducted at month 3, month 12 and/or the product use end visit) were either randomly or purposively selected and had to have used the ring in the previous 3 months and be HIV-negative at the time of her first interview. Characteristics of this sample in comparison with non-qualitative participants at the qualitative sites has been previously described (Montgomery et al. 2017).

[1]The vaginal ring is a flexible silicone elastomer vaginal matrix which releases medication slowly over time.

IDIs lasting approximately 1 hour, and FGDs around 2 hours, were conducted at study sites by trained female social scientists in local languages: Chewa (Malawi), Luganda (Uganda), Shona (Zimbabwe), and Xhosa, Zulu and/or English (South Africa). Semi-structured interview guides included topics such as women's motivation to join ASPIRE and disclosure of study participation and ring use; the influence of others' opinion on participants' willingness to use the ring; perceptions about the trial and vaginal ring amongst participants, their partners and communities; and participants' experiences in ASPIRE, including ring use/non-use. Audio recordings of IDIs and FGDs were translated verbatim into English transcripts; these were subsequently reviewed by social scientists fluent in both local and English languages for accuracy, and by the qualitative data management centre for quality control. Transcripts were coded in NVivo11 qualitative software by a team of 8 coders using a codebook developed iteratively (Montgomery et al. 2017). Inter-coder reliability of more than 90% for key codes was maintained among 10% of interviews. During data analysis, text referring to positive or negative rumours about the trial, vaginal ring and trial procedures were coded into a single 'rumours' node; the 'rumours' code was applied to any text relating gossip, stories (positive or negative), or stigma in the community about research in general, antiretroviral drugs (ARVs), HIV transmission, and the ASPIRE study. 'Rumours' code reports were summarized by salient themes in analytic memos by study sites, to enable comparing and contrasting themes. Baseline demographic characteristics of the qualitative participants were summarized using Statistical Analysis System [SAS] software (v.9).

In reporting on findings, direct quotes from the English translations are provided in italics and all names are pseudonyms. Details in brackets include participants' age, country (and city for South African participants) and interview type. We also present a case study detailing the use of a laboratory tour to address rumours related to blood draws at 3 research sites in Zimbabwe (Box 1). The study protocol, including its qualitative component, was approved by the Institutional Review Boards at each corresponding study site, overseen by the regulatory infrastructure of the US National Institute of Health and the Microbicide Trials Network (MTN).

Findings

Study population

Table 2 shows the baseline demographic characteristics of the ASPIRE qualitative participants. In this sample a large variety of ethno-linguistic groups were represented, mean age was 26, 45% were married, and 73% completed secondary school. At baseline, 72% had disclosed study participation to their primary partners, while 59% had disclosed ring use.

Rumours about the vaginal ring

Across study sites rumours were mostly negative, reflecting fears concerning the ring, given its novelty as a drug delivery system in Africa, and its investigational nature in the ASPIRE trial. Rumours centred on severe health outcomes from ring use, and around the ring as an object of witchcraft or Satanism. According to participants' perspectives, sources of rumours included women who had been screened out for not meeting ASPIRE study eligibility criteria, enrolled study participants, sex partners, and the community at large. Participants'

narratives suggested that rumours impacted on willingness to participate in the trial and on correct ring use. However, participant engagement activities implemented during ASPIRE reportedly helped address rumours, resulting in enhanced trust and rapport between staff and participants.

Vaginal ring as a cause of cancer and infertility

Rumours relating ring use to potential severe health consequences, primarily cancer and infertility, were salient in all the four study countries. Central to stories in the community or participants' reported perceptions, fear of the ring was based on the premise of it being an unlicenced, foreign investigational product for which safety was still being evaluated. Linked to this was fear around the ring containing carcinogenic drugs. For example, Njemile reported: '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). Nyasha reported a similar concern regarding the product's investigational nature: 'because of the issue that the product is still under investigation, not yet approved, so they were saying you can develop cancer because it is a thing that is still under investigation' (34, Zimbabwe, FGD). Women described the ring as an artificial foreign object, the vaginal insertion of which was regarded as unnatural and even dangerous, possibly causing cervical cancer. Amaka heard that 'Having something artificial in the body was likely to cause cancer' (26, Uganda, serial IDI). Community members where Bonang live expressed fear that ring use was linked to delayed manifestation of severe health consequences such as cancer: 'They say negative things sometimes… what if the ring does something bad to me as time goes on, things like cancer' (25, Durban, South Africa, serial IDI). In Pretty's community, there were fears relating to long term harm caused by the ring because it was an object from abroad: 'They said some products from outside the country cause cancer… what you are wearing now will cause diseases afterwards ….'' (26, Zimbabwe, FGD). Reportedly, rumours of scientists deliberately putting carcinogenic drugs in the ring to kill African people and control population growth were common in study communities. These stories frightened Amaka, resulting in her temporarily removing the ring:

> 'Some of the women threatened us that these things (rings) were for the whites, they see that the population in the world is big and so use these things, put drugs in them to kill us or that we could get diseases like cancer… I would get worried of such things and decide to remove the ring for some time, keep it somewhere for two weeks...' (26, Uganda, serial IDI).

Salient at all sites was fear associating infertility with vaginal ring use; this fear was based on several aspects of the product including the fears of the toxicity of the investigational drug, the need for vaginal administration of the ring, and suspicion that the ring could be used to deliberately cause infertility. Chikondi explained that the belief about the ring causing infertility was based on the vaginal administration of the drug: '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). Also apparent in rumours relating to infertility were perceptions that white researchers were using the ring to limit the Black population as previously explained by Amaka: '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). Similarly, Vimbai described beliefs in her community that participants would have their wombs removed by researchers; given the community's knowledge of hysterectomies having been performed at the same clinic where ASPIRE was based, this motivated her to hide her study participation:

> 'I did not tell my husband about this study because he had said that he heard that where I am going to at (that) clinic, they remove wombs so that they cannot bear children. I lied, even today he does not know that I wore the ring' (38, Zimbabwe, FGD).

Vaginal ring as an object for witchcraft

Rumours associating the vaginal ring with witchcraft were present in all four countries but most pertinent in South Africa, where it was perceived to also cause harm to male partners.

Milly explained that vaginal practices are used in some communities to bewitch men, so they remain faithful; further, she stated that men are unlikely to accept the vaginal ring, fearing that it is a form of witchcraft: 'As black people, black men believe that anything that is 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, FGD). Sihle referred to ring insertion as a form of witchcraft because traditional Christian beliefs do not allow women to insert objects in the vagina: 'That guy will tell you about the church, he says we are witches; where did we ever see such a thing that the ring is put in the vagina?' (21, Cape Town, South Africa, serial IDI).

Chimwala, also explained that in the context of non-disclosure, a partner might think the ring is a form of witchcraft if he discovers it during sex: '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). Amaka echoed Chimwala's sentiment, describing the severe consequences for a woman suspected of witchcraft: '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).

Vaginal ring as a Satanic tool

Rumours associating the ring with Satanism circulated in all study countries, with most prominence in Malawi and Zimbabwe. Dalitso narrated that in her community, the ring was perceived as a Satanic object that sucks blood of both participants and their sex 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). Nyasha also reported links between Satanism, ring use and infertility: 'people said a lot about Satanists… if you have the ring inserted you will have your uterus damaged … so you will fail to deliver other children' (34, Zimbabwe, FGD). Chikondi also cited concern in her community that the drug in the ring could disturb the body's natural biological functioning because it is Satanic: 'Others say the ring has some drugs which disturb our natural body systems, and these are Satanic!' (19, Malawi, serial IDI).

A generally held community perception at all sites whenever a participant fell ill was that the illness was caused by the ring, an ‘unnatural’ device, possibly connected to the devil. For Karabo’s friend, the ring was malevolent: ‘I had a problem with my womb and she [friend] told me that it was the ring that I was using, it’s a Satanic thing’ (23, Johannesburg, South Africa, single IDI). In Zimbabwe, beliefs about the ring’s Satanic power was also connected to men’s loss of sexual potency and libido, as reported by Chipo: ‘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 … used by Satanists.’ (22, Zimbabwe, FGD).

Effects of Rumours

Participants’ narratives across the four countries reflect that rumours instilled fear of the ring and study, reportedly negatively influencing both ring adherence among some participants and willingness to participate in the study among other women in the community. Waiting room discussions among participants was a forum in which stories about the ring were shared. Zizo described how these stories influenced her and other participants to remove the ring: ‘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, serial IDI).

Rumours from outside the trial also negatively influenced adherence, as Dalisani described: ‘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). Desire reported that some women did not join the study altogether fearing severe health consequences from the ring: ‘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).

According to Takondwa, rumours of Satanism relating to the ring created fear which deterred people from joining: ‘my neighbour… told me that she cannot join because the ring sucks blood’ (28, Malawi, serial IDI). Masauso described her partner’s resistance to her study participation in similar terms: ‘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).

However, some participants such as with Mary seemed unaffected by these rumours and continued with the study: ‘People were saying this is a Satanic organisation, so we just stopped telling them and 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).

In summary, rumours fuelled a general mistrust about the research and the investigational product. According to participants’ accounts, rumours had a negative effect on joining the trial, on women’s adherence to the ring, and at times, resulted in a lack of support from male partners, family, and the wider community.

Addressing Rumours

Study sites implemented a variety of strategies to address the rumours circulating during the trial, and to build trust between participants and researchers. Women noted that participant engagement activities fostered positive group norms towards the ring and the study. Charity felt that group activities promoted ring adherence because they offered peer support and an opportunity for participants to share and learn from each other's experiences:

> 'The adherence support meetings are helpful because everybody in that meeting takes part in ASPIRE… so we encourage one another. Everybody is able to say what challenge she faces and then we find out how many people face that challenge. 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 IDI).

Chikondi, who earlier had noted Satanic rumours associated with the ring, said that adherence support meetings were used as a platform to allay participants' concerns: '"… these discussions encourage us not to be worried about whether the ring would go in the abdomen or that it will disturb the body systems' (19, Malawi, serial IDI). Participants thought that study engagement activities had a positive effect on rumours, helping to disseminate accurate information about the study, and allaying fears about the ring and study.

Addressing rumours sometimes required the involvement of partners. For Dalitso, clarification from community educators helped address her partner's worries:

> 'He was worried of the rumours. People were saying that the ring sucks blood in the uterus, so community educators visited us and explained everything to him and that was when he understood, and all his worries were gone, and we now live without any problems' (21, Malawi, serial IDI).

To Nakai, male involvement was helpful, empowering partners with correct information about the study: 'If he comes here the study staff explain to him so he will be able to explain himself whenever there are rumours. His friends will also get a 'sense' of things and understand about the study' (27, Zimbabwe, serial IDI).

The Laboratory Tour to address Satanist rumours

A sentiment shared by participants at qualitative study sites was the belief that blood collected from participants at monthly visits was used for Satanic purposes or was being sold for profit. Noluntu described her friend's belief that monthly blood draws were Satanic due to her failure to account for what happens to the blood collected from her: 'She [friend] said that maybe it's Satanism because when they take blood from me I don't know what they are doing with it' (23, Johannesburg, South Africa, serial IDI).

To address rumours of Satanism related to blood draws, three study sites in Zimbabwe organised a laboratory tour (see Box 1 for details).

Narratives of participants who heard about the laboratory tour in Zimbabwe were positive. For Chenai, the tours helped dispel rumours related to blood collection, clarifying the fate of the collected blood samples and used rings:

> ‘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 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 IDI).

Discussion

A variety of rumours associated with the vaginal ring, and with participation in the ASPRE trial, circulated at the study sites in Malawi, Uganda, South Africa and Zimbabwe. Three key findings emerged from this analysis: firstly, rumours were a manifestation of fears relating to the vaginal ring and to trial participation. Factors contributing to the emergence of rumours included mistrust of the white researchers by the people in the communities in which the trial took place, and the ring’s investigational nature, as well as it being a product manufactured abroad. Ring use was rumoured to cause negative health outcomes such as cancer and infertility and was associated with witchcraft and Satanism. Secondly, rumours reportedly affected participants’ adherence to the vaginal ring, and other women’s willingness to participate in the study. Thirdly, participants reported that on-going trial participant engagement activities helped address rumours, resulting in enhanced trust and rapport between staff and participants.

The context in which the vaginal ring trial was conducted may have fuelled some of the rumours reported here. In all the study countries were on-going public health campaigns to raise awareness about cervical cancer and human papilloma virus; one example was the Ugandan Cervical Cancer Awareness Campaign introduced in 2013 to sensitise communities about cervical cancer and provide free screening. The backdrop of such campaigns, running concurrently with the ASPIRE project, may help explain the emergence of fears relating cervical cancer with vaginal ring use amongst women and their communities. Similar reports of fear, and concern about perceived side effects from investigational products, have also been reported in previous studies (van der Straten et al. 2014; Corneli et al. 2014) and can co-exist with otherwise positive attitudes about the products and the studies themselves (Montgomery et al. 2017). As the ring moves towards registration as an HIV prevention device, there is need to consider mainstreaming cervical cancer messages within the ring use messaging to allay any concerns the community may have with ring use.

Some participants reported that rumours relating to severe health consequences of ring use instilled fear, which influenced ring removal. Fear of the ring was based on it being vaginally administered or being an unnatural product. Paradoxically, the literature confirms that some women in sub-Saharan Africa are comfortable using vaginally inserted substances, both natural and inorganic, for various reasons including vaginal warming, tightening and drying (van der Straten et al. 2010; Lees et al. 2014). Vaginal practices have also been linked to negative health outcomes such as bacterial vaginosis and HIV acquisition and

transmission (Alcaide et al. 2017; Hilber et al. 2010; McClelland et al. 2006). This finding suggests that basis for mistrust of the dapivirine ring may have been related to it being both investigational and a novel HIV drug delivery technology, rather than the mode of administration. Women's discomfort using unfamiliar products in the vagina corroborates findings from other studies; acceptability studies of the ring conducted in Kenya, Rwanda and Tanzania also found that some participants feared the ring would cause cervical cancer or that it could be pushed deep inside the body and get lost (Eakle et al. 2017; van der Straten et al. 2012).

Another important finding in this study was the perceived association between aspects of the vaginal ring and infertility. Related to this were discourses of black population control by white scientists, fear of drug toxicity, and vaginal administration of the ring. The centrality of reproduction and procreation is apparent in literature relating to rumours on sterility. Fears around sterility have been seen to cause significant obstacles to public health interventions and research (Kaler 2009; Feldman-Savelsberg, Ndonko and Schimidt-Ehry 2000).

Rumours relating to witchcraft and Satanism were prominent. Across sub-Saharan Africa, beliefs in witchcraft are pervasive; negative views of witchcraft centre on its association with the use of supernatural forces for evil or harmful intent (Ashforth 2005; Chavunduka 1980; Evans-Pritchard 1937). Witchcraft discourses exist within specific social and institutional contexts (Niehaus 2012). Of note, in this study, rumours linking the ring to witchcraft were narrated in a context where women expressed concern about partners unintentionally discovering the ring. In the sub-Saharan African countries in which this research was conducted, pervasive gendered sexual norms tend to give men greater decision-making power in sexual and reproductive matters (Duby et al. 2015; Leclerc Madlala, Simbayi and Cloete 2009). Men's beliefs around women's use of witchcraft to infringe on male autonomy have been described in South Africa (Parle and Scorgie 2012). In a qualitative study in South Africa, men viewed an HIV-prevention vaginal gel with suspicion believing it to prevent their detection of their partners' infidelity (Gafos et al. 2010). Research from Uganda describes male anxiety over female-controlled methods of contraception due to the belief that men should control fertility (Pool et al. 2000). Although the ring as a delivery mode for a microbicide provides women with more agency in protecting themselves from HIV infection, this may be perceived by men as a challenge to their control over sexual interactions (Duby et al. 2015). Rumours of witchcraft associated with the ring suggest men's fear of women having control over their sexuality. Rumours of witchcraft related to the vaginal ring may be critical to monitor, given that witchcraft is viewed seriously among men and has potential for intimate partner violence if men inadvertently discover the vaginal ring. Also, given that the ring is being considered as an HIV drug delivery device, there is need to engage men given that they influence women's uptake of HIV PrEP (Montgomery et al. 2015).

Gavin (1993) has defined Satanism as a religious cult characterised by the inversion of Christian norms and ideology. Rumours of Satanism in the study were associated with monthly collection of blood from participants, perceptions that the ring sucks blood, and belief that the ring could result in loss of sexual potency for male partners. The fear of

giving blood in clinical trials in Africa is well documented, sometimes fuelling similar rumours (O'Neill et al. 2016). Discourses of Satanism and witchcraft have also been interpreted as symbolic expression of people's concerns relating to the supernatural and evil, or to tensions between traditional ways of living and traditional belief systems around sickness and health, with modernity and Western biomedicine (Bornstein 2001).

Rumours of Satanism and witchcraft in the context of other clinical trials are linked to perceptions that the trials can cause sickness or even death through the use of human blood or body parts (Dillon-Malone 1988; Geissler and Pool 2006; Kingori et al. 2010). Regarding the vaginal ring, it can be hypothesised that the rumours of Satanism and witchcraft emerged because participants were perceived as potential victims of white researchers who were maybe using supernatural powers to bewitch them using the ring or collecting their blood for Satanic purposes. It is critical that researchers address study related rumours regarding Satanism and witchcraft as these have potential to affect study product acceptance and adherence.

Importantly, the existence of rumours about the ring co-existed with, and were not mutually exclusive of, participants' overall acceptance of and adherence to the ring. Other ASPIRE qualitative analysis showed that the ring was very acceptable to participants after overcoming initial fears and becoming more familiar with ring use (Montgomery et al. 2017) and that the ring was preferred over other methods for its long term and discreet usage (van der Straten et al. 2017).

One question that requires more systematic investigation in future studies is the extent to which rumours may directly or indirectly impact product use or how much they contribute to other factors influencing decision-making about use. In this qualitative sample, there were mixed reactions to rumours. Some women reported not being influenced in any way, whereas others reported temporary discontinuation from ring use, or removing the ring after a study visit and re-inserting the ring immediately before their next study visit – the 'white coat effect' (Montgomery et al. 2017). Further research about rumours may help elucidate their direct and attributable effect on product adherence in clinical trials.

Overall, participants felt that engagement activities that directly addressed rumours about study participation and ring use enhanced trust and rapport between research staff and participants. Specifically, the laboratory tour conducted in Zimbabwe helped do this, dispelling rumours related to blood draws by increasing transparency of procedures related to blood handling and storage. Literature confirms the utility of participant and community engagement activities (Morin et al. 2003); the laboratory tour exemplifies a successful strategy. Furthermore, at all study sites, Community Advisory Boards alerted investigators to study related stories circulating in the community. These stories, as well as rumours or misinformation revealed during IDIs and FGDs, were timeously communicated to site investigators and addressed with urgency, together with several other strategies implemented during ASPIRE to support adherence and retention (Schwartz et.al 2014). Limitations requiring consideration in interpreting our findings include the focus on negative and potentially harmful rumours in the analysis; positive rumours may have also informed behaviour, but these were not salient in this data. Most of our sample was urban or peri-

urban; it is unknown if findings would have differed in a different setting. Also, participants may have exaggerated rumours from the community to excuse or justify their own behaviour. We did not collect data on religion; further research could investigate the link between religion and beliefs in witchcraft and Satanism with vaginal ring use. Nonetheless, the application of qualitative methods is well-suited to explore and offer valuable insights regarding the extent to which contextual factors such as rumours affect recruitment, retention and adherence in clinical trials.

Conclusion

These findings reflect the inevitability of rumours in a context of evaluating a novel technology. Rumours co-existed with participants' acceptance of and adherence to the ring. Implementation of interventions including on-going education and engagement activities in the larger study reportedly mitigated some rumours that otherwise had the potential to adversely affect the trial.

Acknowledgements

The authors acknowledge with gratitude the MTN-020/ASPIRE study participants who participated in this study and the MTN 020/ASPIRE study staff.

Funding statement

The MTN 020/ ASPIRE study was designed and implemented by the Microbicide Trials Network (MTN) funded by the US National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the US National Institute of Mental Health, all components of the U.S. National Institutes of Health (NIH). The work presented here was funded by NIH grants UM1AI068633. The funders did not play any role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript. The content is solely the responsibility of the authors and does not necessarily represent the official views of the US National Institutes of Health. The International Partnership for Microbicides (IPM) supplied the vaginal rings used in this study.

References

Alcaide Maria L., Rodriguez Violeta J., Fischl Margaret A., Jones Deborah L., and Weiss Stephen M.. 2017 "Addressing Intravaginal Practices in Women with HIV and at-Risk for HIV Infection, a Mixed Methods Pilot Study." International Journal of Women's Health 9: 123–32.

Ashforth A 2005 Witchcraft, Violence, and Democracy in South Africa. Chicago: University of Chicago Press.

Baeten JM, Palanee-Phillips T, Brown ER, Schwartz K, Soto-Torres LE, Govender V, Mgodi NM, et al. 2016 "Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women" New England Journal of Medicine 375: 2121–2132. doi:10.1056/NEJMoa1506110. [PubMed: 26900902]

Bornstein Erica. 2001 "The Verge of Good and Evil: Christian NGOs and Economic Development in Zimbabwe." Polar 24 (1): 59–77.

Campion-Vincent Veronique. 2002 "Organ Theft Narratives as Medical and Social Critique." Journal of Folklore Research an International Journal of Folklore and Ethnomusicology 39 (1): 33–50.

Chavunduka GL 1980 "Witchcraft and the Law in Zimbabwe". Zambezia, viii (ii):129–147.

Corneli Amy L., Deese Jennifer, Wang Meng, Taylor Doug, Ahmed Khatija, Agot Kawango, Lombaard Johan, et al. 2014 "FEM-PrEP: Adherence Patterns and Factors Associated with Adherence to a Daily Oral Study Product for Pre-Exposure Prophylaxis." Journal of Acquired Immune Deficiency Syndromes 66 (3): 324–31. [PubMed: 25157647]

Difonzo Nicholas, and Bordia Prashant. 2007 “Rumors Influence: Toward a Dynamic Social Impact Theory of Rumor” In Frontiers of Social Psychology. the Science of Social Influence Advances and Future Progress, edited by Pratkanis AR, 271–95. New York: Psychology Press.

Difonzo Nicholas, Robinson Nicole M., Suls Jerry M., and Rini Christine. 2012 “Rumors About Cancer: Content, Sources, Coping, Transmission, and Belief.” Journal of Health Communication 17 (9): 1099–1115. [PubMed: 22724591]

Dillon-Malone Clive. 1988 “Mutumwa Nchimi Healers and Wizardry Beliefs in Zambia.” Social Science & Medicine 26 (11): 1159–72. [PubMed: 3393933]

Duby Zoe, Hartmann Miriam, Montgomery Elizabeth T., Colvin Christopher J., Mensch Barbara, and van der Straten Ariane. 2015 “Sexual Scripting of Heterosexual Penile-Anal Intercourse Amongst Participants in an HIV Prevention Trial in South Africa, Uganda and Zimbabwe.” Culture, Health & Sexuality 18 (1): 30–44.

Eakle Robyn, Bourne Adam, Jarrett Caitlin, Stadler Jonathan, and Larson Heidi. 2017 “Motivations and Barriers to Uptake and Use of Female-Initiated, Biomedical HIV Prevention Products in Sub-Saharan Africa: an Adapted Meta-Ethnography,” December. BMC Public Health 17 (1): 1–23. doi: 10.1186/s12889-017-4959-3. [PubMed: 28049454]

Evans-Pritchard E 1937 Witchcraft, Oracles and Magic among the Azande of Anglo-Egyptian Sudan. Oxford: Clarendon Press.

Feldman-Savelsberg P, Ndonko FT and Schmidt-Ehry B. 2000 “Sterilizing Vaccines or the Politics of the Womb: Retrospective Study of a Rumor in Cameroon.” Medical Anthropology, International Journal for the Analysis of Health 14 (2): 159–79.

Gavin I1993 “The Psychology of Satanic Worship.” South African Journal of Psychology 23 (4): 180–185.

Gafos Mitzy, Mzimela Misiwe, Sukazi Sizakele, Pool Robert, Montgomery Catherine, and Elford Jonathan. 2010 “Intravaginal Insertion in KwaZulu-Natal: Sexual Practices and Preferences in the Context of Microbicide Gel Use.” Culture, Health & Sexuality 12 (8): 929–42.

Geissler PW, and Pool R. 2006 “Editorial: Popular Concerns About Medical Research Projects in Sub-Saharan Africa – a Critical Voice in Debates About Medical Research Ethics.” Tropical Medicine & International Health 11 (7): 975–82. [PubMed: 16827698]

Hilber Adriane Martin, Hull Terence H., Eleanor Preston-Whyte Brigitte Bagnol, Smit Jenni, Wacharasin Chintana, Widyantoro Ninuk, and For the WHO GSVP Study Grouph. 2010. “A Cross Cultural Study of Vaginal Practices and Sexuality: Implications for Sexual Health.” Social Science & Medicine 70 (3): 392–400. [PubMed: 19906477]

Hooper E 1999 The River. A Journey Back to the Source of HIV and AIDS. Harmondsworth: Penguin Books.

Kaler Amy. 2009 “Health Interventions and the Persistence of Rumour: The Circulation of Sterility Stories in African Public Health Campaigns.” Social Science & Medicine 68 (9): 1711–19. [PubMed: 19282080]

Kingori Patricia, Muchimba Maureen, Sikateyo Bornwell, Amadi Beatrice, and Kelly Paul. 2010 “‘Rumours’ and Clinical Trials: a Retrospective Examination of a Paediatric Malnutrition Study in Zambia, Southern Africa.” BMC Public Health 10 (1): 556–58. [PubMed: 20849580]

Suzanne Leclerc Madlala, Simbayi Leickness C, and Cloete Allanise. 2009 “The Sociocultural Aspects of HIV/AIDS in South Africa” In HIV/AIDS in South Africa 25 Years on, edited by Rohleder Poul, Swartz Leslie, Kalichman Seth C, and Simbayi Leickness, 13–25. New York: Springer.

Lees Shelley, Zalwango Flavia, Andrew Bahati, Vandepitte Judith, Seeley Janet, Hayes Richard J., and Francis Suzanna C.. 2014 “Understanding Motives for Intravaginal Practices Amongst Tanzanian and Ugandan Women at High Risk of HIV Infection: The Embodiment of Social and Cultural Norms and Well-Being.” Social Science & Medicine 102 (c): 165–73. [PubMed: 24565154]

McClelland R. Scott, Lavreys Ludo, Hassan Wisal M., Mandaliya Kishorchandra, Ndinya-Achola Jeckoniah O., and Baeten Jared M.. 2006 “Vaginal Washing and Increased Risk of HIV-1 Acquisition Among African Women: a 10-Year Prospective Study.” AIDS 20 (2): 269–73. [PubMed: 16511421]

Montgomery Elizabeth T., van der Straten Ariane, Stadler Jonathan, Hartmann Miriam, Magazi Busisiwe, Mathebula Florence, Laborde Nicole, and Soto-Torres Lydia. 2015 “Male Partner

Influence on Women's HIV Prevention Trial Participation and Use of Pre-Exposure Prophylaxis: The Importance of 'Understanding'." AIDS & Behavior 19 (5): 784–93. [PubMed: 25416076]

Montgomery Elizabeth T., van der Straten Ariane, Chitukuta Miria, Reddy Krishnaveni, Woeber Kubashni, Atujuna Millicent, Bekker Linda-Gail, et al. 2017 "Acceptability and Use of a Dapivirine Vaginal Ring in a Phase III Trial." AIDS 31 (8): 1159–67. [PubMed: 28441175]

Morin SF, Maiorana A, Koester KA, Sheon NM and Richards TA. 2003 "Community consultation in HIV prevention research: a study of community advisory boards at 6 research sites." Journal of the Acquired Immune Deficiency Syndromes 33 (4): 513–20.

Nel Annalene, Bekker Linda-Gail, Bukusi Elizabeth, Elizabeth Hellström Philip Kotze, Louw Cheryl, Martinson Francis, et al. 2016 "Safety, Acceptability and Adherence of Dapivirine Vaginal Ring in a Microbicide Clinical Trial Conducted in Multiple Countries in Sub-Saharan Africa." Edited by D William Cameron. PLoS ONE 11 (3): e0147743–19. doi:10.1371/journal.pone.0147743. [PubMed: 26963505]

Niehaus Isak. 2012 "Witchcraft and the South African Bantustans: Evidence From Bushbuckridge." South African Historical Journal 64 (1): 41–58.

O'Neill Sarah, Dierickx Susan, Okebe Joseph, Dabira Edgard, Gryseels Charlotte, d'Alessandro Umberto, and Peeters Grietens Koen. 2016 "The Importance of Blood Is Infinite: Conceptions of Blood as Life Force, Rumours and Fear of Trial Participation in a Fulani Village in Rural Gambia." Edited by Aric Gregson. PLoS ONE 11 (8): e0160464–13. doi:10.1371/journal.pone.0160464. [PubMed: 27525652]

Parle Julie, and Scorgie Fiona. 2012 "Bewitching Zulu Women: Umhayizo, Gender, and Witchcraft in KwaZulu-Natal." South African Historical Journal 64 (4): 852–75.

Pool Robert, Hart Graham, Green Gillian, Harrison Susan, Nyanzi Stella, and Whitworth Jimmy. 2000 "Men's Attitudes to Condoms and Female Controlled Means of Protection Against HIV and STDs in South-Western Uganda." Culture, Health & Sexuality 2 (2): 197–211.

Stadler Jonathan. 2003 "Rumor, Gossip and Blame: Implications for HIV/AIDS Prevention in the South African Lowveld." AIDS Education & Prevention 15 (4): 357–68. [PubMed: 14516020]

Schwartz K, Ndase P, Torjesen K, Mayo A, Scheckter R, van der Straten A, Torres Soto-L, Palanee T and Baeten J. 2014 "Supporting participant adherence through structured engagement activities in the MTN-020 (ASPIRE) trial." Oral Poster presented at HIV Research for Prevention (HIVR4P), Cape Town, 10 28 - 31.

UNAIDS. 2018 http://www.unaids.org/sites/default/files/media_asset/unaids-data-2018_en.pdf

van der Straten Ariane, Cheng Helen, Chidanyika Agnes, Guy De Bruyn, and Nancy Padian. 2010 "Vaginal Practices and Associations with Barrier Methods and Gel Use Among Sub-Saharan African Women Enrolled in an HIV Prevention Trial." AIDS & Behavior 14 (3): 590–99. [PubMed: 20352318]

van der Straten A, Montgomery ET, Cheng H, Wegner L, Masenga G, von Mollendorf C, Bekker L, et al. 2012 "High acceptability of a vaginal ring as a microbicide delivery method for HIV prevention in African women." AIDS & Behavior 16 (7):1775–86. [PubMed: 22644068]

van der Straten Ariane, Stadler Jonathan, Montgomery Elizabeth, Hartmann Miriam, Magazi Busiswe, Mathebula Florence, Schwartz Katie, Laborde Nicole, and Lydia Soto-Torres. 2014 "Women's Experiences with Oral and Vaginal Pre-Exposure Prophylaxis: the VOICE-C Qualitative Study in Johannesburg, South Africa." PLoS ONE 9 (2): e89118–12. doi:10.1371/journal.pone.0089118. [PubMed: 24586534]

van der Straten Ariane, Mary Kate Shapley-Quinn Krishnaveni Reddy, Cheng Helen, Etima Juliane, Woeber Kubashni, Musara Petina, et al. 2017 "Favoring 'Peace of Mind': a Qualitative Study of African Women's HIV Prevention Product Formulation Preferences From the MTN-020/ASPIRE Trial." AIDS Patient Care and STDs 31 (7): 305–14.

White L 2000 "Speaking with Vampires: Rumor and History in Colonial Africa" Berkeley: University of California Press.

Box 1

The Laboratory Tour

During the implementation of ASPIRE, study staff at the three Zimbabwean ASPIRE sites learned that rumours were circulating among participants and the community at large about what was happening to the samples collected from participants. It was believed that participants' blood was being used for Satanic purposes or being sold for profit. Furthermore, some participants had also expressed uncertainty of how their blood would be used or where it went after collection, despite being informed about this procedure during informed consent. Rather than simply explaining the procedure again, staff took six participants on a laboratory tour so that they could see for themselves first-hand what happened to the blood and the other biological specimens collected during ASPIRE.

Each laboratory tour team comprised of a staff member and two participant representatives from each site and two Community Advisory Board (CAB) representatives. Participant representatives, individuals sufficiently eloquent and confident to give feedback about the tour to fellow participants, were purposefully selected by study staff. As part of the laboratory tour, participants observed biological specimen management (processing, storage and destruction).

During the tour, participants took notes and were encouraged to ask questions as laboratory technicians demonstrated and described specimen management and testing procedures. Immediately after the tour, the participants debriefed their tour experience to study staff. Participants' reaction to the laboratory tour was positive and those invited for the tour felt honoured to participate. CAB members were encouraged to give feedback and share information with the broader community at meetings and consultations. After the tour, the participant representatives were invited back to the clinic to share their tour experiences with groups of 10 to 12 fellow participants until all the 654 participants at the three Zimbabwe sites had had a chance to attend a laboratory tour feedback session.

Table 1:

Qualitative sample by interview modality and by site

	All sites	Malawi	South Africa	Uganda	Zimbabwe
Total qualitative participants enrolled	N = 214	Lilongwe = 38	Cape Town = 35 Durban = 25 Johannesburg = 38	Kampala = 39	Harare = 39
Single IDI	34	6	13	7	8
Serial IDI	80	15	39	13	13
Exit FGD	100	17	46	19	18

Table 2:

Participants' characteristics in the qualitative component of the ASPIRE study

	Total	Malawi	South Africa	Uganda	Zimbabwe
Number of participants enrolled	214	38	98	39	39
Age, years median (mean, min-max) [n]	25.5 (26.4, 18-42) [214]	24 (24.6, 18-32) [38]	25 (25.6, 18-42) [98]	27 (28.2, 18-42) [39]	27 (28.5, 18-40) [39]
Currently Married	96(44.9%)	31(81.6%)	7(7.1%)	28(71.8%)	30(76.9%)
Highest level of education					
No schooling	5(2.3%)	-	-	4(10.3%)	1(2.6%)
Primary school (partial and complete)	45(21%)	20(52.6%)	2 (2%)	15(38.5%)	8(20.5%)
Secondary school (partial and complete)	156(72.9%)	18(47.4%)	88 (89.8%)	20(51.3%)	30(76.9%)
Attended college or university	8(3.7%)	-	8 (8.2%)	-	-
Participant earns an income of her own	107(50%)	17(44.7%)	39(39.8%)	29(74.4%)	22(56.4%)
Primary partner knows of trial participation	153(71.8%)	33(86.8%)	67(68.4%)	18(46.2%)	35(92.1%)
Primary partner knows about the ring	125(58.7%)	31(81.6%)	49(50%)	12(30.8%)	33(86.8%)
Ethnicity, tribe or language					
Zulu	45(21%)	-	45(45.9%)	-	-
Luganda *	39(18.2%)	-	-	39(18.2%)	-
Shona	34(15.9%)	-	2 (2%)	-	32(82.1%)
Xhosa	30(14%)	-	30(30.6%)	-	-
Chewa	16(7.5%)	16(42.1%	-	-	-
Ndebele	10(4.7%)	-	10(10.2%)	-	-
Ngoni	11 (5.1%)	11(29%)	-	-	-
Yao	4(1.9%)	4(10.5%)	-	-	-
Lomwe	3(1.4%)	3(7.9%)	-	-	-
Tonga	2(0.9%)	2(5.3%)	-	-	-
Other African tribe	16(7.5%)	-	9(9.2%)	-	7(17.9%)
Other	4(1.9%)	2(5.3%)	2(2%)	-	-
Time in ASPIRE (months) median (mean, min-max) [n]	25 (25.4, 4-34.1) [214]	19 (18.8, 11-25) [38]	28 (26.1, 7-34.1) [98]	31 (27.2, 4-34) [39]	31 (27.2, 4-34) [39]

(*) ethnic or tribal group not collected; only language available.