Round Table on Commercialization and Social-Behavioral (CSB) Issues for Multipurpose Prevention Technologies (MPTs)

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IMPT for Reproductive Health
The Initiative for Multipurpose Prevention Technologies (IMPT) is a global collaborative partnership aimed to advance the development and introduction of products that simultaneously address multiple sexual and reproductive health needs, namely unintended pregnancy and sexually transmitted infections (STIs), including HIV. Established in 2009, the IMPT has engaged product developers, scientific researchers, health care providers, funders and community-based advocates in Africa, China, India, the United States and Western Europe behind this common agenda. The IMPT Secretariat is housed at the Public Health Institute.

Multipurpose prevention technologies (MPTs) for reproductive health are products that combine protection against unintended pregnancy and STIs, including HIV. The vision for MPTs is a suite of accessible products that are woman-initiated, efficient and easy to use. Safe and effective MPTs that are acceptable, affordable, and made widely available would greatly improve health and save resources across the globe.

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Background

With an overarching agenda to advance the development and introduction of Multipurpose Prevention Technologies (MPTs) that are efficacious in clinical trials and effective in real world settings, the Initiative for MPTs (IMPT) is building a global product development strategy to provide guidance and tools for the MPT field. With a product-neutral perspective, the IMPT produced a variety of technical resources, including an online MPT product development database, dosage-form MPT Target Product Profiles (TPPs), regulatory guidance for MPTs, and country-specific messaging for MPT advocacy.

In alignment with recent recommendations from the IMPT Steering Committee and Supporting Agency Collaboration Committee (SACC), the IMPT has prioritized investigating the complex commercialization and social-behavioral (CSB) issues relevant to developing successful MPTs as a component of the larger product development strategy. As a first step in this effort, a sub-group of the IMPT Scientific Agenda Working Group (SAWG) convened to develop a theoretical framework that outlines CSB activities to be conducted along the product development timeline. This framework has been vetted by key MPT stakeholders and is in the final stages of revision.

As a next step, the IMPT organized its first in-person Round Table on CSB Issues for MPTs, aiming to guide the **prioritization of CSB activities outlined in the theoretical framework**. The Round Table was convened in conjunction with the Microbicide Trials Network (MTN) Annual Meeting, and thus the discussion was designed to draw on the experience of the MTN's clinical trials site staff and other in-country experts. Discussion was focused on three main areas: end-user perspectives, service delivery, and policy and advocacy. Key insights are summarized under main themes below, outlining the most pressing issues that emerged out of the discussion. These insights are not intended to serve as guidelines or recommendations for the field, but rather a summary of perspectives gathered from several MTN trial site staff members that will factor into a larger prioritization exercise for CSB activities. This Round Table is the **first in a series of small convenings** organized by MPT stakeholders in different settings to provide additional data to inform the prioritization of CSB activities for the MPT field.

**Integrating End-User Perspectives: Product Preferences and Presentation**

There was agreement that end-user perspectives must continue to be sought and integrated into the product development process. Much is already known from past research about end-user preferences with regard to sexual and reproductive health (SRH) prevention products, and the MPT field should build upon these knowns in its strategy. For example:

- Women’s product preferences vary based on many factors: relationship status, age, and geographic setting. Access to particular products may also vary across settings. **Different formulations will be needed to meet diverse user needs, preferences, and access issues.**

- Women have fairly **consistent concerns about any SRH product**: product efficacy; side effects or harm to the woman, her partner, or infant; potential to jeopardize her future fertility and how quickly fertility will return after stopping product use; potential to change her relationship with her partner(s); and cost and convenience.
• Perceptions about **drug-drug interactions** may prompt additional concerns among users, providers, and policymakers.

There was some debate as to whether an **MPT would be best presented and marketed primarily as a contraceptive, or clearly for contraception and HIV prevention**. On the one hand, contraceptives may be less stigmatized than HIV prevention products and may be of interest to more women based on their perceived pregnancy risk versus HIV infection risk. Most, but not all, of the anecdotes offered from MTN clinical trials staff and in-country experts supported the notion that pregnancy prevention is a more immediate concern for women than HIV prevention. On the other hand, MPTs could possibly stigmatize contraception by linking it with HIV-related stigma, which may compromise product delivery and use.

For future research on end-user preferences, it will be important to **identify which women are most likely to need an MPT** and focus on determining which characteristics they find most important given the range and complexity of CSB issues and women’s diverse perspectives. Again, building on experience and literature from the family planning (FP) field, the MPT field could benefit from further exploring topics such as the importance and acceptability of **different bleeding patterns, return to fertility, and the ideal duration of protection** (i.e., for intravaginal rings).

Obtaining robust and meaningful data from end-users to be incorporated into product design and development has proven challenging. Alternative preferences from different populations inhibit definition of consensus product attributes. Data obtained from interviews based on hypothetical products lack the perspective of actual product use. Also, most of the funding available for product development is dedicated to the technical requirements with little resources made available for robust assessments of users and other social-behavioral factors relevant to development. Given what is known about end-user product preference and insights from the MTN clinical trial site staff, however, the Round Table participants highlighted several key issues to consider in product development:

• Given that product use in gel trials has been inconsistent, MPT product development may want to consider **longer acting, more provider-dependent products** (i.e., a provider is needed administer the product) over coitally-dependent products.

• Determining the **importance of regular bleeding patterns** to women is important to informing the selection of hormones or other contraceptive agents.

• Determining women’s **willingness to use a ring for 1, 3, or 6 months** is important to inform whether developing a longer-acting ring, which could be lower cost, would be attractive to some women.

**The Intersection of Service Delivery and Policy in Garnering MPT Support and Access**

Healthcare provider and policymaker support are pivotal to the successful public health impact of any SRH product, and the Round Table participants raised many important issues to consider in garnering this support for MPTs specifically. Critical in setting the stage for provider and policymaker support is the **identification of the service delivery setting**. Several key factors were posed as those that determine whether new products can be delivered in given service setting, including staff workload capacity, the additional resources necessary to provide the product, and the level of provider who can prescribe the
product. In most settings, antiretroviral drugs (ARVs) are not delivered through FP services, and in high HIV prevalence, high HIV incidence settings, MPTs may be best delivered in a clinic where HIV testing is integrated with FP. Ideally, the clinical infrastructure would provide integrated services for women that include maternal and child health (MCH), HIV, TB and FP services. **Piloting different approaches to service delivery will be necessary to see what works** in different settings and for different user groups.

There is much to consider for the field in developing approaches to ensure that providers have the necessary support to understand and endorse MPTs in various delivery settings. Significant investment will likely be needed to generate and sustain support among local providers, particularly given that providers may experience a wide range of barriers to decision-making within their practice. Providers often will determine the appropriate users for a product based on their own perceptions and biases and urge certain clients toward particular products. In the discussion, **experience with the Intrauterine Contraceptive Device (IUCD) in South Africa was cited** to illustrate the challenges with product introduction and use among providers. This experience highlighted the need for increased provider support in terms of training, capacity, and infrastructure. As one strategy, a meeting participant proposed that the MPT field could **look to elements of pharmaceutical company product introduction and provider training strategies**. However, it was suggested that ultimately, provider support for MPTs might hinge on the appropriate policymaker support in that setting, given that many providers are primarily responsible to their employers. If, for example, **Ministries of Health promote the implementation of certain products or interventions as a deliverable for providers**, providers working in public sector clinics will have an incentive to provide them. This can be a useful strategy but must also be balanced against the importance of informed choice and the potential for coercion.

Efforts to garner provider support, then, may tie in directly with efforts to garner policymaker support. There was agreement among several participants that questions and approaches to policymaker buy-in will likely vary by country setting with cost as the likely key driver. Participants asserted that while researchers work to develop products assuming they can be made available at a low price with donor support, policymakers generally will not engage with new products or innovations without clear budgetary support. Therefore, in most settings, making the case for the introduction of new products or interventions such as MPTs should consider the budgetary perspective, including information on product cost, cost estimates for the health care system for product delivery, and potential cost savings and public health impact. Overall in this approach, the Departments/Ministries of Health should be **engaged early in the research process** and made aware of the products’ attributes. Other considerations for this engagement from the discussion include:

- **Given that different government entities can be involved in prioritizing and budgeting for new health innovations, government at all levels should be engaged.**

- **Developing consistent policy support for a long-term investment can be challenging given frequent changes in government and government appointees; thus, working with key high-level staff in government departments may be a successful strategy.**
MPTs should be positioned within the context of existing national policies, for example, the National Strategic Plan in South Africa. Strategies such as modelling may be needed to demonstrate how an MPT that reduces maternal mortality and HIV infection would support national strategic goals with budgetary considerations.

**MPT Introduction at the Community Level: Community Sensitization and Advocacy**

Additional considerations for successful MPT introduction raised during the Round Table concerned sensitizing and educating communities about MPTs and advocacy efforts at all levels:

- As a new concept, MPTs will need to be explained carefully to providers and users, and on-going efforts will be needed to address emerging beliefs and concerns. For example, ARVs are seen as tablets that are swallowed, not active ingredients that would be contained in a ring or other dosage-form. Also, misunderstandings may emerge once a program introduces an ARV combined with a contraceptive method. Shifting these perceptions will be challenging and will require significant education and investment.

- **Engaging men may be important** so they can support rather than impede women’s use of MPTs, but it is not clear how best to do so. A main premise of MPTs, that women could leverage their contraceptive use to justify protecting themselves from HIV, suggests some of the challenges in involving men in HIV prevention.

- **Advocacy can be an important strategy to demonstrate demand** for new innovations and products to policymakers, funders and sponsors. However, work to engage beneficiaries can become mired in the complexity of the still hypothetical products while the larger issues of need and strategy become lost. Similarly, engaging policymakers in advocacy too early can be counterproductive, especially without a clear sense of the timing or resources to purchase and deliver the new products.

**Looking Ahead**

Moving forward with the overarching IMPT CSB efforts outlined in the beginning of this summary, the feedback from participants indicated that beyond the identification and prioritization of key CSB activities as a resource for the MPT field, it will be important to further explore the methods, stakeholders, and timelines relevant to carrying out these activities. Round table participants underscored additional pragmatic considerations in prioritizing CSB activities to inform the development of products that women and girls will want and be able to use worldwide: notably, to be cognizant of cost limitations and to avoid duplicating efforts by building on what is already known in the FP and other related fields.

- Consider alternative study designs for qualitative research to minimize the high costs typically associated with large qualitative research projects.

- Given the extensive research and experience from the FP field that can inform many of the issues outlined in the Round Table, a review of the relevant FP literature and experience will enable the field to build on what is known.
• Strategic work is needed to identify and understand the specific questions that women, policymakers and gatekeepers have about the intersection of HIV prevention and contraception. New research should concentrate on the questions that derive from this intersection while existing knowledge can address broader issues.

Overall, the insights that emerged from the Round Table discussion are valuable perspectives as the IMPT works to prioritize CSB activities as part of its global MPT product development strategy. The IMPT aims to iteratively refine its approach and recommendations in this domain through additional Round Table discussions in other settings. MTN clinical sites, for example, are well positioned to explore these issues with trial participants, team members, and communities.
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List of Acronyms (in alphabetical order)

ARVs – Antiretroviral drugs
CSB – Commercialization and social-behavioral
FP – Family planning
HIV – Human Immunodeficiency Virus
IPM – International Partnership for Microbicides
IMPT – Initiative for Multipurpose Prevention Technologies
IUCD – Intrauterine contraceptive device
JSI – John Snow, Inc.
MCH – Maternal and child health
MPTs – Multipurpose Prevention Technologies
MTN – Microbicide Trials Network
NIAID – National Institute of Allergy and Infectious Diseases
NICHD – National Institute of Child Health and Development
NIMH – National Institute of Mental Health
PHI – Public Health Institute
SACC – Supporting Agency Collaboration Committee
SAWG – Scientific Agenda Working Group
TB – Tuberculosis
TPP – Target Product Profile
UCSF – University of California San Francisco
UNC – University of North Carolina
USAID – United States Agency for International Development