ACCEPTABILITY OF A VAGINAL RING TO PREVENT HIV AND PREGNANCY: INTEGRATING MULTIPLE QUALITATIVE METHODS

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ACCEPTABILITY OF A VAGINAL RING TO PREVENT HIV AND PREGNANCY:
INTEGRATING MULTIPLE QUALITATIVE METHODS

A DISSERTATION

by

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Concentration: COMMUNITY HEALTH AND HEALTH POLICY

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fulfillment of the requirements for the degree of Doctor of Philosophy

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ABSTRACT

Acceptability of a Vaginal Ring to Prevent HIV and Pregnancy:
Integrating Multiple Qualitative Methods

by

Dana Watnick, MPH, MSSW

Advisor: Diana Romero, PhD, MA

Heterosexual vaginal sex can simultaneously put women at risk for unintended pregnancy and sexually transmitted infections, such as HIV, disproportionately impacting poor women around the world. Both unintended pregnancy and HIV are persistent public health concerns associated with negative outcomes for mothers, families and communities. The current mix of prevention tools available to women to protect against unintended pregnancy and HIV is limited. Multipurpose Prevention Technologies (MPTs) are innovative products that simultaneously offer protection against pregnancy and HIV. However, MPTs will only be effective in reducing unintended pregnancy and incident HIV if women are willing to use them. With an understanding that product use relies on some level of product acceptability, I designed my dissertation study to produce a conceptual model of women’s acceptability of an MPT intravaginal ring (IVR).

Toward this end, I used grounded theory methodology and multiple qualitative methods (in-depth interviews, focus group discussions and card sort data) with 18-45 year old women in
the US, in the context of a Phase 1 trial of an antiretroviral IVR, to explore acceptability of an MPT in vaginal ring form. Concurrent to the conceptual analysis necessary for model development, I conducted a methodological assessment of the three forms of data to increase overall validity and complexity of findings in the new model. I integrated conceptual findings generated from the interviews, card sorts and focus groups with insights generated from evaluation of features inherent to each method.

The emergent model “Dynamic Considerations for Acceptability and Likely Use of an MPT Ring” identified a narrative of acceptability and use that includes three main constructs. The first construct related to product acceptability was “Episodic Factors”, which includes MPT product, use, and sexual encounter attributes that women consider per life episode (e.g. a sexual encounter). A second construct is “The Priority Triad”, which is a core process within the model that drives both women’s acceptability and commitment to use an IVR MPT. This triad describes how women (re)prioritize, (re)shift and (re)balance their acceptability of an IVR MPT based on the dynamic needs of relationships, partners and the self. A third construct describes the “Rationale for Need” of an MPT, based on women’s perceived risk of HIV and/or fertility desires. Women who determine there is no rationale for needing an MPT will be unlikely to use one, regardless of triadic priorities or episodic considerations. The conceptual components of this newly developed model were generally comparable across all three data collection methods, and data triangulation efforts demonstrated strong complementary results.

The new model elucidates the complexity of women’s acceptability and expected use of a vaginal ring for simultaneous prevention of HIV and pregnancy. The integration of multiple qualitative methods adds validity, depth and further insight into this model. Results from this study can inform clinicians and clinical guidelines for improving decision-making about
prevention methods that is woman-centered but also partner- and relationship-aware. Product developers should not develop a ‘best’ product, but rather a suite of MPTs that can fit a woman’s needs at different moments in her life. New MPT study designs should consider involvement of both partners; assessment of use during menstruation and sex; and should include women in different types of relationships, with varied perceptions of HIV risk and fertility desires. Study designs that incorporate multiple or mixed methods should embrace the inherent benefits of the respective data collection methods for deeper contextualization and meaning-making of conceptual findings. Future research efforts should test, augment and clarify this new model conceptually, as more MPTs are developed and evaluated and in different populations.
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This is a product that grew from the shoulders of many people and over nearly a decade. First, I would like to acknowledge the 30 women who took part in the investigation of a new sexual and reproductive health technology. Their generosity of body and mind will inform science and help to improve and save women’s lives. Relatedly, I would like to thank the investigator of the parent study, Marla Keller, who recognized the importance of biobehavioral data in technology development and thus supported my work intellectually and financially.

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SECTION 1: BACKGROUND AND SIGNIFICANCE

Introduction

Unprotected heterosexual intercourse simultaneously puts women at risk for unintended pregnancy\(^1\) and HIV, disproportionately impacting poor women around the world. Multipurpose Prevention Technologies (MPTs) are products that can be used to simultaneously prevent HIV and pregnancy\(^2\) and are in early stages of biomedical development, a process that typically neglects user perspectives on product acceptability. This qualitative dissertation is one of the first studies to include women’s perspectives concurrent to vaginal ring use during the course of a clinical trial.

Although many multi-level factors contribute to contraceptive and microbicide acceptability, to date there is no conceptual framework that incorporates individual, relationship and social level factors. This dissertation research therefore addresses a critical gap in understanding the multi-level factors that influence women’s acceptability and likely use of vaginal ring MPTs. Further, this dissertation systematically identifies the way in which we know what we know through a methodological assessment of data collection methods, which will allow us to identify useful methodological approaches for future research on product acceptability.

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\(^1\) ‘Unintended pregnancy’ is typically a composite measure of mistimed or unwanted births, induced abortions, and miscarriages from unintended pregnancies. Further discussion of this measure can be found in this dissertation in Section 1: “Women and Unintended pregnancy”.

\(^2\) Multipurpose prevention technologies (MPTs) are designed to prevent two or more sexual and reproductive health (SRH) issues at once; for example, preventing Herpes and HIV, or pregnancy and HIV. For the purposes of my research, however, I limited the focus to MPTs that are designed to explicitly prevent HIV and pregnancy, although other SRH issues, though not targeted, may be concurrently prevented as well.
The dissertation is organized into 4 sections. Section 1 provides the rationale for this study, including relevant literature, along with background information about the study. Section 2 describes the study design and introduces the methodological approaches to data production and analysis and introduces the ways in which grounded theory methodology informed the study overall. Section 3 first provides an overview of the substantive grounded theory developed from the data; then describes each component of the theory in-depth; and, finally, explores how specific features of each data collection method added to the overall understanding of acceptability and likely use of a vaginal ring MPT. Section 4 contextualizes the contribution of this research in relation to other knowledge informing the development of acceptable HIV/pregnancy prevention products for women and presents conclusions and implications for product development as well as the research process. A discussion of Study Limitations is also included as well as steps taken to minimize potential negative effects on study validity and overall findings.

**Sexual and reproductive health prevention needs of women**

Over the sexual and reproductive life course, women are faced with many challenges associated with pregnancy prevention and prevention of sexually transmitted infections, including HIV. The bodies of literature regarding these prevention methods (contraception/family planning and HIV prophylaxes) are vast, yet insufficient attention has been paid to the overlapping imperatives of these two needs. For those women with intersecting risk for pregnancy and HIV infection, the availability of MPTs adds an important option to their contraception and disease prevention method mix that is crucial for supporting overall sexual and reproductive health.
During this early stage in MPT development efforts, it is important to identify sub-populations of women at greatest risk for HIV or unintended pregnancy for whom the impact of multipurpose prevention might be greatest. Although interest in MPT development has been growing substantially over the past decade, financial resources have been limited, making it especially important to identify sub-populations who would benefit most from an MPT. However, identifying these sub-populations is difficult as surveillance data are not typically aggregated by overlapping risk for HIV and unintended pregnancy. Therefore, in the following review of the literature, I identify sub-populations that can be reasonably projected to be at highest need for an MPT based on risk for HIV and risk for unintended pregnancy separately and together. Within these sub-populations of women at risk, I call attention to specific demographic factors such as geographic region and age, as well as individual and couple-level characteristics such as occupation and relationship status.

**Women and unintended pregnancy**

Worldwide, 40% of pregnancies are ‘unintended’, defined as mistimed or unwanted births, induced abortions, and miscarriages from unintended pregnancies.1 Women in heterosexual relationships who use traditional contraceptive methods (defined as rhythm method or withdrawal) or no method at all have a higher likelihood of unintended pregnancy than women who use a modern method of contraception (such as barrier methods, pills or devices).2 Unintended pregnancy is a persistent public health concern associated with negative outcomes for mothers, families, and children including unsafe abortion, increased maternal substance abuse and depression, relationship instability between parents, inadequate prenatal care, and increased infant morbidity and mortality in children who were unintended.3–10 Sequelae from the 85
million unintended pregnancies in 2012 included 42 million abortions, many of which are unsafe in the developing world, 11 million miscarriages, and 32 million unwanted or mistimed births.¹

The direct causal association between unintended pregnancy and these negative outcomes is difficult to tease apart, as maternal social and economic disadvantage is correlated with both pregnancy intendedness and poor health.⁷,¹¹ Further, unintended pregnancy is itself a complicated construct to measure, as it does not capture the complexities involved with the phenomenon of getting pregnant, which may not always fit with a cognitive intentionality,¹²–¹⁴ and it presents difficulties in collecting valid retrospective data.¹³,¹⁵–¹⁸ Thus, global family planning interventionists frequently use a proxy indicator to identify those at greatest risk for poor pregnancy outcomes, called ‘unmet need for modern contraception’ (UNMC).¹,¹⁹,²⁰ This metric captures women (15-49 yrs) who are sexually active, capable of pregnancy, and say they want to stop or delay childbearing for two or more years, but nevertheless are not using any form of modern contraception.²¹ Women who are classified as having an UNMC make up a large share of those experiencing unintended pregnancies, accounting for 79% of all unintended pregnancies.²²,²³

Unintended pregnancy rates and UNMC are not uniform for all sub-groups of women, however, with large disparities existing across region, age, and relationship status. The global unintended pregnancy rate in 2012 was 53 per 1000 women with higher rates in developing (54 per 1000 women) vs. developed regions (44 per 1000 women).¹ Further, proportions of total pregnancies that were unintended vary dramatically by region, with the highest in the Caribbean (64%), South America (62%) and Southern Africa (55%), and the lowest in Western Africa (26%), Northern Africa (29%), and Western Europe (34%).¹ In 2010, UNMC among married or cohabiting women was lowest in the North America region (under 10%) and highest in North
Africa (approximately 15%) and sub-Saharan Africa (over 25%) with Asia, Europe, Latin America & the Caribbean and North America around 10%. It is important to note that low rates of unintended pregnancy (and associated low UNMC) do not necessarily equate to high rates of contraceptive use or prevalence, evidenced by high overall fertility in North and West Africa where large family size is desired and low overall fertility in Western Europe where family size is small.

In a 2016 analysis, scientists from The Guttmacher Institute evaluated UNMC in developing countries, using demographic and health surveys data. In general, women with less education, experiencing deeper levels of poverty, and those living in rural areas had higher rates of UNMC than their counterparts with more education, relatively less poverty, and urban living environs. Although the United States is a high income country, we see similar patterns of unintended pregnancy being disproportionately higher among Black and Latina women and girls who have overall lower socioeconomic status than white women and girls.

Reasons for contraceptive non-use in those with UNMC include side effect concerns and long-term health impact; perception of not being at-risk for pregnancy because of not having experienced a pregnancy in the past thus assuming infertility; low frequency of sex; amenorrhea due to breastfeeding, or being post-partum; and conceptual disapproval of family planning. Although these themes appear frequently for women across the globe, there are important variations. For example, 46% of all married women cite sexual inactivity because their husband ‘was away or staying elsewhere’ as a reason for contraceptive non-use. If we examine differences by country—e.g., Tanzania (16%) vs. Haiti (79%)—women’s sexual inactivity may reflect larger demographic factors such as male migration for work.
Another example of differences in contraceptive non-use exists by age. Younger women cite being ‘not married’ almost three times as often as older women, possibly indicating sporadic relationships or the stigma that would come with admitting to sexual activity outside marriage. In the United States, married women had the lowest rate of unintended pregnancy in 2011 compared to cohabiting women who had more than four times that rate (141/1000 vs. 29/1000 women and girls, 15-44 years old).25

Unintended pregnancy among adolescent girls (typically defined as 15-19 years old) is of special concern because of the high risks associated with pregnancy, clandestine and unsafe abortion, and childbirth in girls and young women.28–30 Adolescent pregnancies are projected to increase by 1.5-1.8 million per year in Eastern, Western, Central, and Southern Africa over the next decade, where currently one-third of adolescent pregnancies are unintended.31,32 About half of adolescent pregnancies (in women 15-19 years old) are unintended in developing countries, and half of those are estimated to end in unsafe abortions.33 There are approximately 38 million adolescent girls in developing countries who are sexually active, and 23 million of them have a UNMC putting them at risk for unintended pregnancies, unsafe abortions, and increased morbidity and mortality associated with adolescent pregnancy.33 Lack of knowledge and access to contraception, increased intimate partner violence and lack of control over contraceptive use and timing of first birth (married girls are often expected to reproduce soon after marriage) are all reasons why adolescent girls are especially vulnerable to increased fertility and unintended pregnancy compared to older women.23,24

**Women and HIV**

HIV transmission during heterosexual sex persists as a global problem, disproportionately affecting poor, young women. UNAIDS estimates 2.1 million individuals
acquired HIV in 2015 and, in sub-Saharan Africa, incidence is more than twice as high for young women than young men (15-24). Prevalence of HIV infection in women has remained stable, at approximately half of all cases globally. However, when these data are disaggregated by region it is clear that there is a disproportionate HIV burden on women living in regions with high community viral loads, especially sub-Saharan Africa and the Caribbean, where 58% and 61% of HIV cases, respectively, are among women. Other sub-groups of women at relatively higher risk for HIV include sex workers, young women, and women in HIV sero-discordant relationships. In the United States, HIV incidence among women was small (19% in 2014) compared to men, yet 87% of those infections were attributable to heterosexual sex.

Compared to men and boys in heterosexual relationships, women and girls are at increased risk overall for HIV. It is well-established that HIV is transmitted more easily from a man to a woman than the reverse during condomless vaginal sex because of increased HIV susceptibility in the cervicovaginal area compared to the penis. However, physiological differences are merely one component of a much larger framework involving extensive sociopolitical and gender-based inequality between women and men. Social and cultural norms around masculinity, femininity, and sexuality and power dynamics between men and women often limit women’s ability to access healthcare, education, and employment, or to negotiate condom or microbicide use with male partners.

The intersection of gender, power, and poverty creates a system in which many women are at disproportionately increased risk for HIV. For example, male-to-female intimate partner violence is one manifestation of gender inequality that is indicative of increased HIV infection in women, with violent male partners more likely to have multiple partners than men who are not violent toward their partners. A lack of prioritizing education for girls and women may also
increase HIV risk. In a review of school dropout internationally, many households had gender-based preferences to educate boys instead of girls in resource-constrained contexts resulting in increased school dropout for girls.\textsuperscript{48} One study found that, compared to women with at least 6 years of schooling, under-educated women are doubly likely to acquire HIV.\textsuperscript{46}

For poor women, maintaining financial security for themselves and their children often means that women are beholden to their male partners’ wishes, including sexual activity, that puts them at increased HIV risk including sex without a condom or partaking in intravaginal practices such as ‘dry sex’ which creates increased HIV vulnerability through increased vaginal abrasions.\textsuperscript{44,49} Regional increases in poverty have forced both men and women into migrant labor increasing women’s HIV risk in two ways: male migrants who travel to cities with disproportionate HIV prevalence have a greatly increased likelihood of bringing infection home to their female partners, and female migrant workers are often greatly limited in their labor options, and therefore often end up doing high-risk sex work to feed their families and contracting HIV themselves.\textsuperscript{50-52}

**Young women and girls** (typically 15-24 yrs old \textsuperscript{34}) are a sub-group of particular concern because they are vulnerable to all of the above risks for HIV at a younger age, meaning a lifetime of disease management and potential transmission to others. Young women account for 20% of all new HIV infections globally, despite making up only 11% of the adult population and are mainly acquiring HIV from heterosexual sex.\textsuperscript{34} In 2013 nearly 60% of incident cases of HIV among 15-24 year olds occurred in girls and young women. Of all the 15-24 year old girls and women living with HIV globally, 80% of them live in sub-Saharan Africa where 450,000 new infections occurred in this age and gender group in 2015.\textsuperscript{53,54}
Young women face particular risks due to physiology as well as social factors. Biological researchers are investigating whether girls’ potential for increased susceptibility to HIV is due to increased likelihood of mucosal injury in the immature female genital tract potentially as a result of sexual violence. In recent studies of young South African women in 2015 and 2016, scientists have also discovered the effects of vaginal bacteria that can protect or disrupt the protective properties in the vaginal microbiome as well as bacteria that nullify or “gobble up” the microbicide tenofovir in young women. In addition to young women’s increased physiological susceptibility to HIV infection, the interaction with gender inequalities such as vulnerability to rape and having an older partner further increase their risk.

HIV infections vary by relationship status and region. For example, South African married partners have lower rates of infection than unpartnered individuals, or women in new or non-marital relationships. Yet, in Kenya, girls in early marriages (ages 14-19) have higher HIV risk than girls in out-of-marriage relationships. More research is needed to understand the different risk levels relationship status may confer in regions with different background HIV prevalence, and norms related to age at marriage. One review explained the compelling forces driving poor, young girls to transactional sex with older partners as payment for basic needs, increased social status, and confirmation of a partner’s love and commitment. Regardless of the underlying causes, however, tracking the effect of relationship status on HIV risk is critical to understanding HIV prophylaxis in women across sub-groups, and for understanding the markedly increased risk that young women face.

In a 50-country systematic review of the literature, female sex workers were found to have 13.5 times the prevalence of HIV than the general population of women 15-49 yrs, and prevalence estimates from 2013 demonstrate that 11.8% of sex workers were HIV positive.
globally. \(^{37}\) HIV prevalence in sex workers varies regionally; the highest pooled prevalence is in sub-Saharan Africa estimated at 36.9% compared to 1.7% in the Middle East and North Africa. Despite this extraordinarily high prevalence of HIV in sex workers, and risk of transmission, HIV preventive services reach less than 50% of this target population. \(^{37}\) Although sex workers are one of the highest prevalence sub-groups impacted by HIV, they are also one of the most likely to respond to HIV prevention programs given their motivation to preserve their health and ability to maintain a living. \(^{61}\) In some cases, sex workers are prohibited or dissuaded from using condoms for financial benefit and face violence if they refuse. \(^{62}\) However, a female-controlled prophylactic device that does not require negotiation with a male client (such as a vaginal ring) could be one way for sex workers to protect themselves, their partners and their clients.

**HIV-negative women in a serodiscordant relationship** have increased risk of HIV via sexual transmission from their partner. A ‘heterosexual serodiscordant’ couple is typically defined as a couple that is married, co-habiting, co-parenting or in a longer-term relationship length (>3-6 months) wherein one partner is HIV negative and the other is HIV positive. \(^{63}\) Serodiscordance in heterosexual couples can translate into substantial reproduction of disease and disease burden within a population. For example, estimates from high prevalence settings show that approximately half of HIV positive people have an HIV negative partner, and in low prevalence settings up to 75% of HIV positive people are in a serodiscordant relationship. A 2013 study that mathematically modeled HIV infection rates among serodiscordant couples in sub-Saharan Africa found that 29% (ranging from 10-52%) of new infections would occur among serodiscordant couples. \(^{41}\) In these relationships, recommendations include antiretroviral medication (ARVs) for the HIV positive partner to reduce viral load, as undetected viral load
prevents transmission, and PrEP for the HIV negative partner (where available) to prevent infection.\textsuperscript{64,65}

The belief that monogamy can reduce HIV risk does not hold true in serodiscordant relationships, whether status is known or unknown. Rather, for women, the likelihood of infection increases the longer an HIV negative woman remains in a sexual relationship with her positive male partner. One study that modeled HIV transmission among serodiscordant couples demonstrated that over one year, women’s risk of contracting HIV (from a male partner living with HIV) ranged from 0.05% to 20%, but over the course of 10 years women’s risk increased, ranging from 0.5% to 89%.\textsuperscript{66}

Consistent use of PrEP or a condom, with or without the male partner’s use of antiretroviral medication, decreases a woman’s risk of acquiring HIV to 2% or less at the one-year mark.\textsuperscript{66} In a 2016 study in South Africa, however, it was found that incidence of HIV infection was lower in serodiscordant married couples where spouses cohabited than in other serodiscordant marriages or in unmarried cohabiting serodiscordant couples (which had the highest incidence). Thus, the type of relationship also matters for likelihood of transmission within serodiscordant couples.\textsuperscript{67,68} The difference in infection for these different relationship types may reveal important vulnerabilities to HIV risk such as lower level of commitment or concurrent partnerships.\textsuperscript{68} The label ‘serodiscordant’ necessitates that the status of both partners is known and shared. However, there is likely a large number of couples for whom the HIV+ partner’s status is unknown or undisclosed, and therefore those couples are not classified as serodiscordant and thus cannot be targeted for intervention. The risk of disease transmission may be underestimated for this subpopulation because the size of this group itself is likely underestimated.
Women at the intersection of risk for HIV and Unintended Pregnancy

There are many countries in which rates of HIV, unmet need for contraception and unintended pregnancies are similarly high. In a 2016 mapping study of countries with overlapping high rates of UNMC and HIV, Schelar et al. used three different analytic techniques (principle component analysis, additive prevalence, and graphical overlap) to determine the composite burden of HIV and UNMC in countries or regions around the world, to demonstrate places where MPTs could have the greatest impact\textsuperscript{21} (Appendix A). Their triangulated analyses used multiple sources of country-level demographic data and showed that countries within sub-Saharan Africa exhibited the highest prevalence of composite burden of HIV and UNMC. Unsurprisingly, many of the countries with relatively higher levels of gender-based inequality and poverty were among the countries with high composite levels of HIV and UNMC (e.g., Albania, Kenya, Tanzania, Zambia) of HIV and UNMC.

Although women can be at risk for HIV and unintended pregnancy from an unprotected sex act, there is also the potential that pregnancy risk and/or HIV risk can increase because of an interactive effect between the two risk factors.\textsuperscript{69} A handful of researchers have demonstrated a risk association between pregnancy and HIV acquisition, where HIV infection doubled\textsuperscript{70} or tripled\textsuperscript{71} during pregnancy, and demonstrated a four-fold increase in HIV incidence among pregnant vs. non-pregnant women.\textsuperscript{72} These increases in risk have been attributed both to physiological changes occurring during pregnancy putting a woman’s body at increased risk of disease acquisition as well as behavioral changes including partner infidelity and HIV-unprotected sex.\textsuperscript{70,73} Babies are also greatly impacted by the intersection of HIV and unintended pregnancy in mothers. In one South African study (n= 10,178), babies who were exposed to HIV in-utero were more likely to have been unintended than babies of HIV negative mothers; among
babies exposed in-utero to HIV, 61% were unintended as compared with 39% who were not exposed to HIV in-utero.\textsuperscript{74}

Epidemiologically, we are able to identify sub-populations of women at increased risk for HIV and unintended pregnancy. However, this does not always translate into perceived risk for either of these outcomes. Although many studies document an association between low perceived risk (despite actual risk) for pregnancy and contraceptive use,\textsuperscript{75–77} little is yet known about how HIV risk perception impacts uptake of preventive devices like PrEP, microbicides or MPTs.

**MPTs for Dual Prevention of HIV and unintended pregnancy**

*The emergence of MPTs to bridge historical silos of family planning and STI/HIV prevention*

The emerging field of MPT research and development has built upon two historically siloed fields of health services and research mainly in Low and middle income countries, but also in high income countries: 1) Family planning (FP)/reproductive health, and 2) HIV treatment/prevention.\textsuperscript{78–82} Despite calls made by international health bodies for bidirectional integration (HIV into FP and FP into HIV), this goal has faced many challenges at multiple levels.\textsuperscript{80,83–85} Some of the main challenges have included funding shifts like restrictions on US family planning services and increases in international HIV aid; service delivery problems related to provider training and keeping supplies stocked at ‘brick and mortar’ clinics; and patient fear of stigma for accessing contraceptive or HIV services.\textsuperscript{80,86}

As researchers, organizations and government bodies persist in trying to meet integration goals, one concrete approach to deconstructing the silos is the development of an integrated product that can simultaneously prevent HIV and pregnancy. In 2009 an international collaborative, the Initiative for Multipurpose Prevention Technologies (IMPT), was launched to
bring together autonomous disciplines of HIV/STIs and contraceptive research to collaborate and advance the science around biomedical MPT research and development.\cite{87} The IMPT is a “product-neutral collaboration” of members (researchers, product developers, funders, policymakers and advocates) from multiple disciplines who work together toward development of impactful MPTs. This unique approach to product development is responsive to the historical divisions between disciplines and market competitors, among others.\cite{87} The IMPT also recognizes that the success of new MPTs will rely on a deep understanding of the lessons learned from the currently available MPTs.

**Lessons learned from currently available MPTs: male and female condoms**

Currently, the only two MPTs available to guard against pregnancy and HIV simultaneously are male and female condoms. Most of the behavioral research around both types of condoms has examined attributes of one condom type or the other, although some studies have actually compared acceptability of male vs. female condoms, generally finding greater overall acceptability and use of male condoms among both men and women.\cite{88, 89, 90} Male condoms have had a longer history of use globally, having been marketed first as a contraceptive device and more recently to stop the spread of STIs/HIV, as more effective methods of contraception have been developed and the threat and severity of STIs/HIV have become more pressing. With perfect use, male condoms have a high rate of efficacy for pregnancy prevention, with only a 2% failure rate.\cite{91, 92} A recent estimate taken by global modeling analysis demonstrated that condoms have averted approximately 50 million HIV infections since the epidemic began.\cite{93}

Female condoms emerged more recently in the 1980s as a ‘female-initiated’ option for contraception and STI/HIV prevention. Female condoms have a slightly higher pregnancy failure rate than male condoms with perfect use (5% vs. 2%), or typical use (21% vs. 14%) and have an
STI failure rate of 3-6% with correct and consistent use. Studies of women in stable relationships showed that female condoms were somewhat acceptable to both female and male partners, with acceptability increasing with continued use, and product failure decreasing over time. Women report feeling safer and more capable of protecting themselves, having better lubrication and even heightened sexual pleasure from the outer female condom ring when compared to the male condom. However, significant drawbacks to female condoms have been highlighted including difficulty with insertion, foreign sensation, messiness, and noisiness (with the original FC1) thus, initial bad impressions of its use as an MPT have dissuaded further product use. Price is often cited as a barrier to female condom accessibility and uptake (the unit cost is higher than male condoms; in 2008 the UNFPA was paying 29 times the price for a female condom than male condom for country-wide distribution), making female condoms more difficult to access than male condoms, especially for poor women. The cost differential, however, has been cited as a function of initial price monopoly and supply failure rather than a true failure of user demand based on acceptability.

Despite the potential effectiveness of both male and female condoms to prevent pregnancy and HIV, most people do not or cannot always use either type correctly or consistently. There are multiple reasons cited for incorrect or inconsistent use including a variety of individual-level factors such as low risk-perception, interrupting the momentum of sex and decreased sensitivity. Couple-level factors include expectations of monogamy precluding need for a condom for disease prevention, concerns over partner trust, relationship saliency and positive fertility desires. Provider-level factors have been cited such as lack of training, lack of available pelvic demonstration models, or providers’ own discomfort with sexuality. Social or community-level factors include stigmatization of sexual behavior and
STIs, gendered power dynamics that dictate men to carry and approve of use of condoms and women to comply. Finally, problems with low government-level prioritization, under-investment in research and development of the female condom, supply chains and distribution have been cited as reasons for low uptake. Lessons learned about acceptability and use from current barrier-method MPTs thus include a variety of factors at multiple levels of potential intervention.

**MPT product development: lessons learned from contraceptives and PrEP**

Although male and female condoms have benefits of lower cost, lack of side effects and availability, (among others), they also have a host of issues that make them undesirable for women and men, especially in the context of a committed or long-term relationship. Thus, developers of new MPTs are aiming to address some of the problems associated with condom use in order to make the next generation of MPTs more acceptable to potential users. The approach to this work requires integration of lessons learned from both previous contraceptive research and the relatively new knowledge around adherence and acceptability learned from microbicide and other PrEP trials. Because the only MPTs currently available to the public are barrier methods (male and female condoms), evaluation of user preferences for drug-based MPTs in a real world setting is not yet possible. To proxy for this gap in product availability, I will present information from three separate literatures that can contribute to our understanding of MPT acceptability: 1) contraceptives; 2) Pre-Exposure Prophylaxis (PrEP)/microbicides and trials; and 3) hypothetical MPTs and MPTs in early development stages.
Lessons from contraceptives

Contraceptive methods to control fertility in women include birth control pills; patches; vaginal rings; long-acting injectables; cervical caps; diaphragms; IUDs; implants; emergency contraception; spermicides; and male and female condoms (also MPTs). It has been shown through an analysis of data from 80 countries, that improving access to a wide range of contraceptive options is associated with higher rates of contraceptive use.\textsuperscript{112} Some of these existing forms of contraceptive devices are also being considered for use as microbicide and MPT delivery systems, thus only those forms will be discussed here further: a pill, vaginal gels, vaginal rings and diaphragms. The oral contraceptive pill has been available in the US since it was FDA-approved in 1960, and since then approximately 82\% of US women have reported using it at some point during their reproductive lives.\textsuperscript{113} Although the pill has a possible effectiveness of over 99\%, the typical failure rate is 8\%\textsuperscript{91}, which is attributed to adherence issues such as forgetting or having logistical barriers to taking a daily pill (e.g. refilling prescriptions on time) and decreased acceptability from hormonal side effects such as weight gain, headaches, change in mood and decreased libido.\textsuperscript{114}

In a study to understand a spermicide in gel vs. vaginal film form of contraception, women liked the ease of gel use but disliked the messiness. In response, women would use less product to decrease messiness, decreasing product efficacy.\textsuperscript{115} The film was much harder to insert and caused dryness. Across different sites, however, the ‘wet’ or ‘dry’ attribute was preferred differently as related to regional cultural norms about preferences for wet or dry sex, which has been seen in other contexts testing microbicide products.\textsuperscript{115,116}

Contraceptive research with vaginal rings demonstrated that overall, rings have been acceptable to most users, especially the monthly ring which is controlled by the woman,
providing hormonal drug for three weeks of wear and one week out for withdrawal bleeding, which many women like because users are reassured they are not pregnant.\textsuperscript{117,118} Although there are higher than expected ring removals partly due to hormonal side effects, other reasons such as discomfort with vaginal touching, expulsions during toileting, and objections to a partner feeling the ring during sex have been attributed to non-acceptability of the device itself.\textsuperscript{117}

Diaphragms with spermicidal jelly are used as contraceptive barrier methods, and are available in a provider-fitted style as well as a single-size option. Diaphragms are less effective at pregnancy prevention than condoms, with a failure rate of 6\% with perfect use but a similar failure rate as condoms with typical use of approximately 20\%.\textsuperscript{95} In one study comparing the fitted and single-size diaphragm failure rates were found to be similar at approximately 11\% for both.\textsuperscript{119} One large qualitative study of women in seven countries showed a broad range of acceptability of the diaphragm varying across regions, cultures, socioeconomic status and relationship status.\textsuperscript{120} American women, who had the most experience with diaphragms, had different levels of acceptability based on suburban vs inner-city profiles: suburban women appreciated using a non-hormonal contraceptive device, yet disliked the messiness vs. inner-city women disapproved of touching themselves for insertion and were worried about inconvenient clinic visits for fittings. Cambodian, Peruvian, Mexican and Pakistani women were unfamiliar with diaphragms but expressed hypothetical concerns including cost, dirtiness associated with re-use, lack of time to plan for insertion and lack of privacy for insertion in shared sleeping quarters.\textsuperscript{120}
Lessons from PrEP/microbicide clinical trials:

As of 2016, the one method of PrEP that has been approved for use by the US FDA is oral Truvada (a combination of tenofovir disoproxil fumarate (TDF)+ emtricitabine (FTC)).\textsuperscript{121} Although Truvada has been approved for use as PrEP since 2012, many women have been reluctant to take it prophylactically, so there are little data of female PrEP use.\textsuperscript{122} In contrast to the way we can understand contraceptive acceptability in real-world users, we can only study issues around acceptability and uptake of PrEP more generally, by examining participant experiences in the large clinical trials that evaluate(d) safety, pharmacokinetics, efficacy, acceptability and adherence of microbicide-based drugs and other forms of PrEP in development.

Trials of both oral Truvada and oral TDF have demonstrated reduction of relative risk of acquiring HIV ranging from 44-86% with high-risk populations, with questions remaining about the impact of low adherence on risk reduction. These include the iPrEx, IPERGAY and PROUD studies with men (and transgender women) who have sex with men;\textsuperscript{123–125} the Partner’s PrEP study with serodiscordant couples;\textsuperscript{126} the TDF2 trial with heterosexual men and women in high prevalence regions;\textsuperscript{127} and, the Bangkok Study with injecting drug users.\textsuperscript{128} However, two additional efficacy trials of oral Truvada (FemPrEP\textsuperscript{129} and VOICE\textsuperscript{130}) with heterosexual women failed to show efficacy of oral dosing due to widespread product non-adherence and subsequently ended prematurely. One study with heterosexual women (CAPRISA-004\textsuperscript{131}) demonstrated efficacy with an overall 39% HIV risk reduction and by 54% in women who used it consistently. It involved pericoital use of tenofovir-based intravaginal gel applied within 12 hours before and 12 hours after sex (with no more than 2 doses in 24 hours). However, a
subsequent study (FACTS 001 trial)\textsuperscript{132} utilizing 1\% tenofovir vaginal gel found no such efficacy with daily\textsuperscript{130} or pericoital gel use, also citing product adherence as a barrier to efficacy.

Reasons for non-adherence in the three failed trials (FemPrEP, VOICE and FACTS) were complex and are important to understand if the microbicide and MPT fields are to advance. Compared to trials with MSM or serodiscordant couples where HIV risk is understood and acknowledged more openly, heterosexual women in these 3 failed trials had a lower perception of risk. For example, in the Partners PrEP study, HIV negative partners had nearly 100\% adherence, citing that taking the study product decreased their anxiety about contracting HIV, compared to 70\% of women in FemPrEP reporting they were at low risk for contracting HIV.\textsuperscript{133–135} Risk perception was measured among all women in FemPrEP, four weeks prior to testing. Among women who seroconverted during FemPrEP, when asked about risk perception four weeks before HIV diagnosis, they justified their low risk perception as related to prior non-infection, trusting their partner not to infect them and sometimes an inability to protect themselves despite perceived risk.\textsuperscript{136}

In addition to risk perception, there have been significant barriers to user acceptability and product adherence in oral and vaginal gel PrEP trials. Investigational gels have been noted for their messiness, leaking\textsuperscript{137} and dosing schedules that require a high level of planning that is incongruous with sexual activity in most couples.\textsuperscript{138} (It bears noting that gels have also been discussed positively as providing lubrication during sex.\textsuperscript{139}) In a qualitative sub-study to evaluate non-adherence in the VOICE trial of daily oral pills and vaginal gel, African women associated taking the daily ARV with stigmatized treatment instead of prevention for HIV.\textsuperscript{140} Because of this women were secretive about taking their daily pill or using a vaginal gel, often hiding it from other members in the household and their partners. Trials have shown that partner support or
disapproval also heavily influenced overall product acceptability and adherence to a trial or regimen.\(^{140-143}\)

Because of the significant adherence challenges with FemPrEP, VOICE and FACTS 001, scientists and product developers have expanded the repertoire of medication type and delivery systems for PrEP use by women. Other PrEP medications are in development and are currently being tested for efficacy in a variety of delivery systems. These include maraviroc as a daily pill and vaginal ring\(^{144}\); rilpivirine and cabotegravir as an injectable\(^{145,146}\); dapivirine in a vaginal ring\(^{144,147}\); and tenofovir or TDF as a vaginal gel, vaginal ring or a rectal gel\(^{148}\). For women engaging in penile-vaginal sex, the use of vaginally localized microbicides (eg. ring, gel or film) over oral administration has benefits of higher drug concentrations in the cervicovaginal area and resulting in greater HIV protection.\(^{149-151}\) Also, adherence to PrEP and its delivery system remains a crucial and relatively new area of inquiry as efficacy of ARV-based PrEP appears to be highly dependent on adherence.\(^{152-155}\)

In response to the trial failures of pills and vaginal gels in women, biobehavioral scientists are beginning to emphasize the need for developing additional medications and devices for HIV prevention, particularly ones that do not require daily or peri-coital-dependent use, and that are acceptable to women, their partners and communities. Most of these newly designed devices are female-initiated, in response to gender norms that allow for a man to override a female partner’s agency over protection from HIV and unintended pregnancy.\(^{156,157}\) Longer-acting approaches, such as sustained delivery of ARVs from an intravaginal ring (IVR) or long-acting injectables, may overcome some of the acceptability and adherence challenges observed in previous PrEP trials given the higher acceptability of these methods for pregnancy prevention.\(^{158,159}\) Although research has been conducted on acceptability of ARV-containing IVRs, there is a
dearth of behavioral research to understand the breadth of issues for potential users, their partners and communities. 153,160–163

Since the failures associated with microbicide gels have been reported, scientists have begun to favor the development of intravaginal rings to deliver PrEP drugs. Recent studies with women in sub-Saharan Africa showed microbicide IVRs to be very tolerable and comfortable during everyday use as well as during sex. 153,160,161 In the two most advanced clinical trials of dapivirine rings (the ASPIRE trial and Ring Study), microbicide rings reduced HIV acquisition by 27-31% in the overall study samples. However, in girls 18-21 years of age, no significant HIV protection was conferred, potentially indicating differences in young peoples’ acceptability of IVRs and/or a biological difference in the cervicovaginal area that makes young women more susceptible to infection than older women. 164,165

Studies of acceptability of dapivirine and placebo IVRs in African and US women demonstrated that the rings were comfortable, not noticeable during daily activities, but approximately 10-20% expressed a preference not to wear the ring during menses. 152,161,163,166 When a dapivirine IVR was tested in post-menopausal US women, over 90% of women reported liking the ring after 12 weeks of wear. 167 Social and cultural level issues including gender-based violence, intravaginal practices, menstrual practices and sexual pleasure have also been noted in trials as key factors for microbicide user acceptability. 168–172

A rationale for developing an IVR for both pregnancy and HIV prevention is that it is a female-initiated method. Because it is worn internally and is not used episodically, women do not need to negotiate or even disclose ring use to male partners, as they might with condoms or vaginal gels. 156,157 However, previous microbicide gel research showed that covert use was not a concern in most serious or monogamous relationships. 173–177 Therefore, more research is needed
to develop a product that can properly address individual and relationship needs to guide responsive product development.

**Early stage development of MPTs**

Unlike contraceptive or microbicide devices in development, MPTs are in an earlier stage of development and so there is no published literature on effectiveness of these products, and limited information on efficacy is based on current trials.\(^{87,178}\) The MPTs currently in pre-clinical or clinical development are IVRs, gels, suppositories, films, oral tablets, intrauterine reservoirs and a diaphragm (a modified, silicone, one-size-fits-most “SILCS” diaphragm\(^{179}\) releasing a microbicide). According to the IMPT database tracking MPT technology in development, as of July 2019 there are five vaginal ring MPTs in preclinical trials and two that are in Phase 1 clinical trials. Four of the five rings are a combination of a previously tested microbicide + hormonal contraceptive, and one is a microbicide + nonhormonal contraceptive.\(^{87}\) The vaginal rings are being developed to range in duration of use from 28 to 90 days, with some question about if and when menses will occur in relation to ring exchange. The modified SILCs diaphragm could be designed for use over the course of a year and the gels are being designed to be long-acting and coitus-independent.\(^{179}\) From a historical perspective, we can surmise that these products arose in response to acceptability knowledge accrued from microbicide trials that 1) developed products localized to the cervicovaginal area for women because of behavioral barriers to oral daily dosing and pharmacological problems with sufficient drug levels at the exposure sight, 2) a range of pericoital and coitus-independent products, and 3) hormonal and non-hormonal products.

Only one study to date reports on primary data regarding MPT-specific concerns and preferences from a hypothetical MPT. In this study, the data were collected from participants
who had participated in two microbicide trials using candidate gel or gel + diaphragm in Malawi and Zimbabwe. Women, their partners, healthcare providers and community stakeholders were asked about hypothetical acceptability of a gel MPT. Some of the advantages named of an MPT were the health protection provided for multiple indications at once, specifically protecting women from compounded health challenges related to being HIV+ and pregnant; the ability to hide or downplay importance of either drug component (microbicide or contraception) to a partner; and an (incorrect) assumption that a combined product had fewer drugs and subsequent side effects than contraceptive + microbicide separately. There was also a division among women: some prioritized HIV-only prevention, some prioritized pregnancy-only prevention and others HIV and pregnancy prevention, potentially indicative of women in different life contexts and reproductive stages perceiving needing protection from different things.

What is still not known about MPTs is women’s preferences for MPTs wear duration, interaction with menstruation, partner concerns and coitus dependence. While we can conjecture about these preferences by cobbling together what we know from women’s PrEP and contraceptive preferences separately, it is time that we prioritize and explore this construct in the context of actual product development efforts. Until recently, research for microbicide and MPT development has excluded user experience and acceptability, and reasons for non-adherence are discovered much later in the product development pipeline (after Phase 1 clinical trials, often when products are more difficult to modify). Acceptability research on long-acting approaches to prevent HIV and unintended pregnancy is critical early in product development, however, so that user and partners’ perceptions, concerns, and preferences can be identified and incorporated into subsequent design iterations. Incorporating user preferences in early phase clinical trials may shorten the product development timeline, prevent costly large-scale clinical trials that fail due to
participant non-adherence, and improve likelihood of product adoption once developed. MPTs, are still in the early development stage, and are already following a similar trajectory of clinical testing as microbicides; it is crucial that user perspective is incorporated early for these same reasons.
Study Purpose and Specific Aims

The purpose of this research is to develop a theory of MPT vaginal ring acceptability. Toward this end, I use multiple qualitative methods (in-depth interviews, focus group discussions and card sort data) from US women 18-45 years old in the context of a Phase 1 trial of an antiretroviral IVR to explore acceptability of an MPT in vaginal ring form. My dissertation:

1. Uses grounded theory methodology to explore multiple levels of influence (individual, couple, social) on acceptability of an IVR MPT and identify thematic differences by experimental group (ex. side effects) and by potential theoretically emergent factors (ex. relationship status).
   a. Implements in-depth interviews to understand women’s individual and relationship contexts, perceptions and attitudes about an IVR MPT.
   b. Implements a card sort activity to identify relative value of identified acceptability factors and to provide insight into the way women group, sort and describe components of IVR MPT acceptability.
   c. Implements focus groups to further examine emergent factors found in 1a and 1b, and to understand socio-cultural factors related to IVR MPT acceptability.
2. Conducts a methodologic assessment of the comparability and complementarity of acceptability findings across the three different data collection techniques employed to inform both the validity of the findings as well as potential differences attributable to the method.
3. Develops a conceptual model for IVR MPT acceptability among women in the US, based on the findings from Specific Aims 1 and 2.
Significance

Understanding women’s need for sexual and reproductive health products for prevention, and specifically MPTs, requires an understanding of both single and combined risk factors for HIV and unintended pregnancy. Eventual MPTs offer a positive addition to women’s options for supporting and protecting their sexual and reproductive health. By targeting both kinds of risks with the same preventive device, health workers and advocates may redouble the positive impact of their work by offering a product responsive to the needs of some women.

New MPT products present challenges related to combining drugs and device technology, highlighting the need for scientists to ‘cross the aisle’ between the family planning and HIV prevention fields in order to make effective and acceptable products that serve women’s varying needs for contraception and disease prevention. There is international commitment from these two disciplines to pursue a collaborative model to MPT development. Incorporating user input into early phase clinical trials may shorten the product development timeline, prevent costly large-scale clinical trials that fail due to participant non-adherence, and improve likelihood of product adoption once developed.181

In order to best understand the parameters of MPT acceptability it is essential to speak directly to women to learn how potential users define components of acceptability as they relate to the context of their own lives including their sexual relationships, families and communities. Since our understanding of MPT acceptability is minimal, and limited to barrier methods only, qualitative inquiry is the appropriate methodological choice to explore the breadth and depth of ‘acceptability’ as a construct and how this construct applies to women and their partners at multiple levels of influence. Using multiple qualitative methods adds strength and allows for exploration of multiple levels of influence on women’s MPT acceptability, ultimately leading to
a new theoretical model grounded in the data. The development of a new model of MPT acceptability will help guide future inquiry into MPT product acceptability and development. Further, an evaluation of the methodological contributions to this model will be helpful to future study design choices of other MPTs.
SECTION 2: GUIDING FRAMEWORKS and METHODOLOGY

In this chapter I describe the approach and present the rationale for using grounded theory methodology to explore and develop an integrated theory of women’s acceptability of technology to prevent HIV and pregnancy. Grounded theory offers an approach to both gathering and interpreting data to inform this acceptability construct, and consequently develop an empirically based theory, where currently none exists.

Using Grounded Theory to understand acceptability of MPTs

In their seminal work on the method, Glaser and Strauss (1967) broadly defined grounded theory as, “the discovery of theory from data systematically obtained and analyzed in social research”\(^\text{182}\) (p. 1). It is a systematic and inductive approach to conducting data collection and analysis that aims to clarify concepts and conceptual relationships within the data for the purpose of ‘grounding’ theory from those data.\(^\text{183}\) Grounded theory has been heralded as both a methodology—indicating presence of an overall research strategy and its underlying epistemology—and a method—focusing solely on specific techniques and procedures for data collection and analysis.\(^\text{184,185}\) Contemporary grounded theory scholars typically align this methodology with appropriately chosen qualitative methods to generate findings that are ‘grounded’ in the data.\(^\text{185,186}\) My dissertation research follows in this tradition of incorporating grounded theory methodology with concrete qualitative methods to ultimately develop a theory of MPT vaginal ring acceptability. Specifically, my dissertation research takes a grounded theory approach to overall study design, guiding participant recruitment, data collection, analysis and theory/conceptual framework generation.\(^\text{186–188}\)
There are many examples of qualitative studies exploring acceptability of sexual and reproductive health products using grounded theory. However, reports of using grounded theory in this growing field are nearly always restricted to specific data analysis techniques focusing on the coding process; approaches to thematic analysis that use constant comparison; and, the incorporation of inductive and deductive thinking. Only one of the previously reviewed studies report the development of theory from analysis, and the same study was the only one reporting the use of theoretical sampling. This gap in applied methodological approaches to acceptability of MPTs is one that my dissertation aims to fill, both in terms of breadth and complexity.

**Grounded Theory and multiple qualitative methods**

The general purpose of grounded theory is to help the researcher find a more complete understanding of a phenomenon at hand through various techniques in order to generate new theory. According to leaders in the grounded theory movement, these various techniques include four broad components considered as its ‘foundational pillars’:

1) All is data
2) Emergence (of categories, relationships, theory and research design)
3) Constant comparative analysis
4) Theoretical sampling

With these pillars in mind, one of the basic applications of grounded theory is to move from one stage of understanding into another, which often requires further data collection to explore emergent findings. These iterative data collection efforts are not prescriptively qualitative or quantitative but are more so responsive to the emergent and developing pathway of
understanding. Hence, using more than one type of data is a sensible process for developing a grounded theory.

*Mixed methods* and *multiple methods* research strategies are often logically indicated in the process of doing grounded theory. While the definitions of mixed and multiple methods are the center of ongoing methodological debates, the main distinction of importance to this dissertation is that mixed methods research typically includes at least one quantitative component, and multiple methods research offers a broader array of possible methods used within one larger project that can be all qualitative if indicated.\textsuperscript{202} The overarching strategy for answering a research question using multiple methods is to “attack [it] with an arsenal of methods that have non-overlapping weaknesses in addition to their complementary strengths”\textsuperscript{203} (p. 6). Thus, the process of doing grounded theory offers a theoretically congruent approach to the use of multiple qualitative methods by its inductive nature. This dissertation research attempts to add methodological insight into ways in which multiple qualitative methods can be effectively triangulated to best inform grounded theory development. The choice of which qualitative methods were used and their timing in this study is discussed later in this Section.

**Guiding conceptual frameworks**

In current clinical trials for microbicides, product *acceptability* is of interest because of its potential to explain product use or adherence both in the context of a trial and in daily life of potential users. The acceptability construct, however, has been difficult for researchers to define, and consensus has not been reached by either the HIV prevention or family planning fields.\textsuperscript{168,204} Research on acceptability has been guided by an array of social and behavioral theory that has been applied to contraceptive and microbicide products, and, in this study, was extended to MPT Rings.\textsuperscript{154,205–207}
Two prominent conceptual frameworks of microbicide acceptability guided my research questions and implementation. The first was The Holistic Model of Microbicide Acceptability originally developed by Woodsong et al. to clarify key factors relevant to willingness to use a microbicide gel and diaphragm product pair.\textsuperscript{208} It was built in response to a union of relatively linear, individual-level theories that have been used to guide behavior change research on HIV prevention.\textsuperscript{209–212} While Woodsong’s model acknowledges individual levels of influence on microbicide acceptability, it also takes into account socio-cultural and relationship factors that can influence an individual’s acceptance of a product. Woodsong’s Holistic Model has guided studies of microbicide acceptability and is a flexible conceptual framework that could feasibly include elements related to pregnancy prevention.\textsuperscript{154,161,213} Thus, it was initially adapted for use in this dissertation (adaptations indicated in italics) to guide initial understanding about the multiple and interacting levels of influence on MPT IVR acceptability (Figure I).

The model identifies three domains within microbicide acceptability: Product Attributes (such as sensory experience, side effects or interruption of fertility); Relationship Attributes (e.g., how the product impacts relationship trust or partner approval); and Sexual Experience Attributes (such as impact on sexual pleasure or interruption of the sex act). These domains are believed to interact with an individual woman’s situation, her perceptions of partner preferences and socio-cultural norms that, when considered together, may contribute to a robust understanding of microbicide acceptability. The model appearing in Figure I is an adaptation of the Holistic Model of microbicide Acceptability, with additional factors related to pregnancy prevention and fertility that have been found to be important to contraceptive acceptability (e.g., changes in menstruation, fertility intentions, experiences and concerns).\textsuperscript{209,214,215}
It is worth acknowledging that this conceptual framework as applied to MPT acceptability also reflects a feminist epistemology, which prioritizes women’s voices and gender-aware perspectives in the scientific process to produce MPTs that can be responsive to women’s needs. Specifically, the framework accommodates the complex interplay between device technology, a woman, and her contextual environment such that MPT acceptability must be conceptualized as “relative, conditional and user-driven.”

Figure I: Conceptual framework for acceptability of an intravaginal ring for multipurpose prevention of HIV and pregnancy

SOURCE: Adapted from Woodsong C and Alleman P. Sexual pleasure, gender power and microbicide acceptability in Zimbabwe and Malawi. AIDS Education and Prevention, 2008 Apr;20(2):171-87. 213
Study Design

My dissertation research was designed as an integrated multimethod qualitative sub-study implemented within a larger parent study: a first-in-human Phase 1 randomized placebo-controlled trial to assess the safety of a polyurethane reservoir tenofovir disoproxil fumarate (TDF) intravaginal ring (IVR) in US women. The parent study was conducted in New York City with 30 healthy, HIV-negative women who were using low-dose combined oral contraceptives. The control arm wore a placebo polyurethane reservoir sodium chloride IVR. Both the TDF and placebo IVRs resembled the NuvaRing in outer and cross-sectional diameters of 55 and 5.5 mm, respectively. Eligible participants to the parent study were randomized 1:1 to receive either a TDF or placebo IVR for 14 days of continuous use, which was inserted and removed by a study clinician to ensure proper placement and participant blinding. Participants were instructed not to remove the IVR, to refrain from oral, anal or vaginal sex, and not to insert any objects into the vagina. The two weeks of continuous ring use occurred when women were not menstruating.

The objectives of the parent study were to assess the safety of the TDF and placebo IVRs, and to examine the systemic and genital tract pharmacokinetics of TDF and its metabolites. The objective of my sub-study, by contrast, was to understand how user experiences, beliefs, attitudes and preferences could shape acceptability of a TDF-based IVR that would prevent both pregnancy and HIV if it also had contraceptive properties (Aim 1). It is important to note that the TDF IVR used by the participants in the parent trial did not include any form of contraception, so

\[ \text{iii Unfortunately, a second Phase 1 trial of the TDF IVR ended early due to adverse physical events in participants, and thus further investigation of a TDF-only ring has been delayed along with further development of a TDF-based MPT ring.} \]
participants in my study were asked to explore some issues hypothetically (contraceptive and fertility-related) and others answered based on their lived experience with a TDF-only IVR from the parent trial (drug or ring-related). Some results from this ongoing research have been published elsewhere in a paper titled “Acceptability of a tenofovir disoproxil fumarate vaginal ring for HIV prevention among women in New York City”. Those findings will be incorporated into this dissertation without further regard to citation.  

**Recruitment**

The **parent study** recruited 30 female participants from the gynecology and medicine practices at Montefiore Medical Center (MMC), the local University community of the Albert Einstein College of Medicine in the Bronx, NY, as well as community-based locations using flyers posted along building and office entry points. For recruitment into my **qualitative sub-study** I used a two-stage sampling approach in order to work within the confines of the parent study sample, while still allowing for exploration of emergent findings as is characteristic to a theoretical sampling approach used in grounded theory studies. For a complete list of parent study inclusion and exclusion criteria, please refer to Appendix C. The recruitment criteria most relevant to this study were:

- **Age**: 18-45 years old
- **Sex**: Female
- **Health status**: In general good health, including not having an active STI and being HIV uninfected via blood test at screening.
- **Reproductive factors controlled**: Have a regular 28-day cycle, to ensure women did not menstruate normally during the 14 days of ring wear, thereby isolating any potential bleeding as not being due to menstruation; menses regulated prior to ring
insertion via three months of oral contraceptive pills; could not be pregnant (tested via urine test at screening); were not breastfeeding or trying to get pregnant.

- **Behavior:** Agreed to abstain from any oral, anal or vaginal sex during the course of the trial until 7 days following ring removal; agreed to refrain from inserting any non-study vaginal products or objects into the vagina, including but not limited to contraceptives, douches, lubricants, sex toys and tampons until the end of the study.

- **Location:** Lived within reasonable proximity to the study site in the Bronx, NY, to improve retention at each of the clinical and qualitative behavioral visits.

**Sample Selection**

I used multiple sampling strategies based on type of data to be collected (interviews, card sorting and focus groups), progressing stages of data collection, and overall logistical considerations as described below.

**Interviews and Card Sorts**

**Sampling Stage 1 – Stratification**

One of the key questions in this research is to understand potential differences in women’s acceptability of an MPT IVR based on the acceptability of the investigational drug TDF. Specifically, I wanted to know if women’s acceptability of an MPT ring was different if the TDF drug was present. To address this goal, I used a segmented (ring vs. placebo) purposeful sampling approach throughout the sampling process aided by the parent study research coordinator to maintain my masking to participants’ study arm.²¹⁷ This stratification is important to be able to identify potentially different patterns in the data based on the presence of drug. With five participants being the rule of thumb for minimum number of participants per cell for
comparison in a segmented sample, I invited the first 10 participants (5 Experimental, 5 Control) who enrolled in the parent study to also participate in my qualitative sub-study.\(^{218}\)

**Sampling Stage 2 – Theoretical saturation and theoretical sampling:**

As with other qualitative methods, grounded theory aims to reach theoretical saturation, meaning that no new themes are emerging from the data and findings are becoming redundant.\(^{219}\) One of the key features, however, that distinguishes grounded theory from other methods of qualitative analysis is the process of *theoretical sampling*, which is a cyclical (i.e., iterative) approach to sampling and preliminary analysis whereby the researcher selects subsequent participants such that they can further explicate a phenomenon until “no new properties emerge” and theoretical saturation of the developed themes has been achieved.\(^{186}\) In this approach to sampling, “the analyst jointly collects, codes and analyses [the] data and decides what data to collect next and where to find them, in order to develop [the] theory as it emerges.” (Glaser and Strauss, p. 45)\(^{182}\)

Following enrollment of the first 10 participants, I had not reached theoretical saturation on developing themes either within the segmented groups or across the sample as a whole, so I continued to recruit participants. For selection of the 11\(^{th}\) and subsequent participants, I continued to recruit participants from the parent study pool, comparing themes emerging from the new participants to the previous participants until I was confident saturation had occurred.\(^{187}\) Following interviews with the first 13 participants, the emergence of new themes slowed, signifying that I was nearing theoretical saturation of findings. The 14\(^{th}\) participant brought no new findings, yet the 15\(^{th}\) participant expressed idiosynchratic discomfort with and strong disapproval of the ring. She was the first, and youngest, participant to report such disfavor, and thus I began to explore this issue as a potentially emergent finding.
Inherent to this grounded theory process of theoretical sampling is *abductive reasoning*, an approach to making sense of puzzling or odd findings. Abductive reasoning allows and pushes researchers to go beyond inductive reasoning to develop hypotheses, based on insights, connections and grappling with data to see what fits the newly emergent theory and what does not. In this case, after reaching saturation on nearly all themes with 15 participants, I began to recruit only younger participants to further pursue a specific emergent issue, i.e., if and how young age may be related to product acceptability. Not only was the sampling narrowed in response to early findings, but also based on new evidence from the microbicide field demonstrating that young women had significantly lower rates of product adherence. In an aim to shed light on this seeming phenomenon of lower acceptability, adherence or potential effectiveness among young women, I continued to enroll only the younger women who entered into the parent study (age 18-21) resulting in a total of 18 women in the in-depth interview (IDI)/card sort study sample.

The parent study was necessarily double-masked to reduce potential bias; participants were masked to their randomized experimental condition (treatment or control), and I (in the roles of both data collector and analyst) was masked to experimental condition of the interviewee until all data were collected. However, it was essential that a nearly even distribution of women in both experimental conditions were recruited into my study to allow for this comparison in my analysis. To achieve this, I conferred with parent study staff about the aggregate distribution of theoretical sampling was based solely on emergent findings from the interview data (not the card sort data), due to the rapid turnaround of participant recruitment and time limits on intermediate data analysis.
participants randomized to treatment vs. control following the 10th, 15th, and 18th participant in the IDIs. There were no refusals.

Focus Groups

For focus group recruitment, each of the 30 women who participated in the parent study, regardless of participation in the IDIs/card sort, were invited to participate in a focus group. For women who were interviewed, the focus group invitation was extended following completion of both interviews and card sort data collection points. For women who were not interviewed, a focus group invitation was extended following completion of the final clinical visit. I conducted three focus groups, with 5 to 8 women in each group. The first two focus groups only included women I had previously interviewed, and the third focus group only included only women who had not been interviewed.

The sampling plan for the focus groups was crafted based on Morgan’s (1997) consideration for segmentation to manage a group’s composition by strategically choosing participant characteristics to be homogenous within a single group.\textsuperscript{220} The goal of segmentation and homogeneity of participants is meant to improve group dynamics via the overall free-flow of dialogue and information exchange. Homogeneity of participant profiles typically includes background characteristics such as age, race, gender or social class.\textsuperscript{220–222} I incorporated grounded theory principles to identify participant characteristics that could potentially impact group dynamics in a negative way. To do this, I developed criteria for homogenous focus groups based on emergent findings about potentially clashing participant characteristics from the interviews. At the time of recruitment for each of the focus groups, the two main characteristics that emerged as having potential to harm group dynamics was age (younger vs. older) and education level (PhD students studying infectious disease vs. others). I hypothesized that age or
education or both of these factors could negatively impact the group dynamic and findings, whereby younger and less educated women might feel uncomfortable sharing experiences or beliefs alongside older, more experienced or highly educated women. I also was concerned of the complement, that older, more experienced, or highly educated women might be disrespectful or overshadow their counterparts. I therefore considered constructing one focus group of PhD level students only vs. others and one group of younger women only vs. others. Logistically, this was not possible in order to hold focus groups of 4 or more participants. Therefore, groups were formed as soon as enough parent trial participants were available to participate in a focus group, without segmenting the groups by demographic homogeneity factors of age or education.

**Data Collection**

*Phases of data collection*

I collected three forms of data with women in my study: two sequential In-depth Interviews (IDIs); a card sort exercise; and focus groups. All women approached to participate in the interviews accepted invitation and enrolled. Nearly all participants (17/18) completed both interviews; only one was unable to complete a second interview nor her card sort because of a restless infant (Table I). Focus group recruitment happened on a rolling basis, according to parent trial enrolment and the subsequent acceptance of focus group invitation by 8 women, to ensure a minimum of 5 women per group. Each of the 30 women from the parent trial were eventually invited to participate in one of three focus group discussions, and 18 women attended, of whom 13 also participated in IDIs. There were no active refusals for focus group participation, with the remaining 12 women unable to attend a group because of scheduling, or unknown reasons due to no-shows or non-response. All IDIs were conducted in a private office in a university setting. The focus groups were held in a conference room in a university setting.
Figure II describes my study in relation to the goals of the clinically-based parent study, which required 9 total visits and aimed at 100% retention for each participant at each data point. The first data collection point for this sub-study was ‘Interview 1,’ occurring following menstruation and on the same day as ‘Visit 6’ of the parent study, one week after ring insertion (‘Visit 3’ of the parent study). ‘Interview 2’ took place approximately two weeks after interview 1, one week following ring removal, and prior to the next menstruation. A card sort activity immediately followed Interview 2, in the same location as the interview. The two-week time lag between Interviews 1 and 2 allowed me to identify and document in the interviews any changes in women’s experiences with the ring during use, removal and following removal. Once participants had completed the parent study (completing two weeks of IVR wear, IVR removal, final interview and card sort) and were eligible for a focus group, I conducted three focus groups each with 5-8 women.

**In-depth Interviews**

In-depth interviews are an appropriate data collection method for learning about new areas of inquiry.\(^{223,224}\) Because of the minimal existing knowledge on MPT acceptability (with the exception of male and female condoms), IDIs are well suited as a data collection technique to gain a deeper understanding of a potential user’s context, perspectives, needs and questions about MPTs that could impact eventual use and/or help shape the approach to new MPT development.\(^{82,225}\) As discussed in Section 1, microbicide trials have suffered because of product acceptability issues and subsequent non-adherence.\(^{129,130,132}\) Judging from those trials, it is possible that the development of new technologies would benefit from an earlier and deeper understanding of user preferences and acceptability based on product type and characteristics, risk perception and relationship status, among others. By inviting discussion and feedback from
participants regarding their experiences, IDIs offer prospective insight into user experiences measuring previous, current and changing product experiences and perceptions of use. In the case of newly developing MPTs, IDIs can help generate understanding about MPT acceptability factors. Further, IDIs provide a safe space for individuals to talk about topics considered to be sensitive or private.226,227 For these reasons, IDIs were chosen for this relatively uncharted MPT research on sensitive and/or stigmatized socio-behavioral topics such as sexuality, reproduction, relationships and HIV.228

I developed semi-structured interview guides (for IDI 1 and 2) that included questions and probes and was designed to be used flexibly, whereby the ordering of questions changed due to participants’ responses, but with enough specificity to ensure pursuit of areas of importance to my research questions across all respondents.223 I chose to use a semi-structured guide because it is ideal in circumstances where there exists some previous breadth of knowledge, but simultaneously allows the researcher to follow emergent topics important to the participant that may not have been anticipated by the researcher.229,230 The guides were designed (See Appendix D) to allow for questions to be probed for depth, and for relevant topics to emerge from participants other than those explicitly included in the guides.

IDI 1 and 2 were designed to be sequential and complementary in order to build rapport and meaning-making231 between participant and interviewer about topics that were potentially uncomfortable or difficult. The two guides contain some similar questions to help ease participants into deeper sharing at both data collection points. The IDI 2 guide was designed to be tailored to each participant based on findings from the first interview so that depth of responses could be flexibly explored for each woman individually. Topics covered in both guides included experiences with the ring; expectations of an MPT ring with HIV prevention and
contraceptive properties; concerns about wearing the ring for extended periods of time including during menstruation; perception of partner acceptability, potential barriers to use and willingness to use an MPT ring if it were available in the future. The first interview lasted approximately 45-60 minutes, and the second 30-45 minutes to accommodate administration of the card sort activity (see below). All transcripts were entered into Dedoose, an online qualitative analytic package that facilitates the coding and data retrieval process.

**Focus Groups**

The general purpose of the focus group as a data collection method is to capture data on a researcher-defined topic via group interaction. Although the researcher defines the focus, participant interaction is key to the process of data generation. Used as part of a multi-method approach (as was done in this study), focus groups can add depth, augment or clarify findings from another method (e.g., IDIs or self-administered surveys), consequently allowing for triangulation of data or capture unique perspectives only attainable through a combination of data sources.

In this research, all parent-trial participants were invited to participate in a focus group discussion. The purpose of the focus group was to further ascertain women’s experiences using an IVR and perceptions of use for an MPT IVR; to explore unexpected findings from the interviews and card sort activity; to allow participants to “share and compare” their own experiences; and, to generate understanding about group-level norms and perspectives. Although I defined the topics of interest for the focus group guide, participant interaction was essential for data generation on those *a priori* topics as well as other emergent topics. I facilitated each of the focus groups, accompanied by an assistant whom I trained to take notes on content and process within each of the groups. Special attention in note-taking was paid to significant
shifts in group dialogue based on interaction among group participants and with the facilitator.\textsuperscript{236} As facilitator, I was mindful of potential problems in group dynamics between younger and older women, and those with less and more education, as I was not able to conduct separate focus groups based on these characteristics. For example, if a PhD student dominated the conversation, I would make equal time for a non-PhD student to respond. If no one volunteered or only offered a minimized response, I would catalyze further participation by offering up alternative perspectives that had arisen in the IDIs, if appropriate, such as “In the interviews I conducted, some women mentioned another perspective. What do you think about [naming the perspective]?”

The focus group guide addressed themes that emerged in the interviews and card sort, with emphasis on social and relationship-level influences on acceptability such as HIV stigma, relationship norms and social understanding of HIV risk, pregnancy desires and potential conflict between the two (Appendix D). The focus group(s) were audiotaped, transcribed, and reviewed by the facilitator for accuracy, and entered into Dedoose for analysis.

\textit{Card Sorts}

The card sort technique has been used successfully to explore sensitive topics among women such as post-partum concerns,\textsuperscript{237} violence or abortion,\textsuperscript{238} that may otherwise be considered taboo to discuss in the research environment. I chose the card sort method to both facilitate conversation about sensitive topics such as sexuality and reproductive health and to collect ranked importance data. Using a closed card sort technique,\textsuperscript{239} I asked participants to sort and then rank approximately 25 \textit{a priori} statements (Appendix D) on physical cards about ring acceptability that were selected from previous themes in the microbicide and family planning
literature along with statements made by women in previous interviews. Individual cards were conceptualized as part of seven different domains (Table II).

This approach encouraged discussion about topics that might not have emerged without prompting in the IDIs or focus groups. First, women were asked to sort statement cards into one of three piles: 1) reasons to use a vaginal ring, 2) reasons not to use a vaginal ring, and 3) does not matter to me. During this sorting process, they were asked to ‘think aloud’ to provide qualitative insight into the meaning they assigned to their preferences or choices. The comments they made as they ‘thought aloud’ were captured on the recording and transcribed as part of the second interview. Following this sort, they were then asked to rank all cards from piles 1 and 2 by level of importance. Some of the statements were purposefully neutral in direction, forcing participants to engage with the concepts and vocalize their struggle to understand and hierarchically categorize the statements in a meaningful way. The card sort activity was piloted with 3 females of child-bearing age using hormonal birth control methods and components were adjusted to improve clarity of instructions; to add the category ‘it doesn’t matter to me’ into the first stage of the sort; and to add blank topic cards for participants to generate their own areas of importance.

This card sorting approach aimed to both encourage discussion about topics that were currently being discussed in the microbicide and family planning literatures, and to help understand the ways women order or rank the relative importance of different factors contributing to overall acceptability of an MPT. The card sort was administered immediately following the second interview, in the same room, and lasted approximately 15-20 minutes. Completed card sorts were photographed upon completion and transcribed into Excel for organizational and analytic purposes.
Table I: Participant Data Points

<table>
<thead>
<tr>
<th>Name (Pseudonym)</th>
<th>IDI 1</th>
<th>IDI 2</th>
<th>Card Sort</th>
<th>FG 1</th>
<th>FG 2</th>
<th>FG 3</th>
<th>Any IDI</th>
<th>Any FG</th>
<th>Completed IDI + Card Sort + FG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carly</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>X</td>
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<td>Marina</td>
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<td>x</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>X</td>
</tr>
<tr>
<td>Celia</td>
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<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
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<td>x</td>
<td>x</td>
<td>X</td>
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<tr>
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<td>x</td>
<td>x</td>
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<td>-</td>
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<td>x</td>
<td>X</td>
</tr>
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<td>-</td>
<td>-</td>
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<td>x</td>
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<td>x</td>
<td>X</td>
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<td>-</td>
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<td>-</td>
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<td>X</td>
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<td>-</td>
<td>-</td>
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<td>-</td>
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<td>x</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>Jenna</td>
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<td>x</td>
<td>x</td>
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<td>-</td>
<td>x</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Ellen</td>
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<td>x</td>
<td>x</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>-</td>
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<td>Jamie</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>-</td>
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<tr>
<td>Rachelle</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>-</td>
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<td>Kelsey</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
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<td>Natasha</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>x</td>
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</tr>
<tr>
<td>Brianna</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>-</td>
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<tr>
<td>Jean</td>
<td>x</td>
<td>x</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
</tr>
</tbody>
</table>
**Figure II: Research Design**

<table>
<thead>
<tr>
<th>Menstruation</th>
<th>Day 1</th>
<th>Day 7-13</th>
<th>Day 14</th>
<th>Days 14-35*</th>
<th>Menstruation</th>
<th>Days 45-90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ring Insertion</td>
<td>IDI 1</td>
<td>Ring Removal</td>
<td>IDI2</td>
<td>Focus Group</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*end of parent study
## Table II: Card Sort Statements and Their a priori Domains

<table>
<thead>
<tr>
<th>(a priori) Domain</th>
<th>Card Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menses</td>
<td>The ring will stay clean</td>
</tr>
<tr>
<td></td>
<td>The ring won’t get menstrual blood on it</td>
</tr>
<tr>
<td></td>
<td>My period would still come once a month</td>
</tr>
<tr>
<td>Sexual Experience</td>
<td>My physical comfort during sex</td>
</tr>
<tr>
<td></td>
<td>My Partner’s physical comfort during sex</td>
</tr>
<tr>
<td></td>
<td>Wetness during sex</td>
</tr>
<tr>
<td></td>
<td>Sex would be better</td>
</tr>
<tr>
<td></td>
<td>My sex drive or being turned on might change</td>
</tr>
<tr>
<td>Side Effects</td>
<td>Discharge during sex*</td>
</tr>
<tr>
<td></td>
<td>Side effects from the ring</td>
</tr>
<tr>
<td>Ring characteristics</td>
<td>Type of Hormone/Birth control in the ring</td>
</tr>
<tr>
<td></td>
<td>Higher cost compared to my regular contraceptive method</td>
</tr>
<tr>
<td></td>
<td>Material that the ring is made out of</td>
</tr>
<tr>
<td>Disease prevention</td>
<td>Having sex without thinking about getting HIV</td>
</tr>
<tr>
<td></td>
<td>Feeling safe during sex</td>
</tr>
<tr>
<td></td>
<td>The ring will prevent STIs/STDs other than HIV*</td>
</tr>
<tr>
<td>Ring Exchange</td>
<td>Putting my finger inside my vagina to put the ring in and take it out</td>
</tr>
<tr>
<td></td>
<td>Being able to put the ring in and out of my body</td>
</tr>
<tr>
<td></td>
<td>I can take the ring out for short periods of time</td>
</tr>
<tr>
<td>Fertility</td>
<td>Having sex without thinking about getting pregnant</td>
</tr>
<tr>
<td></td>
<td>The ring will NOT prevent pregnancy</td>
</tr>
<tr>
<td></td>
<td>The Ring will prevent pregnancy</td>
</tr>
<tr>
<td></td>
<td>Will not affect me getting pregnant in the future</td>
</tr>
<tr>
<td>Relationship Factors</td>
<td>My partner supports my choice to use this ring</td>
</tr>
<tr>
<td></td>
<td>NOT needing to tell a partner it prevents HIV transmission</td>
</tr>
<tr>
<td></td>
<td>Not needing to tell my partner it prevents pregnancy</td>
</tr>
<tr>
<td></td>
<td>My partner trusts that I am faithful</td>
</tr>
</tbody>
</table>

*Cards generated by participants*
Data Analysis

Grounded Theory, integration and triangulation

Grounded theory analytic methods have been used by others exploring acceptability of sexual and reproductive health products (e.g., contraception and PrEP). Specifically, analysis of acceptability data on contraceptive vaginal rings, contraceptive IUDs, general contraceptives, male condoms, female condoms, rectal and vaginal microbicides, and oral PrEP. Practically speaking, grounded theory analysis is conducted by moving "back and forth between empirical data and emerging analysis", it is a constant comparison approach to analyzing qualitative data throughout the research process from data collection through to theory development. A grounded theory approach to data analysis is well suited to the exploration of acceptability of MPTs, as it is a new area of research where little is known.

In addition to the grounded theory approach to data analysis, I followed an integrated methodological approach to this research that began from the conceptualization of the study using three different types of data; was enacted throughout the implementation of the research in which data collection was influenced by ongoing emergent findings; and concluded with the integrated analysis of the stories understood through these different forms of data. Some generally identify this approach as methodological triangulation, but it has been more explicitly defined by Moran-Ellis et al. as methodological ‘integration’, which “involves the generation of a tangible relationship among methods, data and/or perspectives, retaining the integrity of each, through a set of actions clearly specified by the research team, and that allows them to ‘know more’ about their research topic.” I therefore followed this integrated approach within
grounded theory to further explore, compare and ‘know more’ about the complexity of the social phenomena informing acceptability of an MPT ring.

The term ‘triangulation’ originated in the quantitative paradigm, where there is a desire to measure a single concept or construct with different questions or items so a researcher can feel confident in the validity of the findings when the measurements converge: the greater the convergence, the greater the confidence in the captured measurement. Small (2011) alternately refers to this as ‘confirmation’, to “ensure that…findings do not depend on the particular kind of data collected” (p.63). This validation approach to triangulation, which can include both convergence and divergence of findings across measurements, I am labeling in Section 3.4 as a comparability analysis. As applied to this research, I compared ring acceptability themes according to the data collection approaches that were used to elicit them: interviews, card sorts and focus groups.

Conceptually, however, triangulation need not be limited to concept validation. In the qualitative paradigm, and certainly in mixed methods research, there are different ways that researchers have come to apply triangulation—and more specifically, ‘integration’—including consideration of complementary findings across different data sources. Denzin and Lincoln (1994) task qualitative researchers with using “a wide range of interconnected methods, hoping always to get a better fix on the subject matter at hand.” They further specify:

“…the use of multiple methods or triangulation, reflects an attempt to secure an in-depth understanding of the phenomena in question. Objective reality can never be captured. Triangulation is not a tool or strategy for validation, but an alternative to validation [emphasis added]. The combination of multiple methods, empirical strands, perspectives and observers in a
single study is best understood then as a strategy that adds rigor, breadth and depth to any investigation” (p.5). Therefore, I conducted a *complementarity analysis* to triangulate the data in order to more robustly synthesize thematic findings across different types of qualitative data to better understand a complex social phenomenon: MPT ring acceptability and likely use.249,250

In-Depth interviews

IDI analysis was conducted in four phases. The first phase included coding the dataset for themes specific to acceptability of the TDF-only vaginal ring because of early demands of the parent trial. This first round of coding helped to identify, divide and ultimately compare key themes that were specific to the TDF ring, the MPT ring and those that were applicable to both. In this phase, I approached the interview data using grounded theory’s constant comparative method of analysis, whereby one categorized segment is compared to previous segments in the same or different categories to help refine, combine and/or distinguish one concept from the next.182 The coding process consisted of *initial coding* to group basic categories of data, *focused coding* to determine higher level analytic groupings of codes as they compare to initial codes, and *theoretical coding* to assemble a story to integrate themes or constructs emergent from the focused coding phase.231 I concluded the coding process with the development of theoretical codes, which were assembled to extract the story line present in the data.243

During the second phase of IDI analysis, I began by writing case profile memos for each participant, drawing on data from IDI 1, IDI 2 and the card sort that included key components of my research questions (MPT acceptability components, method-specific issues to IDIs) as well as important quotes or data segments to maintain closeness to the data. Concurrently, I re-read
transcripts, alongside their first-round codes and iteratively identified new, irrelevant or different codes to be added, removed or adjusted (respectively) to a second-round codebook.

In the third analysis phase, I re-coded the IDI data using the revised codebook consisting of more honed, higher-level themes. (Appendix E) During the second-round coding process, as new themes unfolded, I wrote analytic memos to document insights as well as perplexing issues needing resolution. These memos created a foundation for conceptualizing and re-conceptualizing findings from the data based on what I learned during data collection, coding, constant comparison, and early stages of theory development.\textsuperscript{182} Memos such as the ‘duality of menses as both dirty and cleansing’ and the ‘importance of male partner’s health’ clearly pertained to my initial research questions and helped expand my understanding of MPT acceptability overall. These and other thematic memos provided a medium for connecting emergent themes, categories and concepts, eventually laying a foundation for developing a new theoretical framework grounded in the data.\textsuperscript{182,186}

In the fourth phase of analysis, I segmented the coded IDI data by the following \textit{a priori} or emergent participant characteristics of interest: experimental condition (\textit{a priori}), race(\textit{a priori}), age(\textit{a priori}), relationship status(emergent), prior NuvaRing use(emergent) and tampon use in the past month(emergent).

Focus Groups

Grounded theory analysis techniques are well suited to focus group data because of their methodological foundation in \textit{symbolic interactionism}. This is a theoretical perspective which embraces the notion that meanings are “social products formed through the activities of people interacting”.\textsuperscript{182,251} Focus groups capitalize on this perspective by creating a space to facilitate
interpersonal interactions, and thus, meaning-making of reality is emergently co-produced by focus group participants.

Scholars have recently acknowledged the need to pay more attention to interactions within focus groups. Typically though, the stated purposes of these analyses are distinct from one another: either for “purposes that are oriented to substantive content” to explain what data participants are creating or for purposes “that relate to the conversational dynamics” to explain how participants create those data. In an attempt to integrate these two analytic purposes to address my overall research questions, I used a multi-dimensional process to analyze both the thematic content and the interactions between participants in order to identify the potential for synergistic findings.

The first dimension of the analysis consisted of a debriefing session between the facilitator and assistant which took place immediately following each focus group. The debriefings were designed to capture nuances that might otherwise be lost over time and space as I moved further from the data collection environment. During these debriefing sessions, we noted issues related to group composition, rapport between the research team and participants and other contextual factors that may have been influential on the data produced. Further, we reviewed assistant notes and discussed facilitator insights interactively for each topic of focus group discussion, with attention to both thematic content and process. Final summaries from these debriefings were then dictated into a tape-recording device, reviewed and transcribed.

The second dimension of the analysis included deeper exploration of thematic content generated within and across focus groups using similar techniques of constant comparison as used in the IDI analysis described above. For these analyses, which occurred sequentially following the second round of IDI coding, I first applied the IDI codebook to the focus group
data, noting similarities and differences within thematic findings, across the three focus groups, and across the IDI and focus group data collection methods. Analytic memos were concurrently developed to identify and discuss these thematic similarities and differences between individual focus groups’ data and between the focus group data and IDI data.

A third dimension of the focus group analysis included studying specific interactions between focus group participants. Morgan and Hoffman (2018) offer a concrete approach to coding focus group interactions called the “Co-Production of Interaction.” This is an approach that builds on and attempts to incorporate 1) techniques used in conversation analysis, which focuses on micro-dynamics of participant interactions and ‘turn-taking’; and 2) the concept of the co-creation of meaning, which relies on interactions to co-produce knowledge in ways that are most meaningful to participants. The co-production of interaction suggests a particular coding system that is based on typical interactive processes where participants share and compare experiences, perspectives, and specific life moments with one another in their dialogue. Thinking of the co-production of interaction as a framework for facilitating the integration of content and process of focus group data, I coded the focus group interaction data using relevant codes from its affiliated coding system. (Appendix E for Focus Group Interaction Codes) Specific moments of interaction that I coded for included 1) nonverbal behavior captured in observational field notes taken at the time of the focus group, and 2) key conversational interactions (continuing topics, changing topics and interpersonal connections) between speakers. Therefore, in addition to thematic coding of the focus group data, I also coded the data for these specific moments of interaction to explore how participants described their own experiences and acceptability factors in relation to one another.
Card Sorts

Card sort data were analyzed in three different ways. First, I identified common clusters of cards across participants to understand potential factors or themes within the acceptability construct. I grouped these cards into ‘clusters’ based partly on emergent themes found in the IDIs and focus groups and partly on themes or items found only in the card sorts. I used a process of constant comparison to identify similarities and differences between the presence of card sort ‘clusters’ and previous themes developed in the IDIs and focus groups.

Second, I examined patterns in the way women ranked the cards to determine relative importance of factors for MPT use and non-use. During this process, I paid special attention to patterns hypothesized yet not systematically studied during the IDIs and focus groups. The patterns I specifically queried included the most important and least important reasons for use and non-use; the ranking of factors related to partners vs. self vs. relationship priorities; and the relative importance women paid to contraceptive vs. HIV preventive properties of the ring. The rank-ordered results were then comparatively analyzed for differences by experimental condition, age and relationship status to explore potential typologies of respondents.

To more closely analyze individual and then aggregate patterns in the card sort activity, I color coded each individual’s card sort by a priori domains. Color coding included each of the cards within the a priori domains. For example, the cards entitled ‘the ring will stay clean’, the ring won’t get menstrual blood on it’, and ‘my period will still come once a month’ were all coded in pink representing the ‘Menses’ domain. After each individual card sort was color coded by domain, I first evaluated patterns in the clusters within and across the sorts. To ensure that I was visually identifying clusters correctly according to color-coding, I also entered all data into SPSS to query and verify emergent patterns across all cases.
**Data Reporting**

In Chapter 3, most results are reported in narrative form, using verbatim excerpts of raw data to illustrate key findings. Exceptions include the use of [bracketed text imputed by the researcher], that replaces colloquial or difficult to interpret text and “…” in cases where data were not sequential. In the few cases where qualitative data have been summarized in quantitative form, I parenthetically report a numerator and denominator. In these cases it can be inferred that all participants were asked the same question and provided a response.

**Human Subjects Protections**

The study was approved by the Albert Einstein College of Medicine Institutional Review Board (10/2/2013, protocol: 2013-329) and then subsequently was granted “exempt” status by the CUNY Human Research Protection Program for purposes of dissertation research (11/03/2017, protocol: 2017-1225) (Appendix B). Written informed consent was obtained from all individual participants included in the study. Qualitative data were collected confidentially between the participant and this researcher and were de-identified prior to sharing with clinical research staff. Participants were assigned pseudonyms and quoted text identifies the data collection type (and sequence, if applicable), participant name, and age in years (i.e., “IDI1, Nora” is from Nora’s first interview; “FG3, Jamie” is from Jamie in Focus Group 3).
SECTION 3: STUDY FINDINGS

The following Section of study findings presents a new model that describes acceptability and likely use of an MPT vaginal ring for prevention of pregnancy and HIV along with a detailed description of methodological factors that helped to produce this model. This Section is divided into four sub-sections. Participant characteristics are presented first (Section 3.1), for those who provided interview, card sort, and/or focus group data. Section 3.2 then presents the overview of the model (Figure III). This overview is then followed by a detailed description of the conceptual components of the model and the relationships among those components (Section 3.3). Throughout the presentation of findings, thematic contributions based on data collection method are identified and discussed as they influenced model development. Following this detailed description of the model, there is a summative discussion of how the different data collection methods uniquely contributed to production of thematic findings and associations (Section 3.4).
Section 3.1: Participant Characteristics

Of the 18 participants who participated in the in-depth interviews, 8 were in the TDF arm and 10 in the placebo arm; the card sort included 17 of the 18 women from the IDIs (8 TDF, 9 placebo), missing one because of her restless child; and across the 3 focus groups there were 18 women (9 TDF, 9 placebo), of whom 13 had participated in an IDI (Table I). There was no evidence of participant unblinding. The IDIs and FGDs had similar racial and ethnic makeup; respectively, 44% and 39% were white; 22% and 22% were Black; 17% and 28% were Hispanic. The median age of participants was similar in the IDIs and FGDs (30.2 vs. 31 years, respectively), but the median number of years of education was slightly higher in the IDIs (15.5 years) vs FGDs (14 years). In both the IDIs and FGDs, 67% were in a current relationship; and almost all participants were sexually active in the past two months (Table I). Approximately half of the IDI participants (10/18) and FGD participants (8/18) had used tampons during their most recent menses prior to ring insertion. None of the IDI participants considered themselves at risk for HIV on a dichotomous quantitative measure used in the parent study (“Do you think you are at risk for HIV?”) (Table III).148
Table III: Participant Characteristics of IDI and FG Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>IDIs: Median (range) or n (%)</th>
<th>FGs: Median (range) or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)(^a)</td>
<td>29.6 (19.4-39.4)</td>
<td>32.3 (25.2-45.4)</td>
</tr>
<tr>
<td>Education (years completed)</td>
<td>16 (12-22)</td>
<td>14 (13-22)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black/African American</td>
<td>4 (22%)</td>
<td>4 (22%)</td>
</tr>
<tr>
<td>White</td>
<td>8 (44%)</td>
<td>7 (39%)</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>‘Other’(^b)</td>
<td>2 (11%)</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>&gt;1 race</td>
<td>2 (11%)</td>
<td>4 (22%)</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>3 (17%)</td>
<td>5 (28%)</td>
</tr>
<tr>
<td>Tampon use: past month</td>
<td>10 (56%)</td>
<td>8 (44%)</td>
</tr>
<tr>
<td>Prior tampon use: ever used</td>
<td>16 (89%)</td>
<td>16 (89%)</td>
</tr>
<tr>
<td>Prior NuvaRing use: ever used</td>
<td>3 (17%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>Sexually active past 2 months</td>
<td>17 (94%)</td>
<td>18 (100%)</td>
</tr>
<tr>
<td>Relationship status (at first IDI)(^c)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>2 (11%)</td>
<td>3 (17%)</td>
</tr>
<tr>
<td>Partner, not married</td>
<td>10 (56%)</td>
<td>9 (50%)</td>
</tr>
<tr>
<td>No partner</td>
<td>6 (33%)</td>
<td>6 (33%)</td>
</tr>
<tr>
<td>Perceived risk for HIV</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Randomized to TDF (vs. placebo)</td>
<td>8 (44%)</td>
<td>9 (50%)</td>
</tr>
</tbody>
</table>

\(^a\) Sixteen years is equivalent to a 4-year college degree.

\(^b\) ‘Other’ includes those who declined to answer or who responded ‘yes’ to the following racial categories: American Indian, Alaska Native, or Native Hawaiian/Pacific Islander.

\(^c\) Relationship status does not infer cohabitation status. Participants did not systematically report on whether or not they lived with a current partner, married or not.
<table>
<thead>
<tr>
<th>Name</th>
<th>Age (yrs)</th>
<th>Educ (yrs)</th>
<th>Race (^a)</th>
<th>Hisp.</th>
<th>Tampon use: last month</th>
<th>Tampon use: ever</th>
<th>Nuvaring use: ever</th>
<th>Sex: last 60 days</th>
<th>Rel. Status (^b,c)</th>
<th>BMI</th>
<th>Group (^d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carly</td>
<td>31.0</td>
<td>18</td>
<td>A</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>M</td>
<td>28.3</td>
<td>E</td>
</tr>
<tr>
<td>Marina</td>
<td>31.9</td>
<td>18</td>
<td>W</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>NP</td>
<td>24.6</td>
<td>E</td>
</tr>
<tr>
<td>Celia</td>
<td>26.4</td>
<td>14</td>
<td>B</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>P</td>
<td>22.8</td>
<td>E</td>
</tr>
<tr>
<td>Tracy</td>
<td>27.3</td>
<td>22</td>
<td>A</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>NP</td>
<td>21.3</td>
<td>P</td>
</tr>
<tr>
<td>Adele</td>
<td>27.0</td>
<td>20</td>
<td>W</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>P</td>
<td>23.2</td>
<td>P</td>
</tr>
<tr>
<td>Nora</td>
<td>39.4</td>
<td>14</td>
<td>W</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>M</td>
<td>27.4</td>
<td>E</td>
</tr>
<tr>
<td>Laura</td>
<td>25.4</td>
<td>16</td>
<td>W</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>NP</td>
<td>23.9</td>
<td>P</td>
</tr>
<tr>
<td>Angela</td>
<td>36.0</td>
<td>14</td>
<td>O</td>
<td>x</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>NP</td>
<td>28.6</td>
<td>P</td>
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<tr>
<td>Rose</td>
<td>37.1</td>
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<td>W</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>P</td>
<td>37.3</td>
<td>E</td>
</tr>
<tr>
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<td>-</td>
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<td>-</td>
<td>x</td>
<td>P</td>
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<td>E</td>
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<td>-</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>P</td>
<td>22.4</td>
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<td>W</td>
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<td>x</td>
<td>x</td>
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<td>NP</td>
<td>23.5</td>
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<td>x</td>
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<td>x</td>
<td>x</td>
<td>x</td>
<td>NP</td>
<td>25.4</td>
<td>P</td>
</tr>
<tr>
<td>Maureen</td>
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<td>-</td>
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<td>x</td>
<td>-</td>
<td>x</td>
<td>P</td>
<td>28.3</td>
<td>P</td>
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<td>P</td>
<td>21.8</td>
<td>P</td>
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<td>x</td>
<td>-</td>
<td>x</td>
<td>P</td>
<td>24.1</td>
<td>P</td>
</tr>
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<td>-</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>-</td>
<td>P</td>
<td>20.2</td>
<td>E</td>
</tr>
<tr>
<td>Jamie</td>
<td>25.2</td>
<td>15</td>
<td>B</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>P</td>
<td>26.1</td>
<td>P</td>
</tr>
<tr>
<td>Rachelle</td>
<td>37.9</td>
<td>14</td>
<td>&gt;1</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>P</td>
<td>22.5</td>
<td>P</td>
</tr>
<tr>
<td>Kelsey</td>
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<td>13</td>
<td>&gt;1</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>-</td>
<td>x</td>
<td>P</td>
<td>26.3</td>
<td>P</td>
</tr>
<tr>
<td>Natasha</td>
<td>25.7</td>
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<td>B</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>M</td>
<td>30.3</td>
<td>E</td>
</tr>
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<td>Brianna</td>
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<td>14</td>
<td>B</td>
<td>-</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>x</td>
<td>P</td>
<td>39.3</td>
<td>E</td>
</tr>
<tr>
<td>Jean</td>
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<td>O</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>-</td>
<td>x</td>
<td>P</td>
<td>31.7</td>
<td>P</td>
</tr>
</tbody>
</table>

\(^a\) Race categories were collapsed to include A=Asian; B=Black; W=White; O=Other; and >1=more than 1 reported racial category.

\(^b\) Relationship status does not imply cohabitation status. Participants did not systematically report on whether or not they lived with a current partner, married or not.

\(^c\) M=Married; NP=No Partner; P=Partner, not married.

\(^d\) Group categories included those randomized to the (E)xperimental vs. (P)lacebo conditions.
Section 3.2: Overview of the grounded theory model - Dynamic Considerations for Acceptability and Likely Use of an MPT Ring

The main goal of a grounded theory study is theory generation.\textsuperscript{182} This dissertation research aimed to understand multiple facets of women’s experience with and perceptions of an MPT vaginal ring. The understanding generated from these findings informed a new conceptual model for general MPT acceptability and use. Toward that end, throughout the research process I used grounded theory techniques, as others in the sexual and reproductive health field have done,\textsuperscript{189–196} to question and expand on existing models in order to produce a new theory to understand MPT IVR acceptability among women (Figure III). Initially, my research questions and study design were guided by Woodsong et al’s framework of microbicide acceptability, which identifies multiple attributes of microbicide acceptability (e.g., product, relationship and sexual encounter attributes) and nests these attributes completely within socio-cultural norms and individual and partner preferences.\textsuperscript{208} This framework was helpful to guide study design, data collection and early analytic thinking about iterative findings. This study expanded on this microbicide acceptability framework to include issues of fertility and contraception that are germane to an MPT, as well as to clarify pathways between emergent themes and higher order constructs.

As this new model of MPT acceptability matured, it was clear that women defined MPT acceptability as distinct from, but intertwined with, likely product use. This empirical finding was supported by an existing conceptual framework that distinguished the potential role of product acceptability from product adherence, as it related to microbicides.\textsuperscript{154} This model by Mensch et al. proposed “a revised definition of acceptability that clearly and operationally separates product acceptability from product adherence, and the factors that may influence these
two constructs”. The Mensch model added a necessary guiding framework to my own developing model, in that it acknowledged both a clear distinction between acceptability and likely use in the presence of product choices and alternatives, as well as an association between the two.\textsuperscript{154,205} Hence, the Woodsong and Mensch frameworks together helped to guide and generally frame the ideas about product acceptability for HIV prevention, but were missing key pieces about pregnancy prevention (with respect to MPTs) and were also missing the detailed connective tissue that could demonstrate associations, directionality and subsequent intervention points.

Developing a grounded theory involves multiple steps, achieved through a non-linear process that can be sequential, overlapping and circular.\textsuperscript{186} I used the constant comparative method to iteratively evaluate and incorporate relevant components from both of the guiding models alongside emergent findings from this study into the developing conceptual model. The resultant “Dynamic Considerations for Acceptability and Likely Use of an MPT Vaginal Ring” model, therefore, reflects incorporation of components from both guiding frameworks (Woodsong et al and Mensch et al) as well as empirical findings from primary data collection and analysis of MPT ring acceptability.

The new model has several parts:

The Priority Triad: First is an interrelated triad, called the ‘Priority Triad’, prioritizing oneself, partner or relationship. The Priority Triad emerged as the core process for women as they evaluate the acceptability and potential use of an MPT ring. As the analysis of the interview, card sort and focus group data will show in detail, the components of the Priority Triad are dynamically (re)prioritized, (re)shifted and (re)balanced as part of the contextual considerations
that women make toward potential ring acceptability and use. The Priority Triad drives the complete narrative of acceptability and likely use of an MPT ring.

**Rationale for Need:** The rationale for need of an MPT ring refers to a woman’s evaluation whether she needs a product to prevent pregnancy and/or HIV. This is typically based on her fertility desires and/or HIV risk perception. For women who establish that there is a rationale for her need for an MPT, the model demonstrates bi-directional relationships between The Priority Triad and Episodic Considerations (below). However, when women determine there is no rationale for needing an MPT, regardless of how acceptable a product may be, acceptability attributes are largely irrelevant to likely MPT use.

**Episodic considerations:** Episodic considerations capture various attributes of an MPT vaginal ring that women temporally consider, per life episode, as part of their overall assessment of product acceptability and use. The distinction between Episodic Considerations and the Priority Triad is a critical part of the model. A product may be deemed acceptable to a woman in terms of its attributes, but commitment to use an MPT is driven by things that change, like their relationships. For example, if a woman’s partnership status changes from being in a committed relationship to being single, ring acceptability and likely use may change. An example of an Episodic Consideration might include device interference during sex, which acts as a deterrent to acceptability and further use.

**Product Use Preferences:** Lastly, the category for ‘product use preferences’ highlights women’s agency in her choice of prevention method. While this study explored MPT ring acceptability, a woman may prefer attributes or experiences associated with alternative products, such as a barrier method, or to use no method at all.
Together, the Priority Triad and Episodic Considerations make up what is generally referred to as “acceptability”. These considerations for acceptability can be jointly connected to expected product use when a woman has an identified rationale for needing an MPT above all other prevention methods.
Figure III: Dynamic Considerations for Acceptability and Expected Use of an MPT Vaginal Ring: A Grounded Theory Model
Section 3.3: Detailed Model Description - Dynamic Considerations for Acceptability and Likely Use of an MPT Ring

Introduction

In this section, I describe the components of and associations within the model, “Dynamic Considerations for Acceptability and Likely Use of an MPT Ring,” referred to as ‘the Model’ moving forward. There are three major components described in the model: The Priority Triad, The Rationale for Need and Episodic Considerations. The remaining two components (Product Use Preferences and Expected MPT Use) are necessarily integrated into the other three and are therefore not discussed separately. The Model components are presented in the order that best crafts a coherent narrative but does not align with the sequence in which they are presented in the visual model.

EPISODIC CONSIDERATIONS

In this study, ‘episodic considerations’ includes three types of attributes that can shape acceptability and expected use of MPT rings: product attributes; use attributes; and sexual encounter attributes. These attribute types sometimes overlap and are interconnected to one another in women’s descriptions.

Product Attributes

‘Product attributes’ refer to considerations that are specific to the product such as size, material or dosing regimen. Although ‘appearance’ of the ring has been included here in other research on ring acceptability in this study it was discussed by women relative to other themes (e.g., menstruation) and thus it is classified elsewhere.
Size and Material

In other trials of microbicide and vaginal ring perceptibility and use, product attributes such as circumference and thickness, texture and pliability have been examined in-depth as these dimensions were considered critical to efficacy and user behaviors. In my study, by contrast, women were not shown the ring prior to the focus groups. If they were interested in relative size or shape prior to insertion, the parent study medical practitioners would show them photos of a NuvaRing, which was similar in size to the TDF ring they would wear as part of the trial. This approach appeared to assuage women’s fears or concerns; they all continued to participate in the trial and have a ring inserted. In the focus groups, women were shown a sample ring that they could handle, which was identical to the placebo ring worn by participants in the trial. The placebo ring differed from the TDF ring by the amount and type of white powder (TDF, experimental) or granules (salt, placebo) inside the ring’s reservoir. Using a show of hands, nearly all of the women (16/18) reported seeing the ring for the first time during the focus group. The dialog that ensued about participants’ real-time reactions to the look and feel of the ring, reflected surprise to the size and hardness of a sample ring.

Angela: What size is that?
Tracy: I would say it’s about two inches.
Adele: It looks a little intimidatingly larger than I thought it was. (FG 1)

To ensure masking, women were not able to see or touch the ring during this trial or subsequent data collection, which included restrictions placed on self-insertion and removal. Because of these restrictions, exposure to the look and feel of a ring was limited to a brief exercise during the focus group where women were shown a sample placebo ring. Still, women
in the focus groups had strong reactions to their first visual and tactile experience of the ring. They connected their expectations of the ring (its appearance, size and material) to their actual personal experiences of comfort or, more specifically, the absence of discomfort. “I didn’t know it was there” (Jamie, FG 3). Their expectations were incongruous with the actual look and feel of the ring; women were surprised at how hard and large the ring actually was compared to what they had imagined. They had assumed that if they could not feel it then it must have been more diminutive.

The ‘material’ that the ring was made from did not seem to affect women in the way that has been described in other perceptibility research about product attributes. In other research, ‘material’ was evaluated more for the feel and flexibility of the ring’s material to the touch or inside the body. In this study, however, women did not identify preferences or distaste for the ring ‘material’ as it would relate to their personal experience with the ring through touch and feel, but instead spoke solely about their partner’s potential perceptibility and acceptability of the ring. Women perceived their partners might object to a material that felt “unnatural” or that could potentially cause physical problems such as “rash” or “allergic reaction.” This finding was seen most clearly in the card sort findings; as women talked about and sorted the card “Material that the ring is made out of,” most of their narrative centered on partner health rather than their direct exposure to the ring’s material.

**Dosing Regimen:**

A key decision in IVR development is how long the ring should be left inside the vagina before being exchanged for a replacement. Each participant was asked about the ideal length of time to leave the ring inside her body before exchanging it, without providing contextual cues
about the possibility that replacement could involve a clinic visit or be self-administered. Women had clear and strong opinions but disagreed about how long a ring should remain in place before exchanging it. Most of the women participating in the IDIs (11/18) thought that monthly exchanges were ideal, while a smaller sub-group (5/18) preferred the ring to stay in for a longer duration, ranging from 3-12 months. One participant had no preference and the other wanted weekly or biweekly exchange.

*Monthly ring exchange*

While most women preferred a monthly ring exchange their reasons for this choice differed. For most monthly timing was familiar and fit with their monthly menstrual cycle. These women already calendared their cycle by a 28-day pack of oral contraceptives, so a monthly interval was easily tied to starting and stopping birth control medication. This familiar cycle would help them to remember that the ring should be changed and a new one inserted.

I think a month is appropriate because it’s easy to track, like four weeks long or however long and then every month you would just be able to get a new ring from wherever you get it from. (Kerry, IDI 1)

Other women preferred a one-month interval because they did not want the ring inside their body for too long. Some worried that they might forget the ring was inside:

You don't feel it so it's going to be hard to remember to take it out or change it … Because I think if it's longer, we'd probably forget about it. (Madison, IDI 1)

Some had preferences for a shorter duration of wear due to fear that the ring -- either the ring itself or a drug inside the ring -- might deteriorate the longer it was left inside the body:

Because you’re putting a foreign object inside of your body and I think, you know, there might be effects on it, wear and tear on the material. Because it’s man-made material, whatever it is. (Nora, IDI 1)
In focus group 1, the women played with some ideas about what monthly ring exchange might entail. As part of a conversation about potentially removing the ring during a week of menses, or foregoing menstruation altogether, the group began to talk about their feelings about monthly menstruation. One reason many women liked monthly menstruation was that it acted as an indicator that they were not pregnant. In the absence of monthly menstruation, there was concern that women would be unaware of a pregnancy. Adele describes worrying about effectiveness of the MPT for reliable pregnancy prevention.

If I were wearing it for three months straight, I would have a probably psychological concern about whether it’s still efficacious. So there’s no way to test them? What if something went wrong and I’m no longer protected? The next checkpoint for that will only be in a few months. (Adele, FG 1)

This description captured women’s expressed anxiety about leaving the ring inside for an extended period of time. The desire to bleed was a marker of trust that the ring would still be working as intended to prevent pregnancy. For women like Adele, who wanted monthly menstruation, a 3-month window without bleeding seemed like a long time to wait to find out about accidental pregnancy.

For those who preferred to wear the ring for longer than one month, two separate but related themes emerged: they preferred a provider to insert the ring because they felt uncomfortable with self-insertion; consequently, longer wear was more convenient. In comparison to the women who preferred a monthly exchange, none of these women questioned ring effectiveness or durability. Instead, they cited current life circumstances; four were graduate students who preferred the convenience of a ring that they could ‘forget about’ for anywhere between 3-12 months.
In the IDIs, two women explained that although convenience was still paramount, their
desire for longer duration was more closely tied to reducing the frequency with which they
would need to make a doctor visit. These two women were strongly against self-insertion
because they did not feel comfortable inserting anything into their vaginas, yet they were still
willing to use a ring if a medical provider would insert it for them. Celia was one of the two
women who stated in the IDIs that they rejected the idea of self-insertion due to reluctance to
touch her own body. She attributes her hesitation over self-insertion to familial and cultural
beliefs that stigmatize menstruation and the female body more generally. However, Celia was
open to the idea of a medical provider inserting it for her.

I wouldn't want to [insert] it for myself ….it would be like a fishing expedition
literally. And to me, I probably wouldn’t go far enough…. I’d probably just go
half-way and I’ll put it in there and it would just fall out after a while. (Celia IDIs
1 and 2)

Drug Combination: Doubling drugs

In the focus groups, the facilitator gave women a list of instructions for using an MPT
ring, to generate conversation about areas of agreement, disagreement and overall acceptability
of dosing regimen possibilities (Appendix D: Focus Group Guide). During this exercise women
expressed many concerns about the potential effects of combining two drugs inside one ring,
with a few raising the questions about whether using two drugs in combination would result in
their losing effectiveness, by in some way “cancelling each other out.” Since this hypothetical
MPT ring was not the one developed, tested or worn, women had not been given any instructions
or assurances about the potential mechanisms of action or interaction as might be the case for
women wearing an actual MPT ring. However, the descriptions women gave during the focus
group exercise are suggestive of potential users’ acceptability prior to use, outside the context of a clinical trial.

In both the IDIs and FGs, women were particularly interested in how they would be able to stay protected from both HIV and pregnancy concurrently, and ultimately what would be indicators of effectiveness. Being able to trust efficacy of an HIV preventive ring has been found to be an important factor in product choice. For an MPT, this finding is escalated, such that women questioned not only efficacy of prevention of HIV singly, but also prevention of pregnancy. Specifically, however, women were uneasy with a possibility that their protection from pregnancy might be jeopardized by the presence of the TDF.

While there was some discussion in the IDIs about the potential of multiple drugs working against one another or potentially causing problems because of a possible drug interaction, the discussions in the focus groups approached the matter of two drugs in combination from a slightly different angle. The impact on effectiveness of the “double drugs” themselves was questioned; does the presence of both drugs “cancel each other out”? Further, women in the focus groups questioned how having the two drugs was necessary for dual protection, but the combination of the two drugs seemed like it would be incompatible with women’s preferences for removal during menses. When these group participants were asked to evaluate criteria for MPT ring use, they could not reconcile how a ring could provide trusted continual protection against both HIV and pregnancy if the ring was removed at any time, especially for a week duration while menstrual blood flowed out of the body. These data precipitated from the exercise where women reflected on the instructions for using an MPT Vaginal Ring; one section discussed ‘wearing the ring during menses’. A vocal majority in each of the focus groups established that ring removal during menstruation was a leading feature that
they wanted. Following this, they were confused about how they would be protected from contracting HIV during menstruation, assuming they would remove the ring from their bodies during that time.

[You wouldn’t get pregnant during menses]---not with the pregnancy ring, my one thing is if you took out the HIV ring for your period, for those people that did have sex while on their period, I would just be scared that they may---there may be some kind of misconception that [they’re] still protected but [they] need to take it out during their period and then they put themselves at risk by possibly taking it out and then you know, participating in [sexual activity]. (Laura, FG1)

Laura is one of the 3 women who had self-inserted, used and removed a NuvaRing in the past, so may have been primed to conceptualize an MPT ring as one that would be removed during a week of menstruation. However, the other women in the group nodded in agreement at this statement.

**Use Attributes**

‘Use attributes’ refers to experiences associated with ring use such as comfort, side effects or even secondary benefits. ‘Use attributes’ generally differ from the forthcoming category of ‘sexual encounter attributes’ in terms of the type of experiences women are describing. In this section, I describe attributes of the ring that mainly are discussed in the context of daily wear, rather than during sex. It bears noting that women themselves did not always explicitly distinguish between these two categories (use attribute vs. sexual encounter attribute), and therefore some of the themes within these categories appear to overlap. Therefore, I am presenting these categories as separate but also connected with dotted lines in the visual model.
Comfort in Use

During the IDIs, I systematically asked all women about bodily comfort with the ring, and there was near unanimous reporting (17/18) that they felt no discomfort while wearing the ring. Although not asked systematically in the FGDs, there were no spontaneous reports of discomfort among the FGD participants. The overwhelming sentiment was surprise that “[I] didn’t even notice it was there” (Carly 2, 30). However this comfort had a downside. Seven of the 18 women in the IDIs reported checking on the ring to make sure it was still in place, despite being told not to insert anything inside the vagina, because they expressed concern that it may have fallen out or become lost during the course of the study.

Megan was the only participant who reported discomfort with the ring and consistent trouble with the ring staying in place throughout both weeks of wear.

I mean it just like slides down…. And I like can't do anything about it, so I’m trying to cramp up like try to use my muscles to make it go back up…. And it makes me feel uncomfortable when I got to [have a bowel movement], to like use a piece of tissue to try to hold the ring up and go to the bathroom…. Sometimes I lay down, you can feel the rubber. It’s like bent, so you can like feel it poking me. (Megan, IDI 1)

It was common for women to compare the IVR to other vaginal devices they had experienced personally or had heard about before, such as tampons or NuvaRing. “I wasn’t able to see how big it was [prior to insertion], but I don’t think it’s that big cause you don’t feel it. Like you know when you wear a tampon.” (Angela, IDI 1) Prior to ring insertion, however, participant expectations were different: participants who had never used a vaginal ring prior to the study anticipated that the ring would be noticeable during daily activities and could easily fall out at any time. Marina compared her expectations of the ring to her previous experiences with cotton tampons and the Instead menstrual cup.
I know with tampons, they're cotton or whatever and so it kinda sticks in there, I guess. Maybe it's because I had such a hard time with that Instead thing and I felt like it wasn't staying in place, I guess I just felt like wearing something plastic in there for a long time, it would be more likely to move around than something cotton. (Marina, IDI 2)

In the IDIs it was clear that women interpreted ideas about comfort as having to do more with activities of daily living rather than during a sexual act. However, the card sort allowed for exploration of a priori topics, including further hypothesizing about comfort specifically during sex. In the card sort context, ‘comfort’ was a use attribute that was seen as equally relevant for the woman and man during sex. In nearly all cases, the participants grouped together the cards for ‘my partner’s comfort during sex’ and ‘my own comfort during sex’ adjacent to one another (typically with ‘my own comfort during sex’ being prioritized directly ahead of ‘my partner’s comfort during sex’ card) (See Figure IV). Nearly all women (14/17) who participated in the card sort grouped these two cards next to one another in terms of level of importance for use. This adjacent grouping of cards regarding own and partner’s comfort during sex demonstrated the linked importance of mutual comfort during sex with ring use. In nearly every case (12/14), however, women elevated their own comfort during sex above that of their partner’s. (Figure IV).

In the focus groups, participant expectations prior to ring wear were articulated early in the sessions. The facilitator’s first prompt (following an icebreaker exercise) was “Tell me what it was like for you to use the vaginal ring.” This opening statement was designed to invite the discussion of the full range of participants’ lived experiences with wearing the ring during the trial. In each of three focus groups, responses to this question included combinations of mostly negative expectations associated with ring wear prior to insertion alongside actual experiences of comfort wearing the ring. In the following passage, Hillary described a thought process that
others in the group identified with, as was indicated by other participants nodding their heads up and down along with implicit statements of agreement in the dialogue which followed. Such indications of assent and concurrence have been identified by Morgan as a special feature of focus groups such that the data are dynamically co-created among group participants. 257 Hillary described her anticipated feelings of physical discomfort (which she equates to the discomfort she feels with tampons) alongside her established ideological discomfort of wearing a product inside her vagina.

I don’t really like to have anything in there, like I said so, just the idea of it, it makes me feel uncomfortable, like I’m not going to be comfortable under my own skin, so I was actually surprised when I didn’t feel anything… I swear I wasn’t going to be able to sit properly or anything but I realize that it was all in my head. And I know I had other friends that had the NuvaRing before and they said, no, it’s comfortable, you don’t feel it. But you know, it’s something that I still couldn’t---you know, get my head wrapped around until I actually experienced it myself. (Hillary, FG 2)

The three trial participants who had used NuvaRing prior to the study reported no negative expectations of the physical sensation or comfort of a vaginal ring (including sensation for their sexual partners), yet their concerns over using an HIV preventive drug and related implications were similar to the concerns of those who had never used NuvaRing.

Overall concern for the TDF drug was low for a few different reasons. First, women explained that the short duration of wear during the trial was unlikely to impact their health. Second, as part of the consent process to enroll in the parent study, women were made aware that the Food and Drug Administration had already approved a form of TDF for use as oral PrEP (marketed to the public as ‘Truvada’). That a similar formulation of the study drug was available on the open market allayed fears about drug safety. However, a few of the women mentioned that a longer exposure probably would have impeded their interest in using the drug inside their
bodies. Even though the drug was available as Truvada, and therefore ruled ‘safe’ by a governing body, there was some skepticism over the perpetuity of this safety rating:

I guess, you know, how they used to use mercury in fillings, not that there’s mercury in this but you know, they learn things as time goes on, right?... In my mind this is how it works—that they knew mercury was toxic for a long time but they put such a small amount in the fillings and thought that it doesn’t leak out, that they weren’t worried about it. But as science gets more sophisticated or we start to understand things about biology and chemistry more you can learn things that contradict what you previously thought. (Marina, IDI 1)
Figure IV: Rose’s Card Sort Activity: Ranking Her Own and Her Partner’s Comfort During Sex
Side Effects and Secondary Benefits

The only side effect spontaneously mentioned by women in the IDIs was increased wetness or discharge, reported by 7 in the TDF group and 3 in the placebo group, but only 2 reported distress from the amount or presence of wetness or discharge.

In the card sort, the exercise was designed to encourage women to think about all possible types of side effects and to reflect on their meanings to them, personally. One card was entitled “side effects” that women were instructed to sort into reasons to use or not use a ring. This card was most often placed in a participant-generated pile “it depends,” meaning the decision to use or not to use would depend on the specific type of side effects: whether they were perceived to be beneficial or detrimental to the woman, her partner or to their relationship in some way. Laura described how some side effects would be worrisome or difficult, but anticipated other side effects might not bother her or even could provide benefits:

It would depend on the side effects…And not all side effects are bad. I mean, maybe a side effect is I’m wetter. I have increased libido. So those are side effects that I would be like, “Yeah, I’m totally okay with those side effects.” If decreased libido, dryness…which can always be overcome but I guess the side effect is the risk-benefit factor for me and not knowing which side effect it would be I don’t know whether I would choose the ring or not choose the ring. (Laura, Card Sort)

Side effects were critical to all the women, but it was difficult for them to classify how these theoretical side effects would impact their acceptability, and even in the card sort it was difficult for women to rank the card relative to other factors. Women often explained that this was because there could be a range of side effects, some of which might be more or less difficult to manage. Those would need to each be evaluated in the context of all other factors.
Some of the side effects that women identified as potential barriers were also considered a possible secondary benefit depending on the circumstances. These secondary benefits included features akin to some of the benefits women were already receiving from their contraceptive methods. Women named benefits like being protected against ovarian cancer, clearing up acne, and regulating menstrual cramps that would make a ring more acceptable to women. Both side effects and secondary benefits were discussed in the context of the interviews and card sort but were not a topic of discussion in the focus groups.

**Impact on future fertility**

All of the women in this trial were trying to avoid pregnancy to some degree and were taking oral contraceptives as a prevention mechanism. They were all of childbearing age, but at different stages of reproduction. A few were clear that they had completed childbearing, but most were either considering an additional child or imagined that they would have a first child at some point in the future. For the women who had not yet completed childbearing, they reported strong sentiments that acceptability of an MPT ring would be contingent upon their fertility not being impacted in any way. Additionally, women wanted assurance that upon discontinuation, their return to fertility would not be delayed.

I want to finish school in a year and you’re thinking about having a baby after or, you know, start your job for that first year, you want to---you and your partner decide that you want to get pregnant, what’s going to be the, you know, the long term effects of getting pregnant? Their biological clock is ticking… is it going to be a year, two years, three years before I can conceive? (Maureen, FGD 2)

While some participants spoke about fertility and return to fertility in the context of the interviews and focus groups, most of the data supporting this theme was generated during the card sort in response to two different cards: ‘side effects’ and ‘Will not affect getting pregnant in
the future.’ In the card sort, because there were pre-determined card topics that women were asked to reflect upon, all of the women were asked to think through the different ways that specific side effects and possible future pregnancy might impact their decision to use a ring. Because of these cards, women were able to comment on this attribute even if they had not organically brought this up in the context of the interviews. Women highly valued a ring that did not interfere with future fertility. This was evidenced in the card sort where 10 of the 17 women ranked the card “will not affect me getting pregnant in the future” within their top 4 reasons to use a ring. Hillary describes her rationale for ranking this attribute as the single-most important reason for her.

Yeah, that would be a reason to use it because right now I don’t want to have children right now, but in the future, I’m open to [pregnancy] so I would want to have something that’s not going to be affecting me negatively and in a way that I won’t be able to have children. (Hillary, Card Sort)

Menstruation:

Menstruation was discussed as a key episodic consideration affecting ring acceptability. Different from other episodic considerations for acceptability, menstruation considerations were not limited to a single set of ring acceptability attributes (product attributes, use attributes or sexual encounter attributes), but rather it crossed all three of these attribute categories. I am arbitrarily presenting the theme of ‘menstruation’ as part of the ‘use attributes’ section of this dissertation, but it could be equally discussed within the ‘product attributes’ or ‘sexual experience attributes’ section as well. Menstruation emerged as a factor toward acceptability in two main ways: as it was related to keeping the body ‘clean’ which precluded wearing a ring
during menstruation, as well as desires to menstruate at different intervals if wearing a ring. The two factors were highly intertwined in women’s descriptions.

Participants did not menstruate during the two weeks of ring use but were asked about what they anticipated it might be like to menstruate with a ring in place every month. In the IDIs, nearly half of the participants (8/18) expressed no concerns about wearing the ring during menstruation, while the remaining 10 women did report worries that would prevent them from using an IVR during menstruation. The card sort data echoed this clear divide within the sample of those women for whom menstruation considerations generally “did not matter” vs. those for whom menstruation factors limited their acceptability of a ring.

In both the IDIs and FGs, about half of the participants said that because they would not wear the ring during menstruation it was a deal-breaker in terms of acceptability and use; the other half cared very little to not at all. However, in the card sort, these concerns fell to lower priority levels than they were seemingly expressed in the IDIs or FGDs. For example, we can see Rose’s card sort where she ranked the cards “The ring will stay clean” and “The ring won’t get menstrual blood on it” as having lower importance in her likelihood to use a ring (See Figure IV). Among the other women participating in the card sort, these two menstruation cards tended to get clustered together (potentially identifying a sub-theme connecting menstruation and cleanliness) and were ranked certainly near the bottom of all reasons to use a ring for nearly all of the women. In other words, menstruation was a factor in ring acceptability, yet when considering it in relation to other potential factors, menstruation held less importance than when women discussed it relatively independent from other factors as they did in the IDIs or FGD.
Ridding the body of menstrual blood: the need to be ‘cleaned out’

The most common reason cited for not wanting a ring during menses was that menstrual blood was perceived as ‘dirty’ and could cause ‘infections’ if its exit from the vagina was obstructed by a ring in the vaginal canal. Women perceived their bodies as being naturally programmed to expel menstrual blood monthly as both a typical and natural process that should not be interfered with. They described the process of menstruation as a cleansing ritual which supported the body’s natural way of ‘flushing out toxins’ and ridding itself of any unnecessary ‘waste.’

Women did not like the possibility of the ring would change appearance in the presence of menstrual blood. When interviewed about this, Rose and Megan discussed the reasons for their disgust, as it being ultimately tied to hygiene and maintaining good health.

“So everything is like coming out of your body the ring should come out too. It would be really nasty to have something that’s had menstrual blood all over it and then…yeah. I would feel like dirty and stuff like that.” (Megan, IDI 1)

“[The ring] would absorb [blood], and if it's too much it would cause an infection or something. You shouldn't really have something, you know, blood stuck up in there.” (Rose, IDI 1)

Therefore, these women explained that having a device inside the vagina while the body was trying to rid itself of unhealthy or unnecessary material would potentially cause health problems such as infection if the blood was somehow ‘caught’, ‘stuck on’ or ‘stained’ the ring. In the middle of a discussion about this topic in focus group 1, Nora blurted out the word “skevatz”, a derivation of an Italian word for ‘disgusting’, to capture the conversation in one word. In the focus groups and IDIs, menstrual blood stains on the surface of the ring were
described as unacceptable to many women. Previous ring trials, where women were instructed to leave it inside the vagina during menstruation, found that women removed their rings during menstruation to clean their vaginas.¹⁵²,¹⁵³

*Aligning intervals of menstruation with ring exchange:*

During each of the focus groups, I introduced the topic of desired frequency of menstruation. Within each of the three focus groups, there were two distinct groups of women that formed: one group that wanted to menstruate monthly, and the other group that wanted to menstruate over differing intervals ranging anywhere from three months to never menstruating. This breakdown was fairly similar in the IDIs as well. For those who preferred less frequent menses, they typically pointed to reducing the logistical burden and “mess” involved in menstruation. They liked the idea that an MPT ring might be designed to elongate the interval between menses to be longer than one month. For women who preferred monthly bleeding, there was a wide range of reasons given including verification of not being pregnant, cleaning the body of “waste” regularly and maintaining a schedule that could be anticipated.

In FG1 for example, Adele, Angela and Marina formed one group who were vocal opponents of monthly menses. In contrast, Rose and Nora formed a group in which they were proponents of it. Rose and Nora refined their positions about why they preferred monthly menses including “not feeling normal,” a desire for “feeling refreshed,” and it being “natural for all that discharge to come out,” as they exchanged reasons for frequency preferences with Adele, Angela and Marina. In the following exchange, Angela and Rose engage in a dialogue that highlighted their divergent attitudes about the desired time interval between menses.
#1: Angela:  I would prefer that way to only have your period four times a year because I don’t like periods. I hate them. I hate them with a passion.

#2: Rose:  I would prefer to get it every month because I’ve been on a pill that I got it every three months and I didn’t like it.

#3: Adele:  Was there a major thing that you didn’t like about it?

#4: Rose:  I just didn’t like it. It didn’t feel normal, maybe the hormones maybe in the pills in everything. different type of hormones that made me not get it for three months. I was still spotting in between so it’s not like you don’t get it, so what’s the point then?

It is important to understand here how these data were produced or ‘co-produced’, so we can identify the benefit of the focus group method toward these findings. 257 This coding approach compares each subsequent participant statement to the previous, to identify a range of possible directions where the conversation might flow. Applying Morgan’s co-production of interaction coding scheme here, we can see how this conversation between Angela and Rose (and facilitated by Adele) opened deeper exploration of how menstruation is clearly connected to desired intervals for product exchange.

At first (#1), Angela firmly states her distaste for menstruating without much explanation (although she does explain later that she “hates” menstruating because of restrictions on her daily living and sexual activities), justifying her desire to menstruate less frequently, “four times a year.” Rose’s response to Angela (#2) then differentiates Rose’s perspective about monthly menstruation from that of Angela’s, both expanding on what Angela first established but also comparing it to her own experience of having used a contraceptive pill that was designed for her to menstruate every three months instead of every fourth week. In Rose’s response, she explicitly
differentiates her own attitude towards menses from Angela’s. Following Rose’s response, Adele then prods Rose (#3) to give more detail about Rose’s experience with this 3-month interval. Rose complies (#4) and expands upon her own previous statement (#3): Rose first mentions (#4) hormones made her feel not ‘normal’ and then connects back to Angela’s expressed distaste, adding that she was also breakthrough bleeding during the months when she was not supposed to be bleeding.

In the focus group forum, Rose is able to clarify her reasons for wanting monthly menses through the narrative that she develops to respond to Angela, who had a conflicting viewpoint to hers originally. Rose supported (#4) her position with evidence from her own lived experience. Further, in an effort to support her own stance Rose circled back to implicitly agree with Angela (#1) about breakthrough bleeding as a deal-breaker reason for not wanting an MPT with longer than monthly menses intervals. Breakthrough bleeding was not something that Angela had experienced, but it was also not favorable to her. Rose’s determination to explain why she felt differently from Angela about desired intervals, exposed another component of acceptability that had not emerged previously from Rose on her own. Thus, Rose’s ultimate point about disliking breakthrough bleeding was produced in response to Angela’s perspectives and would not have emerged on its own. This interaction between participants therefore encouraged new and more detailed data to emerge that might not have in the context of an individual card sort or IDI.

*Limiting foreign objects in the vagina*

There was some concern that the presence of a ring might cause additional distress during the menstrual cycle in which women were already experiencing discomfort, such as menstrual cramps, bloating or restrictions on daily activities or sexual activity. In focus group 3,
participants discussed their worries over the potential for a ring worn during menses and how they might not want to take the chance of worsening their menstrual symptoms. Brianna captures this concern.

I’m feeling all the menstrual cramps that I never knew existed so if it’s going to make me feel uncomfortable even more during that time –I would probably don’t want to go through any more uncomfortableness. (Brianna, FG3)

Menstruating with a ring also posed some ideological challenges for women who used tampons. “Crowding” the vagina by using a tampon and a ring simultaneously was a deterrent for use during menses, described by one focus group participant as “a double whammy”. In a recent study of a PrEP-only vaginal ring, participating women experienced displacement and expulsion of a vaginal ring with tampon use during menstruation. In this study, women worried about this exact thing, questioning if tampon insertion would somehow move or displace the ring or vice versa, causing discomfort or expulsion of either product. For the tampon users in this study, this consideration was prominent.

Just it shifting if you put a tampon in there - it might shift. You know, too many things up in there. (Rose, IDI 1)

One respondent questioned the impact of menstrual product use on effectiveness of the drugs inside the ring to prevent HIV or pregnancy. Specifically, she noted that since tampons are intended to soak up blood, there was potential for the tampon to soak up drugs emitted from the ring, limiting its intended function.

If I were to get my period I would want to use a tampon, and I would be concerned about putting the tampon in with the ring for fear of the tampon absorbing whatever the ring is giving off. (Laura, IDI 1)

In the focus group discussions, women went into more depth about concern of using the ring alongside tampons and other vaginal products. While most of the women disagreed that
tampons could ‘soak up the drug’, there was some concern that other vaginal products might interfere with expected effectiveness of the drugs inside the ring. Natasha said:

I’m a product user, too. I’ll use douches and there’s other you know, different items I guess with my husband. You know is that safe? Can I use that during the ring? You know different types of jellies. Will it make the product ineffective? (FG 3)

In addition to questioning a possible reduction in drug effectiveness due to vaginal product use, the use of tampons made the women especially uneasy, even comparing it to potential side effects from tampons alone. These concerns came mainly from the women who did not regularly use tampons.

There’s certain side effects to using the tampon. You have the toxic shock syndrome and there’s already that worry that if you know, don’t use a tampon properly or keep it in there too long. It might be overwhelming. (Natasha, FG 3)

A few of the women in the focus groups agreed with one another (Natasha and Kelsey) about a negative impact of leaving a tampon inside for too long and extended that concern to leaving a ring inside the body for a long time period. In 2 of the 3 focus groups, participants discussed the possibility of getting toxic shock syndrome (TSS) as a deterrent to their own tampon use during menstruation. They equated the possibility of getting TSS from a tampon with the possibility of getting TSS from a ring and were therefore disinterested in using a ring during menstruation for fear of TSS.

The card sort activity was the only method that generated no data about ‘crowding’ in the vagina. As the developer of the card sort, I did not recognize this as an important dimension of the broader ‘menstruation’ domain until the card sort data collection had been completed; it was only during focus group data collection and retrospective analysis of the IDI data that the crowding dimension became clear. Additionally, it is important to call attention to the fact that
participants also did not develop a card to represent the crowding dimension spontaneously during the sort. The absence of this card suggestion may be related to crowding being a more distal theme for participants, and one that might not occur to women in the absence of the sensory experience related to actual product use and physical crowding; this should be studied in subsequent studies of acceptability of an MPT ring specifically if designed to be worn alongside other intravaginal menstrual products.

Abstinence precludes the need for protection

Some participants preferred not to engage in vaginal sex during menses because they saw it as being “dirty” or “messy.” It has been noted in other research about menstruation and sexual intercourse that women’s abstinence during menstruation is a deeply entrenched cultural and social expectation in some communities, such that women can be branded as “unclean” and physically or spiritually hazardous.\(^{263,264}\) In this study, women only discussed this theme in the interviews, not in the FGs or card sort). Angela rationalizes this cultural expectation as justified because nothing (including a penis) should obstruct the outward flow of menstrual blood.

It doesn’t sit right with me to be bleeding and have sexual intercourse. I wasn’t taught to do that or raised to do that and I just think that’s when all our bacteria is… that’s when all the bacteria that we have carry in us is being discharged. So why would I want it to cause like a back-up or something?
(Angela, IDI 1)

Women who practiced abstinence during menstruation said they had no need to wear the ring during menses because they would be at no/very low risk for getting pregnant or contracting HIV through sexual transmission.

I don't like to have sex during my cycle. So why would I have it on anyway? It's just supposed to prevent HIV that's when you normally have it on when you're about to have intercourse so during my cycle I don't have intercourse for sure. So that's why I would take it off and then I put a new one in right after my cycle is
done and then take off. So it would be every month I guess or every 28 days. (Hillary, IDI 1)

Some participants thus assumed that the protection conferred by the ring could be episodic, not continual, and removal during menstruation would be an expected feature. This theme of abstinence precluding the need for a prevention device was not solely limited to the time during menses, but also extended to include abstinence in general.

**Sexual Encounter Attributes**

‘Sexual encounter attributes’ of a ring include aspects of sexual episodes that potentially shape acceptability of the ring for the woman, her partner or their relationship. While these attributes were originally conceptualized only in terms of the ways the ring might negatively ‘interfere’ physically with the sexual encounter, instead a more positive outcome ‘sexual pleasure’ emerged as a clear theme for women within each of the three types of data collected. In general, sexual experience attributes were discussed with great emotion, but were limited. This was potentially a function of the hypothetical nature of the inquiry, as women were asked to refrain from sex during the course of the study.

**Sexual pleasure**

Sexual pleasure was discussed as a basic requirement for overall ring acceptability and product use but was discussed in more abundance and depth during the card sort than in the other data collection forums. Consistent with the trial requirements, all of the participants reported refraining from vaginal, anal or oral sex during the study period. However, women were asked to comment hypothetically on what they anticipated the experience of having vaginal sex with a ring might be like. There was a clear connection for women relating sexual pleasure and physical comfort. Most women assumed that they would not feel any discomfort or pain during sex from
the ring, however their partner’s physical comfort was discussed as being just as important as their own. But it was not just the avoidance of discomfort that concerned women, it was also the ability to prioritize and enjoy sexual pleasure, both personally and together with a partner.

If my partner is not comfortable sex wouldn’t be pleasurable for both of us. Being intimate, that’s something you share together.” (Carly, IDI 2)

I can’t be bothered. You know it’s going to be uncomfortable for him and uncomfortable for me, and I just want to enjoy the sex. I just don’t want to have to think about it. What if he doesn’t like it? And then it’s going to get interrupted. (Natasha, FG 3)

Reciprocity during sex was a common theme; ultimately, sexual pleasure was compromised for women if their male partners were distracted or uncomfortable. Sex was described as being “good for both of us or it’s not good at all” (Laura, Card Sort). If reciprocity of intimacy were interrupted, women were clear that they would not want to use the ring and would remove the ring, even if only temporarily during the sex act (Figure IV).

Interference with (or facilitation of) sex

The introduction of a foreign object or substance into a sex act was previously noted as one reason that women posited the ring might interfere with intimacy. While there were questions about the potential for the ring to cause physical interference in a sex act, most of the conversation regarding theoretical interference was related to secondary effects of ring use such as increased wetness or discharge and were contextualized, respectively, as a facilitator of or barrier to vaginal sex. More than half (10/18) of the women reported actual increased wetness from ring use, which was generally viewed as a benefit for providing extra lubrication during sex for women and their partners. “Extra wetness is never a bad thing…you just can’t go wrong with
lubrication”. (Sara, IDI 2) A clear distinction was made, however, between wetness and ‘discharge’ in the card sort, so much so that when Laura was contemplating where to place a card labelled “discharge during sex”, she talked through her thought process and eventually generated a new card entitled “wetness during sex”. While wetness was described as a clear and familiar substance that the body made naturally, discharge was considered to be unfavorable, as it would disrupt the natural experience of sex and have a negative impact on intimacy.

It’s not necessarily always bad but when I think of discharge I don’t think of normal wetness. I think of actual discharge and if I were to be having sex with my boyfriend and he were to want to get me closer to coming I don’t want him to go down there and say eat me out and have more vaginal discharge that then makes it an unpleasant experience for him during sex. (Laura, Card Sort)

Carly went further to question how discharge could be potentially related to the drugs used in the ring.

The ring is giving out something. It’s releasing something. If it’s going to be like a different discharge, even if it’s going to mix, like with the semen and the vagina discharge, like if there will be a smell, if there will be an odor, a different color. If that’s going to turn the mood on or off while, you know, using the ring? (Carly, IDI 2)

In FG 1, the opening conversation mirrored Carly’s concern about discharge she perceived as due to the drug inside the ring. Two of the women talked about having extra wetness and discharge and questioned if that was indicative of wearing an experimental ring that “put out” the drug into their vaginas (as compared to the placebo group). In one set of exchanges, Angela, Rose and Nora wondered aloud if their excessive wetness and discharge was due to the TDF drug being released from the ring into the vagina. Marina countered that possibility by suggesting that the discharge may have occurred from the presence of the ring device itself, but
Angela, Rose and Nora instead settled together on the explanation of drug release as the cause. This may have implications for how women believe they can decipher effectiveness of a device in the future: if they experience discharge, then the drug must be present and working whereas absence of discharge indicates lack of effectiveness (FG 2).

In the card sort, ‘wetness during sex’ held value for most women as a component of their sexual experience, yet they distinguished it from discharge. When women spoke about how much discharge mattered to them, however, the distinction was less profound than indicated by women in the FGDs or IDIs; women expected and were satisfied to experience wetness during sex and would not be happy to experience ‘discharge’ during sex. When challenged to rank the presence of wetness or discharge as reasons to use or not use, these two factors were idiosyncratic across the group but neither card (wetness or discharge) rose to a high level of importance to use or not use a ring.

The prioritization of sexual experience was one of the tightest cluster of cards in the card sort, meaning that these cards in this category all hung together more closely than any of the other a priori categories (See Table II). Further, this category of sexual encounter attributes always ‘mattered’ to women to some degree, indicated by these cards always being chosen for the second ranking exercise. In sum, women described that if the ring did not interfere with sex and sexual pleasure, then that would be a reason to use it, and conversely, if it did interfere with sex or sexual pleasure, then that would be a reason not to use it.

All researchers in the parent trial and this qualitative study were careful to maintain participant masking throughout the trial and at all data collection points to discourage potentially false or otherwise influential conjecture among participants.
If you are sleeping with someone you’d be very conscious of that person feeling the ring inside of you. Like there would be lots of oral sex and fingering tonight, I do not want a ring inside me. That would be a reason to take it out for a short period. (Adele, Card Sort)

However, it is important to note that these reasons were not ranked as top priorities to use or avoid a ring. Rather, they tended to hang somewhere in the middle of the rankings of importance for women. Potentially this reflects an idea that a device that is used for prevention of pregnancy and HIV should not impact the sex act; but the middle-of-the-road prioritization of sexual experience relative to other factors suggests that women would value effects of the device on sex a moderate amount.

**THE PRIORITY TRIAD: PRIORIZING THE RELATIONSHIP, PARTNER OR SELF**

I explored how relationship dynamics between partners could impact ring acceptability and use. It was this factor that generated the construct of the Priority Triad. Acceptability and likelihood of ring use depended on circumstances that were quite distinct from the episodic considerations just discussed and reflected sometimes competing priorities: those of the relationship, the partner and the woman herself.

All three types of data clearly demonstrated each of the three individual components within the triad, but the focus group data were the first to elucidate the connections between the components of the Priority Triad. The emergence of a new concept around balancing priorities led me to return and further investigate how it played out in the card sort and interview data. Across the three data collection methods, women identified interconnections within this triad of priorities such that what might impact her priorities could subsequently impact the health of a partner or the relationship. The reverse was also true. The concepts hence became multi-directional and intertwined. The forthcoming sections describing the three components of the
Triad are presented in 3 mutually exclusive sections both for clarity of presentation but also to stay close to the way that women generally spoke about each, as distinct priorities, despite acknowledgment of their overlap.

**Prioritizing the Relationship**

**Relationship type and the complexities of ring disclosure**

The use of devices such as an IVR does not require prior consent from partners, but women’s decision-making process about device disclosure can be complicated. I asked women to talk about if and how ring disclosure to a partner might transpire. Nearly all women said they would talk to a partner about the ring prior to sex with the ring in place, and the ultimate decision would involve what was “best for the relationship,” even if it only factored to a small degree in the decision-making process. These decision-making conversations, however, were anticipated in different ways.

In the interview context, ring disclosure was described as being deeply dependent on relationship status and type. Hillary explained the nuances of disclosure based on the dynamism associated with relationship status and type, specifically, of being in a long-term, serious relationship vs. a new relationship.

> The thing with my boyfriend, yeah I would tell him right away because we are sexually active. If it’s just somebody that I’m dating, I just met, I don’t really just jump in the sack with anybody that I wouldn’t tell them there’s [some]thing in my vagina … Yeah, so it depends on where I am with [a partner]. (Hillary, IDI 2)

During the course of the study Hillary rekindled a relationship with a long-term boyfriend, and shared the complicated but focused scenario of how trust, ring disclosure and relationship status interacted. She explained that if she used the ring without having told him, and he felt it during intercourse, she feared she would lose his trust because he would expect to
have been involved with the decision to use it. However, Hillary went on to explain that in a new relationship she might choose to conceal a ring at least initially, mainly because calling attention to the presence of a ring would imply promiscuity and potentially ruin the spontaneity of sex early in a relationship.

I wouldn’t mention. It’s kind of the same way of saying, ‘Oh I have condoms in my purse.’ It’s implying that, ‘Yeah, you’re a good candidate for me to get laid with,’ and I don’t want to give that impression because it’s not something you plan…and I don’t want to give out the idea that I am going to jump in the sack with you right away. (Hillary, IDI 2)

However, not everyone would conceal the ring from a new partner. Angela described how non-disclosure would preclude the possibility of transitioning into a more serious relationship status at some point in the future.

You know, some people would be like, ‘Well, I don’t want to see you again…why did you lie? Why didn’t you tell me you had something? What’s it for? Do you have a disease?’ You know, all things could run through their mind. (Angela, IDI 2)

Laura further explained how transitioning from a new relationship to a more established one would warrant disclosure. Uncomfortable situations in a new relationship would be exacerbated by concealing ring use, which would make it awkward to explain after sex had occurred and more difficult to establish an open and trusting relationship moving forward.

Like if you’re on a first date and it’s already uncomfortable or like on a third date and it’s uncomfortable already, you might be like “Oh, this is uncomfortable.” What if he feels the ring? What if he finds out I have that ring? How is he going to react? Like this is already uncomfortable as it is, I don’t want to make it more uncomfortable. (Laura, IDI1)

In FG 1, Marina, Rose and Angela discussed how wearing a vaginal ring without disclosing it to a long-term partner could cause trouble for a woman during sex. “She might be
afraid of his reaction.” (Marina, FG1) When the facilitator asks them to clarify what type of ring they were talking about, Adele went further to refine that different rings could provoke different responses from a long-term partner:

I think any HIV ring will cause more conflict than a pregnancy ring. Even if the pregnancy ring is actually a dual ring. . . Whereas an HIV ring, he’s like, “Either you’ve been sleeping around and you’re worried about getting infected or you think I’ve been sleeping around.” So either way I could see a potential partner becoming more upset at an HIV ring. (Adele, FG 1)

In the card sort, I examined ranking patterns among the disclosure-specific cards in the ‘relationship’ category (“I would not need to tell my partner this ring prevents HIV”; “I would not need to tell my partner this ring prevents pregnancy”) to determine the relative importance that women placed on these relationship-communication considerations for overall acceptability, as compared to other considerations or categories. While women expressed strong feelings about covert use or ring disclosure within a relationship in the context of the interviews and focus groups, they ranked these disclosure considerations as having relatively less importance when reported in the card sort activity. Specifically, regarding ring disclosure within the relationship, over half (9/17) of the women ranked the potential for non-disclosure as ‘not matter[ing]’ to their decision-making process for using a ring.

Women also acknowledged that both the presence or lack of partner support would guide her ring acceptability and use during their relationship. When examining the placement of the card ‘my partner supports my choice to use this ring’, 13 out of 17 women stated that her partner supporting her choice to use the ring would matter to her ring use decisions, potentially indicating that women wanted their partners to be involved with the decision overall. “If he's in support, it just makes it a little bit easier to use.” (Jenna, Card Sort)
**Partner communication**

Women went further to explain that ring disclosure was viewed as just one element within the larger experience of overall partner communication about sex and reproductive decision-making that affected ring acceptability. Megan explains that wearing a ring to prevent pregnancy should be considered a marker of necessary trust within a sexual partnership. She sees pregnancy as a critical decision that should be part of a couple’s reproductive plan, and one that requires communication to execute.

I would tell my partner it prevents pregnancy because if we’re not planning on having a baby or the partner don’t want a baby, I would definitely tell him. Like you're not ready to have kids, both of you all, you guys should talk about ‘oh this protects you against getting pregnant.’ I mean it’s not a negative thing to tell somebody. (Megan, IDI 2)

In the focus groups, participants acknowledged that committed or married couples should absolutely discuss the possibility of getting pregnant as part of the future planning of the relationship. However, the decision to use a ring with contraceptive properties would be predicated on both partners’ comfort with overall communication about the topics of sex and family planning in general, not just specific to ring use.

So if that lack of communication was there, [if] we never even spoke about birth control or any of you know, anything concerning that, I would be either hesitant to make a move or I wouldn’t make a move at all until the time is right, and I guess up until that point we’d be using condoms. (Natasha, FG 3)

A couples’ lack of communication about sex and childbearing was discussed as a potential indicator of poor prospects for the future of their relationship as well as a warning sign of lack of fidelity within the relationship. Some women believed that lack of partner communication would justify use of an MPT ring to avoid the unknown and “undiscussed”
issues of potential pregnancy or HIV risk. In the context of a relationship where the desire for children or HIV risk/status were not discussed, these women believed ring disclosure was optional but unlikely. Others expressed an alternative view: that lack of general partner communication would preclude ring use. These women described situations where partners would have sex regardless of communication or joint decision-making about using protection against HIV or pregnancy.

In focus group 3, there was an exchange between Natasha, Brianna and Jamie, wherein they described different ways that a couple’s communication could impact MPT acceptability and use. Brianna contended that, in the face of poor communication with her partner, a woman would proactively evaluate her own preferences for avoiding pregnancy and HIV. Brianna’s rationale gave prominence to a woman prioritizing her own health, after carefully evaluating her risk level within her relationship and within her community. Jamie and Natasha maintained a competing perspective explaining how both partners within the relationship were responsible for and expected to communicate about their desires and concerns regarding pregnancy and disease prevention to jointly decide on an appropriate prevention device or not.

Like with me and my husband, I wouldn’t make a move concerning [an MPT ring] if we didn’t discuss it and I get the approval and his opinion of it. We agreed collectively that the pill was the best thing for us... So if we wanted to get pregnant we would have to wait for it to wear off. (Natasha, FG 3)

Jamie describes communication as a function of a strong partnership and, in the absence of communication, it would be difficult to make any decisions about ring use for contraception or for HIV prevention. Further, it would also be difficult to effectively evaluate one’s own risk in the absence of information communicated from a partner.
That’s like going from zero to one hundred, not talking about sex and not communicating to ‘hey, I would like to try this NuvaRing that dispenses HIV, preventative medication’. He’s going to look at you like you’re crazy because we don’t have that open dialogue. There isn’t that comfort of talking about sex, of talking about feelings. So to jump from that to ‘hey, I would like to introduce this’, he’s going to look like ‘huh?’. (Jamie, FG 3)

**Using a ring primarily for HIV prevention is inconsistent with assumptions of fidelity**

A clear threat to ring use is the perception that using a ring might imply mistrust and infidelity to a partner. In a long-term relationship, wearing a ring could be interpreted by a male partner that the woman cannot be trusted to be faithful, and that the ring might even increase the likelihood of her cheating and engaging in behavior that could transmit HIV.

If you were wearing a ring that prevents HIV and you have a partner, they may think the worst situation which would be you are wearing an HIV ring because you could potentially be sleeping with other people and you’re just trying to be careful but that may make them feel insecure and question your motives of why you’re wearing it. (Tracy, IDI 2)

Conversely, using a ring could imply that a woman did not trust her male partner’s faithfulness.

I think my current boyfriend would question why am I using a ring to prevent HIV and him knowing that he’s negative and he knows my status too. He’s like, ‘Well what’s the point of using it if we’re just going to be monogamous together? It implies to me . . . that you might just want to fornicate and do your thing with other people and have that as a preventative measure from you getting the disease. So that would be a reason not to use it just because of what he might think about it. (Hillary, IDI 2)

For women already in a serious relationship where fidelity was assumed, initiating use of condoms or other disease-prevention devices like an MPT ring would challenge fundamental
tenets of trust. This dynamic, whereby relationship trust precipitates discontinuation of disease prevention behavior, is corroborated in literature on other methods such as male and female condoms and, more recently, Truvada.\textsuperscript{104,265,266} Nora discussed her marriage, and how they are open communicators. Yet still, as she noted above, it would be difficult for her to communicate a justified rationale for wearing a device solely for the purpose of HIV prevention.

If all of a sudden I came home and said ‘Oh honey, this thing has HIV [prophylaxis]…?’ He wouldn’t be angry but he would just be like ‘We’ve been together for so many years. Why all of a sudden would there be a need to have HIV protection?’ It might be strange to bring up in the middle of a relationship, especially marriage. I don’t know. It might throw a red flag up. (Nora, IDI 2)

In the card sort, when women were asked to rank the importance of how their partner might perceive her fidelity to him, this sentiment was ranked as less important relative to other considerations. Looking specifically at the placement of the card ‘my partner might question if I am faithful’, over half (10/17) of the women stated that this would be an irrelevant factor to them. Of the remaining seven women who ranked this as a reason not to use the ring, three of them ranked it as the least important reason not to use it.

**Prioritizing the Partner**

**Protecting men’s health**

Implicit in their participation in the ring trial, women understood that they were assuming a certain level of risk to their own health by testing ring safety, and they were well informed by study staff of risk to their own bodies associated with wearing an investigational drug device. However, women expressed concerns that if they used the ring during sex, their male partners would be exposed to a drug without their explicit consent. Women thought this would leave men
vulnerable to harm in some way if they were unknowingly exposed or not fully informed about risks. Health concerns for men included allergy, rash, infection, side effects, or more generally how they would react to medication coming in contact with their penis.

I mean he would have a right to know that I’m using a product that kills the HIV virus and what the effects are. I mean, you know, he may have a different medical history. I mean obviously his medical history is different from mine. So something that may not affect me, could affect him. (Nora IDI 1)

Health concerns for male partners were only limited to the TDF medication component in the ring, as women did not express concern for exposure to contraceptive drugs.

Women also worried that even the possibility of negatively impacting a male partner’s health would cause negative consequences for their relationship. Sara explains below that any negative impact on her partner’s health would cause her distress both from her partner’s anger and from her own sense of guilt for negatively impacting his health.

I know tenofovir is FDA approved but then you never know what people are allergic to and what they’re not allergic to. I don’t want to be responsible for that because I’ll never hear the end of it, trust me, never. If I were to have sex and he had a break out down there or god forbid some type of reaction that maybe he needed to be rushed to the hospital, no way. . . I would feel bad. (Sara, IDI 2)

By contrast, some women framed ring use as a way to preserve men’s health and well-being. Keeping oneself safe from contracting HIV or getting pregnant was a way for a woman to ensure that her partner did not contract HIV from her or face an unplanned pregnancy either. “Hey buddy, I’m protecting both of us here.” (Maureen, FG2)

**Prioritizing the Self**

**Demonstrating agency to protect personal health**

Seemingly in contrast to the strong narratives about joint decision-making around ring use just described, this next section showcases women’s clear statements of self-determination to
keep themselves free from HIV or pregnancy, even in the face of partner dissent. “Being in charge of my own body” was a strongly held value echoed by women in all relationship types and statuses.

I would tell him that he would have to live with it. Because if I really like the ring and I feel safe with it and I want to use it, I’m going to use it. Because I feel like it's about me. It's about our relationship. It's not really about him. It's about me. So I should be able to make my own choices about myself. (Ellen, IDI 2)

Here, Tracy aims to reconcile the contrast between prioritizing women’s health over the health or desires of a male partner.

I think at the end of the day it’s really the woman’s decision what she wants to use to protect or not protect herself. So, I’m a firm believer that it’s up to the woman. So I would think my partner would, can weigh in but I don’t think he would have much of an influence unless he provided a better option. (Tracy, IDI 2)

Nora held multiple and sometimes competing perspectives about the relative importance of her own vs. her partner’s considerations for acceptability and use of a ring. In the early part of her second interview, Nora said of her partner’s health was a strong factor in ring disclosure and use. Later in the interview, however, Nora described her own agency as being primary in terms of acceptability and choice of using the ring. She asserted that as long as the ring would cause no physical harm to her husband, a diabetic, her desires would ultimately win out.

I mean I feel like it’s my body and it’s too bad for you, to be honest with you. You know, if I’m telling you and it doesn’t interact with anything that you’re taking, unless it affected him in some way, if maybe he had an allergic reaction or he had a bad reaction, then I would discontinue it but if there was no effect on him and this worked for me, it’s my choice. (Nora, IDI 2)

Women prioritized their own health and agency over that of their partner’s or their relationship, yet all women acknowledged they contextualized this prioritization within their
experiences with their partner and their relationship. Throughout all three data types, women expressed the presence of this Priority Triad; which priority was elevated at any given moment varied over time and across women. Some women believed the decision to use a ring would need be a mutual one, whereas others would inform their partners of their intentions to use the ring, believing that ultimately the decision should be made by the woman.

The focus group data demonstrated a wider range of perspectives about the Priority Triad. The focus group exchanges were rich with agreement, disagreement and back-and-forth discussions about women’s considerations for ring use. In the following exchange, Angela and Nora discuss ring disclosure to a partner, presenting their different perspectives on prioritizing oneself or a partner. This excerpt also highlights Nora’s ambivalence about shifting considerations for prioritizing her own agency or her partner’s health.

Angela: Because it’s with me. He’s not carrying the drug.

Nora: I feel like I would have to tell my partner because if there are drugs inside of me it could affect his health.

Angela: Well, he ain’t telling me when he’s sleeping with someone else.

(FG 1)

In Focus Group 3, the women discussed how trust within a relationship is an important consideration for acceptability and use of a ring. Kelsey participated in an exchange with Rachelle and Jamie, in which each of the three women eventually defined their own positions about trust and ring use. The dialogue itself created a unique space for these women to define
and clarify their own feelings about the interconnectedness of relationship trust, prioritization of one’s own health, and acceptability and use of an MPT ring.

Kelsey: I personally, I’m in a relationship with one eye open, one eye closed.

[group laughter] So I don’t care what he thinks. Yes, I trust you but why not [use a ring]? Let’s protect ourselves just in case. You know we are in the war. Anything can happen. A couple of drinks extra. You know I know. You know if I can protect myself I’m definitely going to do it because I trust myself and I don’t really trust nobody else a hundred percent.

Rachelle: Sure.

Jamie: Man, I mean that – I disagree. I think – I mean I think either you’re going to trust or not. It’s either black and white. It’s not no gray area with trust, but I think that the way his reaction is and that’s what we’re speaking about, depends on how the relationship is on a regular basis. (FG 3)

Women’s descriptions of how they prioritized their own agency did not exclude considerations for their partners or their relationships. Rather, women described agency as the ability to simultaneously evaluate the health and well-being of their partner and relationship, while still granting herself the ultimate right to decide what would be best for herself. Having the power to consider, evaluate and prioritize these considerations was an act of agency.

**RATIONALE FOR NEEDING AN MPT**

The ‘rationale for needing an MPT’ refers to whether an individual or couple believes there is sufficient justification to use an MPT. This construct lies outside the typical realm of product acceptability as defined by leading scholars. However, in this study it emerged as a
critical pathway variable for understanding how components of acceptability connect to one another, and how acceptability considerations can be completely circumvented in a woman’s decision to use or not use an MPT ring. When individuals or couples have no rationale for needing an MPT, acceptability is irrelevant in the decision to use a ring or not. The two main factors that women and couples consider in determining a rationale for need was their HIV risk perception and pregnancy intentions. In this group of women, 15 out of the 17 card sort respondents rated that not having to think about getting pregnant or contracting HIV during sex was one of their top five reasons for using a vaginal ring.

**HIV Risk Perception**

Although the focus of the interviews was to understand components of product acceptability and potential for future use, one of the central issues that emerged was risk perception for HIV. Thus, I explored women’s descriptions of their own and others’ risk for HIV and its relationship to acceptability and potential use of the ring.\(^{186}\)

*Community-level HIV risk perception is irrelevant to individual risk perception*

Epidemiologically, actual risk for HIV is based on individual risk behavior, partner risk behavior and HIV status, and high community viral load.\(^{267,268}\) The majority of the participants lived in or near the South Bronx within a few miles of one another at the time of data collection (2013-2014). During that time, the Bronx had the highest prevalence of HIV in all NYC boroughs (1.9%-2.0% of the Bronx population), and the HIV prevalence of the South Bronx specifically, ranged by neighborhood from 2.5%-2.7%.\(^{269}\) Despite this, women were confident that they were not at risk for HIV. They attributed all of their confidence to their own low-risk behavior, including abstinence. There was no discussion in the interviews acknowledging or
questioning the high community-level risk that surrounded them. The only expression of the concept was associated with naming “other women” at risk where HIV prevalence was assumed to be high.

During each of the focus groups, one of the exercises included a scenario about risk perception (Appendix D—focus group guide) of a fictitious young woman ‘Carla’ who lived in the South Bronx neighborhood of New York City. The script stated that Carla also knew a few people who had HIV; she only had one partner at a time; and was currently married for 3 years. During the focus group discussions, participants generated multiple interpretations of Carla’s risk for HIV (and pregnancy), with some focusing solely on the potential risk brought from her relationship with her husband, and others on the awareness of and response to her community-level risk. Brianna and Jamie debated how Carla’s overall risk perception may or may not be shaped by her awareness of the HIV prevalence in her community.

Brianna: If she’s aware that people in the community is getting the virus she’s aware. She’s educated to it. She’s open to it. If she’s oblivious, then I could say ‘well, why would she even bother with the ring’ but if I’m aware of something is happening in my neighborhood, I’m going to get protected unless I’m you know, stupid.

Jamie: Not necessarily because there are a lot of people who are aware of the HIV numbers and they’re aware of the single mothers and the unwanted pregnancies, and they still practice behaviors that could possibly get them into that result. (FG 3)

In the focus groups, it was clear that women did not identify their own risk for HIV to be greater because they were living in or near community with a high HIV prevalence. Further, only a few (all of whom were receiving graduate-level training in infectious disease research) identified community-level HIV prevalence as a potential influence on personal HIV risk and even then only did so when prompted in the focus group discussion about the fictional character,
Carla. In fact, women went as far as to explain that community level risk was not a relevant factor of influence on any woman’s perceived risk and subsequent ring use.

While women could identify community-level risk for HIV in a given scenario, they still calculated their own risk based solely on their own behaviors and expectations of their partner’s behaviors, disregarding community prevalence completely. In FG 3, Jamie succinctly explains how awareness of HIV prevalence (as well as rates of unintended pregnancy) in her community would have no impact on her own risk perception. Interestingly, she does not distinguish between risk for an infectious disease with risk for pregnancy.

I mean I could be in the community of people who have HIV and who have unwanted pregnancies, doesn’t mean that it’s going to have an effect on me. It doesn’t mean that I’m educated on the ramification. So it could be happening all around me but in my own world, I don’t know the seriousness about it. So then if I don’t know or understand, why am I going to go look for a ring to prevent it? (Jamie, FG3)

**Risk, Relationships and Ring Use**

Women generally described HIV risk as a function of the partner relationship. Further, they connected the potential use of a vaginal ring that included HIV prophylaxis as a function of risk perception for HIV. All of the women, regardless of current partnership status related to these equations.

Laura did not have a partner at the time of the first interview, although she perceived her HIV risk to be low because of previous relationships and her typical partner “type”.

I feel like I’m at low risk, I guess. I’m also one to date someone and end up dating them for a significant amount of time and I guess in that time I wouldn’t feel like I would need the HIV preventative [drug], because I only have one sex partner who I feel will always be faithful. (Laura, IDI 1)
Laura equated a low level of risk with having a single, long-time partner whom she had determined to be faithful. At the time of her first interview, she did not have a current partner but at the second interview two weeks later, she had a new boyfriend and was anticipating the relationship to turn sexual after the study ended within a few weeks. She explained that, in the early stage of a new relationship, she insisted on condom use and testing. However, if her partner tested negative, Laura considered her HIV risk to be low going forward and would no longer indicate a need for condoms. Other women expressed similar confidence that they were at low risk because their long-term, committed and trusting relationships indicated a disease-free partnership.

I wouldn’t be interested in the HIV ring. Because I’m married and I do trust my husband and I’m not sleeping with anyone else. (Nora, IDI 1)

I would not [use this ring] because I’ve been with my boyfriend for like six or seven years so he…if I’m in a monogamous long-term relationship and we both at least annually get tested for STDs there’s not a sufficient incentive. (Adele, IDI 1)

All three women (Laura, Nora and Adele) explained they were not inclined to use a ring because they perceived their risk for HIV to be minimal. Even though Laura’s new relationship warranted an initial period of questioning her partner’s HIV status, she expected this period to transition quickly into one that relied on monogamy and trust, as Nora’s and Adele’s did. Adele bolstered her confidence in her low-risk status with mutual annual testing for STDs. She was the only study participant who reported any type of persistent testing behavior during a long-term relationship.

Some women acknowledged that, although monogamy is expected, infidelity is still possible in committed relationships. Those currently in committed relationships talked about
infidelity as something that happened in other relationships, while those not in a committed relationship accepted that infidelity could happen to anyone, including them.

It's like you can never trust anybody. I'm like, who knows if they could be exposed at any point so it is always good to have [the ring] as an option… Last month I found out that he went on a date with someone…So we took a break. I kind of broke up with him…. I would have sex with him before [last month], no protection, because I was thinking he's okay...It's going to take me a while to trust him again but we'll see what happens. (Hillary, IDI 1)

Specifically regarding disease prevention considerations outlined in the card sort, (‘Having sex without thinking about getting HIV’; ‘Feeling safe during sex’), women discussed these considerations as relevant to both self and the relationship, and varying alongside relationship type changes (ex. changing from non-monogamous to inferred monogamous relationship types). Women in more serious relationships would face negative repercussions and appear to be actively downgrading the priority of their relationships with their partners if women prioritized this self-focused priority of using an HIV prophylactic ring.

Sexual abstinence was another reason for perceived low risk. Women who were not in a relationship explained that they had no need for a ring to prevent sexual transmission of HIV or pregnancy.

If I wasn’t, if I was planning on being abstinent for a period of time like I am now, I probably wouldn’t wear it just because I’m not at risk. (Marina, IDI 2)

Unsurprisingly, Marina and other women not in current partnerships were the only subgroup of women who articulated this idea of abstinence precluding the need for HIV protection. Despite their lack of current partnerships, all of these women reported having sex in the past 60 days. For these women, it appeared that it may be the combination of lack of opportunity for sexual encounter and related abstinence expectancy contributing to their
diminished interest in a longer-term use MPT ring. To them, it seemed “overboard” to commit to using a ring that would have a deeper meaning (including HIV prophylaxis) than their current contraceptive pill.

Using a ring without contraception is stigmatizing: It’s for “other” women

All of the women in this study recognized they were at risk for pregnancy (and were contracepting to prevent it), however none of the women in this study described herself as being at risk for HIV. When asked to think about who might be interested in using a ring that included HIV prevention medication, participants were quick to identify women who they deemed to have high HIV risk profiles and two related themes became clear: 1) women who are at risk and would need the ring are “the other” – “not like me”; 2) these “others” engage in stigmatized behavior, such as having multiple partners or engaging in sex work, don’t think through their actions, or live in regions with high HIV prevalence.

I wouldn’t feel it was necessary…unless you’re someone who’s having sex, promiscuous sex you know, with a lot of different partners, unprotected…I don’t ever like expect to be a part of either of those groups of people. (Kerry, IDI 2)

I think prostitutes definitely because I can imagine that a lot of their customers don’t want to use a condom, right? So for them that would, wearing something like this would be great, I think. (Marina, IDI 1)

It was clear that participants recognized and also enacted stigma associated with what they termed to be risky sexual behavior and, by extension, using a product specifically designed to prevent HIV. In addition to the stigma they assigned to the TDF-only ring, they also anticipated rebuke from sexual partners, creating “unnecessary problems” in the relationship specifically around issues of fidelity as previously described.
**Rare, yet extreme risk: The case of rape**

Participants identified only one circumstance that posed a faultless risk to themselves for HIV acquisition, and that was rape. Unprompted, some of the women mentioned that the potential for rape put women at risk for HIV and might warrant wearing this ring regardless of the contraceptive properties. However, rape was talked about only as a remote possibility and not a major factor in determining one’s risk for HIV. Rape was not mentioned as a risk factor for pregnancy. On balance, the fear of rape alone did not warrant wearing a prophylactic device:

I mean people are raped and they could contract HIV but you’re not going to wear or take a drug just in case you get raped. I mean because that would be crazy and just very emotional. I mean you shouldn’t just assume that you’re going to be raped, that’s like emotionally really depressing. (Kerry, IDI 1)

**Fertility desires and intentions, not risk.**

While all the women acknowledged they could become pregnant in the absence of their regular contraceptive method, there was minimal explicit discussion of this awareness in either the IDIs or FGDs. When women did speak about the act of becoming pregnant, they did not use fatalistic or ‘risk’ language, as they did when they discussed the possibility of contracting HIV. Instead, pregnancy was talked about as something they “wanted” now or in the future, or something they were or were not yet “ready for.” This contrast in language use between HIV risk and pregnancy desires was stark, likely reflecting women’s underlying distinction in the way they thought about the possibility of pregnancy vs. the possibility of contracting HIV. While women saw contracting HIV as a condemning outcome, the possibility of pregnancy effected a range of more positive feelings.

Potentially the lack of discussion about pregnancy as a risk is also related to the fact that these women were also current contraceptive users, so most had implicitly acknowledged
unwillingness to become pregnant presently, demonstrated by their choice to use a contraceptive method in the first place. Even in the card sort data, where women were explicitly directed to address fertility desires as they related to ring use (“The ring will prevent pregnancy”; “The ring will not prevent pregnancy”), there was little in-depth discussion regarding current considerations about pregnancy desires or intentions. The little that women did discuss (even when probed) about wanting pregnancy was related either to satisfy one’s own desires “my biological clock won’t stop ticking” or in response to the changing fertility desires within the relationship context, “until we want more [children].”

**MPTs offer a joint solution to multiple concerns**

Women described the benefits of using a ring that could simultaneously prevent both HIV and pregnancy. They overwhelmingly saw it as a solution to some of the tensions they envisioned having with partners or internally as they weighed acceptability of various attributes of an MPT ring. Specifically, women lauded the device for its efficiency and the ability to subvert the stigma related to using an HIV-only prevention product by casting it as a health promotion tool.

**Efficiency of a dual-purpose device**

The most commonly described and clearly articulated benefit of using an MPT ring was the fact that the ring could prevent two undesirable outcomes at once: HIV and pregnancy. Women used colloquial expressions about efficiency, to provide descriptions of this idea: “tackling...two birds with one stone” or “getting a two-fer”. Here, the idiomatic language used in both the IDIs and focus groups to describe the efficiency of using an MPT for dual prevention
potentially demonstrates women’s perceptions of the obviousness of this benefit. In the IDIs, I probed women to further describe these idioms, and typically women would offer up another idiom or a terse rephrasing of what they had first stated about why more was better, as if their rationale was obvious and self-explanatory. Jenna was one of the few women in the IDIs to explain what she meant by “two for one”:

That's just - it's like a two for one; you're handling your responsibilities in both ways, it makes it easier because then also, some people might use a pill and then also use condoms to be protected, but with the ring, it seems like we have both of them. It makes things easier, an easier option. (Jenna, IDI 2)

This finding was highlighted in the focus groups. Specifically, there was a focus group exercise where women were asked to compare the instructions for use first for the TDF-only ring and then for an MPT ring. The instructions were the same, including: wearing the ring daily (including during sex and menstruation); inserting and removing the ring yourself; and replacing it monthly. In this context of comparison between the TDF-only vs. the MPT ring types, women expressed clarity about the superior acceptability of an MPT ring attributed to its ability to also prevent pregnancy: a desirable goal. Women explained that they were more likely to accept an MPT ring over a TDF-ring because it conferred more protection, and more protection was typically seen as better. Jamie describes how she would feel if the ring she was wearing in the trial was an MPT ring instead of a TDF ring.

It would motivate me to continue on because now I know that not only is it going to prevent me from getting HIV, but it’s also altering my life in a very serious way by preventing pregnancy. I would still feel the same, but I would be more motivated to follow the rules because now okay, you’re telling me that this can also prevent me from getting pregnant and HIV. I’m getting more bang for my buck. (Jamie, FG3)
One important caveat to this sentiment, however, was that women would accept an MPT only if the PrEP component caused “no extra burden” on top of what was already acceptable in their current contraceptive. Women named “weight gain”, “discharge” and “problems getting pregnant” as some of the reasons why an MPT ring would be unacceptable and get in the way of them using it.

While women did like the idea of an MPT ring efficiently providing protection against both HIV and pregnancy, the card sort data showed an uneven distribution of women’s desires for preventing HIV or pregnancy during sex (“Having sex without thinking about contracting HIV”, “Having sex without thinking about getting pregnant”) relative to one another. Specifically, 11 women prioritized pregnancy prevention as a reason to use the ring; 5 prioritized HIV prevention and 1 ranked them as equally important in a decision to use a ring. Despite this ranked division of preferences, almost half of the women (7/17) placed the two cards adjacent to one another, signaling the desirability of a ring that could prevent both outcomes nearly equally.

**MPTs de-stigmatize using HIV prevention methods**

Another reason that justified MPT use was the way it could de-stigmatize HIV prevention behaviors, such as wearing a prophylactic device. In contrast to the clear stigma women assigned to a TDF-only ring, when women discussed the possibility of an MPT ring, it was overwhelmingly positive and focused on the way that adding a contraceptive component could “mask” the HIV preventive function. In their explanations for preferring an MPT to a TDF-only ring, women talked about MPT rings as a direct solution to the stigma they might face socially or the questions of sexual infidelity that might be asked by their partners. “No one would be so suspicious” that a woman was cheating or that she was participating in stigmatized sexual behavior, if she were using a device designed for preventing pregnancy. Preventing pregnancy
was discussed as virtuous, “part of normal life” and empowering whereas preventing HIV was laden with stigma because it implied that one was having “promiscuous sex” or practicing infidelity.

Women also believed that their partners would find an MPT ring more acceptable overall if it were framed as a vaginal ring with primary contraceptive benefits and secondary HIV prevention benefits. Women liked this idea for themselves as well, thinking of it as a contraceptive ring with an “added bonus”.

If it was just an HIV thing he might say, well, we just have sex with each other so what is the need for that. Especially after being married for, for some people that might raise flags out of, you know, left field you’re wearing contraceptive with HIV. That’s a bit strange but if it was, “I want to try something new. I want to try a ring. It’s a contraceptive birth control and HIV.” That’s a little bit different. I think that most partners would be more accepting of that. (Nora, IDI 1)
Section 3.4: Methodological Considerations

“A theory generated from just one kind of data never fits or works as well, as a theory generated from diverse slices of data on the same category.”

-Glaser and Strauss, p. 68

Introduction

In Section 3.4, I explore how specific features of each data collection method informed the overall development of the model, Dynamic Considerations for Acceptability and Likely Use of an MPT Ring, and I identify specific features of each method that can inform future study designs for similar products. For organizational purposes, Section 3.4 also includes most of the discussion and implications regarding this methodological assessment. Many of these acceptability findings have already been discussed in Section 3.3 of this dissertation. Differently, in the forthcoming section, I further examine the thematic findings with regard to specific features of each method that produced those data.

To satisfy Specific Aim 2 of my research, I triangulated my data by examining the comparability and complementarity of the thematic findings from each of the three methods. This required acknowledging the inherent features of each data collection method. I therefore triangulated the data by exploring 1) the convergence and divergence of thematic findings; 2) the complementarity of thematic findings; and 3) the complementarity of findings that were generated as a result of special features of each of the methods used to deliver those findings. I used a hybrid approach to triangulation of multiple methods, which combined a traditionally quantitative approach as lain out by Campbell and Fiske (Comparability),244 with a traditionally qualitative approach as defined by Denzin and Lincoln (Complementarity) for the overall
purpose of integrating the findings from all three data collection methods with attention to features specific to different methods.248

**Comparability**

One reason why it is useful to determine the comparability of findings across multiple qualitative methods is to increase confidence in the overall believability (i.e., trustworthiness) of the thematic findings. Thus, when the data collected using any of the three methods overlapped, I could be fairly confident that the narratives were coalescing and telling a robust story irrespective of method type. It was also important to assess comparability in order to identify areas that required further thinking to fit the developing theoretical model to the data, rather than the other way around. As Flick explains:

“‘The aim of triangulation…should be less a matter of obtaining convergence in the sense of confirmation of what has already been discovered. [Instead, T]he triangulation of methods and perspectives is particularly useful for theory-development, when it can elucidate divergent perspectives’” (p. 181).270

Non-comparability of themes across methods, therefore, presented a ripe opportunity to further investigate why one type of data produced one finding, and another data type produced a different finding. I therefore explored the possibility that the methods themselves may have produced different kinds of data possibly due to attributes inherent to the method.

The first step in evaluating the comparability of findings across method type was to identify the depth of discussion about each of the themes identified in the theoretical model (Table V). If the topic was not discussed at all in one of the data collection methods, it would otherwise be difficult to compare agreement or disagreement on the themes with that method. Therefore, I focused my comparability analysis of findings primarily on the methods where thematic data were available to compare. For example, the theme ‘Partner Priorities: Health’ was
only discussed in interviews and focus groups, but not in the card sort. Therefore, I could not make any assertions about comparability of thematic findings across all three of the methods. For methods that only produced ‘limited discussion’ (lacking depth of information) of the data, (Table V) this is noted.
Table V: Methodological Comparability: Presence (x), Limited Discussion (l) or Absence (o) of Themes

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<th>Card Sorts</th>
<th>Focus Groups</th>
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<td>x</td>
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<td>X</td>
</tr>
<tr>
<td><strong>Menstruation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Ridding blood/cleaning out</em></td>
<td>x</td>
<td>x</td>
<td>X</td>
</tr>
<tr>
<td><em>Crowding the Vagina</em></td>
<td>x</td>
<td>o</td>
<td>X</td>
</tr>
<tr>
<td><em>Abstinence</em></td>
<td>x</td>
<td>o</td>
<td>O</td>
</tr>
</tbody>
</table>
Complementarity

In contrast to assessing comparability of findings across methods, I also assessed the complementarity of findings across methods. These complementary findings did not contradict one another, rather they enhanced, deepened or created more nuance in the emergence of themes or relationships within the model in all of their richness. Additionally, when we see complementary findings where one method may have produced more insight than another method, we can see that there may be some benefit to using a particular method for a specific topic, theme or process. In Sections 3.2 and 3.3, I triangulated the complementary findings within the discussion of the emergence of themes. In the following, I will highlight if and how particular features of the data collection method uniquely added to understanding about MPT acceptability.
Table VI: Thematic Findings across Interviews, Card Sorts and Focus Groups

<table>
<thead>
<tr>
<th></th>
<th>Interviews</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONTEXTUAL CONSIDERATIONS (2a)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Relationship Priorities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type/Length</strong></td>
<td>Longer/more serious relationships expect inclusion in use decisions</td>
<td>Limited discussion</td>
<td>Any length/type relationship matters for acceptability and ring use decisions</td>
</tr>
<tr>
<td></td>
<td>Shorter/less serious relationships shift acceptability and use decisions to women</td>
<td>Regardless of relationship length/type, women want partner support of ring</td>
<td>Relationship transitions are key moments for shifting acceptability priorities</td>
</tr>
<tr>
<td></td>
<td>Relationship transitions are key moments for shifting acceptability priorities</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fidelity</strong></td>
<td>HIV-only prevention implies mistrust and infidelity for the woman and the man</td>
<td>HIV-only prevention implies mistrust and infidelity for the woman and the man</td>
<td>HIV-only prevention implies mistrust and infidelity for the woman and the man</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td>Communication is critical for family planning</td>
<td>Communication was a low-ranking priority for overall ring acceptability</td>
<td>Communication is critical for family planning</td>
</tr>
<tr>
<td></td>
<td>Lack of communication indicates a weak relationship and permits a shift in a woman’s prevention priorities</td>
<td></td>
<td>Lack of communication indicates a weak relationship and permits a shift in a woman’s prevention priorities</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MPT – related</td>
</tr>
</tbody>
</table>


\(^{vi}\) As part of the analyses reported in this table, I used a segmented analysis approach and also analyzed the data separately by experimental condition to identify any potential differences in emergent themes or reported concerns related to ring acceptability. Aside from increased reports of wetness or discharge from the TDF group, there were no other notable differences between the two groups of women on any of the themes presented here, or other components in the model. This is unsurprising as there were few side effects reported by women about the TDF itself, and these women were already using a hormonal contraceptive. Therefore, the results reported in this table are for the complete sample of women, not divided by experimental condition.
Interviews | Card Sorts | Fo Groups
--- | --- | ---

**Disclosure**
- Relationship stage dictates disclosure decisions
- Non-disclosure can prevent relationship growth
- Non-disclosure can imply promiscuity, infidelity or lack of trust

---

**‘Self’ priorities**

**Health**
- Recognized potential challenge to prioritizing self vs. partner health
- Self-health sometimes trumps partner health

**Agency**
- Strong statements of self-determination
- Agency is also important for feeling good within a relationship
- Agency=sexual pleasure

---

**Partner Priorities**

**Health**
- Men’s exposure to TDF (not contraceptive) could be harmful
- Partner health is sometimes a factor for acceptability
- Recognized potential challenge prioritizing self vs. partner health

---

**EPISODIC CONSIDERATIONS (2b)**

<table>
<thead>
<tr>
<th>Product Attributes</th>
<th>Interviews</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td>o</td>
<td>o</td>
<td>Larger than expected</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Relevant to partner health (not to personal health)</td>
<td>Relevant to partner health (not to personal health)</td>
<td>Harder than expected</td>
</tr>
<tr>
<td>Interviews</td>
<td>Card Sorts</td>
<td>Fo Groups</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-----------</td>
<td>-----------</td>
<td></td>
</tr>
</tbody>
</table>
| **Dosing** | • Monthly, aligning with menstrual cycle and wish for reliable effectiveness  
• Non-monthly, wanted convenience/fewer trips to care provider (assuming provider insertion) | • Monthly, aligning with menstrual cycle  
• Menstrual marker of no pregnancy  
• Monthly, wanted convenience | • Monthly, aligned with menstrual cycle  
• Menstrual marker of no pregnancy  
• Monthly, wanted convenience |
| **Double Drugs** | • Drug interactions with two drugs  
• Question effectiveness of 2 drugs in 1 ring  
• No discussion of relationship to menses | 0 | • Questioning ring effectiveness of two drugs in one ring (drugs cancelling each other out)  
• Mechanism of action unclear if ring removal during menses |

**Use Attributes**

<table>
<thead>
<tr>
<th>Comfort</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
</table>
| • Absence of discomfort  
• Referencing activities of daily living | • Absence of discomfort  
• Referencing sexual activity  
• Own comfort relative to partner’s | • Absence of discomfort  
• Referencing activities of daily living |

<table>
<thead>
<tr>
<th>Discreteness</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
</table>
| • Relative to relationship considerations  
• Covert use would challenge relationship trust  
• Women would tell partners | • Relative to relationship considerations  
• Telling partners was a low priority | • Relative to relationship considerations  
• Covert use would challenge relationship trust  
• Women would tell partners |

<table>
<thead>
<tr>
<th>Side Effects/benefits</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
</table>
| • Wetness is ok/discharge is not ok  
• Difficult to identify hypothetical side effects other than common OCP side effects  
• Side effects can be secondary benefits | • General side effects were potential barriers but also secondary benefits  
• Hypothetical side effects included common OCP side effects | • Limited discussion |

**Sexual Experience Attributes**

<table>
<thead>
<tr>
<th>Pleasure</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
</table>
| • Physical comfort connected to pleasure  
• Reciprocity as pleasure | • Physical comfort connected to pleasure  
• Reciprocity as pleasure  
• Women and men’s comfort prioritized jointly, with minor prioritization of women’s over men’s | • Physical comfort connected to pleasure  
• Reciprocity as pleasure |

<table>
<thead>
<tr>
<th>Interference/facilitator</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Interpreted as having a</td>
<td>• Interpreted as having a</td>
<td>• Interpreted as having a</td>
</tr>
<tr>
<td></td>
<td>Interviews</td>
<td>Card Sorts</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>secondary impact on acceptability (wetness vs. discharge) spoiling the mood</td>
<td>having secondary impact on acceptability (wetness vs. discharge) spoiling the mood</td>
</tr>
<tr>
<td></td>
<td>Wetness is a welcomed facilitator of sex</td>
<td></td>
</tr>
<tr>
<td>Menstruation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Ridding blood/cleaning out** | Most discussed ring use during menstruation as a deal-breaker (i.e. ring would get ‘dirty’) | Ranked as lower importance than other factors | Most discussed ring use during menstruation as a deal-breaker (i.e. ring would get ‘dirty’)
|                          | Aligned with strategy for monthly exchange of ring                        | Alignment of menstruation and removal of the ring so no blood on the ring | Aligned with strategy for monthly exchange of ring
|                          | Minority wanted to flush toxins from ring                                 |                                                                            | None wanted to flush toxins from ring                                    |
| **Crowding the Vagina**  | Additional items in the vagina during menstruation adding unnecessary burden (i.e., cramps, bloating) |                                                                            | Additional items in the vagina during menstruation add unnecessary burden (i.e., cramps, bloating)
|                          | Concern about physical crowding and presence of multiple items displacing one another |                                                                            | Did not question tampon soaking up drug, but did question other products' impact on ring effectiveness (i.e., douches)
<p>|                          | Concern the tampon soaks up medication                                    |                                                                            | Concern over illness if ring left inside body too long                   |
| <strong>Abstinence</strong>           | Some women do not have sex while menstruating                             |                                                                            |                                                                          |
|                          | Strong beliefs that menstrual flow acts as a self-cleaning tool            |                                                                            |                                                                          |
|                          | Belief that periodic abstinence would warrant periodic break in ring use   |                                                                            |                                                                          |
| RATIONALE FOR NEED (2c)  |                                                                            |                                                                            |                                                                          |
| HIV Risk Perception      |                                                                            |                                                                            |                                                                          |
| <strong>Community risk</strong>       | Limited discussion                                                        |                                                                            | Identified community viral risk for other women                           |
|                          |                                                                          |                                                                            | Did not identify                                                          |</p>
<table>
<thead>
<tr>
<th>Interviews</th>
<th>Card Sorts</th>
<th>Fo Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk, Relationships &amp; Use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All perceived low risk bc of partner type or relationship length</td>
<td>All perceived low risk bc of partner type or relationship length</td>
<td>All perceived low risk bc of partner type or relationship length</td>
</tr>
<tr>
<td>Infidelity acknowledged, only for other relationships</td>
<td>Infidelity acknowledged, only for other relationships</td>
<td>Infidelity acknowledged, only for other relationships</td>
</tr>
<tr>
<td>Use positively impacts self-health</td>
<td>Use positively impacts self-health</td>
<td>Use positively impacts self-health</td>
</tr>
<tr>
<td>Use negatively impacts the relationship</td>
<td>Use negatively impacts the relationship</td>
<td>Use negatively impacts the relationship</td>
</tr>
<tr>
<td><strong>Abstinence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abstinence precludes ring use (only discussed among the unpartnered)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Stigma</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labeled ‘other women as being at risk (not self)</td>
<td>0</td>
<td>Labeled ‘other women as being at risk (not self)</td>
</tr>
<tr>
<td><strong>Rape</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rare but extreme case</td>
<td>0</td>
<td>Limited discussion</td>
</tr>
<tr>
<td>Fear of rape does not justify the ring</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Joint Solution</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventing two undesired outcomes at once</td>
<td>Preventing two undesired outcomes at once</td>
<td>Preventing two undesired outcomes at once</td>
</tr>
<tr>
<td>More prevention is better</td>
<td>More prevention is better</td>
<td>More prevention is better</td>
</tr>
<tr>
<td>Acceptable, only if no extra side effects</td>
<td>Acceptable, only if no extra side effects</td>
<td>Acceptable, only if no extra side effects</td>
</tr>
<tr>
<td>Diverse preferences for HIV vs. pregnancy prevention goals</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Destigmatization/Bonus Prevention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contraceptive component masks stigma of using HIV PrEP</td>
<td>0</td>
<td>Contraceptive component masks stigma of using HIV PrEP</td>
</tr>
<tr>
<td>PrEP is therefore bonus prevention to contraception</td>
<td></td>
<td>PrEP is therefore bonus prevention to contraception</td>
</tr>
<tr>
<td><strong>Fertility Desires</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>future fertility</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No current desires for pregnancy</td>
<td>Highly prioritized fertility not being impacted by MPT use</td>
<td>No current desires for pregnancy</td>
</tr>
<tr>
<td>Desire quick return to fertility</td>
<td></td>
<td>Desire quick return to fertility</td>
</tr>
<tr>
<td>No impact on fertility</td>
<td></td>
<td>No impact on fertility</td>
</tr>
</tbody>
</table>
**Triangulating Comparable and Complementary Findings**

*Comparability*

The overwhelming majority of the thematic findings, when discussed, were comparable across the three data types: focus group, interview and card sort data. In Table VI, individual themes are identified and basic components of those themes are condensed into bullet points. To summarize the findings, many of the thematic components are similar regardless of method, despite some methods capturing differing depth of themes. Throughout the whole dataset there was only one theme in which the data were NOT comparable across data collection methods. I explore this finding in detail to determine if and how the methods themselves may have contributed to the discrepancy.

This exception to the thematic comparability across methods was introduced during a few of the participant interviews. Although mentioned by only two women (Angela and Megan), the TDF drug itself was mentioned as a possible “toxin,” which the body should cleanse away with menstrual blood. A few of the women in the IDIs expressed beliefs that the flow of blood from menstruation would be a natural mechanism for the body to rid itself of the TDF. Of note, none of the women remarked about a concern or a need to rid the body of a contraceptive/hormonal drug emitted from the ring. This may have been related to the fact that these women were already using a hormonal method of contraception, so they were potentially less fearful of the impact that a hormonal contraceptive drug might have on their bodies.

I think that would be a smart idea if somebody had a ring in and their menstrual time came to take it out. I don’t know, I guess nobody wants a drug in their body. They want to be clean, clean from the drug. Yeah, that’s for me. I would want to be cleansed from that drug. Everything leaves your body anyway when you have your menstrual. (Megan, IDI 1)
This finding about ridding the body of the TDF in the ring was only expressed by two women but made sense ideologically as part of women’s complex concerns regarding menstruation and ring use. Sometimes in qualitative research it is as important to further investigate results further from a minority or ‘negative case’ -- to compare and contextualize an emergent finding in the interest of theory building.\textsuperscript{271} In this case, the grounded theory method of data collection allowed me to explore this new line of inquiry based on emergent and credible findings, even if coming from a small minority. When this somewhat surprising yet understandable finding emerged in the interviews about wanting monthly menstrual blood flow to wash out “toxins” from the drug, I therefore took the opportunity to question that finding further in the forum of the focus groups.

In each of the focus groups, I therefore adjusted the focus group guides to ask participants what they thought about this assertion. None of the participants in any of the focus groups (including Angela and Megan who had originated the idea in the IDIs) endorsed the theme of wanting their menstrual blood flow to expel potentially toxic drugs in the ring. In fact, the general sentiment in the room for all of the groups was a moderate amount of incredulity that women might feel this way, expressed mainly in facial expressions with raised eyebrows or brief exclamations like “that’s crazy” and “that makes no sense.” Rhetorically, Maureen captured the general sense of the groups’ reactions:

\begin{quote}
Why would you want it to leave your body if it’s to protect you, from pregnancy or HIV or both. (Maureen, FG 2)
\end{quote}

It is possible that the minority group of two women somehow changed their minds between their interviews and focus group discussions. However, this possibility seemed too simple. I therefore decided to further analyze the individual and group data using a case-based
approach, to determine if there were additional factors to explain the discrepancy around this theme across data methods. Angela’s data are thus presented here in condensed form.

In her first interview, Angela introduced the idea that she would want menstruation monthly to help rid her body of the toxins that the ring was secreting. She contextualized her belief as being grounded in the information that her mother discussed with her about menstruation when she was younger.

[My mother] said that’s when our reproductive system is getting rid of whatever it doesn’t need. And basically she said that’s when new cells are being created.... If there’s a drug being dispersed when I have the ring, I also want that drug to also get released with my menstrual as well. (Angela, IDI 1)

While Angela expressed this strongly and clearly in the interview context, in the focus group she remained silent when I asked the group their thoughts about the general assertion and group dialogue ensued. Following the group discussion she vocally changed course, acknowledging that she had “doubts now.” This discord within her own data was a notable phenomenon, so I explored it further within Angela’s IDI and FGD data to help understand if this was idiosyncratic to her or if there was potentially more meaning involved with her change of heart that could be explained by features of the methods that helped produce those different responses.

To help understand this change in Angela’s response, it is important to contextualize Angela’s statement within the focus group in which she participated. Her statement about having doubts closely followed two lengthy statements from fellow focus group participants, Tracy and Adele, both of whom were PhD students in a related field to this dissertation research. In contrast, Angela did not have a college degree. In their lengthy responses to the question about wanting menstruation to flush out drugs emitted from the ring, Tracy and Adele debated high-
science and metabolic reasons for and against having monthly menstruation. Tracy and Adele both heightened the level of academic language and their own derivative scientific hypotheses, using complex and depersonalized statements throughout: “homeostatis”, “shedding of your endometrium”, “based not on my own research, but on a couple studies that I read”, etc. This was not the first time one of the PhD students spoke using this type of scientific or sophisticated language during the group, but it was the first time that these students held the floor for such an extended period of time (approximately 2-3 minutes, together). The other women in the room quieted themselves during this period. Following this dialogue between Tracy and Adele, the stage had been set such that the language of science and budding scientists had overtaken the direction of the conversation about monthly menses, leaving little room for the non-scientists to hold the floor or for discussions of the women’s lived experiences to be vocalized.

While this topic was not explicitly about menstrual blood shedding toxicity from the ring, temporally it set the contextual stage in which Angela rescinded her original statement. Surrounded by academic discussion and clinical jargon about how the body worked and responded to external medications and hormones, Angela retracted her earlier statement of her perceptions, deferring to the vocal and more academically poised participants in the group.

This ‘non-homogeneity’ in the focus group (i.e., PhD vs. high school education) has been recognized as a methodological concern in focus groups in general, whereby there is a worry that power dynamics can subvert ideas that might have thrived if otherwise in the presence of focus group participants with similar characteristics. In this case, Adele and Tracy’s exchange had shaped the tone and context of the focus group, likely impacting Angela’s stated perspectives in subsequent moments. Perhaps Angela was intimidated or believed that her way of thinking might not have as much purchase among these group members.
Recalling data previously presented in the IDIs, Angela clearly had stated that she would want a ring that would allow her to menstruate monthly, partly for the purpose of flushing out the drug/toxin. But here, in the aftermath of a conversation dominated by two PhD students, Angela changed her own perspectives about menses, deferring to the scientific voices in the room, effectively retracting her earlier stated preference for ‘cleansing’ her body of the TDF “toxin” with menstrual blood monthly. It therefore became unclear whether this sentiment regarding menstrual flow and ridding the body of toxicity might have been held among other women who, while not mentioning it in the interviews, might have done so in the focus group in the absence of the dominant participants. The non-homogeneity of the focus groups created a context that made it difficult to determine participants’ beliefs. The focus group environment potentially limited women’s ability to express themselves, whereas the IDIs and card sort allowed a space for individual expression with less self-censorship.

Complementarity

Nearly all of the acceptability themes were comparable across data collection methods (Table VI), the majority of which were described in greater detail in earlier parts of Section 3 and will not be repeated in detail here to minimize redundancy. Many of these complementary findings emerged as a result of the combination of data collection methods employed and the different types of data they produced, respectively. These methodological features, along with examples of associated findings, are discussed through this lens in the following sections.

Complementary Card Sort Findings: Ranking importance of acceptability factors

Relative importance of acceptability factors

One of the unique features of the card sort method was its capacity to help women rank the level of importance of individual factors of MPT ring acceptability, relative to other factors.
As designed, the card sort elucidated relative value that women placed on acceptability factors including the importance of fidelity, communication, discreteness, pleasure and menstruation among other themes.

The rationale behind a two-step card sort was to provide multiple opportunities for women to think through different aspects of ring acceptability. First being asked to generally think about reasons why she would or would not choose to use a ring, or reasons that did not matter, opened the dialogue and allowed women to triage factors that were not relevant to them. During the second card sort step (i.e., ranking cards) they were then asked to think more specifically about the level of importance each of those factors might have on their choice to use or not use the ring. Methodologically, this sequential sorting approach, of first sorting cards into general piles and then ranking the relevant cards, prompted women to explore questions they may not have accessed on their own (e.g., during an interview) and then provided an opportunity to dive deeper into individual topics, order topics by importance and potentially revise their choices once the whole card set had been lain out. This two stage process has been successfully used by others to help participants elucidate categories within constructs such as social support.

This two-stage, iterative process is a special illustration of the reason why it was important to capture both the card sort product (i.e., ordered piles) as well as the commentary that participants provided tandem to their card sorting process.

One example of the complementary findings added from the card sort was related to the level of importance women placed on ‘ring disclosure’ as a factor of MPT acceptability and likely future use. The basic narrative about women disclosing ring use to a male partner included the following shared components across all three of the data types, and there were seemingly no disagreements across the data types (Table VI):
1. Relationship stage closely dictated the decisions women would make in their decision to disclose ring use to a partner.

2. Non-disclosure could prevent further growth of a relationship.

3. Non-disclosure could also imply that a woman was sexually promiscuous, was unfaithful to a current partner and/or was untrustworthy or untrusting of her partner.

However, the card sort data provided complementary findings about ring disclosure that were absent from the IDI or FGD data: card rankings showed that women weighed the importance of ring disclosure lower than other acceptability factors, such as risk perception, fidelity, and personal agency. In Megan’s card sort, during the first phase of sorting cards, she first explained how she generally felt about the concept of disclosure within a relationship.

For me [disclosure]’s a good thing. HIV is like really bad to have. You can die from HIV. So I would think that would be something positive to share with him or whoever’s using this because it’s a positive thing. A lot of people are getting sick from this. (Megan, Card Sort)

In the second phase of her card sort, however, she is asked to rank the disclosure factor in terms of level of relative importance to other factors. Here, Megan explained that she cared more about ability to prioritize her own health vis-a-vis ring use than she valued the need to disclose use to a partner, ranking the disclosure cards lower in importance than other cards.

For me I would tell him. But if I was the type of person I would be like, “It’s really none of your business as long as I’m protecting myself it’s none of your business.” When it comes to the female body, I think a female has a right to do whatever she wants. (Megan, Card Sort)
In Megan’s case and others, the card sort data explained an additional feature of ring disclosure that was only decipherable in the presence of the ranking of other acceptability factors. When describing the theme of ring disclosure in depth, as she and others did in the first phase of the card sort, the interviews and the focus groups, it appeared that this factor held great meaning. Participants often used hyperbole and fatalistic language ‘You can die from HIV,’ which guided me to initially think that women weighed this factor highly. However, when asked to examine this factor relative to others in the second phase of the card sort, Megan and others generally ranked the action of ring disclosure to a partner at a lower level of importance than they did regarding factors related to prioritizing the relationship or things that impacted fertility.

An inability to rank?

While it was convincing that the card sort did explain women’s ranked order of priorities around specific acceptability factors, there was a significant minority of women who were not able to complete the factor ranking as requested. Out of 17 women who completed the card sort, there were 5 who expressed they could not rank all topics sequentially. This was manifested by participants deciding to place some cards next to one another, to signify equal value for reasons why or why not to use a ring. While it is possible that some women actually held multiple topics at the same rank, it might also mean that participants had difficulty ranking some of the cards at all because it did not make conceptual sense to them or they were unrankable. The cards were a pre-determined set of hypothesized acceptability factors and all of them may not have resonated for each woman. Therefore, asking participants to rank factors when they did not rank those factors in real life decision-making might have been an impossible task. This is a finding in and of itself.
The field of cognitive psychology may help explain this cognitive process using the concept of ‘mental models’, which is a person’s way of creating a small-scale version of reality to aid in understanding it, regardless of its accuracy. When there is a mismatch between reality and ‘modeled’ reality, it is noted in cognitive psychology as a barrier between researcher and participant or designer and user. Further, this mismatch in mental models can also cause participants to try to remedy inconsistencies by reworking their original mental model to fit a new experience. The implications of this mental model reconciliation process during the card sort could mean that women may have artificially ranked factors in the study context only because they were asked to. They may in fact have had no way to rank some or all of these factors because a hierarchy among factors simply didn’t cognitively exist for them. It is difficult to know which women were able to rank the cards to accurately represent their mental model of acceptability factors, and which women fabricated or “satisficed” their rankings at the time of the card sort to accommodate the researcher and/or avoid inconsistencies. Regardless, this is certainly an area for future research to better understand the way women can or cannot order factors of acceptability in a linear hierarchy.

Complementary Card Sort Findings: Addressing sources of response non-validity

There are several reasons why data on sexual behavior, sexual relationships, and beliefs about sex and how one’s body works is difficult to collect with validity.

Addressing Social Desirability Bias

One is Social Desirability Bias (SDB), which is a common occurrence in research (both qualitative and quantitative) on sexual behavior and acceptability of vaginal products. Women are reluctant to admit to behavior that reflects poorly on them (e.g., risky sexual behavior, how
they treat partners, cheating, nonadherence). In a Phase 2 trial of microbicide gel and condom use in South Africa, researchers found that SDB was enacted as politeness, avoidance of criticism/seeking praise and embarrassment, leading to misreporting of product adherence in over three quarters of the sample. In another study participants named interviewer characteristics, interview techniques and privacy of location as important contributors to giving socially desirable responses to sensitive topics instead of their lived experiences. In this study, the card sort method may have helped to ameliorate SDB by normalizing potentially stigmatizing behaviors through the act of naming them on cards.

**Addressing sensitive topics**

Another source of response bias is related to discussing cultural norms about women’s sexuality, a topic that is controversial and sensitive in American society. It is often difficult for women to have open and frank conversations about sexuality and reproductive issues with other women or with researchers especially if their reports are inconsistent with societal expectations. Scholars have noted the social and cultural expectations placed on American girls (especially as they compare to American boys), whereby girls are limited in learning about sexual pleasure in educational structures or in experiencing it in their own relationships. These social expectations shape the sexual lives of girls and women such that they receive and embody messages that sexuality and sexual pleasure should be subverted. In their study on the way women talk or don’t about sex, Montemurro et al. explain the social norms that make it difficult for women to discuss sexual pleasure with strangers, as well as the gendered limitations they impose upon their limited talk about sexual pleasure in an effort to sanctify their sexual relationships and protect their partner’s masculinity in his ability to give her pleasure.
In this context of gendered norms around remaining quiet and protectionist about sexuality and sexual pleasure, we can begin to understand that response bias is not limited to the data that are produced, but it can also be responsible for the omission of participant data, such as appeared to be the case in this research regarding sexual pleasure. Therefore, it is not surprising that women were less likely to discuss sexual pleasure in the focus groups or individual interviews but were able to use the card sort as a mechanism for sparking data production vis a vis pre-constructed cards. Thus, sexual pleasure was discussed in greater depth in the card sort, augmenting the minimal findings produced in the interviews and focus groups.

During the card sort, women were cued to discuss their perspectives on sexual experiences from five specific cards in the sexual experience category (Table II):

1. My physical comfort during sex
2. My partner’s physical comfort during sex
3. Wetness during sex
4. Sex would be better
5. My sex drive or being turned on might change

The card sort, however, was able to facilitate discussion of sexual pleasure by presenting the participants with cards that inquired about specific features of sexual experience. This created a nonthreatening opportunity for women to address these features without judgment or fear. In comparison to the IDIs, where women were limited in their descriptions or concerns about sexual encounters unless prompted, and to the focus groups, where women jested about sexual pleasure with brevity, the card sort elicited the richest data about sexual encounter attributes overall. Women detailed components of partner intimacy and sexual pleasure in ways that only appeared when probed specifically. For example, Marina responded to the card titled ‘Sex would be better’.
That would be a reason to use it. I feel like I kinda have a hard time and it's hard for me to have an orgasm as it is. So if it made it easier in that way, that would be a good reason to use it.

I conclude that this relative openness about sexuality in the card sort was due to the nature of the data collection method.

**Complementarity: Providing depth of understanding through the interviews:**

Many of the concepts and themes in the Dynamic Considerations Model, which was developed from an integrated analysis of all three of the data collection methods, have been described earlier in Sections 3.1-3.3. However, the interview data collected from individuals at two points in time uniquely add a level of depth and richness not present in the focus group or card sort data.

In-depth interviews are well suited as a data collection technique to gain a deeper understanding of a potential user’s context, perspectives, needs and questions about MPTs that could impact eventual use, and/or could inform new MPT development. In this study, participants spent approximately 2 hours with me discussing their user experiences with a ring; contemporaneous perspectives on acceptability factors; and hypothesizing about the complexities of potential future use. The interview context was designed as a safe space for women to discuss these topics, any or all of which could be considered to be sensitive or private.226–228 While some participants may not have felt comfortable one-on-one (e.g., preferring a card sort) with me, others certainly did and generally developed rapport over the course of the 2 sessions. The intimate setting of the interview context had few outside distractions, thus facilitated sessions of close listening, tailored responses, and directed probing to encourage participant comfort with sharing their rich experiences with me.223,287,288 I probed their responses for complete
descriptions, and encouraged them to speak about connective thoughts that emerged for them in the context of the interviews. When new or related topics emerged, the interview context allowed a flexible space for deeper probing of emergent ideas and themes.

One example of the richness of emerging data shared in the interviews was in the broad-reaching theme of menstruation. All of the women in this study had many experiences with menstruation over their lifetime and could therefore speak in realistic detail about their previous and projected experiences with menstruation in the context of an MPT ring. As previously noted in Section 3.3, menstruation related to multiple themes. In fact, throughout the many stories that women shared about their experiences, expectations and perceptions, menstruation was integral to MPT acceptability including product attributes, use attributes and sexual experience attributes of the ring. Women spoke with rich detail about the way menstruation would be likely or not to influence their desires for ring exchange intervals. They described their desires to menstruate with or without menstrual products and/or additional products (ring). Menstruation was also discussed as a reason for abstinence and was connected to the lack of a rationale for needing a ring. The depth with which women described themes and relationships among themes was facilitated by the open-ended nature of inquiry and rapport developed with me in the context of the interviews. The interview format provided the space for theme exploration and an opportunity for me, as the data collector and analyst, to openly ask for clarification and rich descriptions to interactively broaden and deepen my understanding of women’s thoughts and experiences.

Complementarity: Clarifying and reconciling complex connections in the focus groups:

The Dynamic Considerations Model includes the Priority Triad: an active prioritization, balancing and rebalancing of acceptability factors related to the woman herself, her partner and
their relationship. Each of those factors (self, partner, relationship) were discussed in depth and breadth throughout the interviews, card sorts and focus groups. However, it was only in the context of the focus groups that the connections among factors were established.

In the focus groups, the dialogue among women highlighted the struggle of prioritizing the health or agency of oneself or one’s partner. Some participants held firmly in their convictions about prioritizing the health and agency of oneself or that of her partner, throughout the course of the focus group. In contrast, other participants’ convictions about their priorities shifted over the course of the focus group discussion, often changing in reaction to statements made by other women in the group. In either case (holding firm or shifting convictions), the focus group was a unique method in which women clarified their positions on how they balanced or prioritized their partners, their relationships or themselves. It was through the facilitated process of comparing and contrasting their own experiences with those of other women that these participants could affirm their own beliefs or change them.

Recall the dialogue between Kelsey and Jamie in Focus Group 3. The two women reflect on and converse about the connections between relationship trust and ring use from their own perspectives, but also as informed by one another’s perspectives. Thus, the general pattern observed in the focus groups, different from the IDIs and card sorts, was one of connections: between participants (through dialogue) and subsequently between themes (analytically). The overarching benefit from the focus group data was that they helped to connect the richly described themes from the interviews and card sorts into a cohesive narrative: one that participants grappled with in order to make sense of it to themselves, each other, and me as the observer. The focus group findings that emerged were therefore a result of the interactions among participants, the stories they presented, and the way they presented them. Participants
connected or disconnected themselves to various acceptability narratives based on their awareness of their own shifting contextual and episodic factors.

I argue that this rich discussion among focus group participants, and the resulting clarification over their convictions about personal, partner and relationship priorities was only possible because of the heterogeneity of participants based on relationship status and beliefs. The women who were in newer relationships or no relationship initially gave more weight to personal priorities in ring use, whereas women in longer term relationships tended to prioritize their relationships or partners’ perspectives on acceptability. These differing perspectives shifted over the course of the focus group, as women clarified their own positions about the meaning of the Priority Triad within their own current contexts and through recalling previous relationships and projecting new ones. However, all of this clarification and conjecture was made possible because of the diversity of relationship statuses of the women in the room: heterogeneity of participants. While there are clearly understood benefits to ensuring homogeneity, such as ensuring minority participant voices are not subverted by majority voices, there are also benefits to heterogeneity on some factors around attitudes and perceptions. As Morgan stated, “The goal is homogeneity in background, not homogeneity in attitudes” (p. 46)^289

**Conclusion and Implications of Methodological Considerations:**

I began Section 3.4 with a quote from the founders of grounded theory, Glaser and Strauss, prompting us to acknowledge that a theory is always better informed by using multiple forms of data to investigate various emergent findings. In Section 3.4, I evaluated the process by which the data from the interviews, card sorts and focus groups were collected to explore potential impact of those processes on the emergent grounded theory Model. That evaluation
highlighted a few key points. First, the overwhelming majority of the data across the three methods were comparable to one another. In the few cases of non-comparability, it was helpful to understand the context in which the data were collected in order to investigate these negative cases and to incorporate that understanding into appropriate conclusions. Second, each of the methods provided a unique lens through which to understand thematic findings. Thus, there was an additive benefit of integrating multiple methods in the analysis. Third, there is an overarching benefit to integrating multiple methods (also applicable to mixed methods) in study design in the early stages of understanding complex processes involving multiple levels of influence on a phenomenon or behavior. In this case, the narrative of likely MPT use became richer and more complete following the back and forth analysis inherent in using multiple methods to identify associations between themes and constructs. The emergent model was therefore a combination of conceptual findings with the evaluation of the process undertaken to identify those concepts.

It is clear that not all research settings will have the good fortune of a research design that can include multiple forms of qualitative data. I am not suggesting that every study do this. However, when researchers do undertake multiple or mixed methods designs (driven by research questions, above all else), it behooves them to explore not only purely conceptual findings produced from those methods, but also to contextualize those findings based on features of those methods that helped to produce them. In this way, studies that attempt to generate understanding of complex processes or constructs should not overlook the inherent benefits of evaluating data collection context and production, as it will likely increase overall understanding of complex social and behavioral phenomena.
SECTION 4: DISCUSSION, LIMITATIONS AND CONCLUSIONS

The final section of this dissertation begins with a brief review of the study purpose (Section 4.1). I then provide a summary of the analytic findings and my interpretations, including a review of the grounded theory of MPT Ring Acceptability and Likely Use (Section 4.2). Next, I provide a detailed description of the study’s strengths and limitations (Section 4.3). Finally, the section concludes with implications for future clinical, programmatic and research recommendations (Section 4.4).
Section 4.1: Study Purpose

This dissertation sought to understand women’s acceptability of a vaginal ring used as an MPT to prevent HIV and pregnancy. Several related priorities guided this research. First, global efforts to reduce HIV and unintended pregnancy rely on the availability of sexual and reproductive health products that are acceptable to potential users. Second, the current mix of prevention methods available to women to protect against unintended pregnancy and HIV is limited. Third, MPTs are innovative products (e.g. vaginal rings, diaphragms, injectables) that simultaneously offer protection against both pregnancy and HIV. Despite their promise, MPTs will only be effective in reducing unintended pregnancy and HIV incidence if women are willing to use them. Therefore, it was clear that research to understand user acceptability of MPTs early in the product development process was needed to inform device development and trial design, and ultimately improve product uptake and adherence. Last, in order to promote rigorous studies on acceptability, this research explored optimal use of individual or multi-method designs in early stage MPT trials.

This study was one of only two Phase 1 trials of an IVR with HIV prevention properties, that incorporated behavioral science in early phases of product development to address the concern ‘if women won’t use it, why make it?’ Hence, rather than examining participant behavior following product design, trial implementation and failure due to lack of product acceptability and adherence, the bio-behavioral design used in this trial was intended to prospectively inform the development of more acceptable and user-friendly products in the future. The parent study was the first of its kind to enroll women to wear a TDF-based IVR for 2 consecutive weeks, enabling their reflections on acceptability of the ring under study (parent trial), as well exploring acceptability of an MPT IVR (this dissertation research).
This research, therefore, helps to answer some early questions about how to develop an MPT ring from inception that women will accept and use properly that can inform research methodology employed in subsequent trials.
Section 4.2: Summary of Key Findings

In Section 3.2, I provided an overview of the theory that emerged from analysis of data content and data production. This grounded theory is titled “Dynamic Considerations for Acceptability and Likely Use of an MPT Vaginal Ring” and proposes specific pathways and relationships among themes and constructs of MPT ring acceptability. This new model was informed by two previous frameworks from the field of microbicides (Woodsong et al; Mensch et al)\textsuperscript{154,208} as well as literature from the field of family planning, and empirical findings from my current study. The theoretical model developed in this dissertation therefore integrates two distinct fields of research and practice and provides a blueprint for further research to test the model’s assertions in the newly developing field of MPT acceptability. Section 3.3 provided in-depth descriptions of three key factors that helped to explain women’s overall perceptions of acceptability and potential future use of an MPT vaginal ring.

1. The Priority Triad

The first key factor, The Priority Triad, explained how acceptability was influenced by changing prioritization of her relationship, her partner and herself. This triad of contextual considerations were described sometimes as competing, but also women described their active attempts to achieve balance among them.

In other research on the dapivirine ring in the ASPIRE trial, women identified relationship dynamics with male partners as a strong driver of their perceptions of the ring’s acceptability and future use of the ring, with male attitudes toward the ring as being salient to women’s decision-making behavior.\textsuperscript{291} An extensive body of work has demonstrated the concept that male partners and relationship dynamics are influential on women’s decision-making for
method use in the microbicide field.\textsuperscript{143,153,291–296} In the field of family planning, there is a large body of research and consensus among researchers that male partners and relationship dynamics also play a strong role in women’s contraceptive acceptability, choices and use.\textsuperscript{297–299} Contraceptive research also demonstrates that joint decision-making within the couple typically has a positive effect on contraceptive use outcomes.\textsuperscript{300–302} In this research, women were conflicted about if or how to involve their partners in ring use decision-making. Many insisted that the choice to use or not use the ring was solely theirs, regardless of the opinion of their partner. At the same time, many expressed concerns for their partner -- they worried that partners might experience side effects from TDF (but not hormonal contraception). Women’s claims that they were in charge of the decision were contradicted by their prioritization of partner preferences and health. Women attempted to reconcile some of this conflict by extolling personal agency as not excluding partner or relationship considerations, but rather as having the ability to ultimately make a balanced decision about what would be best for all involved, including herself as one of three priority players.

Women discussed the possibility of joint decision-making around MPT use but were fraught with concern that their male partners might assume they were cheating, if HIV prevention was part of the decision-making process. This concern over an assumption of infidelity is a key factor of women’s lack of disclosure to a partner as well as poor adherence in other trials of PrEP products.\textsuperscript{303,304} Assumptions of infidelity can have multiple meanings for women, some of which result in fear of or actual intimate partner violence (IPV) or the risk of relationship dissolution.\textsuperscript{213,293,303–306}

The ability to successfully balance these priorities was especially challenging at moments of relationship transitions such as in early stages of relationship formation, during a breakup or
reigniting a previous relationship. Women highlighted the importance of good communication and a joint understanding about fertility goals (i.e. to prevent, delay or become pregnant), but did not share the same ease of communication regarding the use of a product that clearly prevented pregnancy and HIV.

A rationale for developing an MPT IVR is that it is a female-initiated method. Because it is worn internally and is not used episodically, women would not need to negotiate or necessarily disclose ring use to male partners, as they do with condoms and may need to do with vaginal gels. Moreover, an MPT IVR is intended to be used for long periods to avoid adherence problems associated with daily or coital use. Unfortunately, this product rationale was contradicted by data from the women in this study, who did not want a long-term product, and felt strongly that their ongoing partners should know they were using it, with mixed findings for new partners. Women valued MPT disclosure but explained that it would hinge upon her ability and interest in the difficult task of communicating with a partner about the decision to use one. Women held different opinions about whether to disclose ring use to a new partner based on their relationship status and partner type. Some believed their partners had the right to know that they were being exposed to a drug that could cause side effects. Others believed that disclosing the ring too early in the relationship might send the message that they were promiscuous. Women were torn, because withholding it might become problematic later if the relationship matured into a committed one and that information had been withheld.

Previous microbicide gel research showed that covert use was inconsistent with a serious or monogamous relationship. Recent data on the dapivirine ring in the African context suggest that relationship dynamics are a central component to acceptability and further, male partners being unaware of their female partners’ ring use was associated with increased social
harm within the relationship in the bivariate models. However, in this research with American women, there were mixed findings about the relative importance of ring disclosure within a relationship. Future research on the introduction of vaginal rings for HIV and pregnancy prevention should explore how relationship dynamics can influence individual (for both women and men) and couple-level decision making around ring use. Study design and product distribution efforts should offer women the opportunity to involve men if women believe it will be helpful for uptake and use. Including male partners in these efforts offers opportunities to educate men about drug exposure, STI and contraceptive counseling and to support joint decision-making and trust-building within the relationship. It also, encourages men to take responsibility for pregnancy and HIV prevention within a partnership.

2. Episodic Considerations

The second key factor in The Dynamic Considerations Model explained how acceptability is shaped by Episodic Considerations that are event-driven, being relatively short in duration, such as a single sex act or a week of menstruation. The main episodic considerations for acceptability that women described were related to attributes of the ring itself (Product Attributes); attributes about use of the ring during daily activities (Use Attributes); attributes about use of the ring during sexual encounters (Sexual Experience Attributes); as well as issues around menstruation which were integral to all three attributes.

Product attributes, such as size and material, have been extensively investigated in other vaginal product research. In this study, comfort was reported to be overwhelmingly positive. Wetness was reported in a positive light, and discharge, although disapproved of theoretically, was minimally reported. However, general expectations of discomfort prior to ring
use were high among many and might impede interest in the device outside of the trial context. Initial perceptions of vaginal rings have been noted as generally negative for many women prior to use, with approval ratings increasing only after an adjustment period. However, while concerns over discomfort have been shown to diminish over time with use, other concerns such as side effects and impact on fertility remained. In the TRIO study of choices among different placebo forms of MPTs (pills vs. injectables vs. ring), women liked all forms better after adopting them for 1 month with the largest increase in ring acceptability compared to other products despite no previous knowledge of vaginal rings. This indicates that rings may not be an initially attractive device to women, but acceptability increases when women are made aware of their existence and receive early counseling.

Part of the rationale women gave for not wanting to use a ring, despite no feelings of active discomfort, was that they were hesitant to accept a foreign object inside their bodies. This is a sentiment that has been expressed in acceptability research on Long Acting Reversible Contraception (LARC) and vaginal rings for PrEP: manifested as disapproval of an object that cannot be seen or easily removed and that is located in the epicenter of reproduction and sexuality. For those women who accepted the idea of inserting or wearing an intravaginal device (i.e., vaginal ring, tampon), they were still worried about harboring too many devices inside their vaginas. The idea of wearing more than one intravaginal device simultaneously was unacceptable to all of the women who offered commentary on this practice. Women in Malawi, Zimbabwe, Uganda and South Africa also expressed concerns about ‘vaginal crowding’ and how this would be a barrier to uptake and use of a device vis-a-vis the blockage of necessary outward flow of menstrual blood. Although some evidence exists showing that tampon use alongside NuvaRing does not reduce effectiveness of the drug, this concern of overcrowding still should
be examined closely by product manufacturers if a ring like this is to be worn during menses, as ‘effectiveness’ is not always women’s top priority in method choice.\textsuperscript{316}

The complexity of ring use around monthly menses was extensive. Women varied idiosyncratically in their willingness to consider wearing the ring during menstruation, with the sample split nearly in half of women reporting they would and would not be willing to wear a ring during menses. The unwilling half voiced concerns about cleanliness, contamination, or the desire to flush out toxins (including TDF) via the menstrual flow. Because of similarly-held personal and cultural beliefs about menstruation, women may decide to clean\textsuperscript{152} and/or remove a ring during or after menses, even if advised against it. This practice could leave women open to HIV infection at least monthly. In an MPT where use is indicated for prevention of both HIV and pregnancy, it is possible that women may overextend their understanding about the mechanisms of prevention: favoring what they know about hormonal contraception and incorrectly applying it to TDF or other forms of PrEP, which may require a longer duration or continual wear for effectiveness. Future development of MPT rings should explore the option of ring removal during a specified period of menses, to heed women’s objections over vaginal crowding for purposes of both effectiveness and cultural beliefs around menstrual flow.\textsuperscript{317} Implementation studies will then be needed to define the limits of practice (i.e., how long it can remain outside the body; safe cleaning solutions, etc.).\textsuperscript{262}

\section*{3. Rationale for Need}

The third key factor for understanding MPT ring acceptability in The Dynamic Considerations Model is women’s \textbf{Rationale for Needing} a device to prevent HIV and pregnancy. This rationale reflects a woman’s evaluation of her need to actively prevent HIV or
pregnancy, including perceptions of risk for both outcomes. None of the women in this study believed herself to be at risk for HIV and explained that as the major reason they would be unlikely to use the MPT ring themselves. The women in this study were all using oral contraceptives (likely indicating some level of pregnancy risk aversion); research has documented that pregnancy risk perception is artificially low due to some women assuming they are infertile in the absence of a medical diagnosis.\textsuperscript{318-320} Perception of infertility is associated with decreased contraceptive use. Women’s lower risk perception for HIV was explained as being related to their relationship status.

Theoretical models of health behaviors such as Protection Motivation Theory,\textsuperscript{321} the Health Belief Model,\textsuperscript{322} Social Cognitive Theory,\textsuperscript{323} Extended Parallel Process Model,\textsuperscript{324,325} and the AIDS Risk Reduction Model\textsuperscript{210} all identify perceived risk as an important predictor of risk-related behaviors. Motivation to use a product for HIV prevention depends directly on beliefs about one’s personal risk for acquiring HIV.\textsuperscript{326,327} Although perceived risk alone is not sufficient to motivate attitude or behavior change, it is necessary for change. In this study, risk perception was a central organizing factor related to use, regardless of components of acceptability. For example, a woman could believe the ring was comfortable, not problematic during sex or for her partner, and overwhelmingly an acceptable product. However, if her relationship was serious or long-term, her perception of (no) HIV risk would drive her decision to not use a ring, regardless of how acceptable it might be. Pregnancy was not discussed in the same ‘risk’ language as HIV, and potentially reflects women’s differential feelings about pregnancy vs. HIV as a potential outcome of unprotected sex; whereby pregnancy may be a welcome surprise, HIV is an unwelcome and incurable illness. Additionally, women may not be or perceive themselves to be at risk for HIV, which may guide their disinterest in an MPT.
Relative to other regions where HIV prevalence can be as high as 35% for women of childbearing age, the women in this study lived in a relatively lower risk region. However, relative to other areas in New York City and the United States overall, the prevalence of HIV in the Bronx was comparatively high. Despite this relatively higher risk profile of their community, they were almost entirely unconcerned about this. Perceived low risk for HIV will remain a barrier to uptake of any HIV-preventive IVR, regardless of actual personal or population-based HIV risk status.

This finding may be different in high prevalence regions in sub-Saharan Africa, however, it is also possible that this unawareness or dismissiveness of risk based on community prevalence is more universal. Women in this study mainly perceived their risk status to be low, yet, the inverse relationship between perceived risk and relationship trust is one that permeates romantic relationships globally. The Model therefore explains that lack of perceived risk, regardless of actual risk, can completely circumvent the acceptability of an MPT and the likelihood of MPT use.

Despite decreased perception of risk for HIV and pregnancy, women in this study did herald an MPT ring as a positive prevention option for women more generally. They appreciated the efficiency of a device that provided a joint solution to prevention of pregnancy and HIV. They also talked in many indirect ways about an MPT ring being able to ward off internalized and externalized experiences of stigma for using an HIV-only prevention product. HIV-related stigma around sexual behaviors and identities has been deeply entrenched in many communities, and this stigma has been a barrier to prevention and treatment efforts. HIV stigma has also influenced ‘PrEP stigma’, in which negative meanings around the use of HIV prevention medications are tied to negative feelings about PrEP users. For the women in this study,
the avoidance of PrEP stigma may help explain why women would emphasize the contraceptive component of an MPT so as to avoid being castigated as engaging in ‘risky’ sexual behavior.\textsuperscript{333,334}

Toward this end, women explained that when pregnancy prevention was made primary, the stigma associated with HIV prevention efforts was minimized for MPT use.\textsuperscript{310,311,335} In the context of the relationship, therefore, attempting to prevent pregnancy would make it more acceptable to actively prevent HIV because it would merely be added to the basket of preventive behaviors a couple could conjure to prevent negative outcomes and to support individual and relationship health. When use of an MPT was framed as contraception with this added HIV prevention bonus, women saw this behavior as being less stigmatized and more acceptable to herself and to the couple overall. Therefore, women classified an MPT ring as a joint solution to the problem of perceived risk for HIV and pregnancy without embodying a stigmatized identity. Overall, women accepted an MPT ring if it had little additional impact on her body (e.g., menses and fertility), her partner, their relationship or the sex act. Women envisioned MPTs as an efficient solution to accomplishing two goals if they were already looking to do so.
Section 4.3: Strengths and Limitations

This study was the first of its kind to explore factors of IVR MPT acceptability with women who are using a candidate IVR that is similar in structure and includes a microbicide drug or its placebo. This study was only possible, however, because it was incorporated into an ongoing Phase 1 clinical trial of a TDF PrEP-only ring. Inherent to this parent/dissertation design, however, came some limitations that I detail below.

Recruitment

Phase 1 clinical trials are designed to “evaluate [a drug’s] safety, determine a safe dosage range, and identify side effects” and therefore rely on participant adherence to product use.336 Hence, eligibility requirements for the parent study sample necessarily skewed the sub-study sample toward ‘adherent’ participants in order to ensure product use. These were the need to live in geographic proximity to the study site, ability to maintain sexual abstinence, taking oral contraceptives and willingness to forego vaginal product use for 3 consecutive weeks. Recruitment of women with higher HIV risk profiles (e.g. sex workers or those who regularly douche) was limited. Women in this study therefore had relatively low HIV risk compared to those to whom MPTs will likely be most targeted (e.g., countries with high rates of unintended pregnancy and HIV). It is true that the Bronx, NY does have a higher rate of HIV infection and unintended pregnancy among women than other places in the United States. However, there is still a relatively low prevalence and risk for contracting HIV compared to places where HIV is high, such as countries in sub-Saharan Africa.

Theoretical sampling was difficult to implement with this small sample, and complete saturation was not achieved on all emergent themes.187 Logistically, I was also not able to analyze the data quickly enough to identify appropriate emergent themes to inform successive
participant recruitment for the parent study. I attempted to speed up the process of emergent theme identification by weekly with my research assistant and an expert in qualitative methods to identify early patterns in the data and questions requiring further exploration with each successive participant. However, this was a challenge as I had little control over the speed of parent trial recruitment. I communicated regularly with the parent study team to request recruitment of women with characteristics of emerging interest, but the limited pool of women made this challenging.

**Skewed Participant characteristics**

Participants may have self-selected to be part of the research for a few different reasons, which was not explicitly unpacked during data collection. For example, the sample included multiple PhD students in related health sciences fields. Their motivations to participate may have been altruistic, but also may have been guided by a desire for experience with the research environment or the parent trial investigators. Their motivations remain unknown but may have shaped the overarching narrative of the data such that positive beliefs about the development of a biomedical product were disproportionately positive. In the ASPIRE microbicide vaginal ring trial, a range of participation motivations were identified including women’s ethical predispositions.\(^{294}\) The idea of ‘ethical intercorporality’ has been coined to represent this type of altruism among participants, who care more about social and ethical motivations for the good of their communities when choosing to participate in a trial.\(^{294,337}\) It is important that we recognize there may be a range of motivations influencing different women in this trial and therefore their perspectives on acceptability and likelihood of use may be more optimistic than for women who chose not to participate.
In addition to having a high adherence/low risk profile, women recruited for the parent study were further bounded by a range of characteristics that may have impacted the findings. These women used oral contraceptives over other methods; were at least somewhat accepting of an HIV prophylactic drug, and; were willing to wear an intravaginal ring for two weeks. These eligibility requirements therefore included women who already did not wish to become pregnant and had taken active steps to prevent it; accepted wearing an intravaginal device, accepted user-initiated hormonal contraception and were willing to use an investigational HIV drug. In an attempt to expand the window of experiences with and thoughts about MPT acceptability over the life course, I used a narrative approach to data collection when possible to encourage women to retrospectively discuss previous life experiences (e.g., during a time in their lives when they used a different type of contraceptive) and to identify reasons why other women may or may not accept an MPT IVR.

**Limited discussion of fertility related issues**

The TDF IVR used by the participants in the parent trial did not include any form of contraception, so participants explored some issues theoretically (contraceptive and fertility-related) and others based on their experience in the parent trial (TDF or ring-related). Without a contraceptive ingredient to the IVR, there was likely an underreporting of real or perceived contraceptive-related side effects that would be expected in the presence of an actual MPT. This limitation also may have made it difficult for women to even engage with deeper thinking or considerations related to the acceptability of a product that additionally prevented pregnancy.
Hypothetical discussions about sex, menstruation, and partner experiences

Women were instructed to abstain from sex with a male partner while the IVR was in place, limiting the ability to comment on the lived experience of ring use during sex. Further, I was unable to speak directly to male partners because of parent sample limitations. To address these limitations, I asked women to theorize her own and her partner’s likely perceptions of and experiences with the ring in the context of their relationship and during sex. However, the hypothetical nature of the data collection made it impossible to evaluate women’s and men’s true experiences during a sex act, menstruation or within the context of their relationship.

Without the perspective of men, it is difficult to fully explore how men would actually feel about the product components and the potential impact on use. For example, women expressed the need for agency within their relationships as distinct from but also connected to their desires to prioritize their own health. Their male partners, on the other hand, were perceived to have concerns about their own (male) health, but the parallel issue of male agency within the relationship never emerged, and therefore was not included in this model. I am calling attention to the fact that male agency (as but one example) may or may not be related to overall MPT acceptability. However, we cannot surmise this because of the limitations in study design to restrict sexual activity and limiting the sample to only women.

Questions and Challenges to Methodological Findings

All research methods have strengths and weaknesses. The following details some of these methodological strengths and limitations that may have changed the way the data were produced and, subsequently the conceptual findings of this study.
Focus Groups

Only 3 focus groups were conducted because of the small pool of women to sample from. The third FG generated different dynamics than the first two, such that women had a livelier exchange and disagreements were civil yet abundant. I hypothesize that the different dynamics were related to the fact that participants and facilitator in group 3 had never met before, and therefore the dialogue was about a new topic to them that had some novelty in discussion.

Because of this, women likely were more motivated to talk about their life experiences and participate in the study, including discussion with other participants. According to principles of theoretical sampling, the logical next step would have been to continue recruiting women for additional focus groups who had not yet been interviewed, to best understand their Priority Triads. However, there were no available participants left to recruit for additional groups. Saturation on the focus group process was not met, leaving room for speculation as to why focus group 3 produced more complex interaction data than groups 1 and 2.

Ordering effects or Participant Fatigue?

There is also the question about the sequencing of data collection methods and potential impact of such ordering. Unfortunately, we cannot compare different sequences so that hypothesis remains untested. It may be that the cumulative burden of data collection may reduce participant effort. Alternatively, beginning the data collection sequence with interviews vs. focus groups may have artificially imposed a ‘reverse funnel effect’ on data production whereby participants established their narratives about ring acceptability from a more focused experience, only to be allowed to expand their perspectives and discussion considerations when exposed to others in the focus group format. It could also be that some data are less amenable to focus group collection if they are stigmatizing or sensitive and more likely to be withheld in public. For the
12 women who completed all four possible data collection points, happening in the same sequence (2 IDIs followed by card sort and focus group), there remain questions about the sequencing of data collection techniques and potential for ordering effects to impact the findings. For these women, in particular, I was concerned about a potential maturation effect in which questions from the interviews and topics discussed in the card sort would change the material women discussed in the context of the focus group. It is unclear if this occurred, but definitely I witnessed participant fatigue during the second IDI and card sort, where women cut short exploration of topics they had “already told me about” in IDI 1. Sometimes they rushed through the cards to quickly place or order them. I frequently reminded them to “say out loud for the recording” their choices for card placement or ranking, in an effort to encourage them to refocus via explaining their choices of card placement.

This participant fatigue may have disrupted deeper thinking about ranked order of importance of acceptability factors during the card sort, or it may have made it more difficult to change course once previous statements had been made in the IDIs. I found that there were some themes and constructs that emerged during one method and not in another; during one method and then differently in another; or in one method but then was refined in another. In each of these cases, it would have been necessary to use a crossover design to accommodate a return to a previous method of data collection for confirmation, to test emergent findings or to verify interesting or peculiar findings.

Compared to focus groups 1 and 2, the women in focus group 3 engaged in more spontaneous dialogue between themselves, without my intervention as facilitator. However, topics that were newly discussed in all three of the FGs for all participants, such as reactions to visualizing a ring or community level risk, generated similarly high levels of discussion across
all three groups. It may be that increasing the sheer number of data collection episodes may have pushed the participants in FGs 1 and 2 to the point of boredom due to repetition, such that they may not have engaged fully or as enthusiastically to the research topics they spoke about in their earlier data collection episodes.
Section 4.4: Implications and Conclusions

Clinical and Public Health Programming Implications

Counseling from health care providers should include intermittent assessment of women’s joint HIV risk status and family planning goals, acknowledging that relationships, sexual activity and related priorities change over time and may require new strategies. Relationship types and characteristics vary dramatically in level of commitment, trust, love, monogamy, sero-discordance, intermittence and length. Women’s perception of need for an MPT may shift alongside changes in their relationships and with specific partners, as well as their own priorities.\textsuperscript{104} Healthcare providers should counsel women about the range of prevention products that meet these changing needs. Providers can play a further role in promoting user acceptability by offering initial insertion as has been done with the diaphragm and guiding women to overcome fear associated with device insertion and removal, potentially through comparing and contrasting to other vaginal products like contraceptive rings or tampons.\textsuperscript{152,329,339}

Providers can prospectively alert women to monitor their own changing “seasons of risk” or moments where family planning needs change such as relationship status changes and sexual practices during menstruation. This approach may be particularly effective for women in new relationships, as an opportunity to more easily onboard a new method with a new partner that fits their needs. In the case of MPTs, special attention will need to be paid to match women’s likelihood of use relative to menstruation, individual sex acts and start-up timing so women are aware of potential effectiveness issues.\textsuperscript{329,340}

This study adds more evidence to the growing body of research justifying a variety of prevention options available for women to choose from, so women can make informed and appropriate decisions for themselves regarding their own sexual and reproductive lives. It is
known that method choice and related satisfaction are associated with consistent use.\textsuperscript{105,341–345} It is prudent for clinicians and public health professionals to recognize that women are stewards of their own health, and to proactively prepare patients and communities for future decision-making points and awareness of the option for MPTs. Providers have the responsibility to counsel women (and potentially their partners) on a variety of prevention tools, to help them assess risk and fertility questions, and subsequently support women to choose the best method for them to meet their sexual and reproductive health needs as guided by their own contexts and priorities. Recent efforts in contraceptive counseling have emphasized a patient-centered approach that recognizes women as experts over their own lives, with clinicians acting as medical experts.\textsuperscript{346} Public health systems can collaboratively ensure that a range of products are available and accessible to women and their partners.

The process of method decision-making is complicated and will require clinical and public health practitioners to hone suitable approaches, so that women are equipped to make these challenging decisions that often attend to multiple factors at once and change over time. A recent study exploring women’s decision-making needs for choosing a contraceptive method shows that women turn to family members and peers to discuss contraceptive decisional topics, but often feel ‘decisional conflict’ in the clinical context with their providers, potentially explaining suboptimal choice and subsequent use outcomes.\textsuperscript{343} MPT decision-making will also prove to be complicated when they become available and, thus, deserves a proactive approach where clinicians develop more fluency with appropriate decision-making tools that are patient- and woman-centered. Some of these decisional tools are in development for contraceptive methods, giving MPTs a body of information from which to start building its own toolkit for
appropriate counseling approaches. Health systems will need to adopt appropriate standards for clinical counseling based on a strong evidence base that is woman-centered.

Addressing women’s and couples’ pregnancy desires as well as perception of HIV risk are each challenging tasks, in and of themselves. In terms of MPT acceptability and likely use, however, they are both essential to address as a package for ensuring sexual and reproductive health. Concerted effort should be given to interventions that do not undermine women’s relationships with male partners but instead support women in their relationships, as well as attending to their own desires. One recent study on PrEP uptake among women cautioned “by strongly emphasizing risk as a rationale for PrEP use, we may inadvertently connect the concept of mistrust with PrEP use, forcing individuals to choose between the logic of PrEP and their strong feelings of trust.” (p. 3477) Interventions may therefore benefit from emphasizing community level risk, as perception of high community HIV prevalence has been associated with increased HIV protective behaviors. Alternatively, MPTs can be discussed as a contraceptive that has “bonus” benefits, to minimize concerns around stigma and infidelity.

Offering couples counseling on a suite of prevention products may also avoid harming relationships, especially if messages are framed with the goal of addressing their family planning needs primarily and risk prevention secondarily. According to the contracepting women in our study, preventing pregnancy was an outcome they believed to be easier to communicate than HIV prevention. Perhaps a focus on balancing the needs and concerns of women and men in the context of their reproductive circumstances can help to create equitable prioritization of health needs for both partners, while maintaining the integrity of the relationship. Additionally, public health messaging can focus on insuring women maintain good health for their own sense of well-being, their relationships and the sake of future pregnancies and children.
**Implications for Future Research**

MPT research and development efforts should follow a woman-centered research paradigm in which potential MPT users are integrated at the early phases of product conceptualization and study design so women will find value in them once available in the marketplace. Incorporating user preferences in early phase clinical trials may shorten the product development timeline, prevent costly large-scale clinical trials that fail due to participant non-adherence, and improve likelihood of product adoption once developed.\textsuperscript{129,131,181,355}

For the development of future MPT trials, it will be important to integrate experts and previous lessons learned from the siloed fields of family planning and HIV prevention. As one team of advocates urged regarding MPTs: “Don't reinvent the wheel.”\textsuperscript{82} Future trials of MPT IVRs and other delivery devices that include an actual contraceptive component should include early behavioral design research to assess acceptability and likely use. Some of these trials are currently underway.\textsuperscript{87}

MPT device developers should consider concurrent development of a range of devices and drug combinations that are responsive to women’s changing life contexts, relationships and related preferences. At the moment, there are multiple products in different stages of development, and all may be useful to develop, rather than settling on a single product. Some PrEP studies are evaluating the possibility of differently timed products, that can be event-driven, daily, monthly or longer intervals.\textsuperscript{294,356,357} Following this approach, future study designs should consider recruiting women from a range of relationship statuses, including those who are in-between, recently broken up or participating in more episodic sexual relationships, to understand how these temporally different relationship characteristics may affect women’s choices among MPT features and products.
With MPTs being a relatively nascent field of candidate products, it is essential that early bench research also explicitly investigates the dose-response required to confer protection for women against HIV and pregnancy during periods of removal of up to 1 week, during which menstruation may occur, as these are episodic considerations impacting choice, use and subsequent effectiveness. While we know more about efficacy of a contraceptive vaginal ring, we know less about localized PrEP efficacy for women, and almost nothing about localized efficacy against both pregnancy and HIV from an MPT. As it appears that many women would want to remove a ring during a week of menstruation and potentially during sex, developers will need to explore how to confer protection during these potential periods of removal.

As new MPTs are conceptualized, it will be important to more pointedly address women’s acceptability of an actual MPT ring with contraceptive properties in the geographic and relationship contexts in which they will be used. Cross-over designs can be helpful so that women can compare methods to one another, but acceptability of these products should be evaluated with attention to ordering effects and changing relationships. Male partners’ perspectives are also a critical factor in support and uptake of products; thus, male participation should be seriously considered in study designs.

Study designs do not necessarily need multiple methods to understand basic thematic findings, however, there is an unparalleled richness that is inherent in complementary designs that is unachievable otherwise. A grounded theory is strengthened by using more than one method to explain it and findings can be elevated when the context of data collection and factors inherent to the methods are also evaluated. While it may not always be logistically feasible to include multiple methods, this study reminds us of the inherent strengths and challenges that
exist within individual methods that can be leveraged to help answer different elements of our research questions.

For any new device, behavioral intervention will need to be developed and tested to ensure that perception of HIV risk is adequately addressed. These interventions include clinical interventions for provider counseling but require more thoughtfulness about which messages are appropriate for different populations and who will most effectively deliver those messages. It will be important to understand the impact of a variety of approaches to emphasizing individual vs. relationship vs. community level risk, on a variety of outcomes including relationship dissolution, relationship conflict (including violence), method choice and use.

Lastly, ‘The Model’ produced here is both exciting and preliminary, based on empirical data from this study and from lessons learned from other microbicide and contraceptive research. It should be tested, augmented and clarified conceptually, as more MPTs are developed and evaluated. This would include explicitly testing the proposed associations for directionality and applicability in different populations. This study was conducted with US women. While the findings might apply to women in other contexts, it will be important to determine this with similarly or more rigorous mixed- or multi-method study designs.

**Conclusion**

Qualitative research can be a valuable addition to early phase clinical trials of biomedical HIV prevention methods. By using naturalistic approaches guiding women to discuss their perceptions, attitudes, and concerns, qualitative interviews create opportunities for women to raise problems with product acceptability and use that might not occur to product developers. The intent is not to generalize these themes to other populations, but instead to explore common
threads in the universality of some of these findings. Focus groups allow women a forum to clarify some of their previously unexplored preferences and ideas. Card sorts allow for the discussion of otherwise stigmatized topics as well as the ability to rank factors of acceptability and likely use. Interviews allowed for deep exploration of emergent theoretical data. Each data collection added specific findings that were inherent to their method.

Themes around partner trust, low perceived risk, menstrual practices and beliefs and stigma have been documented in other populations and deserve further exploration, so we can understand how to develop acceptable MPT products globally. Beliefs around tampon use, interference with drug absorption and distaste for overcrowding products inside women’s vaginas are relatively new findings that warrant further study both qualitatively to explore depth and meaning and quantitatively to discern how widely and how strongly held these beliefs are within a population.

Taken together with findings from other ring trials, it seems that women’s acceptability has less to do with the specific drug within a ring or even the ring itself. Instead, women’s acceptability and expected use of any product or drug combination hinges on the complex totality of her experience with using any MPT product that might challenge her relationship, partner and individual health. In a critique of contraceptive acceptability assessment, Heise (1997) makes a similar point that contraceptive acceptability is not “inherent in a product or a method” but rather is informed by contextual factors. My data similarly reflect this point related to MPT acceptability, suggesting that one way to address MPT ring acceptability and expected use is to develop different rings to fit women’s relationships and contexts over time and across separate episodes. The women in this study certainly indicated their preference for an MPT ring over one that solely provided protection against HIV, since all
these women were trying to avoid pregnancy, regardless of their awareness or acceptance of HIV risk. Adding an MPT to the mix of available women’s prevention methods would address vulnerability to both pregnancy and HIV during seasons of risk.\textsuperscript{329}

Actual and perceived risk status fluctuate over time as a function of relationship formations, maintenance, breakups and all phases in-between. Eventual health promotion will need to address the dynamic nature of sexual relationships by using a combination of tailored counseling approaches to women and their partners, broad public health messaging, and the development of multiple forms of preventive devices to increase acceptability more broadly among both women and men. Researchers should also not artificially disaggregate women’s rationale for needing an MPT from the conceptualization of acceptability or use of these prevention products, as they are inextricably linked. Future MPT trials should continue to grapple with how to develop and market an array of products that will be acceptable to women at different life cycles or stages.
APPENDICES
Figure 1: HIV prevalence among women aged 15 years and older by country or region.
Figure 2: UNMC among women aged 15-49 years by country.
Figure 3: Unintended pregnancy rate per 1000 women aged 15-49 years by subregion.
Figure 4: HIV prevalence and UNMC among women.
APPENDIX B: IRB Letter of Exemption
Exemption Granted

11/04/2017

Dana Watnick, MSSW, MPH
The Graduate School & University Center

RE: IRB File #2017-1225
Understanding Acceptability of a Vaginal Ring to Prevent HIV and Pregnancy: Integrating Multiple Qualitative Methods

Dear Dana Watnick,

Your Exemption Request was reviewed on 11/03/2017, and it was determined that your research protocol meets the criteria for exemption, in accordance with CUNY HRPP Procedures: Human Subject Research Exempt from IRB Review (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. You may now begin your research.

Please note the following information about your approved research protocol:

Expiration Date: 11/02/2020

Documents / Materials:

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<td>Data Request Form</td>
<td>Data use memo from Bauman</td>
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Although this research is exempt, you have responsibilities for the ethical conduct of the research and must comply with the following:
Amendments: You are responsible for reporting any amendments or changes to your research protocol that may affect the determination of exemption and/or the specific category to the HRPP. The amendment(s) or change(s) may result in your research no longer being eligible for the exemption that has been granted.

Continuing Review: You are responsible for completing and submitting a continuing review form every three years. The information in this form will keep us up to date on the progress of the study and help to ensure that the study continues to meet the requirements for exemption.

Final Report: You are responsible for submitting a final report to the HRPP at the end of the study.

Please remember to:

- Use the HRPP file number 2017-1225 on all documents or correspondence with the HRPP concerning your research protocol.

- Review and comply with CUNY Human Research Protection Program policies and procedures.

If you have any questions, please contact:
Kristen Cribbs
kristen.cribbs@sph.cuny.edu
APPENDIX C: COMPLETE INCLUSION AND EXCLUSION CRITERIA FOR PARTICIPANTS IN PARENT STUDY FOR TDF RING

Inclusion Criteria:

Women must meet all the following criteria to be eligible for inclusion in the Parent Study:

- Age 18-45 years (inclusive) at screening.
- General good health (by volunteer history and per investigator discretion) without any clinically significant systemic disease (including, but not limited to significant liver disease/hepatitis, gastrointestinal disease, kidney disease, thyroid disease, osteoporosis or bone disease, and diabetes).
- Able and willing to provide written informed consent to be screened for and take part in the study.
- Able and willing to provide adequate locator information.
- HIV-uninfected based on testing performed by study staff during screening procedures (per applicable algorithm in Appendix II).
- Using low dose combined (estrogen and progesterone-containing) oral contraceptive pills dosed as follows: one tablet daily for days 1-21, then one inert tablet daily (or no tablets for days 22-28). (Does not include extended-cycle, 24 and 28-day active pill regimens). Per participant report must be using this contraceptive method with no change in the prior 3 months and intending to use same method for the duration of study participation.
- Currently have a regular 28-day menstrual cycle on combined oral contraceptive pills.
- Normal Pap test at screening or appropriately documented history of Pap test and completed follow-up of any abnormal pap tests consistent with American Congress of Obstetricians and Gynecologists (ACOG) practice guidelines #99 and #109. (Atypical cells of undetermined significance (ASCUS) with no evidence of high risk HPV will be included)
- Per participant report at Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devices, or vaginal products for the duration of study participation.
- At Screening, participant states she is able and willing to refrain from inserting any non-study vaginal products or objects into the vagina, including but not limited to, spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), douches, lubricants, vaginal drying agents, sex toys (vibrators, dildos, etc.), and tampons for the 48 hours prior to Visit 2 throughout the duration of the study.
- Able and willing to abstain from oral, vaginal and anal sex for 48 hours prior to Visit 2 until the sixth day after Visit 2, 48 hours prior to TDF or placebo IVR insertion, the 14 days of TDF or placebo IVR use, and for 7 days after the TDF IVR is removed.
- Vaginal and cervical anatomy that, in the opinion of the investigator, lends itself to easy colposcopy and genital tract sample collection.

Exclusion Criteria:
Women must meet none of the following criteria prior to genital sampling at Parent Study Visit 2. Participant report of any of the following at Screening:

- Known adverse reaction to polyurethane or to any components of the study product or allergy to both silver nitrate and Monsel’s solution.
- Hepatitis B infection (defined as positive hepatitis B surface antigen).
- Chronic, recurrent, and/or acute vulvar or vaginal symptoms (pain, irritation, spotting, etc.).
- Known bleeding disorder that could lead to prolonged or continuous bleeding with biopsy.
- Intending to become pregnant during the period of study participation.
- Currently breastfeeding or having breastfed an infant in the last two months, or planning to breastfeed during the course of the study.
- Menopause.
- History of unexplained or unresolved intermenstrual bleeding in the 3 months prior to screening.
- History of gynecological procedures (including genital piercing) on the external genitalia, vagina or cervix in the last 14 days.
- Hysterectomy.
- Use and/or anticipated use during the study period of an intravaginal or intrauterine device.
- Systemic use in the last 2 weeks or anticipated use during the study period of any of the following: corticosteroids, antibiotics, antifungals, antivirals, anticoagulants or antiretrovirals.
- Plans to relocate away from the study site area during the period of study participation.
- Grade 1 or higher laboratory abnormality, per the August 2009 update of the Division of AIDS, National Institute of Allergy and Infectious Disease (DAIDS) Table for Grading the Severity of Adverse Events (AEs).
- At Screening or Enrollment, is pregnant (based on urine pregnancy test).
- In the last six months, diagnosed with or treated for any sexually transmitted infection (STI).  
  Note: Women with a history of genital herpes or condylomata who have been asymptomatic for at least six months may be considered for eligibility. HSV 1 and 2 serologies will be obtained in order to correlate with CVF antiviral activity. Participants with a positive HSV 2 IgG test, but without a clinical history of genital herpes will be included.
- Reproductive tract infection (RTI) or pelvic inflammatory disease (PID) requiring treatment per current CDC guidelines at Screening or Enrollment.  
  Note: Women diagnosed with symptomatic bacterial vaginosis (BV) as defined by Amsel’s criteria will be excluded. Otherwise eligible women diagnosed with symptomatic vulvovaginal candidiasis (VVC) or urinary tract infection (UTI) will be eligible if Visit 2 (Enrollment) is scheduled after all symptoms have resolved and at least two weeks after completing treatment.
- Positive test for Trichomonas vaginalis, Neisseria gonorrhea or Chlamydia trachomatis at screening.
- Reactive test for syphilis at screening.
Note: Women with a history of syphilis that have been appropriately treated may be considered for eligibility. Women with a history of syphilis diagnosis or treatment in the last six months will be excluded.

- At Screening or Enrollment, has a clinically apparent Grade 1 or higher pelvic exam finding (observed by study clinician or designee) per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Addendum 1, Female Genital Grading Table for Use in Microbicide Studies.
  Note: Cervical friability bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgment of the PL/designee is considered expected non-menstrual bleeding and is not exclusionary.

- At Screening, has severe pelvic relaxation such that either the vaginal walls or the uterine cervix descend beyond the vaginal introitus with Valsalva maneuver.

- Has any condition that, in the investigator’s opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.
These data collection tools were designed for joint use with both the parent study and this dissertation sub-study. Items that apply solely to this sub-study are highlighted in grey.
In-Depth Interview Guide #1

Introduction: Thank you for agreeing to talk with me today. I am here to get a deeper understanding about your experiences with the ring. I would like to hear about ALL of your experiences with the ring since it was inserted, regardless of what you have been instructed to do or not to do by the other study staff. To help you try to feel more comfortable with talking to me about your experiences, the other study staff has agreed to let me conduct this interview with you confidentially. So that means I won’t share any of your identified data with the study staff. Do you have any questions for me before we begin?

1) First, please tell me about the ring -- How is it going so far?
   • PROBE for range: What else? Anything else? (Obtain a complete list of the participant’s reactions/experiences)
   • PROBE for depth: Go back to each thing mentioned and ask for in-depth description, including how, when, how long.
   • PROBE for emotional valence: For each thing mentioned, ask how the participant felt about the event/problem.

2) Have you had any problems since the ring was put in?
   • PROBE: What were the problem(s)? How often? How serious? How do you know the problem was related to the ring?

3) Have you had any (other) concerns or worries about wearing the ring?
   • PROBE: Exact nature of the concern, why the concern happened, when it started, whether the concern got stronger or more serious or less serious over time.

4) Before you had the ring inserted, what did you expect it might be like?
   • PROBE: To have it inserted; To wear it every day; To impact your menstrual cycle.
   • PROBE: How does your actual experience compare to what you thought might happen?

5) What do you like about wearing the ring?
   • PROBE: Was this true the whole time you used it?
   • PROBE: How much do you like the ring?

6) Tell me about when the ring was (inserted)?
   • PROBE: Was the procedure easy or hard?
   • PROBE: Did you take the ring out?

7) I know that study staff has asked that you not have sex while the ring is in. What has that been like for you?
   • PROBE: Partner issues with the ring?
   • PROBE: Any problems during sex?
   • PROBE: Use any vaginal products?
8) I also know that study staff has asked that you not to remove the ring at any time during the last week. What has that been like for you?
   - PROBE: Has the ring been outside of your body for any time at all?
   - PROBE: Did you think about checking on it?
   - PROBE: If yes, why, how easy/hard it was, whether they told the doctor);
   - PROBE: If no, what did you think it might be like to remove it? Why?

9) If you had a choice in designing this ring, do you have thoughts about what would be the ideal length of time to leave it in your body before changing it out for a new one?
   - PROBE: How often you would want to change it out?
   - PROBE: What helped you decide that amount of time?

10) Some women might be more interested in using a ring like this than others. Can you characterize who might be interested in using a ring like this one to prevent them from contracting HIV? What about those who wouldn’t want to use it?
   - PROBE: Any particular lifestyle or life circumstance?
   - PROBE: Why might women want to use it?
   - PROBE: Why wouldn't they want to use it?

11) If this ring is available for use in the future, would you want to use it?
   - PROBE: Why or why not?
   - PROBE: What would they have to change about the ring to increase your interest in using it?
   - PROBE: What else would you want to know about the ring to decide?

12) What if we invented a ring like this one, but it was a ring that prevented HIV and pregnancy, what would you consider before using this type of ring?
   - PROBE: What more would you want to know about it?
   - PROBE: Under what circumstances would you want to use it?
   - PROBE: Why would you not want to use it?
   - PROBE: What concerns might you have?
   - PROBE: Can you describe a woman who would be interested in using it?

13) Think about a sexual partner or relationship. What would HE would think about you using a ring like this?
   - PROBE: What might a partner think about you wearing a vaginal ring that is meant to prevent you from getting HIV and from getting pregnant?
   - PROBE: What problems might he have with you using this ring?
   - PROBE: What might he like about you using this ring?

14) If you were to use a ring that prevented both HIV and pregnancy, it might mean that you would not get your regular period every month. What is your reaction to that?
   - PROBE: Why might you want/not want to get your period every month?
15) If there were 3 types of rings available today: 1) a contraceptive-only ring like the Nuva ring, 2) an HIV-only ring, and 3) a combination ring that did both, which one would you choose?

- PROBE: Why did you choose this one over the other options?
- PROBE: Would you choose a ring over other methods?
- PROBE: How did you make that decision? Walk me through it.
- PROBE: What factors were you considering?
In-Depth Interview Guide #2

Introduction: Thank you for coming back to talk with me about your experiences with the ring. It’s great to see you again. I am just going to remind you once more, that everything you tell me during this interview is confidential from the other study staff. Since our last interview, did you have any further thoughts about what we talked about, or any questions for me?

1) So now the ring is out. How was the experience? Since the last time I saw you has anything changed?
   • PROBE for range: What else? Anything else? (Obtain a complete list of the participant’s reactions/experiences).
   • PROBE for depth: Go back to each thing mentioned and ask for in-depth description, including how, when, how long.
   • PROBE for emotional valence: For each thing mentioned, ask how the participant felt about the event/problem.

2) Have you had any (other) concerns or worries about wearing the ring?
   • PROBE: Exact nature of the concern, why the concern happened, when it started, whether the concern got stronger or more serious or less serious over time.

3) Have you had any problems with the ring since last interview?
   • PROBE: What were the problem(s)? How often? How serious? How do you know the problem was related to the ring?

4) What did you like about wearing the ring?
   • PROBE: Was this true the whole time you used it? How much do you like the ring?

5) Tell me about when the ring was removed?
   • PROBE: Was the procedure easy or hard? Did you take the ring out ever by yourself?
   • Do you have any thoughts about putting it in or taking it out yourself?

6) Did you have sex while the ring was in? Use any vaginal products?
   • PROBE for problems with the ring, partner issues with the ring, did they tell the doctor

7) Was the ring outside your body at any time?
   • PROBE: If yes, why, how easy/hard it was, whether they told the doctor);
   • If no, did you want to remove it? Why?

8) In your opinion, will women want to use a ring like this one?
   • PROBE: Which women would use it? Why might women want to use it? Why wouldn't they want to use it?

9) What if we invented an HIV ring like this one, but it was a ring that also prevented pregnancy, would you be interested in using it?
• PROBE: Under what circumstances would you use it? Why would you not want to use it? What kind of woman would want to use it? In what ways might your relationship or your sex partner influence your use of this ring?

10) If you were to use a ring that prevented both HIV and pregnancy, it might mean that you would not get your regular period every month. What is your reaction to that?
• PROBE: Is that a good thing or a bad thing?

11) If there were 3 types of rings available today: 1) a contraceptive-only ring like the Nuva ring, 2) an HIV-only ring, and 3) a combination ring that did both, which one would you choose?
• PROBE: Why did you choose this one over the other options? How did you make that decision? What factors were you considering?
• PROBE: (query anything different from IDI1 to IDI2)
Focus Group Guide

FOCUS GROUP GOALS:

- To explore participant experiences with the TDF-only ring
- To understand potential barriers and facilitators to using a TDF-only ring
- To understand potential barriers and facilitators to using a “dual” (TDF+contraceptive) ring
- To solicit suggestions for improvement of a TDF-only ring
- To solicit suggestions for improvement of an MPT ring

MODERATOR NOTE: Make sure to ask the questions in bold. Other questions are important and should be probed if they do not come up in the discussion. Adhere to the time guidelines.

INTRODUCTION

The introduction should be individualized as desired. However, the following should be covered:

- Thank you for being here.
- As you all know, my name is Dana and I will be leading our discussion today. My job is to make sure everyone has a chance to talk and that we cover all the questions that we want to discuss.
- This is ______________ who will be assisting me during the group by taking detailed notes on what is said and writing the group’s responses on the board when necessary. The notes will not identify any group members by name.
- We are here today to talk about vaginal rings! I don’t know many groups that come together for this purpose. We really want to understand key issues about HIV preventive vaginal rings, so we can develop one that is appropriate for women to use.
- The questions I ask you tonight have no right or wrong answers. We just want to hear what you think and we want to try to hear from all of you. I have interviewed each of you twice, and I can say that I’ve learned something new from each one of you. So I am confident that every one of you will add value to this overall discussion.
- Also, I have interviewed each of you twice, so I know that you are accustomed to just talking directly to me. But while we are in this group, I hope you will take advantage of the things that the OTHER women say and ask about. I encourage you to talk to one another, but just one at a time. I may ask some clarifying questions or steer us back if we get off-topic, but ultimately I want you to feel free to respond to what other people are saying.
• The discussion group is confidential. The group discussion will be audio recorded just to insure accuracy but your answers will not be linked to you personally, so feel free to say whatever is on your mind.
• The group discussion will last about 60-75 minutes.
• Before we begin the discussion, we would like to go over the group agreement. It’s important to establish a group agreement to abide by in order for everyone to feel comfortable during the discussion.

Group Agreement (The Group Agreement Visual will be posted in the room)

• One mic (one person speaks at a time)
• Cell phones and other gadgets should be turned off or placed on vibrate mode. Only answer for emergency calls.
• No side conversations (no private conversations among group members)
• What is said in the group stays in the group

MODERATOR NOTE: Please review the “Group Agreement” visual. Ask the group if they feel anything is missing from the list that would help the group run more smoothly tonight?

Write down any additional rules the “group” agrees should be added to the list.

• We also ask that you speak up during the discussion so that we can all hear you.
• Any questions? Now let’s begin.

ICE BREAKER 5 minutes

Q1. Let’s first go around and introduce ourselves. Please tell the group:

• Your first name
• The approximate date when you had the ring inserted, and
• How many people (besides yourself and the study team) knew that you were using this ring?

PARTICIPANT EXPERIENCES WITH THE RING 10 minutes

Q2. Some of you told me that you were interested to hear about the experiences of other women in this study. So here is your chance! What was it like for you to use the vaginal ring?

PROBE: Tell me about something that seemed ‘out of the ordinary’ even if it was just a little out of the ordinary?
PROBE: How did this compare to what you thought the ring would be like?
BARRIERS & FACILITATORS TO RING USE 20 minutes

Q3. Many of you talked to me about your curiosity about what the ring looked like. So here is the moment you’ve all been waiting for. How does this compare to what you thought it looked like?

MODERATOR NOTE: show the ring and pass it around to group participants
PROBE: size
PROBE: material
PROBE: texture/feel

Q4. If this ring is made available for women in the general public to use, there will be some instructions for use. I want to know your opinions about the instructions that women will be expected to follow for using this ring.

ASSISTANT MODERATOR NOTE: Tape up the visual titled ‘HIV RING Instructions’ to the front wall/board etc.

A woman will be instructed to:

• wear it every day including when she has her period
• wear it during sex
• remove it and replace it herself
• replace it monthly.

PROBE: I want to hear your opinions about these instructions. What do you think about these instructions?

MODERATOR NOTE: MINIMIZE probing this section. See what they come up with spontaneously that could potentially demonstrate ranking importance of each issue. Then probe for uncovered issues.

PROBE: Inserting it themselves each time and removing it themselves each time (there won’t be a doctor to do this for them!)
PROBE: During their period?
PROBE: Wearing it every day?
PROBE: During sex?
PROBE: Monthly?

TDF RING DESIGN 10 minutes

Q5. If you could change something about any of these instructions, what would you change?
PROBE: What about the way the ring looks or feels. What would you want to be different?

MPT RING DESIGN 10-15 minutes

ASSISTANT MODERATOR NOTE: Tape up the visual titled ‘Instructions-HIV+pregnancy RING’ to the front wall/board etc.
A woman will be instructed to:

- wear it every day including when she has her period
- wear it during sex
- remove it and replace it herself
- replace it monthly.

Q6. What about if we added a hormonal contraceptive to this ring, so that the ring prevented HIV and pregnancy. What is your opinion about these same instructions now?

PROBE: What is different than when the instructions were for a ring that only prevents HIV?

PROBE: Thinking about the instructions from before, is there anything that feels different when the instructions were for a ring that only prevents HIV?

PROBE: Are they easier or harder to follow?

PROBE: What if you DIDN’T get a period with this ring

PROBE: We heard that some wanted to menstruate in order to FLUSH out any toxins coming from the HIV drug. Thoughts?

Q7. If you could change something about any of these instructions, what would you change for a ring that was for both preventing HIV and pregnancy?

PROBE: What about the way the ring looks or feels. What would you want to be different?

Q8. What if we changed one of these instructions because you did NOT get a period every month. How would you feel about not getting a period every month when you used the ring?

(ASSISTANT MODERATOR NOTE: put up blue tape over the item that says ‘During their period’ on the ‘hiv+pregnancy instructions’ list)

Scenario: MPT RISK PERCEPTION; SOCIAL AND RELATIONSHIP FACTORS 20 minutes

Q9. Do any of you remember the “choose your own adventure” book series? We are going to do something like that here. I am going to tell you a scenario, and then give you 4...
possible endings. I want you to tell me which ending you think the story ends up with and WHY!

MODERATOR READS (AND RE-READS): “Carla is 27 years old and lives in the South Bronx. In her community, she knows a few people who have HIV. She has never had more than 1 partner at a time, and she has been married for 3 years with no children yet. She has always felt very uncomfortable talking to her husband about sex, and they have never talked about having kids. Lately, he seems distant.”

Possible story endings:
1. She does not use a vaginal ring of any type.
2. She uses a vaginal ring that is designed to prevent HIV only.
3. She uses a vaginal ring that is designed to prevent pregnancy only.
4. She uses a vaginal ring that prevents HIV and Pregnancy.

(ASSISTANT MODERATOR NOTE: tape up the 4 ‘Story Endings’. Stand at the board and take notes under each of the ‘story endings’).

PROBE: How does her relationship with her sexual partner play a role in the ending to this story?

WRAP-UP 2-3 minutes

MODERATOR NOTE: The wrap-up should be individualized as desired. However, the bullets should be covered in general.

• Thank you so much for participating in our discussion group today. You gave us a lot of valuable feedback.
• I would like to remind you that what was said in this group should stay in this group. It is ok if you want to talk to each other, but for everyone’s privacy, please don’t share outside of the group.
Q.10. Does anyone have any questions or anything else they’d like to share?
• Well, we are done with tonight’s discussion group. Again, thank you so much for coming.
Card Sort

INTRODUCTION:
“Here is a stack of cards. Each card has a reason on it that a woman might give for choosing to use the vaginal ring or for choosing not to use the vaginal ring. Please read each card and put them in one of three piles. One pile is reasons why you personally would use the ring. The other is reasons you personally would not use the ring. And then there is a third pile for reasons that don’t matter to you one way or another in your decision-making process.”

INTERVIEWER INSTRUCTION: Interviewer asks women as they sort each card why they put the reason in each pile.

“No I’d like you to take the pile of cards that are reasons why you personally would use the ring. Please put them in order of importance to you. The card on the top will be the thing that is most important to you, and the one on the bottom will be the thing you think is the least important reason to use this ring. Please do the same with the other pile, with the one at the top being the thing that is most important reason why you would NOT use this ring and the reason at the bottom would be the least important reason NOT to use this ring.”

(NOTE: This list will be modified and expanded over the course of the project.)

- Having sex without thinking about getting HIV
- Being able to put the ring in and out of my body
- My physical comfort during sex
- Lower cost compared to my regular contraceptive method
  - what is your current method/methods previous
- Having sex without thinking about getting pregnant
- The ring will stay clean
  - how might it get dirty?
- I can take the ring out for short periods of time
  - Like during sex?
  - While you menstruate?
- Feeling safe during sex
- My Partner’s physical comfort during sex
- The Ring will prevent pregnancy
- Will not affect me getting pregnant in the future
- Sex would be better
  - better how-easier, safer, more spontaneous
- My sex drive or being turned on might change
- Side effects from the ring
- Discharge during sex
  - What about Discharge NOT during sex?
- The ring will NOT prevent pregnancy
- My partner supports my choice to use this ring
- Not needing to tell my partner it prevents pregnancy
• The ring won’t get menstrual blood on it
• My partner’s trust that I am faithful
• NOT needing to tell a partner it prevents HIV transmission
• Putting my finger inside my vagina to put the ring in and take it out
• My period would still come once a month
• Type of Hormone/Birth control in the ring
• Wetness during sex
• Material that the ring is made out of

INTERVIEWER INSTRUCTION: While the participant is considering placement of each card, interviewer will probe about how participant interprets each topic and ask participant to “think-aloud” to explain their decision-making process. Participants will also have blank cards so they can add new factors or modify existing ones.
Thematic Codes for Interviews and Focus Groups (in alphabetical order):

- **Abstinence**: Descriptions of reasons for abstinence or sequelae of abstinence. Can be double coded with menstruation or HIV risk perception (among others) when abstinence is given as a reason for non-use of a ring.
- **Added Bonus**: How women view the ring as having HIV prevention as an extra benefit (secondary) to contraceptive action (primary). Also include reverse cases (where contraceptive action is secondary to HIV prevention).
- **Comfort in Use**: The physical sensation and feeling associated with ring use
- **Double drugs**: Discussion about combining two drugs or potential effects when two drugs are combined.
- **Female Controlled**: Descriptions of how women were or were not in control of ring use, including initiation and removal.
- **Feminist narrative**: General statements about how women should be in control of their own bodies, make their own decisions, be independent, prioritize their own needs first, make choice independent of their partners, etc. This could include statements both about just the TDF or MPT device.
- **HIV Risk Perception**: Descriptions of being at risk (or not) for HIV. Can pertain to oneself or others’ risk perceptions.
- **Menstrual inevitability**: Women’s statements about the intersection between the act of menstruation and personal control/lack thereof over menses. This is sometimes described as menstruation being something that is controllable via MPT use, creating autonomy for women.
- **Menstruation will interfere with Ring Use**
  - Limiting Foreign Objects in the Vagina
  - Being Clean: How menstruation is described as making one’s body dirty or not. Can include how menstruation is an act of ‘cleaning out’ dirt/waste/toxins in the body.
- **MPT Options**: Having a choice in methods (contraceptive, or MPT); includes types and differences in hormonal methods, dosages, benefits and off-label uses.
- **Partner acceptability of an MPT ring**: What partners think or feel about an MPT ring, including partner concerns for participant or future fertility.
  - Covert Use: Captures descriptions of use that are not disclosed to a partner.
  - Infidelity: Issues raised within the partnership about trust and potential infidelity
  - Men’s health: Women’s perceptions of and impact on men’s health.
  - Sensation during sex and sexual pleasure/Sexual acceptability: How the ring may impact a sex act or pleasure etc.
- **Pregnancy**:
  - Pregnancy risk/Pregnancy Risk Perception
  - Pregnancy Intentions
  - Pregnancy prevention behavior/contraceptive use
- **PrEP in the shadows**: Contraception is described here as holding the limelight, and HIV prevention taking the backseat. Discussions of being able to use a contraceptive because it hides the fact they are using any form of PrEP. HIV drug component can be hidden or subsumed behind the contraceptive component. This can include mentions of destigmatizing HIV via contraceptive frontloading etc.
• **Side Effects/Benefits:** It is assumed that most of the side effects/benefits talked about will be hypothetical. This code will include side effects (negative connotation) and benefits (positive connotation). This is limited to how woman may feel in or about her own body.
  o **Partner:** How a partner may feel about side effects or benefits
  o **Fertility:** includes benefits/concerns about getting pregnant now or in the future

• **Timing and Duration of Use:**
  o **Monthly Ring Exchange**
  o **Longer than Monthly Duration**

• **Vaginal crowding:** Discussion of concern around having multiple items in the vagina (including rings, tampons, penis, drugs etc).

Additional Focus Group Interaction Codes:

• **Questions and Answers**
  o Between moderator and participants
  o Among Participants

• **Continuation of Topic Connections**
  o Implicit (maintains same topic without saying so)
  o Explicit (maintains same topic with an overt statement)

• **Change in Topic (explicit or implicit)**
  o Introduction of new topic-shifts the content of discussion
  o Expansion-shares new aspects of existing topic
  o Differentiation-compares different aspects of topics

• **Interpersonal Connections (always explicit?)**
  o Agreement-reinforcing another participant’s statements
  o Disagreement-disputing another participant’s statements
  o Support-sympathizing with another participant’s statements
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