Laying the Groundwork for a Strategic Evaluation Framework (SEF) for HIV Prevention and MPT Product Development

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The **Initiative for Multipurpose Prevention Technologies (IMPT)** advances the development of MPTs to address the interlinked risks of unintended pregnancy and sexually transmitted infections (STIs) including HIV, believing that the availability of desirable methods that deliver an array of prevention combinations will improve the lives of women and their families worldwide. Established in 2009, the IMPT is a collaborative network that has engaged product developers, scientific researchers, healthcare providers, funders and community-based advocates in Africa, China, India, the United States and Western Europe behind this common agenda. Leveraging the multidisciplinary expertise of this diverse network, the IMPT works to advance the science to support the development of MPTs and their successful introduction into target populations with high unmet need.

Multipurpose Prevention Technologies (MPTs) are an innovative class of products that deliver varied combinations of HIV prevention, other STI prevention, and contraception and will improve the lives of women and families worldwide.

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The status of HIV prevention for young women and adolescent girls

HIV persists as one of the greatest public health challenges of today, particularly for adolescent girls and young women (AGYW) in Sub Saharan Africa (SSA). A young woman or adolescent girl is infected with HIV every minute, making this population one of the fastest growing groups of new infections globally.[1] AGYW make up 30% of all new infections in SSA, and seroconvert five to seven years earlier and eight times more often than adolescent males in SSA.[2] Population growth projections estimate the adolescent population will double in some SSA countries by 2050.[3,4] Prevention is essential to ensure that HIV incidence does not increase in parallel with population growth.

Male and female condoms are the only prevention products currently available on the market that provide protection from acquiring HIV as well as other sexual and reproductive health (SRH) risks. However, consistent condom use rates are low among young people.[5] In addition, women face a range of other factors that can negatively impact their ability to protect themselves using condoms, such as: limited condom access, challenges with condom negotiation, gender inequality, stigma, and educational attainment.[5,6,7]

These barriers are often interlinked. For example, many young people do not have comprehensive knowledge of HIV, partly due to dropping out of school (80% of women do not complete secondary education in SSA before being taught about their sexual health), but also because there is a lack of comprehensive healthcare services for AGYW.[7,8] When services are available, AGYW are often met with stigma and restrictive policies that inhibit them from receiving services without parental consent.[5,9] The normalization of gender inequalities and gender based violence are also commonly cited and interlinked barriers for women, especially AGYW, regarding their ability to protect themselves from HIV and have been proven to increase women's risk of acquiring HIV.[5,6,10] Fear of intimate partner violence deters women from both condom negotiation and HIV testing and counseling.[5,11] Recently there has been an increase in "Sugar Babies," or young women dating older men who receive "blessings" or gifts in exchange for sex. Age disparate relationships, low condom usage, multiple concurrent partners, intimate partner violence (and fear of), lack of knowledge and lack of access to care all play a part in the high risk of burden of acquiring HIV among AGYW, particularly those in SSA.[2,10,12,13,14]

Recognizing the need for increased agency, options, and better SRH prevention for women, microbicide research began in the 1990s. Early studies such as CAPRISA 004 indicated the efficacy of the topical microbicide 1% Tenofovir vaginal gel, laying the groundwork for the VOICE and FACTS clinical trials which tested a daily use microbicide gel and a pericoital microbicide gel among young women. None of the products tested in the VOICE trial proved to be effective among the women enrolled; most participants did not use them daily as recommended.[15] For FACTS 001, "most of this population of young, unmarried women, the majority of whom still live with their parents, using the gel consistently proved to be very challenging."[16] Despite the encouraging acceptability data that exist in the microbicide context, both trials experienced adherence challenges, suggesting that acceptability as measured is not necessarily associated with adherence.[10,17,18, 19]

The FEM-PrEP study of young women in SSA also has shown that daily usage of oral pre-exposure prophylaxis (PrEP) may present adherence challenges for some women.[20] Although oral PrEP has been shown effective in couples, and rollout of oral PrEP has begun in several developed countries, distribution has been focused on men who have sex with men (MSM). The UNAIDS 2016 Prevention Gap Report suggests that PrEP combined with condom usage may be an effective method of HIV prevention for sex workers.[5] Nonetheless, only South Africa has approved the use of oral PrEP among sex workers.

The breadth of aforementioned challenges with current HIV prevention options, from accessibility and stigma to acceptability and adherence, not only support the need for continued innovation around HIV

prevention strategies, but also increased emphasis on building these products around real-world use considerations informed from end-user research.

Innovative, women-initiated HIV prevention only strategies in various stages of development include intravaginal rings (IVRs), injectables, vaginal films, and vaginal inserts. To date, the dapivirine IVR is furthest along in the development pipeline, having undergone phase I clinical trials, the Ring Study and ASPIRE trial, which demonstrated an overall reduction in HIV risk by 31% and 27% respectively amongst all participants.[15] However, women aged 18-21 experienced little to no protection in these studies, and when all participants under 21 years old were removed from the ASPIRE analysis, the efficacy rate increased to 56%.[15] These results are promising for the HIV prevention field, but they also highlight the challenge of reaching AGYW.

Intersecting SRH risks and multipurpose prevention technologies (MPTs)

As previously mentioned, there are a myriad of challenges women face that increase their risk of HIV infection. Compounding these challenges with other realities such as economic stability, HIV prevention is often not the primary concern of many women. Aside from increased HIV acquisition risk, 225 million women in developing countries have an unmet need for contraception.[21] While conception and infection share a common mode of transmission, prevention methods that simultaneously address these risks are either scarce or difficult to negotiate by potential users (i.e., male and female condoms). Sexually transmitted infection (STI) incidence continues to rise as SSA has the highest prevalence of HSV-2 (38%) as well as high rates of HPV.[22] Women need more comprehensive options that are compatible with their lifestyles. Multipurpose Prevention Technologies (MPTs) are innovative products in development that aim to address this gap. New MPTs are expected to deliver varied combinations of HIV prevention, other STI prevention, and contraception and have the unique opportunity to leverage younger women's need for contraception with HIV prevention. For example, experts theorize that MPTs with contraceptive and HIV prevention indications may increase the breadth of HIV prevention coverage given that preliminary data suggesting that AGYW in SSA are more concerned about their risk of unintended pregnancy than of HIV.[23,24,25]

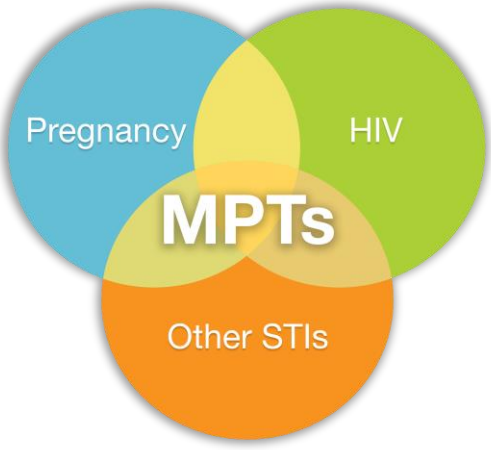

Figure 1: MPTs deliver varied combinations of HIV prevention, other STI prevention, and contraception.

The Initiative for Multipurpose Prevention Technologies (IMPT), founded in 2009, is a product neutral collaboration that advances the development of MPTs to address the interlinked risks of unintended pregnancy and STIs, including HIV. The IMPT believes that the availability of desirable methods that deliver an array of prevention combinations will improve the lives of women and their families worldwide. The IMPT develops tools and guidance to help guide field-wide scientific and investment decisions, including an online MPT pipeline database, regulatory guidance for MPT development, a global funding optimization and enhancement strategy, and a market access framework. The IMPT recognizes that addressing the needs of AGYW requires interweaving the social determinants of their lives into the technical challenges of drug development.

Building a Strategic Evaluation Framework (SEF) for HIV prevention and MPTs

In line with this work, USAID's Office of HIV/AIDS supported the IMPT to develop a Strategic Evaluation Framework (SEF) to inform design and development decisions that maximize market success and impact of products based on the framework developed by Tebbey and Rink.[26] The SEF is intended to ensure that product development programs are driven by marketplace need and incorporate market value drivers so that products have high impact. The SEF is comprised of three key components: the Target Market Profile (TMP), the Strategic Target Profile (STP), and the Target Product Profile (TPP). The foundation of the framework is the TMP, which is rooted in the assumption that proper understanding of the market place is essential for a successful product. The STP is a detailed description of the ideal product that is necessary to address the requirements defined in the TMP. The TPP builds from the STP and is the profile of the actual product to be launched per guidance from regulatory bodies.

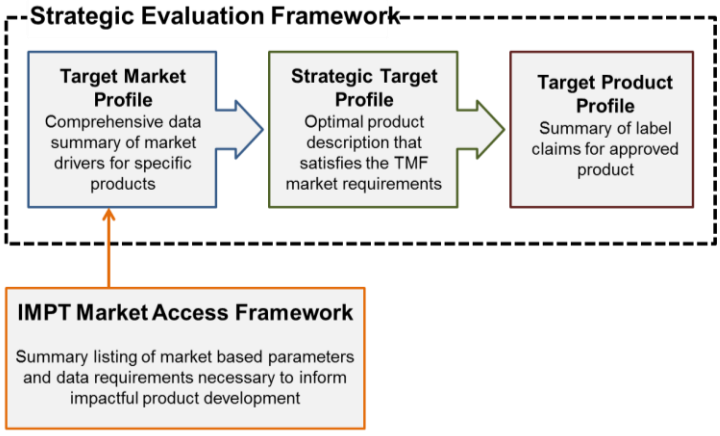

Figure 2: Components of a Strategic Evaluation Framework (SEF)

The building blocks of the SEF described in this document aim to ensure that technical activities for anti-retroviral (ARV)-based HIV prevention products, including MPTs, are aligned with the market drivers for prioritized populations in areas of high HIV burden in SSA. HIV prevention and MPT product development are complex processes, and their meaningful public health impact will require the consideration of a range of factors, from basic science and clinical trials, to market and access, advocacy, and funding; in other words, factors that will ensure that products in development are not only efficacious in clinical trials, but also desired, acceptable, and accessible to AGYW once introduced and commercially available. The SEF will not only be a tool for the MPT field, but also will highlight critical research gaps to advance the HIV prevention and MPT fields.

For the scope of this project, the key product types of interest include daily oral, on-demand (e.g. gel, film, insert), long-acting topical (e.g. IVR), and ultra-long-acting systemic (e.g. implant, injectable, IUD). While the HIV prevention and MPT fields have rapidly grown and evolved in the past decade, research and programs focused on market drivers in these fields are relatively new. Given this context, the IMPT kept a narrow geographic scope for the SEF project target population, focusing on AGYW in South Africa, Nigeria, Kenya, Uganda, and Zimbabwe. These countries were selected due to their high HIV burden as well as the presence of active microbicide and HIV prevention clinical trial sites. The IMPT aims to expand this geographic scope as market-focused research and programs continue to expand in the HIV prevention field.

Data to support the development of an SEF for HIV prevention and MPT product development were collected by conducting a literature review and key informant interview discussions (KIDs). These processes were supported and refined through iterative consultations with IMPT technical advisors and the USAID OHA Microbicide team. The literature review intended primarily to discern what is known about the target market in question and what research gaps persist. The KIDs intended to support and supplement literature review findings, analysis of these findings, define the most critical STP characteristics, and identify relevant work that is new or ongoing. More detailed methods for the literature review and KIDs may be found in Appendix A.

A total of 22 studies met the literature review inclusion criteria. From 66 stakeholders approached, 16 KIDs were conducted, comprising a total of 32 respondents (48.5% response rate). Respondents represented a range of institutional types, including microbicide and MPT product development organizations, pharmaceutical companies, clinical research organizations, academic institutions, implementer and other research organizations, and funding agencies.

Strategic Evaluation Framework (SEF)

Target Market Profile (TMP)

The target market profile (TMP) aims to provide information to understand the needs of the market and identify factors that will impact the viability of a product.[26] Ideally, the TMP portion of the SEF will not only identify the target population(s) and provide an overview of significant epidemiological data about the target population(s), but also describe what is known about the target population's perspective, preferences, and the context for their decision-making. These data may be used to guide product design, testing, and eventual introduction. The TMP outlined here is structured by the following questions: 1) Who are they [the target population]? 2) What is their context? and 3) What do they think? Data from both the review of published literature and the KIDs provided the foundation for "what do they think?" and "what is their context?" It is important to note that the TMP, and SEF as a whole, is and will constantly be evolving as more data pertaining to identified target population(s) are collected.

Who are they?

Identifying the target population(s) for an HIV prevention or MPT product is an absolutely essential first step to guide all subsequent strategies in product development and introduction. As outlined at the outset of this report, these fields have focused on reaching AGYW s, particularly in SSA, because of their HIV burden and other SRH risks. Operationalizing this broad reach by identifying specific target populations on which to anchor development and introduction strategies, however, is complex and, as suggested by several KIDs respondents, is a current challenge in the HIV prevention and MPT fields with many unknowns.

This complexity is rooted in the enormous heterogeneity of the broad population of AGYW in SSA. There is no one type of AGYW in SSA – individuals vary by geographic setting (e.g., urban/rural), social and cultural contexts, HIV acquisition risk, knowledge of HIV prevention and transmission, stigma, marital/relationship status, and age at sexual debut. Each of these factors impact the type of HIV prevention or MPT product most suitable for that individual; thus, not one HIV prevention or MPT product type will fit all women's circumstances. It will be necessary to have a myriad of HIV prevention and MPT products available, but specific strategies around particular product types will need to identify the population factors that will comprise their population of interest. Approaches to hone in on these specific population strata, including collecting stratified data in end-user focused research and conducting market segmentation, are critical.

The complexity of identifying a target population in these fields is also contextualized by the clinical product development approaches. Clinical trial populations do not necessarily represent the same profile as the population to be reached once the product is introduced in the market. While this may be theoretically problematic as product development strategies should include product testing aligned with the intended target population, the difference is sometimes intentional and necessary due to practical and/or ethical considerations (e.g., the ethics of including youth under 18 years of age in a clinical trial).[27] The differences between a recruited clinical trial population and the target population in the market, including demographic factors as well as perspectives, values, and other drivers, are important to recognize in product development and introduction strategies.

As mentioned earlier, with an aim to reach AGYW in SSA in settings with a high HIV burden, this report captures data on women of childbearing age within five countries in SSA: Kenya, Nigeria, South Africa, Uganda, and Zimbabwe. Age-stratified data were provided when possible to focus on AGYW, but these data were often not available. Below are demographic summaries relevant to the population of interest in each country that outline a range of considerations for honing in on specific population strata for a given product development strategy.

Kenya: According to the 2016 UNAIDS Prevention Gap Report, in 2015, Kenya had 1.5 million PLWH and 78,000 new infections.[5] The 2014 Kenya AIDS Response Progress Report describes the HIV/AIDS epidemic as generalized with an overall prevalence of 5.6%.[28] However the epidemic was also said to be concentrated regionally in urban counties compared to rural, as well as amongst the following key populations: MSM (18.2%), injection drug users (IDUs) (12.3%), and female sex workers (FSWs) (29.3%).[28] AGYW are three times more likely to HIV and/or experience sexual violence than their male counterparts.[14,29] Furthermore, an estimated 49,778 women over the age of 15 years old were infected with HIV in 2013.[29] Demographic and Health Survey (DHS) results showed that among AGYW, 64.9% knew of at least one formal source of condoms but only 39.6% reported being able to obtain condoms on their own.[14] Less than half (46.6%) of the AGYW surveyed demonstrated comprehensive knowledge of HIV prevention and rejection of common misconceptions relating to HIV transmission.[14]

Nigeria: Nigeria has the second largest HIV burden in the world. As of 2015, 3.5 million people in Nigeria were living with HIV.[5] Estimated incidence in 2015 was 250 thousand with people aged 15 years old and up accounting for a majority of all new infections; furthermore, national data suggests 1.3% of all AGYW are HIV positive.[30] Regional prevalence differences are thought to be contributed from social norms such as the practice of multiple, concurrent partners, female genital mutilation, and nonsterile traditional bloodletting.[31] Transmission through heterosexual intercourse accounts for 80% of new infections.[31] Modeling studies predict that 40% of future new infections will be concentrated among FSWs, MSM, and IDUs.[31] Sex workers are eight times more likely to have HIV than the general population.[5] 17% of adolescent girls begin having sex before the age of 15, 51% begin having sex before the age of 18 and 25.5% report having premarital sex within the last 12 months.[31,32]

DHS results from 2013 indicate that while 45.5% of AGYW know of a formal condom source, only 12% reported having the ability to obtain condoms on their own.[32] In addition, only a quarter (24.2%) of AGYW had comprehensive knowledge of HIV prevention and common misconceptions regarding transmission and less than half (35.3%) of adults (aged 18 years and older) were in favor of young people being educated about condom usage as HIV prevention.[32] Age disparate relationships were also reported among 17.8% of women aged 15-19 years and increased to 40.2% among 15-24 year olds.[32]

South Africa: South Africa carries the largest HIV burden globally, with women carrying a high amount of the burden. In 2015, there were 380,000 new infections, and 7 million South Africans were reported as living with HIV.[5] 2012 estimated incidence among females 15-24 years old is approximately 113,000 new infections (95% CI) and 175,000 new infections among women 25 years old and older (95%CI).[12] Prevalence varies greatly in different provinces with urban informal settlements bearing more of the burden when compared to urban formal settlements.[12] FSWs have an HIV prevalence that ranges from 40-88% depending upon the region.[33] In 2016, a reported 2,500 AGYW were reported to be infected with HIV every week.[34]

A 2012 National Behavior Survey reported that 10.7% of AGYW have had sex before the age of 15 years old and 33.7% of women aged 15-19 reported having a sex partner who was at least five years older.[14] Comprehensive knowledge of HIV prevention and transmission among AGYW was relatively low at 24.3%.[14]

Uganda: In 2015, 1.5 million people were living with HIV in Uganda with a reported 83,000 new infections.[5] Regionally, the highest prevalence of HIV is within the central region of the country and within key populations at over 34% of FSWs living with HIV.[12,35] Other populations with higher concentrations of HIV include fishing communities, uniformed services, and mobile populations.[13] Key incidence drivers include multiple sex partners, early sexual debut, inconsistent condom use, transactional sex, poverty, and alcohol consumption.[13] AGYW are estimated to account for 4.2% of PLWH and account for a majority of the country's new infections.[6] Data from the 2014 Country Progress Report show that only 35% of women between the ages of 15-24 years old depicted comprehensive knowledge of HIV prevention and common misconceptions about transmission.[13] Also, amongst sexually active AGYW 6.2% began having sex before the age of 15.[13]

Zimbabwe: In 2015, 1.4 million people were living with HIV in Zimbabwe with a reported 64,000 new infections.[5] Although the HIV epidemic in Zimbabwe is considered generalized, 11 districts were identified as being "hot spots" with higher rates of HIV than the national average.[36] These districts include border districts, small scale mining areas, fishing camps, and commercial farming settlements.[36] Similarly to the preceding countries of interest, prevalence is high among FSWs (~%50) and incidence among young women is increasing.[6] The 2014 Zimbabwe Global AIDS Response Progress Report indicated that 51% of AGYW have had sex before the age of 15 and 56% of AGYW have comprehensive knowledge of HIV prevention and transmission.[36]

What is their context?
To further understand the complex realities that contextualize the lives and health behaviors of AGYW in settings with a high HIV burden, it is useful to organize thinking around a theoretical framework such as the Socioecological Model. This model is used to understand how different levels of influence (i.e., individual, interpersonal, community, organizational, and policy) intersect and impact their behavior and health outcomes. The individual level refers to intrapersonal factors such as one's personal beliefs. For example, a common finding from the review of literature is that women are concerned about how their fertility may be affected by prevention products.[23,37] This individual factor is in turn reinforced from both interpersonal relationships and community norms that value fertility and expect for women to have multiple children.[23,38] At the policy level, criminalization of sex work and mandatory permission of a woman's guardian or husband impacts her ability to seek SRH services on her own.[5,6,39] Factors that determine these women's SRH behaviors may also vary in urban versus rural settings; for example, certain community norms may be heightened in rural settings when compared with urban areas. Additional factors and further detail that fit into this model for AGYW in SSA are outlined in the first section of this report.

After identifying a target population, a comprehensive understanding of their context must inform product development strategies that will foster product acceptability and adherence during clinical trials and access and uptake after product introduction. A socioecological perspective provides this necessary context, as Woodsong and Holt state, "development of acceptable vaginal products for prevention of HIV, STIs, or pregnancy will require consideration of a range of social and behavioral issues since product use requires enactment of preventive health behaviors within social (e.g. sexual) relationships, influenced by social and cultural norms".[19] Moreover, this context grounds data on target population perspectives necessary for decision-making around product features, access, and use, suggesting "why" they think what they think.

What do they think?
Having identified a target population and assessed their socioecological context, an understanding of the target population's perspective as related to the HIV prevention and MPT product context is central to a product development strategy.

For women in the identified HIV burdened countries in SSA, literature around their perspectives are based on data collected in clinical trial settings, particularly during or following later stage trials, and thus may not fully reflect the perspectives of the intended target population. The majority of end-user research available for the HIV prevention and MPT fields center around product feature preference and acceptability, generated primarily through behavioral and social sciences research approaches, with little work on value drivers to product uptake and other market factors such as demand forecasting, represented by one market research study.[1]

Literature findings on the perspectives of the population of interest largely fell into two major categories: (1) preference and acceptability around product features, and (2) the impact of interpersonal relationships on product preference and acceptability. Although a majority of the relevant literature review data originated from studies based in South Africa, there were several key themes that appeared through all five countries regarding product feature preference and acceptability and relevant facilitators. A comprehensive summary of all literature review is in Appendix B.

Preference and acceptability around product features
Most data from the literature review focused on preference and acceptability around product features, including efficacy, being female-initiated, dual-protection, and side effects. Notably, while preference is different from acceptability, these terms were often used interchangeably in the literature.

Efficacy, whether proven, perceived, or described as having potential, was a commonly cited reason indicated by participants as to why they would use a particular product.[40,41,42,43,44,45] Most notably, in the Nel et al (2012) clinical trial of safety, acceptability, and pharmacokinetic assessment of a monthly dapivirine ring, 92% of participants had perfect adherence and by week 12, 97% indicated that they would use the dapivirine IVR if it was proven to be an effective form of prevention. Of the seven articles mentioning efficacy potential as an important feature in shaping women's behavior, three referred to an IVR, three referred to a microbicide vaginal gel, and one article referenced using both a diaphragm and gel. These findings were also strongly supported by KID respondents.

Five articles included the feature of being "female-initiated" as a facilitator towards their acceptability of a product.[23,40,41,38,46] Each of these articles derived their findings from key informant interviews and focus group discussions regarding interests, acceptability, and behaviors towards potential women's SRH products.

Three articles specifically mentioned participant interests in a HIV prevention product that also served as a contraceptive.[23,47,48] Terris-Prestholt et al found that women who have difficulty getting their partners to wear a condom were more likely to express interest in different, new prevention methods (2013). In addition, Woodsong et al reported that 70% (n=141) of respondents indicated an interest in an MPT (2014). Furthermore, 78% of male partners (n=28) had favorable impressions of MPTs. These findings were also supported by KIDs respondents who felt that this multi-indication factor was important to provide women with more options.

Side effects, whether proven, perceived, or potential, were most commonly cited as barriers that can

[1] Health behavioral and social sciences research and market research are distinct but complementary methodologies that may answer different questions but may be employed to achieve a common aim. Health behavioral and social sciences research as defined by the National Institutes of Health "have a major and explicit focus on the understanding of behavioral or social processes, or on the use of these processes to predict or influence health outcomes or health risk factors." Healthcare market research as defined by the Centers for Disease Control and Prevention is "research designed to enhance your understanding of the target [market]'s characteristics, attitudes, beliefs, values, behaviors, determinants, benefits and barriers to behavior change in order to create a [product or program] strategy." Market research may be distinguished from behavioral and social sciences research as it generally is oriented towards a health product or program investment case.

impact acceptability and adherence to different formulations of potential prevention products.[20,23,47,49] Of the four studies specifically mentioning side effects as a potential barrier to acceptability and adherence two studies were looking at oral PrEP, one study focused on a long acting injectable, and one study was about a microbicide vaginal gel. These findings were underscored by the majority of KID respondents.

The following other topics were mentioned in the articles included in our scan of the literature as being a facilitator to women's acceptance and adherence to an HIV prevention and/or MPT product: ease of use/comfort[23,41,50,51]; ability to use product discreetly[7,23,38,52]; long lasting/reduced clinic visits[25,38]; size [of ring/insert][51]; and support of study counselor[44]. Other potential characteristics of future MPT formulations that were found to be barriers to women's acceptance and adherence to a product included texture [of ring/insert][38,46,52], leakage[40,46], and hygiene concerns.[38,46,53] Lastly, two articles cited women's concerns for long term effects on fertility regarding prevention products.[23,38] KIDs respondents linked such considerations of potential product characteristics to the importance of methods that integrate end-user feedback early on in the product development process.

Impact of external factors on product preference and acceptability
Partner support and approval was frequently associated with increased acceptability of a SRH preventive product.[40-5,54] For example, as part of a longitudinal cohort study nested within a larger clinical trial, researchers found that the attitudes and actions of male partners impacted women's decisions to use female initiated products.[54] Furthermore, survey results indicated that women who were supported by their male partners (marital status unspecified) were more likely to rank vaginal gels as "strongly like" on a likert scale as well as to be consistent users of the product (AOR 1.80; 95% CI: 1.16-2.80; p<0.01).[54] In another study, women were given a placebo silicone elastomer ring for 12 weeks and asked to complete a product acceptability questionnaire every four weeks. 86% of respondents indicated that their partner's approval of the ring was important.[45]

TMP research gaps
In order for a product development program to effectively identify its target population, the target population's context, and the target population's perspective, additional data and data collection strategies are needed to build upon and complement ongoing end-user research.

Regarding specific data, while the available literature does provide common themes that were supported by the KIDs regarding the target market for HIV prevention and MPT products, there are still many critical unknowns. For example, within the aforementioned key themes, data were not stratified by participant age, setting (e.g. urban vs rural), reported relationship status, or level of education, posing a challenge to market segmentation and strategizing around the unique needs of AGYW of varying circumstances. Also, current measures for preference, acceptability, and adherence need to be further distinguished, defined, and analyzed. Standardization and precision around these measures will better enable effective product development and introduction strategies. Furthermore, no clear potential market and value drivers were ascertained from the available literature, factors that are critically tied to the contextualization and understanding of the target population's health behavior.

In terms of data collection strategies, the majority of end-user focused research are behavioral and social science studies conducted concurrently with clinical trials. This research should be conducted earlier in the product development process, beyond the typical pre- and post-trial acceptability questionnaires, as well as outside the clinical trial setting in general. Moreover, to date there has been only one published market research study focusing on end user preferences for MPTs, with none specifically on HIV prevention products.[25] Additional market research studies are needed and may complement existing and future behavioral and social science research by answering questions related to target population context, value drivers, and decision-making.

Relevant new and ongoing projects

Despite these substantial gaps in the TMP as built by the peer reviewed literature, it is critical to note that the HIV prevention and MPT fields have begun to shift the paradigm of product development to be inclusive of more holistic research approaches, including market research and a greater focus on end-users' perspectives earlier on in the development process. There are numerous projects and studies currently underway and recently launched that intend to address many of the aforementioned gaps with a common objective of creating efficacious products that women want and are able to use. While most of these projects have not yet published findings, information gleaned from KID respondents as well as recent grey literature indicate that many are taking important steps to strengthen what is known about this critical target market for SRH prevention. A few select examples of these projects are listed below (Table 1).

Relevant ongoing market access projects for HIV prevention and MPT development	
Project/study	**Objectives and activities**
TRIO[55]	RTI International leads the TRIO study (Tablets, Rings, and Injectables as Options for women) in South Africa and Kenya, which explores the preference and acceptability of three possible MPT product types.
Quatro[56]	CONRAD leads the Quatro study in partnership with RTI International, MatCH Research in South Africa, and the University of Zimbabwe-USCF Collaborative Research Program. This study will assess the acceptability, preferences, user experience, and effect on sexual behavior of four different MPT delivery forms (vaginal insert, intravaginal ring, film, and gel).
UChoose[57]	The Desmond Tutu HIV Centre in South Africa leads the UChoose study to compare the acceptability and preference among 16 and 17 year old girls for a monthly vaginal ring, bi-monthly injectable contraception or daily oral contraception as proxies for female-controlled ARV-based HIV prevention methods.
OPTIONS[58]	The OPTIONS (Optimizing Prevention Technology Introduction on Schedule) consortium led by Wits Reproductive Health Institute, AVAC, and FHI 360, aims to provide targeted support to expedite and sustain access to ARV-based HIV prevention products in countries and among populations where most needed, including South Africa, Kenya, and Zimbabwe. This includes developing evidence-based business cases, coordinated investment strategies, market introduction strategies, and providing technical assistance to healthcare systems. Partners include Avenir Health, FSG, LCVT Health, LSHTM, McCann Health, and Pangaea.
EMOTION[59]	EMOTION (Enhancing Microbicide Uptake in High-Risk End Users), led by CONRAD, is a project that aims to increase uptake and enhance correct and consistent use of ARV-based HIV prevention products by women at high risk of HIV infection in Kenya, South Africa, and Zimbabwe using a human centered design strategy. Other partners include FHI 360, Lancet Laboratories, UCL, SCHARP, Instant Grass, Abt Associates, Matchboxology, CAPRISA, and IDEO.
POWER[59]	POWER (Prevention Options for Women Evaluation Research), led by University of Washington, develops cost-effective and scalable models for implementation of ARV-based HIV prevention products for women in Kenya and South Africa. Specific activities include conducting research among women and healthcare

	providers, examining facilitators and barriers to microbicide and PrEP uptake, and assessing delivery strategies. Key partners include Desmond Tutu HIV Foundation, KEMRI, Wits Reproductive Health and HIV Institute, Carnegie Mellon University, Massachusetts General Hospital, and RTI International.
Market Manager[60]	The Market Manager project, led by AVAC, aims to ensure the development and efficient use of HIV prevention interventions to maximize reduction of new infections through a comprehensive HIV prevention market landscaping, strategic planning, and provision of guidance and resources to support advancements in the field.

Table 1: New and ongoing market access projects for HIV prevention and MPT product development

The IMPT will continue to monitor the progress of these projects and will update the TMP as data are published.

Strategic Target Profile (STP)
A Strategic Target Profile (STP) is intended to guide a product development program and relevant partners to develop products with maximum uptake and public health impact in a real world setting by setting optimal and minimal targets for specific market-based attributes. It complements a Target Product Profile (TPP), which outlines targets for a product's clinical and technical attributes, such as efficacy, contraindications, toxicology, etc. Like a TPP, an STP can be generalized to a given product category, which may subsequently serve as the foundation for a more detailed, product-specific STP. In the context of this project, product categories for HIV prevention and MPT products include daily oral; on-demand, intermediate acting; long-acting topical; and ultra long-acting systemic.

Ten STP characteristics on which to anchor optimal and minimal targets were identified through the KIDs process and through separate consultations with USAID (Table 2).

STP characteristics for HIV prevention and MPT product development and introduction	
Characteristic	**Justification and other considerations**
Health impact	Demonstration of potential health impact through modeling efforts plays a central role in the determination of cost effectiveness and justification of scale-up. Health impact is determined by factors related to both efficacy (whose targets are listed in a TPP) and effectiveness; i.e., maximum therapeutic or preventive effect coupled with correct and consistent use in a real-world setting among those at highest risk. While the body of literature for HIV prevention and MPT product health impact modeling is relatively limited when compared to other prevention fields, many new modeling projects are underway or have recently been initiated.[61]
Market segmentation	Having outlined the target market broadly in a TPP (e.g., HIV-negative women of reproductive age), market segmentation breaks down this target market into smaller groups to which product development and introduction strategies are tailored. Market segmentation will be a critical approach for HIV prevention and MPT development, as women's product preferences and use may vary depending on their age, geography, culture, marital status, etc. Again, a range of HIV prevention and MPT products will need to be available to meet these diverse needs. Market segmentation data in the context of HIV prevention and MPT products are limited, but KID respondents resoundingly agreed that market

	segmentation is highly informative and relevant to product development: "[Market segmentation is] very much needed to understand what women want and how products may fit into their lives" (clinical research organization representative). The extent to which market segmentation may be measured and evaluated in an STP context needs to be better understood given the wide range of possible strategy differences that may result from the process. One approach could be outlining the identified market segments as an STP appendix, and honing in on one segment and one product for a given STP.
Value proposition	A value proposition is the case made to potential end-users regarding the benefits they can expect to reap from a product and thus why a particular product may be desirable. It includes the importance of the public health risk addressed by the product, the spectrum of potential benefits of using the product (e.g., health, social, etc.), and the extent to which the product is unique and/or advantageous to other products. Critically, the value proposition exists within the real world context of end-users who negotiate competing critical priorities outside of a given health risk on a daily basis, and this context must be understood and incorporated into product development strategies. The arena of health prevention is particularly challenging, as it requires appealing to otherwise healthy end-users. Several KID respondents illustrated this complexity. One product developer explained, "It's even harder as we need to create some value for women who have hard lives and are not sick and get them to appreciate and value the product that prevents infection." A clinical research organization representative adds, "What do women value in life? Women in our HIV clinics - it's not their priority, a meal on the table for that night is and if they have to sleep with the guy next door without a condom to get the meal they will and HIV is far down the line in priorities." No literature yet exists to explicitly identify this value.
Tolerated toxicity/ side effects	As noted in the TMP, available literature on adherence, acceptability, and market research in the HIV prevention domain present a clear, resounding message that product toxicity and side effects must be minimized. Related to safety and toxicology attributes in a TPP, the threshold for side effect tolerance from the perspective of the end user is not well understood. While data are still limited, side effects could be one of the more important barriers to product uptake for HIV prevention products and MPTs. KID respondents agree; a research and product development organization representative underscored, "Side effects are huge, for prevention product they have to be very small. For treatment they will tolerate side effects but not prevention. We need benefits, one has to find the added value. It's like toothpaste [with] no cavities. Find the social value of the prevention products." For HIV in particular, a clinical researcher noted, "Side effects are big with [ARVs], people will stop using it. If you're not sick and have side effects, then what's the benefit? What's the threshold?"
Preferred dosing form features	Data on end-user preferences for product dosing form features, such as shape, color, and size, must be collected and integrated into the product development process in tandem with TPP dosage form and product description targets.
Acceptability	Product acceptability is an important contributor to achieving maximum public

	health impact, but as mentioned in the TMP, the causal pathway from product acceptability to uptake and impact is complex and supported by mixed evidence. An advocacy organization representative asserts, "It's not a simple question [such as:] 'it's acceptable, it's done.'" A product and its range of features, benefits, and side effects may be theoretically acceptable to an end-user, but other factors may act as a barrier to successful product uptake. Moreover, product acceptability is difficult to establish and understand using current methodologies in product development and clinical trial contexts; the same respondent noted: "Clinical trials establish the efficacy but acceptability is difficult to do as you are still talking about experimental products." This assessment is further complicated by the possible acceptability differences in clinical trial and real world contexts.
Uptake and adherence	Product uptake and adherence are critical to achieving maximum public health impact, but pose a substantial challenge in HIV prevention, most recently in microbicide gel and ring trials. As with acceptability, adherence and uptake are difficult to establish and understand, particularly across diverse populations: "Adherence is a major issue as behavior is so different all over the world" (clinical research organization representative). Robust biological and psychometric measures of adherence to establish more objective and accurate adherence rates for HIV prevention products and MPTs in development have not been uniformly established and are themselves still under development. Additionally, the relationship between adherence in a clinical trial setting versus a real world setting is not fully understood.
Costs	Product cost tends to be a dominant factor in go/no-go decision making throughout the product development process, and it is a particularly necessary context in the public sector: "Price is really important and needs to be included in any TPP and we need targets for price as the donor markets are incredibly price sensitive and a very small change in price can adversely affect the market or help the marked when the price is reduced even by 50 cents" (product developer). However, given the range and complexity of cost determinants across the product development timeline, there is some debate over the utility and/or feasibility of emphasizing the importance of cost in the beginning of development, which may be seen as limiting. In the context of limited profit-making potential, the most useful metric for global health innovation and product development is cost effectiveness, a ratio of cost to health benefit that may be calculated in a variety of ways and aims to ensure that the highest risk population is reached. The literature on cost effectiveness for HIV prevention interventions is vast, and most calculate the cost as the initial investment and recurring costs associated with a prevention intervention program or product development program per disability-adjusted life year (DALY) or HIV infections averted. There is a range of accepted thresholds for cost-effectiveness, each with its own limitations, but the WHO-Choosing Interventions that are Cost Effective (CHOICE) threshold is perhaps the most commonly implemented, calculated as the annual per capita GDP per DALY averted.[62] In lower resource settings, cost effective HIV prevention interventions have historically ranged between 5 USD to 18 USD per DALY gained, but cost effectiveness data for HIV prevention and MPT products in development are limited.[63] KID product developer respondents noted the concept of an "affordable" product as desired by both

	donors and target markets is challenging to unpack: "What does affordable mean? We looked at direct costs for insert and removal and then [cost effectiveness] is also about how long do people use it in the field. Lots of factors count and not just [the] commodity."
Accessibility (at all access points)	Product accessibility after its introduction in the market is a complex issue, particularly for multi-indication product that could involve navigating autonomously operating types of health care settings such as family planning and HIV. Given the target market in question within a context of at-capacity health care systems, accessibility should be a consideration: "You need to think about how do you do a design when there are limited access points. What would make it easy for the provider to add the product to their portfolio? What is it in the packaging that would make it easier for the provider to offer the products? In a poor health system it's very important" (product developer). For HIV prevention and MPT products, more work needs to be done to understand what optimal accessibility would look like for products and how product introduction might impact the existing health care system. The socioecological context of the target population is critical to examine here, as factors such as stigma may impact product accessibility.
Community and market engagement	While not strictly a product attribute, engaging the target market and surrounding community, including men and healthcare providers, during the product development process will not only generate demand for the product but will help to facilitate product access and uptake when introduced: "Get the doctors and [lay people] involved and make them aware, as new products are rejected even by healthcare workers. Create excitement about it; make a big deal. Marketing is still a very big thing and the way the message is delivered is a very big thing. All this needs to be done early on. We need their buy in" (clinical research organization). Thus, the extent to which a product development program works to create a market for their product in collaboration with other stakeholders early on in the product development process is an attribute that should be measured and evaluated.

Table 2: Identified STP characteristics and their justifications and other considerations.

Having identified the most salient STP characteristics for HIV prevention and MPT products under current and future development, the next steps to complete an STP would be to establish optimal and minimal targets for each characteristic. Some of these targets may be estimated using existing guidelines as applied to other interventions, such as cost. However, all of these targets should be refined and validating using robust data for each product type. A template STP is included in Appendix C.

STP research gaps
As noted above in the TMP, it is not possible to complete STPs for all HIV prevention and MPT product types with the data currently available, but numerous projects and studies are underway that may generate data to fill these gaps. Data related to market segmentation, value proposition, cost, accessibility, and community and market engagement are perhaps the most prominent gaps, as current clinical trial methods and research strategies are not designed to fully capture these elements. However, data systematically collected on tolerated toxicity/side effects, preferred dosing form features, acceptability, and uptake and adherence still need to be better understood in the contexts outlined above. Moreover, additional product neutral assessments of these characteristics, particularly for specific target population strata, are needed to minimize bias towards a proprietary feature or

product type and to better ensure that a range of products are in development to meet the diverse needs of the broader population in question.

It is worth reiterating that the current clinically-driven paradigm for HIV prevention and MPT product development do not generate the data necessary to holistically establish targets for the outlined STP characteristics, let alone enable product development programs to meet any future targets established. While the paradigm is shifting in noteworthy ways to capture innovative social behavioral and market research methodologies, it may not be reasonable to expect all data gaps to be generated by developers and clinical trialists in the traditional paradigm. Other stakeholders, such as social scientists, market researchers, and implementers focused on product introduction can collaborate with developers and clinical trialists to work towards a common objective of developing and introducing a product with maximum public health impact (Figure 3). Funders, product developers, and other partner implementers will need to work together to ensure that support and guidance are sufficient to meet STP targets.

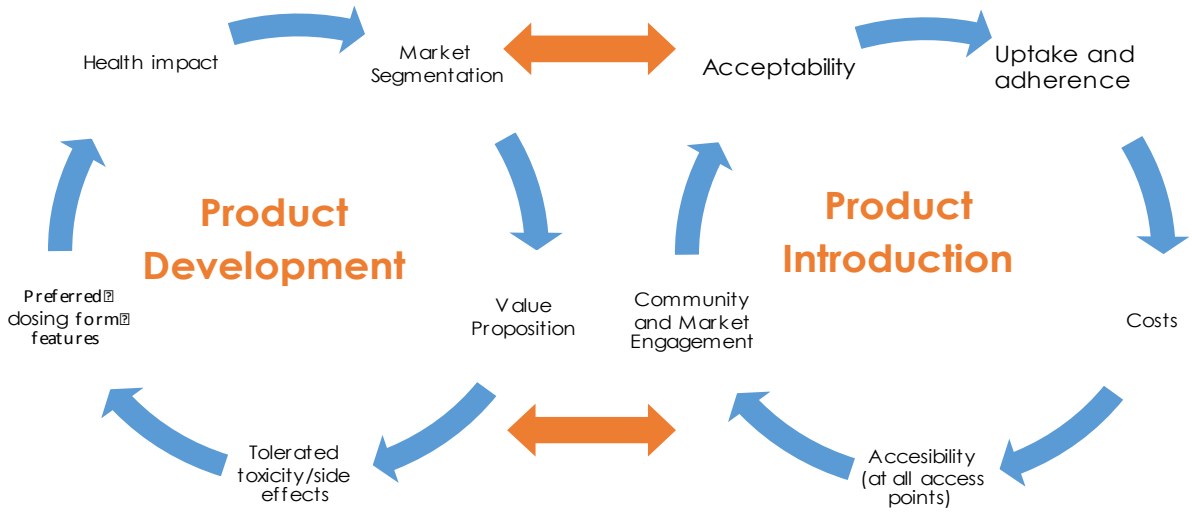

Figure 3: Strategic Target Profile (STP) implementation context

Target Product Profile (TPP)

As a complement to the STP, a Target Product Profile (TPP) outlines the intended clinical and technical product attributes for a product in development. A TPP is structured as a product label or insert associated with a regulatory licensed commercial product and provides information on the product's indications, dosage, mechanism of action, target populations, efficacy, storage/shelf life, preclinical and clinical safety, pharmacokinetics, contraindications, and relevant data pertaining to each of these attributes. The IMPT has developed a technical brief outlining the purpose and functionality of a generalized TPP for a given MPT dosage form.[62]

The IMPT has developed generalized TPPs on intravaginal ring (long-acting topical) and long-acting injectable (ultra long-acting systemic) MPTs containing an ARV and hormonal contraceptive that may be modified to single indication products (e.g., HIV only).[64] Generalized TPPs for daily oral or on-demand, intermediate acting MPT products such as gels, films, and inserts have not yet been developed due to the complexities of multiple indications for these dosage forms. It has been determined that these TPPs will have to be product specific, as there could be potential challenges with intermittent ARV and hormonal contraceptive exposure, clinical evaluation of adherence of these types

of products to date, the potential need to consider non-hormonal contraceptive options in an on-demand MPT, and a wide range of possible STI targets. However, it is possible that the existing intravaginal ring and long-acting injectable TPPs could be used as a template to be tailored to a product specific daily oral or on-demand TPP.

Notably, while the KID process focused on identifying and justifying priority STP attributes, the standard TPP attributes of efficacy and cold chain requirements were also underscored as important to understand from a market context. Product efficacy, as shown in the TMP outline above, has been cited consistently in the literature as central to end-users' desire to use the product in the context of HIV prevention. However, efficacy may be challenging to determine in the context of the current clinical trial paradigm. For example, a KID respondent based in a research and product development organization asserted, "Having a good sense of efficacy is a problem as phase 3 trials are not giving us a good sense of the true product efficacy." In terms of cold-chain requirements, all KID respondents agreed that an HIV prevention or MPT product would ideally not have them: "Cold chain is a definite no-no. If we don't need to have it then don't do it" (clinical trial organization). Given the lower resource context of target market, cold-chain requirements at any step along the supply chain may be problematic.

Next Steps

This is a pivotal moment in the HIV prevention and MPT fields, as they are well-positioned for a shift in the clinical research paradigm that will generate data necessary to build a complete STP, and most importantly, support the development of products with the highest potential for public health impact. Critical research gaps remain on the pathway to identifying the target market(s), their context, and their perspectives in a TMP, and setting optimal and minimal product targets for market-based characteristics in an STP. More specifically, these gaps include work around 1) enhancing the current clinical research methodologies to better unpack and operationalize acceptability and adherence data, to more actively engage the end-user and their intrapersonal relationships at the community level and amongst their male partners, and to initiate end-user engagement earlier in the development process, and 2) integrating market research methodologies into both the product development and introduction landscape to better understand market value drivers, actively link to development with market introduction considerations, and strategize around market segmentation (particularly based on age). However, there is commitment and momentum from product developers, funders, and research organizations alike to increase the focus on and investment in end-user centered research, which is evident from the numerous ongoing and recently initiated projects that are working to fill some of the most urgent research gaps identified by this report.

Optimally, product developers, funders, market researchers, implementation scientists, and other stakeholders would work together from the very beginning of the product development process to ensure that market and market introduction contexts are considered from the design phase. While this is not currently the standard, the ongoing projects mentioned are testing and establishing the critical partnerships and methodologies that will set a critical foundation for future work.

A completed SEF will be a useful tool for funding agencies to work with their product developer and other implementing partner grantees to help fill identified research gaps and break from the limitations of the current clinical research paradigm. Once targets are set through the SEF, however, funding agencies will need to work with their partners to ensure that they have the necessary support and guidance to plan and implement effective strategies to meet those targets. An important starting point will be to recognize that many tools and frameworks already exist to provide guidance around market research and market introduction (see Appendix D: Resource List). Perhaps the most impactful approach, however, will be to continue to build and strengthen multi-sectorial partnerships that leverage the right kinds of expertise in concert with the product development and introduction timeline.

The IMPT will continue to build upon the findings and analyses outlined in this report with the goal of developing a full SEF as the HIV prevention and MPT fields evolve and data are generated around the gaps identified. The lack of available published market research data was a serious limitation, and it will be important for relevant projects to publish their data so that the entire field may benefit. Future iterations of this work may consider exploring ways in which data collected from decades of family planning end-user research may address or inform these gaps. While the scope of the review of the literature was focused to five countries and a majority of the relevant articles found focused on South Africa or Zimbabwe, KID respondents indicated that this is true globally. The IMPT will also pursue the active expansion of its network to facilitate the formation of new and strengthened partnerships with market experts, both to support the progress of this project as well as the HIV prevention and MPT fields.

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Appendix A - Project Methods

Literature Review

A comprehensive peer-reviewed literature review was conducted between January and April 2016 using the following online databases: PubMed, Academic Search Premier, CINAHL, and Google Scholar. Key search term themes included: HIV prevention/ HIV prevention product/ sexual and reproductive health; acceptability/ preference; market study/research; demand forecast; uptake; and adherence/compliance. Article inclusion criteria were: published from 2001-present; data collected in Kenya, Nigeria, South Africa, Uganda, and Zimbabwe; included female study participants of childbearing age (15-45 years old).

Additionally, the citation lists of selected articles were screened for additional relevant articles as well as the citation lists of relevant unpublished and grey literature. Articles were also obtained through the KIDs process as recommended references.

Key Informant Discussions (KIDs)

Key informant discussion (KID) respondents were identified within the international, multidisciplinary network of stakeholders that comprise the IMPT as well as through specific stakeholder recommendations by network members. Respondents were selected for their knowledge of and experience with end-users and markets for HIV prevention, contraceptive, and MPT products and in sum were intended to represent a broad range of perspectives from diverse institutions.

The KIDs were conducted from March to May 2016 using qualitative methods (see Appendix E: Discussion Guide) in both individual and group settings (i.e., a group of respondents from the same project/organization were brought together in discussion in the same session). Responses were transcribed verbatim and coded for key themes in the context of this project's objectives. Topics unsupported by at least three discussions were excluded from the analysis.

Appendix B – Literature Review Data Table

Author / Year	Country	STP Category / Product Type	Study Design / Sample Size	Key Findings	Facilitators / Barriers
Eisingerich et al. / 2012	Botswana, India, Kenya, Peru, South Africa, Ukraine, Uganda	Daily Oral / TDF/FTC	Quantitative analysis N = 1,790	61% of participants indicated "yes, definitely" and 30% answered "yes, probably" when asked if they were willing to use PrEP. When asked about willingness to use PrEP under certain circumstances (i.e. in the presence of side effects, in combination with condom use, if they had to pay for PreP or if they had to be regularly tested for HIV while taking PrEP). Kenyan FSWs were least likely to say yes.	Facilitators n/a Barriers • Potential side effects
Corneli et al. / 2015	Kenya, South Africa	Daily Oral / TDF/FTC	Mixed Methods (participants selected FEM-PrEP clinical trial) N = 312	Over 1/3 of women who were interviewed (n=31) reported that discouragement from their social networks led to their nonadherence and over half (n=72) said that they believed discouragement from within other participant's social spheres is what influenced their nonadherence as well. Of the women who completed the ACASI questionnaire common reasons for nonadherence included: daily regimen of pill taking (54%); the context of the trial (i.e taking an investigational drug) (47%); forgetfulness (29%); fear of side effects (26%).	Facilitators n/a Barriers • Lack of social support • Perceived side effects • Perceived sense of efficacy • Daily regimen • Large pill size
Ware et al. / 2012	Uganda	Daily Oral / TDF/FTC	Qualitative (nested within Phase 3 Partners PrEP study) N = 60		Facilitators • Partner support Barriers n/a
Smith et al. / 2008	Kenya	Long-acting topical / IVR	Qualitative N = 40	Overall, respondents had positive feedback about the ideal of a microbicidal IVR. Both female and men participants seemed to prefer the idea of an IVR over a vaginal cream or gel. The ability for the an IVR to be inserted "covertly" without partners' knowledge was both popular and	Facilitators • Potential efficacy • Long lasting Barriers • Concerns about size and texture • Concerns about hygiene

				unpopular as women liked the idea more so but were afraid that if their client find out it would affect them getting paid and men felt they had a right to know whether or not a woman had an IVR.	• Concerns about fertility • Concerns about an IVR affecting client's pleasure
van Der Straten et al. / 2012	South Africa, Tanzania	Long-acting topical / IVR	Randomized crossover design; mixed methods N = 157	Women expressed great interest and acceptability if an IVR was to become available that could prevent HIV and/or other STIs. Majority (86%) of women said partner approval was important yet over half (59%) also indicated that it was important for an IVR to be used without partner awareness. (Acceptability was assessed based on (1) willingness to use and (2) liking continuous use of the ring).	Facilitators • Potential efficacy • Continuous/ long lasting usage • Partner approval Barriers • Partner disapproval • Fear of expulsion/detection during sex
Montgomery et al, / 2012	South Africa, Tanzania	Long-acting topical / IVR	Randomized crossover design; mixed methods N = 157	High adherence (self-reported) in both study groups (n=147; 93%), 120 (82%) reported no VR removals. Bivarate analysis found that women who indicated that they had no concerns about ring expulsion, women who never experienced emotional problems with the ring and those who had unprotected sex during the duration of the study were significantly associated (p<.05) with high adherence	Facilitators • Ease of use Barriers • Lack of partner support
Nel et al. / 2012	South Africa, Malawi, Kenya, Tanzania	Long-acting topical / IVR	Randomized Clinical Trial; Quantitative N = 265	92% of women had perfect adherence. By week 12, 97% of women reported that the ring was comfortable and that they would be willing to use it if the product was found to be an effective form of prevention.	Facilitators • Efficacy • Comfort Barriers n/a
van der Straten et al. / 2005	Zimbabwe	On-demand, intermediate acting / Diaphragm	N = 186	Diaphragms were well received among women who were at risk of HIV and other STIs and consistent use was significantly associated with women who reported never using condoms	Facilitators • Discreet use Barriers n/a
Montgomery et al. / 2010	South Africa and Zimbabwe	On-demand, intermediate acting / Diaphragm + Vaginal Gel	Randomized control trial; Quantitative N = 5045	71.7% (n=1,583) and 51.9% (n=1138) of the female participants expressed that they "strongly liked" the diaphragm and gel respectively. At the time of the exit survey, 96.6% (n=2,263) expressed that they would	Facilitators • Positive perception of partner's reaction • Comfortability Barriers

				recommend the combination to a friend if it was proven effective. Women who reported that their partners had favorable reactions were more likely to consistently use the diaphragm and gel (AOR 1.59, 95% CI: 1.19-2.13).	n/a
Montgomery et al. / 2011	Zimbabwe	On-demand, intermediate acting / Diaphragm + Vaginal Gel	Longitudinal cohort study nested within a randomized clinical trial (MIRA) N = 995	Attitudes and actions of male partners, both perceived and actual, impact women's decisions to use "female-initiated" products such as the diaphragm and vaginal gels. Women who had disclosed and received support from their male partners about being in the study were more likely to indicate both that they "strongly liked" the gel and be consistent users (AOR 1.80, 95% CI: 1.16-2.80, p< 0.01).	Facilitators • Partner support • Partner involvement in decision making Barriers • Lack of partner support
Sahin-Hodoglugil et al. / 2011	South Africa and Zimbabwe	On-demand, intermediate acting / Diaphragm + Vaginal Gel	Secondary mixed methods analysis N = 146	Attributes of the product, the relationship between the participant and her partner as well as sexual intercourse all impacted participants responses about acceptability.	Facilitators • Convenience • Ease of use • Ability to wash • Partner support • Perception of durability • Dual protection Barriers • Timing of insertion • Excessive vaginal wetness
van der Straten et al. / 2008	Zimbabwe	On-demand, intermediate acting / Diaphragm + Vaginal Gel	Partially blinded, randomized trial N = 117	Using multivariate logistic regression, age (AOR = 1.08, 95% CI: 1.01-1.16), consistent condom usage (AOR = 3.85, 95% CI: 1.54-9.63, and having a partner who supported product usage (AOR = 2.66, 95% CI: 1.1-6.39) were independently associated with consistent product use. While participant feedback indicated high acceptability, it was not independently associated with consistent product usage.	Facilitators • Potential efficacy • Partner support Barriers n/a
Terris-Prestholt et al. / 2013	South Africa	On-demand, intermediate acting / Diaphragm, female condom	Quantitative N = 1017	Effectiveness of HIV prevention was the most important characteristic of a new prevention method based on participants' responses. Nearly half (48%) of respondents chose microbicides as their preferred potential method of HIV prevention and	Facilitators • Potential efficacy • Contraceptive component Barriers • Perceived [lack of] efficacy

				90% of respondents expressed interest in trying a microbicide. Women who have had difficulty getting their partners to use a condom were more interested in the new prevention methods than women who do use condoms.	
Woodsong et al. / 2014	Malawi and Zimbabwe	On-demand, intermediate acting / Vaginal gel	Mixed Methods nested within HPTN and Duet microbicide gel trials N = 81	Overall, results indicate acceptability of a vaginal microbicide that would protect against HIV as well as unintended pregnancy. 70% (n=141) of respondents from the HPTN 035A trial indicated interest in MPTs. 64% of women (n=58), 70% male partners (n=28), 76% (n=28) of health professionals, and 79% (n=27) of community stakeholders from the HPTN 035A trial had favorable impressions of MPTs. Among Duet male partners, 28 of 30 male partners indicated support of MPTs.	Facilitators • Ease of use • Dual protection • Alternative method • Woman initiated Barriers • Concerns of potential long term effects • Fertility concerns
Bentely et al. / 2004	Malawi, Zimbabwe, India, and Thailand	On-demand, intermediate acting / Vaginal gel	Mixed Methods nested within BufferGel study N = 98	Majority of women from the African field sites (Malawi n= 20 (92%) and Zimbabwe n=25 (100%)) indicated favorably that they would use an approved product to prevent HIV when interviewed.	Facilitators • Efficacy Barriers • Worry that use would increase promiscuity • Feasibility of covert use • Hygiene concerns
Morrow et al. / 2003	South Africa, United States	On-demand, intermediate acting / Vaginal gel	Mixed Methods nested within a Phase 1 Clinical Study N = 63 (32 from SA)	Majority of women (77%) indicated a preference for a product that would protect from a range of indicators (HIV, other STIs and contraception); Although it was also indicated that they would like a product that did not have a contraception component. Safety, ease of use, and impact of sexual pleasure were noted as having the greatest impact on women's acceptance of a microbicide product. Authors stressed importance of noting that differences in social constructs of the different populations impacted their responses and that microbicide preferences will vary based on population.	Facilitators • Woman initiated • Clear, odorless, tasteless • Gel consistency • Ability for covert use Barriers • Creamy consistency • Leakage of gel • Hygiene concerns

Moon et al. / 2002	Zimbabwe	On-demand, intermediate acting / Vaginal gel	Qualitative N = 48	Key informants were both excited at the potential of microbicide products yet felt some the qualities that microbicides would provide that condoms don't (i.e. female initiated and ability to use covertly) could also cause tension within relationships should the male partner find out. Further, as fertility is highly valued in Zimbabwean culture, some informants commented that a microbicide that protected from HIV and other STIs may be more acceptable than one that protected from HIV and contraception.	Facilitators • Woman initiated • Partner support/involvement Barriers • Timing of insertion • Potential adverse side effects • leakage
Ramjee et al. / 2001	South Africa	On-demand, intermediate acting / Vaginal gel	Qualitative N = 243	77-87% of men interviewed indicated that they would like their partners to use a vaginal microbicide if one became available and 80% indicated that they would want to be informed of their partner's choice to use a vaginal microbicide. When asked if they would be willing to pay for microbicide product men who were attending university were significantly more likely (75%; p=.019) to say yes than men recruited from STD clinics (54%) or the general population (69%). There was also a significant difference in preference for a microbicide over a condom (82% vs 18%; p=.001)	
Becker et al. / 2004	South Africa	On-demand, intermediate acting / Vaginal gel	Qualitative N = 204	Providers and policy makers support the idea of microbicides but some expressed concern that microbicides would decrease condom usage and stall condom promotion advocacy.	Facilitators • Ability to use covertly • Efficacy Barriers • Odor • Messiness/texture
van der Straten et al. / 2014	South Africa	On-demand, intermediate acting / Vaginal gel + oral tablet	Qualitative ancillary study conducted concurrently with randomly selected participants of the VOICE trial	Few women openly disclosed their nonuse of the trial product they were assigned to and often mentioned other participants as being noncompliant. Women who participated in the ethnographic interviews (a series of IDIs rather than just one) were more likely to discuss nonadherence. Key themes related to product nonadherence were: ambivalence towards research,	Facilitators • Partner support Barriers • Unknown efficacy • Lack of partner support • Side effects • Anticipated/experienced social stigma

			N = 102	preserving a healthy status, and managing social relationships.	
El-Sahn et al. / 2016	Uganda, Nigeria, South Africa	On-demand, intermediate acting; Long-acting topical; Ultra long-acting systemic / Intravaginal film, IVR, implant, injectable	Quantitative N = 1,722	When shown examples and given profiles of four different hypothetical MPTs women were more likely to choose an MPT concept based off of their experience and needs. Preference drivers included administration route, ease of use, form and duration. While 93% reported a preference for an MPT, when asked about their willingness to try the four presented potential products results were as follows: Implant (41%); Injectable (28%); Film (20%); IVR (9%) and none (3%).	Facilitators n/a Barriers • Severe adverse side effects (i.e. migraines, diarrhea, bleeding)
Tolley et al. / 2014	Kenya and Rwanda	Ultra long-acting systemic / Long acting injectable	Mixed Methods N = 223	Strong interest in long acting injectables. Among potential end users, high effectives was ranked as the most important characteristic of an LAI while providers cited side effects to be the most important characteristic affecting acceptability.	Facilitators • Reduced travel time • Reduce frequency to clinic Barriers • Duration of side effects (i.e. longer menstrual cycles)

Appendix C – STP Table Template

*Definition of STP categories**

STP Category	Topical or systemic	Example of in-development product
Daily oral	Systemic	oral TDF/FTC
On-demand, intermediate acting	Topical/Systemic	gel, film, insert
Long-acting topical	Topical	IVR
Ultra long-acting systemic	Systemic	implant, injectable, IUD, AAV

*Strategic Target Profile (STP) Template***

Characteristics	Optimal Target^	Minimal Target^	Notes
Health Impact	----	----	----
Market Segmentation	----	----	----
Value Proposition	----	----	----
Tolerated toxicity/side effects	----	----	----
Preferred dosing form features	----	----	----
Acceptability	----	----	----
Uptake and adherence	----	----	----
Costs	Cost effective in high incidence populations in Eastern and Southern Africa =3xGDP per capita / DALYs gained (or per HIV infection averted)	Cost effective in high incidence populations in Eastern and Southern Africa =1xGDP per capita / DALYs gained (or per HIV infection averted)	----
Accessibility (at all access points)	----	----	----
Community and market engagement	----	----	----

* Courtesy of USAID Office of HIV/AIDS (OHA) Research Team
** Each STP category (product type) will have its own STP table.
^Targets listed are examples based on the current literature and will require further refinement with robust data.

Appendix D – Resource List

Resource
Guide to Introduction and Scale – USAID Center for Accelerating Innovation and Impact
MPT Market Access Framework – IMPT
Commercialization toolkit – PATH
Human Centered Design Toolkit – IDEO
Course on Human Centered Design for Social Innovation – Plus Acumen
Stakeholder Engagement Toolkit for HIV Prevention Trials – FHI 360, AVAC

Appendix E – KIDs Discussion Guide

Key Informant Discussions (KIDs) Discussion Framework
Strategic Framework Evaluation and the Strategic Target Profile

Introduction & Framing the Discussion **~5 mins**

- Introduce R2R, the overall framework of the research program
- Project overview (see talking points document)
- Literature review so far – initial findings and discussion
    - Include perceived efficacy in efficacy targets
    - Partner awareness/acceptability
        - What is most compelling?
        - What is missing?

Topic 1 – Introduction: their role in the field **~5 mins**

- Describe your role in the field
    - Where is it heading?
    - What are the major developments?
    - Where there, if any, major turning points? What were they?
    - What is needed in your field?
- Have you been involved or are you aware of successful or unsuccessful product introductions? What were the major learnings from this?
    - What was successful? What wasn't?

Topic 2 – The Strategic Target Profile: its components **~15 mins**

- Taking into account your experiences and the aim of this research, and the description of the STP (have printed out to share with KID):
    - What are appropriate market-based evaluation indicators/ targets (i.e. for the Strategic Target Profile, complement to Target Product Profile) for ARV-based HIV prevention products and MPTs?

Probe for, and understand value/relevance/impact/limitation/needs of:

- Market segmentation needed?
    - Demographics, life stage, attitudes
- Health impact targets
- Efficacy targets
- Acceptability/uptake/adherence (all in one or one target per)
- What is the value proposition to the target segment?
- Preference data on dosage form features (link to Human Centered Design)
- Accessibility inclusive of intended access points (most products in development Rx only)
- Target procurers?
- Maximum tolerated toxicity/side effects
- Shelf life requirements?

- Cold chain requirements?
- Ability for Co-formulation
- Costs (cost-effectiveness?)

Topic 3 – Moving forward: **~5 mins**

- If you were to lead the introduction of a product into Sub Saharan Africa, what would be the critical points to your strategy?
    - What preparation would you do?
    - What are the steps you would take?
    - What would be the critical knowledge requirements? And what would you consider nice-to-haves (but not necessarily essential)?

- Suggestions for contacts for KIDs, relevant market literature, unpublished grey literature
- Would they be willing to be contacted by the IMPT Secretariat regarding contact suggestions for another project on expanding the MPT pipeline?

- Wrap-up: anything you would like to add/ask/need more information about?

Thanks and Close