

Global Forum on  
Multipurpose  
Prevention  
Technologies  
*for* Reproductive Health



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*Advancing the MPT Agenda*

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The **Wellcome Trust**, which hosted this Forum, is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health through supporting the brightest minds in biomedical research and the medical humanities. The Trust focuses on supporting outstanding researchers, accelerating the application of research, and exploring medicine in historical and cultural contexts. It supports activity across five major research challenges: international, medical history and humanities, technology transfer, public engagement, and ethics and society.

The **Initiative for Multipurpose Prevention Technologies (IMPT)** was established in 2009 to unite researchers, health care providers, policymakers, advocates, product developers, and donors to advance the development and introduction of products that simultaneously address multiple sexual and reproductive health needs, namely unintended pregnancies, sexually transmitted infections (STIs) including HIV, and other reproductive tract infections. Such products are referred to as Multipurpose Prevention Technologies (MPTs; see below). The **IMPT** works to: mobilize financial, scientific, and political resources to advance the development of and access to MPTs; build synergy and collaboration among scientific disciplines to expedite product development and implementation; and use a cross-disciplinary advocacy strategy to promote increased support for MPTs. The IMPT Secretariat is housed at the Coalition Advancing Multipurpose Innovations (CAMI), a project of the Public Health Institute, Oakland, CA, USA.

**Multipurpose prevention technologies (MPTs) for sexual and reproductive health** include vaccines, microbicides and devices (e.g ., intravaginal rings, diaphragms) each of which would simultaneously address multiple sexual and reproductive health needs, including prevention of unintended pregnancy; prevention of sexually transmitted infections (STIs), including HIV; and/or prevention of other reproductive tract infections (RTIs), such as bacterial vaginosis or urinary tract infections. Safe and effective **MPTs** that are also acceptable, affordable, and made widely available would greatly improve health and save resources across the globe.

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The contents are the responsibility of CAMI/Public Health Institute and do not necessarily reflect the views of The Wellcome Trust, USAID or the United States government. An electronic version of this document is available <http://www.cami-health.org/2012-global-forum/index.php>. Other organizations that support the Initiative can post this document on their websites. For questions or comments, please contact: [cami@cami-health.org](mailto:cami@cami-health.org).

## Executive Summary

**Background** Multipurpose Prevention Technologies for Reproductive Health (MPTs) are some of the most innovative health products under development to simultaneously prevent unintended pregnancy, sexually transmitted infections (STIs) including HIV, and provide additional health benefits. These promising innovations include vaccines and gels as well as easier to use vaginal rings and single-sized diaphragms that could lead to marked declines in unintended pregnancies and disease. By addressing multiple health needs, MPTs would offer an efficient approach to delivering and accessing services and would also provide social and economic benefits that would have a major impact on the health and lives of women and their families worldwide .

**Global Forum overview** A two-day Global Forum was jointly convened by the Wellcome Trust and the Initiative on Multi-purpose Prevention Technologies (IMPT) to help shape the evolving strategy for accelerating the development of MPTs, especially in Africa and Asia where MPTs are most urgently needed. Building on previous meetings and work by the IMPT, more than 60 diverse experts reviewed and debated existing evidence and new ideas on a range of issues critical to developing and delivering MPTs: the evolving product development roadmap; the existing pipeline or MPT products; potential regulatory pathways; perspectives from researchers to ensure successful product development; programmatic issues, including involving end-users and providers in ensuring access; the role of innovative partnerships in ensuring successful development and introduction; and policy considerations, including the perspectives and roles of public and philanthropic donors. The Global Forum included side meetings for participants from different regions to plan for advancing work on MPTs specifically to meet the main unmet needs in those regions.

**Next Steps** The Global Forum explored and consolidated the views expressed by colleagues from many different regions of the world. Participants proposed and committed to taking forward a number of concrete next steps to advance the MPT field:

**Create a Roadmap for MPT Development and Delivery** -- Consolidating work to date on MPTs into an overall research and development roadmap was identified as a key priority. This effort would aim to characterize the pipeline from discovery through approval, analyze the pipeline against MPT Target Product Profiles, and link both with potential regulatory pathways. The resulting Roadmap would provide an important framework for researchers and donors to prioritize development actions and investments. The key US government donors at the Global Forum agreed to work together on this process, which will be coordinated by the IMPT.

**Strengthen and Expand Coordination** -- Enhanced coordination among researchers, donors, and global health advocates interested in MPTs will build on CAMI's ongoing efforts. As Secretariat for the IMPT, CAMI provides a forum for exchanging information and ideas across basic science, research and development, stakeholder engagement, and potential delivery of MPTs. The IMPT is working on a five year strategic plan to continue to support and coordinate multi-disciplinary

collaboration, facilitate funding for research and development, expand US and global funding and support, and assist with efforts toward an MPT Roadmap.

**Encourage Harmonized Regulatory Pathways** -- The Global Forum brought together experts who have worked in and with diverse regulatory authorities, most of whom concurred that the definitions surrounding “combination products” and “multiple indications” put forward by the US Food & Drug Administration would provide a useful framework for considering MPTs. Ongoing efforts at regulatory harmonization are creating a climate conducive to addressing public health problems, and the MPT field can build upon these harmonization efforts. The Population Council will continue its work to encourage this dialogue and information sharing.

**Foster new partnerships** -- The Global Forum drew representatives from the private sector and public-private partnerships, key stakeholders in the global health arena with complementary perspectives to the scientific and advocacy focus of the MPT field to date. Working with these and other partners, the IMPT will explore appropriate approaches to technology transfer, manufacture, and distribution in key markets, so that these critical perspectives are fully incorporated into the MPT development process.

**Initiate national and regional communications** -- Recognizing that MPTs have the potential to meet goals and priorities already articulated by national governments, initial work proposed for national and regional settings focused on raising awareness among key stakeholders to the potential and progress of MPTs, including proposals for:

- A **follow up workshop in India** to raise awareness of MPTs in India, to advocate for investment in priority R&D activities aimed at developing novel MPTs, and to attract new participants from government, scientific groups and pharmaceutical companies to the field.
- **Symposia on MPTs in Kenya** at existing SRH meetings aimed at key stakeholders, such as biomedical researchers, OB/GYN groups and midwifery associations, to assess and shape specific needs and interests for further work.
- **Communication, consultation and advocacy in southern Africa** to ensure that the products developed will meet the most urgent unmet sexual and reproductive health needs, and to identify strategies to engage pharmaceutical companies and other new collaborators.
- Forming a **consortium and identifying international collaborations for work in China** where the current environment is very conducive to supporting research and development, especially in technology innovation like MPTs that meet clear national needs.

**Conclusion** -- The Global Forum’s success reflected not only the wealth of experience of the diverse participants but also their readiness to engage in vigorous debate. This meeting significantly highlighted the need for MPTs and the importance of continuing to push forward the scientific and policy agenda. Participants identified a number of clear actions and concrete next steps to be taken forward by research groups and emerging regional networks. Finally, the Forum underscored the

potential of MPTs that meet multiple sexual and reproductive health needs to facilitate efficient delivery of and access to health innovations and services to improve women's health.

## **Background: The Case for MPTs**

Addressing the primary sexual and reproductive health (SRH) concerns of all women involves ensuring healthy timing and spacing of intended pregnancies, safe birth for mother and child, and protection against HIV, other sexually transmitted infections (STIs) and reproductive tract infections (RTIs). Worldwide, some 215 million women in low resource settings experience unmet need for contraception, resulting in 53 million unintended pregnancies and 25 million abortions<sup>1</sup>, as well as compromising their health and economic opportunities. While the percentage of this unmet need for contraception is highest in sub-Saharan Africa, approximately 88 million women in South and West Asia experience unmet need for contraception, making it the region with the highest absolute number of women with unmet need.<sup>2</sup> Each year, some 450,000 women in low resource settings die from complications related to pregnancy and childbirth, with an additional 15-20 million women suffering from debilitating pregnancy complications.<sup>3</sup> New vaccines against HPV infection could ultimately prevent up to half a million new cases of cervical cancer every year in low resource settings<sup>4</sup>, and mathematical modeling suggests that, if effectiveness is confirmed, 1% tenofovir gel could prevent more than 1.3 million new cases of HIV over 20 years in South Africa alone.<sup>5</sup> MPTs that can simultaneously prevent unintended pregnancy, protect against HIV and other STIs, and provide additional health benefits could have a major impact on the health of women and their families worldwide, as well as provide social and economic benefits.

## **Global Forum overview**

The two-day Global Forum was jointly convened by the Wellcome Trust and the Initiative on Multipurpose Prevention Technologies (IMPT). It brought together a multidisciplinary, multinational group of experts to help shape the evolving strategy for accelerating the development of MPTs, especially in Africa and Asia where MPTs are most urgently needed. The Forum was designed to:

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<sup>1</sup> Vlassoff M, et al., Assessing Costs and Benefits of Sexual and Reproductive Health Interventions: Occasional Report, New York: The Alan Guttmacher Institute, 2004, No. 11.

<sup>2</sup> Singh S et al., Adding It Up: The Costs and Benefits of Investing in Family Planning and Maternal and Newborn Health, New York: Guttmacher Institute and United Nations Population Fund, 2009. <http://www.guttmacher.org/pubs/AddingItUp2009.pdf>

<sup>3</sup> USAID Fact Sheet: Improving Maternal, Newborn & Child Health, 2009. <http://www.usaid.gov/press/factsheets/2009/fs090610.html>

<sup>4</sup> Global strategy for the prevention and control of sexually transmitted infections: 2006 - 2015: breaking the chain of transmission, World Health Organization, 2007. [http://whqlibdoc.who.int/publications/2007/9789241563475\\_eng.pdf](http://whqlibdoc.who.int/publications/2007/9789241563475_eng.pdf)

<sup>5</sup> Williams BG et al., Impact of tenofovir gel on the HIV epidemic in South Africa: A mathematical model to estimate the effect of the CAPRISA 004 microbicide trial results. International AIDS Society 2010, Abstract Number: LBPE27. [http://www.aids2010.org/WebContent/File/AIDS2010\\_Abstracts\\_Related\\_to\\_the\\_CAPRISA\\_Study\\_2.pdf](http://www.aids2010.org/WebContent/File/AIDS2010_Abstracts_Related_to_the_CAPRISA_Study_2.pdf)

- Review the current status of MPT development and highlight needs and potential challenges
- Identify populations most likely to benefit from MPTs
- Expand international multi-sectoral and multidisciplinary input into product development plans for MPTs
- Broaden discussion of the critical path for regulatory approval of MPTs to include African, Asian, and European regulatory authorities
- Foster a global perspective and encourage international support for the MPT Initiative
- Identify next steps

The Global Forum built on the outcomes of several previous meetings that together focused on advancing research and investment in MPTs. The first meeting on MPTs, “Advancing Prevention Technologies for Sexual and Reproductive Health”, occurred in 2009 and was supported in large part by USAID. It brought together nearly 150 diverse experts from around the globe to identify and address the opportunities and challenges of developing MPTs.<sup>6</sup> The IMPT was formed as an outcome of this meeting, and began focusing on raising awareness about MPTs among sexual and reproductive health (SRH) researchers and providers. In early 2011, a meeting on Regulatory Nomenclature brought together 25 experts in SRH research to review regulatory issues related to MPTs, and begin attempts to clarify the regulatory approval process.<sup>7</sup> This was followed by the “MPT Think Tank” in May 2011, during which some 30 scientists determined that developing safe and effective MPTs is scientifically feasible, although challenging.<sup>8</sup> Finally, the November 2011 Symposium, “Multipurpose Prevention Technologies for Reproductive Health,” drew nearly 150 SRH experts to discuss and advance the emerging science of MPTs, and to outline steps to ensure that these products are safe, cost effective, accessible and acceptable to the end user.<sup>9</sup>

The January 2012 Global Forum convened a smaller multidisciplinary cadre of experts from around the world working in the areas of family planning, HIV/AIDS and STI prevention, including product developers, regulators, social scientists, policy makers, clinicians, advocates and donors. These stakeholders came primarily from Africa and Asia, those regions with the greatest unmet need for MPTs. This report summarizes key points from the presentations, discussions and recommendations that emerged from the Global Forum.

## **The MPT product development roadmap so far**

A key recommendation from the May 2011 Think Tank was the development of a framework to help assess and prioritize MPT product leads from among the many combinations of targets, active pharmaceutical ingredients (APIs) and devices possible. Following this recommendation, a working

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<sup>6</sup> [www.cami-health.org/APT2009/PDFs/report-aug09.pdf](http://www.cami-health.org/APT2009/PDFs/report-aug09.pdf)

<sup>7</sup> [http://www.popcouncil.org/pdfs/events/2011DayOfDialogueNomenclature\\_Report.pdf](http://www.popcouncil.org/pdfs/events/2011DayOfDialogueNomenclature_Report.pdf)

<sup>8</sup> [www.cami-health.org/documents/050511-MPT-ThinkTank.pdf](http://www.cami-health.org/documents/050511-MPT-ThinkTank.pdf)

<sup>9</sup> [www.cami-health.org/documents/MPT2011-Symposium-Report.pdf](http://www.cami-health.org/documents/MPT2011-Symposium-Report.pdf)

group of the IMPT developed Target Product Profiles for MPTs, consisting of ideal product attributes and parameters that would have the highest potential public health impact. These Target Product Profiles will help focus MPT development efforts through assessing and prioritizing candidate products according to their development potential, likely impact, and market potential, and thus guide strategies for donor investments and sponsor development. (see [www.cami-health.org/documents/050511-MPT-ThinkTank.pdf](http://www.cami-health.org/documents/050511-MPT-ThinkTank.pdf) for the full Think Tank report).

The IMPT formed two working groups to examine (1) Drug-Drug and Drug-Device combinations; and (2) Multipurpose Vaccines. These groups interviewed key stakeholders to identify which product characteristics they viewed as most important, and to solicit ideas about scientific approaches and potential products to explore. The working group chairs presented initial findings at the November Symposium, and expanded on these issues at the Global Forum.

### ***Drug-Drug / Drug-Device Working Group***

Defining broadly applicable product attributes and parameters for all drug-drug and drug-device MPT products is challenging, given the complex and unique interplay among different attributes for each product concept and design. However, it is possible to identify general development priorities and fundamental design targets for MPT products that can be used by developers as they focus their research and development efforts, and funders as they consider investment priorities.

- *Indication:* HIV/contraception was identified as the highest combination priority, followed closely by HIV/Herpes simplex virus (HSV). Other STIs were generally prioritized in terms of their relevance to HIV, the technical feasibility of product development, the condition's prevalence and whether it can be treated, and its overall public health burden.
- *Dosage and Delivery Forms:* Facilitating product adherence was identified as the highest priority. Vaginal rings were seen as a delivery form that could potentially balance adherence, reversibility and burden on the health system, as well as possibly mitigating side effects associated with oral (systemic) delivery.
- *Product Attributes:* Specific product attributes identified as priorities included a relatively long shelf-life (36 months) and high storage temperature (40 C), as well as re-supply and access to testing/monitoring. Other attributes were prioritized as they relate to product safety, efficacy, and other factors.
- *Efficacy Targets:* For contraception, the target efficacy should be as high as currently available products; for HIV, a minimum of 40-50% reduction in risk, and preferably 80% or greater with perfect use; and at least 40-50% efficacy against other STIs.
- *Side Effects:* Should be "acceptable to most women and generally no worse than comparable single use products" such as currently-available contraceptives. These also need to be addressed within the context of product safety and efficacy.

During the Global Forum, it was agreed to expand upon this work by examining the health needs of specific regions, including both developing and developed countries, and identify which types of MPTs would have the highest impact in particular regions.

### ***Multipurpose reproductive health vaccines***

The MPT Vaccine Working Group considered similar factors in developing its Target Product Profile: indication, target population, product presentation or delivery mode, action required by user, boost schedule, typical use efficacy, side effect profile, additional benefits, shelf life, storage needs, price, and infrastructure required for storage and delivery. Because the current pipeline for vaccines is limited, the working group solicited concepts for multipurpose reproductive health vaccines from key scientists and companies working in related areas and then identified what would be optimally preferred across each of the factors listed above for each of the ten concepts submitted (see [www.cami-health.org/documents/London-PDFs/Session1.TargetProductProfilesMultipurposeRHVaccines](http://www.cami-health.org/documents/London-PDFs/Session1.TargetProductProfilesMultipurposeRHVaccines).) The working group drew on these concepts and factors to develop a consensus target product profile with these optimally preferred parameters:

### **Consensus Target Product Profile**

<b>Parameter</b>	<b>Optimally Preferred</b>
<b>Indication and Mechanism</b>	HSV, HIV, HPV Systemic and mucosal protective concentrations of neutralizing antibodies (and cell mediated immunity)
<b>Target Population</b>	Women/girls; Developed and developing regions
<b>Immunogen, Adjuvant, and Delivery Mode</b>	Well-characterized immunogens (but range of adjuvants and delivery modes)
<b>User-action</b>	Pharmacy or self-administered boosts
<b>Boost Schedule</b>	Mucosal boost schedule uncertain
<b>Typical Use efficacy</b>	HSV (70-90%); HIV (70-90%); HPV (>95%)
<b>Side effect profile</b>	Minimal
<b>Additional Benefits</b>	Important
<b>Shelf life</b>	Years
<b>Storage needs</b>	No cold chain required
<b>Price</b>	\$1/dose
<b>Infrastructure</b>	Pharmacy

The working group views multipurpose reproductive health vaccines as technically feasible, and while the timing for developing such vaccines is long-term, they should be pursued. There is limited funding for translational research for non-HIV STI vaccines, and for research or development related to mucosal approaches. While it may be possible to develop separate STI vaccines, the IMPT encourages efforts to determine when it may be appropriate and feasible to initiate combination vaccine studies in parallel for efficiencies of time, resources, delivery and ultimately global health impact.

### ***Bill and Melinda Gates Foundation Dual Protection Initiative***

The Bill and Melinda Gates Foundation (BMGF) is developing a strategy for “dual protection” approaches that focuses on contraception plus HIV prevention. This strategy focuses on new dual protection concepts closest to potential launch; it emphasizes adding HIV prevention to existing contraceptive technologies, and will also invest in new technologies in the early phases of development. Based on its review of the product pipeline the BMGF is prioritizing two approaches: co-administered injectables and the vaginal ring.

- **Injectables:** Co-administration of injections to prevent pregnancy and HIV acquisition will likely require little incremental development cost beyond the investment already being made in efforts to develop injectable HIV prevention based on ARV drugs (by the BMGF as well as others). However, the limited number of leads for injectable HIV prevention are all in preclinical or early clinical development.
- **Vaginal Rings:** Echoing the results of the IMPT drug-device target product profile, the ring may facilitate adherence; however, although acceptability data are encouraging, as a new product concept in sub-Saharan Africa the uptake of vaginal rings is difficult to predict. Dual protection rings can build upon the contraceptive vaginal ring already available in many developed countries, and the dapivirine ring and tenofovir ring being developed for HIV prevention. However, it is still to be determined which contraceptive approach would be best suited to a combination hormonal contraceptive (HC)+HIV prevention ring.

Each of these dual protection approaches has potential advantages as well as drawbacks and questions. To sharpen the value proposition of dual protection approaches, the BMGF initiative intends to: test the dual protection investment case; examine the delivery of dual protection; and study the uptake of vaginal products. The BMGF and the IMPT have been sharing information and collaborating on key activities, such as developing the Target Product Profiles.

### **What is in the pipeline?**

The current pipeline of MPT products was summarized in two presentations that outlined products, product leads and associated technologies in pre-clinical and clinical development.

#### ***Drug-drug and drug-device MPTs in the development pipeline***

In the first presentation, MPTs in pre-clinical and early clinical development were categorized as either “on demand” or “sustained release” products. “On demand” products are used before and/or after intercourse and could be protective for up to 24 hours. These products, which include gels as well as devices combined with active agents, may be particularly attractive to women who have infrequent sex, or who would like to have more direct control over their protection. The “sustained release” devices furthest along in development are vaginal rings that incorporate active agents. Although these rings are user-initiated, they do not require daily action or attention at the time of sex, so they could increase acceptability, adherence, and overall effectiveness. Diversifying delivery and dosing options is key to expanding acceptability and use by meeting the different needs of women for: an “on demand” method that may last up to 24 hours; a non-hormonal contraceptive method, especially for intermittent sex; a highly effective method that a woman

could insert and then not have to think about for some months. This table below summarizes different approaches and status of those MPTs furthest along in the pipeline.

### Multipurpose Prevention Technologies in Development<sup>10</sup>

<b>“On Demand” Products</b>				
<b>Product</b>	<b>Indication</b>	<b>Description</b>	<b>Developer/Funder</b>	<b>Status</b>
<b>Tenofovir Gel</b>	HIV, HSV-2	Gel containing 1% antiretroviral Tenofovir	CONRAD USAID	- Effectiveness demonstrated in CAPRISA 004 trial (39% HIV, 51% HSV-2) - VOICE trial showed no effect of daily gel use - FACTS trial results scheduled 2014
<b>MZL Combination Topical Gel</b>	HIV, HSV-2, HPV Pregnancy	Carrageenan gel containing antiretroviral MIV-150, zinc acetate, LNG	Population Council USAID	- Gel optimization and initial pharmacokinetics in vivo - MZ gel (without LNG) Phase 1 clinical study to begin 2012
<b>SILCS + Tenofovir Gel</b>	HIV, HSV-2 Pregnancy	SILCS Contraceptive Barrier 1% Tenofovir gel	PATH CONRAD USAID/NICHD	- SILCS contraceptive studies completed - Gel reformulation 2012
<b>Woman’s Condom</b>	Pregnancy HIV, HSV-2	Polyurethane condom designed to be easy to insert and use, more comfortable, and potentially less expensive than earlier female condom products	PATH CONRAD USAID/NICHD Dahua Medical Apparatus Corp. Shanghai China	- WC EU CE mark 2010 Shanghai FDA approval 2011 - WHO prequalification underway - NICHD contraceptive effectiveness trial underway in the U.S., with CONRAD as regulatory sponsor; submission for US FDA regulatory approval expected 2013

<sup>10</sup> For more information see Manning presentation slides at: <http://www.cami-health.org/2012-global-forum/presentations.php>

## Multipurpose Prevention Technologies in Development (continued)

<b>"Sustained Release" Products (Vaginal Rings)</b>				
<b>Product</b>	<b>Indication</b>	<b>Description</b>	<b>Developer/Funder</b>	<b>Status</b>
Tenofovir and LNG Ring	Pregnancy HIV, HSV-2	90 day polyurethane ring with ARV tenofovir and LNG	CONRAD USAID	- Clinical studies of TFV+LNG ring to begin 2012
Dapivirine and Contraceptive Ring	Pregnancy HIV	60 day ring containing ARV dapivirine	IPM USAID	- DAP-only ring to begin Phase 3 for HIV prevention 2012 - Formulation with DAP/HC underway
MZL Combination Ring	Pregnancy HIV, HSV-2, possibly HPV	> 30 day EVA or polyurethane ring containing MIV-150, Zinc Acetate, LNG, and possibly carrageenan gel	Population Council USAID	- in vitro studies completed; animal studies to begin 2012

### ***Combination vaccines in the development pipeline***

Between 1994 and 2009, nearly 20 new vaccines or vaccine combinations were licensed in the United States. Continuing vaccine research in public, academic and private sectors focuses on: identifying new vaccine candidates for diseases for which no vaccines currently exist; improving the safety and efficacy of existing vaccines; designing novel vaccine approaches and strategies that could be applied broadly; and developing innovative technologies such as new delivery methods, stabilization techniques and adjuvants. Work to identify vaccines related to sexual and reproductive health is ongoing across the product development process in academia and in industry.

<b>Product Development Stage:</b>	<b>Basic Research</b>	<b>Target Identification and Preclinical Development</b>	<b>Clinical Evaluation</b>	<b>Manufacturing and Post-Licensure Evaluation</b>
<b>Indication:</b>	Chlamydia Gonorrhea HSV Syphilis	Second generation HSV	Hepatitis C Hepatitis B HSV	HPV

This pre-clinical and clinical research on new vaccines is complemented by critical research to make implementation and delivery of existing and emerging vaccines simpler, more affordable and more acceptable. These include needle-free, electrode array and patches for cutaneous delivery; micro-needles; and mucosal delivery approaches such as edible vaccines, spray injectors, and breath-powered nasal delivery.

Vaccines and new vaccine technologies offer both advantages and challenges as an approach to MPTs. New delivery approaches offer a potential variety of systemic or mucosal delivery options, and a range of delivery devices and formulations. There is potentially broad interest among both academic and industrial sectors. However, work in this area is challenged by limits in current understanding of what constitutes mucosal immunity, and uncertainty about when and how to measure responses. Defining appropriate clinical endpoints and correlates of protection remains challenging for new vaccine approaches, as does the risk of immune tolerance or potentiation of infection or disease. Vaccine development and delivery involves many actors from the public and private sectors, and efforts to develop MPT vaccines should seek opportunities to both influence and capitalize on these agendas.

## **Regulatory pathways for MPTs**

As outlined in the examples above, many MPTs currently being developed combine several active pharmaceutical ingredients and delivery devices. As such, they may not fit neatly into the discrete categories of drug, device or biologic used by regulatory agencies – though they may involve any or all of these. In addition, given that MPTs are designed to address different indications, regulatory review may involve more than one section of a regulatory agency, such as antivirals or contraception. Given both the diversity and potential uncertainty associated with regulatory processes for MPTs, regulatory guidance is needed to: inform overall regulatory and development strategies; determine resource requirements and research approaches; and clarify pathways for regulatory review and licensure of MPTs. The Population Council, as part of the IMPT and with funding from USAID, has spearheaded a series of discussions with the USFDA to explore potential regulatory pathways.<sup>11</sup> During the Global Forum, a representative of the USFDA presented that agency’s terminology and possible avenues for MPT review. A panel of regulators from Botswana, the European Union, Kenya, South Africa, the United States and Zimbabwe discussed relevant regulatory processes in their respective settings. The panelists reflected on the USFDA’s proposed approach, outlined opportunities and challenges related to regulatory review for MPTs, and offered insights into how the process could be approached. Key points from the panelists and discussion included:

- Many of the National Regulatory Authorities in resource-limited countries have little or no experience with regulatory review for new drugs. These agencies generally receive a dossier that has already been reviewed by a stringent regulatory authority [such as the USFDA or European Medicines Agency (EMA)], which they then consider in light of their respective national regulations

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<sup>11</sup> Brady, Martha and Heeyoung Park. 2011. “What regulatory guidance exists for multipurpose prevention technologies (MPTs)? A review of key guidance documents and their applicability to MPTS.” New York: Population Council.

and public health context. Given the potentially complex nature of MPTs, it will be important to continue technical dialogues with regulators in key resource-limited countries to familiarize them with ongoing scientific and product developments.

- The EMA offers a centralized procedure primarily for considering medical products intended for marketing in EU countries. However, through its “Article 58” mechanism, the EMA can collaborate with WHO to convene an expert panel about products intended for markets outside the European Union. This process could be a useful regulatory approach for MPTs, especially those designed for use primarily in resource-limited settings.
- Harmonization efforts have been underway in several regions, such as the Southern African Development Community and the Eastern Africa Economic Community, but they are proceeding somewhat slowly and unevenly. These efforts have focused on harmonizing technical requirements as outlined in registration and clinical trial guidelines. A number of countries are moving towards a common technical document with a risk management and pharmacovigilance plan; a common application process, facilitated by WHO, has been used for some vaccines. A number of the regulators and others at the Global Forum emphasized that they would like to work closely with regional partners and organizations to continue strengthening and accelerating these harmonization efforts.
- Regulators’ responsibility with respect to MPTs includes clinical trials as well as dossier review. Several noted that the common practice of clinical trial protocols being presented by investigators rather than sponsors can make it difficult for regulators to gain access to important technical information. Several specific concerns were raised regarding the proposed products, including potential resistance to first line antiretroviral treatment drugs when used for prevention; quality assurance and pharmacovigilance; and technical capacity to review applications.
- All of the panelists underscored their commitment to registering drugs based on safety, efficacy and quality, and measured against the public health needs of their populations. All noted the potential for MPTs to meet critical health needs in their countries and that regulators would do their best to work together and with the developers to streamline the process. Any MPT regulatory strategy will need to consider the whole “life cycle” of the product, including post-marketing surveillance for long term safety and effectiveness.
- Complexity in product development for MPTs may require innovative approaches to trial designs, and guidance on regulatory requirements for development and licensure. At the same time, combination and/or multi-indication products represent cutting-edge science, and promising areas for health improvements, possibly larger markets, and potential cost savings.
- The USFDA representative presented that agency’s definitions (combination products and multi-indication products), jurisdiction for combination products, and other considerations pertinent to combination products. The representative noted that the USFDA recognizes that the development of multi-indication combination products will involve unique regulatory considerations, and that regulatory challenges, strategies and decisions will be product-specific as well as indication-specific. A number of the other panelists agreed informally that the definitions and approaches laid out by the USFDA seemed appropriate, and may be able to inform their deliberations related to MPTs. Such efforts will facilitate the growing collaboration and discussion across regulatory agencies noted during the Global Forum.

## Researchers' perspectives for ensuring successful MPT development

New approaches to basic research, product development, clinical testing and collaboration are needed to complement the ongoing work on MPTs summarized in previous sessions. Fostering new collaborations and innovations is one of the main goals of the IMPT, and several prominent researchers were invited to reflect on new ideas and approaches that could be brought to bear on MPTs for reproductive health. The panelists presented a number of ideas on MPTs and vaccines, combining and co-delivering technologies, clinical trial design, and international collaboration. Key points from the panelists and discussion included:

- Amid growing evidence that different interventions may be partially effective at reducing the risk of HIV infection, some researchers are looking at combining biomedical prevention approaches to optimize drug delivery and overall effectiveness. For example, the combined use of oral pre-exposure prophylaxis (PrEP) and microbicides for intermittent dosing would deliver the drug(s) both systemically and locally, and thus result in more consistent and effective drug levels. Similarly, vaccine efficacy could be increased by co-implementing oral or topical PrEP. There is some indication from animal studies that mucosal exposure to virus in the presence of PrEP can lead to an immune response, and that vaginal vaccination may modify mucosal immunity to HIV. Approaches to mucosal vaccination are being explored, including the possibility of inserting a small freeze-dried vaccine construct into a ring to deliver steady, localized dosing. It may also be possible to use this approach to co-formulate a vaccine candidate with an ARV-containing ring to deliver topical PrEP and a vaccine together.
- Given the very limited funding available for non-HIV STI vaccine research, technical advances in HIV vaccine development could provide important gains for development of vaccines against other STIs. Co-administering vaccines against HIV and other STIs may be possible, although complications such as antigenic competition, immune-dominance, increased activation or recruitment of CD4 cells, or a negative impact on HIV vaccine efficacy would need to be determined and addressed.
- Designing and implementing clinical trials for combined products, as most MPTs are, will be complicated but should be possible. Trial designs and endpoints will vary depending on whether the study products combine established products with a novel one(s), or combine novel products. Trialists need to consider what the control or standard will be for each technology, the endpoint(s) needed to calculate efficacy/effectiveness, measuring and attributing toxicity, and measuring adherence (if the study product is user controlled).
- With growing evidence that oral PrEP, if used consistently, is effective in reducing the risk of HIV transmission, the window for placebo-controlled trials for HIV endpoints may be closing, with trial designs moving increasingly toward active controls. This means that trials will have increased sample size, complexity and cost, and adaptive designs will need to be considered.
- Increasingly complex combination interventions and trial designs may introduce similar complexity in the regulatory environment. One researcher noted that while there is a great deal of scientific justification for using PrEP with vaccines, some national regulatory authorities may be hesitant to combine topical or oral PrEP with vaccine regimens.
- The MPT field should seek to capitalize on research capacity and opportunities in basic science, product development and clinical testing in different settings. For example, the goals of the MPT

effort align with India's policies, where both the public and private sectors are working to develop an environment conducive to research and product development. These efforts are bolstered by a public sector infrastructure for research and clinical trials, a supportive public policy environment, and a growing and increasingly dynamic pharmaceutical sector.

- Given the complexities and challenges of vaccine development, the Target Product Profiles for MPT vaccines should be tied to realistic timelines for applying basic research to developing a product. Addressing such complex scientific challenges warrants exploration and innovative ideas. However, these ideas should be tempered with a realistic assessment of the feasibility of development and testing.
- Finally, at the same time that these new approaches and ideas are being explored, it is important to continue to advocate for and test better ways to increase delivery and access to existing technologies that can improve reproductive health and women's lives. Increasing access to family planning through better services; real method choice with more access to underutilized methods like intrauterine devices (IUDs), emergency contraception, and male and female condoms; access to HPV vaccination and more progressive policies to increase access to adolescents and unmarried women all could have a substantial impact while MPT development continues.

### **Programmatic issues: involving end-users and providers in MPT access**

Incorporating user and provider perspectives is critical to designing and developing successful MPTs and systems through which women can access these technologies. Timing this input is complex as user and provider perspectives and preferences must be balanced with what is technically and scientifically feasible. Dialogue among users, providers and product developers about product attributes and feasibility is ideally an iterative process that can balance these perspectives. A panel addressed a number of key questions regarding the process and timing for incorporating end user and provider perspectives into product development, key dimensions of product acceptability from different points of view, and lessons that can be drawn from other SRH products and applied to MPTs with respect to successful introduction, marketing, market segmentation and product positioning. Key points from the panelists and discussion included:

- MPTs have the potential to meet multiple aims – increase individual rights and choice, improve public health, and enhance opportunities for commercialization for products to be sustainable. These goals, while all important, may not align well at all stages of the process. Experience with other technologies underscores the importance of having realistic strategies at each stage. For example, a “cross subsidization” approach to sustainability may be attainable over the long term, but will likely be unrealistic in the near term.
- Users and providers exist within complex “ecosystems” of actors and events that can strongly influence thinking and decision-making around health technologies. For the end-user, her partner or partners, peers, family, and community all intersect in powerful ways.
- Emergency Contraception (EC) is one of the reproductive health technologies that may be instructive for MPTs, and the Indian experience has both positive and cautionary lessons. EC was approved for use in India in 2001, introduced in the public sector in 2003 and by 2005 was available over the counter. Following a big commercial push, EC sales increased dramatically, soon leading to

a backlash amid concerns about “over use”, promiscuity, use by unmarried women and abortion. At the same time, growth in demand led to more companies entering the market and increased prices, rather than higher volumes leading to lower prices. Commercial advertising has been restricted to those companies that pass a review board. This experience suggests that, while mass marketing is effective for promotion, it is also important to educate potential users and gatekeepers, and build capacity among gatekeepers to ensure quality and appropriate use. Also, although making the product available over-the-counter (OTC) can increase sales and draw new products into the market, in some cases it can result in lower quality, questionable marketing practices, and higher prices.

- Technologies need to be considered in the context of people, policy, public health and health systems. Each of these can help a new technology or innovation to succeed, delay progress or allow it to fail. Examples from existing policy and technologies are sobering: Numerous global health policies have addressed ensuring access to essential medicines, but gross inequity still exists in access to medicines worldwide. When initially introduced, the female condom received inadequate investment due to provider and policymaker bias, and thus has not achieved the level of distribution and use first anticipated. Pricing for HPV vaccines puts them completely out of reach for widespread introduction in low-resource settings, even with a “reduced” price. Many companies charged with producing public health products are too small to create or meet demand. Finally, given current reductions in global health budgets, increasing pressures on national health budgets, and the cost of introducing a new product, it is important to determine where funding will come from to subsidize and deliver new SRH products.
- Delivering MPTs will require the infrastructure necessary for any prevention technology, including a reliable supply chain, functional health system, and clear information for providers and users on the product’s benefits and risks. Introduction and roll out of MPTs will require decision makers and providers to understand the new technology and support its use. Providers can be important advocates – or barriers – to new technologies, and as such should be engaged early and throughout the process of product development, policy-making and introduction. “Providers,” defined broadly, could play key roles in clinical training, advocacy through academic institutions and clinical societies, needs assessments, research and evaluation, expert consultations with regulatory agencies, and other key areas. Provider training and introduction strategies must take into account the often already overburdened health systems. An important strategy will be to emphasize that, by addressing multiple health needs, MPTs will be an efficient approach to delivering and accessing services that improve women’s health.
- Product introduction and service delivery approaches for MPTs should draw on and learn from ongoing efforts to integrate family planning, STI, and HIV services. A number of tools exist that can be adapted to assist providers and health systems to determine how to provide a new MPT within an integrated service. MPTs in effect embody such “integration” in a technology, and as such can potentially reinforce and strengthen such integration efforts and improve overall efficiency of integrated programs.
- It is timely to foster information and dialogue about MPTs at different venues such as international conferences and professional meetings. These efforts are already underway and a number of constructive ideas were put forward for building momentum in this area in different countries (see **Next Steps**, page 17).

## The role of innovative partnerships in ensuring successful MPT development and introduction

At present most MPT products are being developed by academic and not-for-profit institutions whose reach and experience generally does not extend to product manufacturing, pricing, marketing and delivery. Innovative partnerships will therefore likely play a central role in ensuring access to MPTs. Over the last decade, public-private partnerships (PPPs) have increasingly been put forward as a model for product development and delivery, with some notable successes. Speakers from different sectors that may offer important partnership opportunities for MPT development and introduction – Cipla, Ltd., a generic pharmaceutical company; Medicines360, a non-profit pharmaceutical company; and Marie Stopes International (MSI), a major provider of health services worldwide-- offered the following observations and recommendations for the role of partnerships and preparing for access:

- As with any new technology, preparing for delivery of MPTs is challenging given uncertainty around many key issues: the level of efficacy for different indications; the regulatory pathway in different country settings; estimating the market; whether it will require a prescription; manufacturing and delivery costs; pricing and subsidization; the market size and commercial potential; intellectual property arrangements, including patents and competition; the level of medical monitoring that will be needed; approaches to marketing and promotion; and a host of other issues. Addressing these uncertainties can involve multiple actors from diverse disciplines, and companies are generally not used to working with such a complex array. Finally, given that “MPTs” is a broad concept encompassing a range of indications, technologies and product attributes, approaches to some of these issues are sure to vary between different products. While many of these issues will remain uncertain for some time, it is important to have some “fixed points” of surety on certain aspects so that a company or potential partner can determine whether and how to get involved.
- Despite these many uncertainties, MPTs may also present real opportunities that may be attractive to private companies. Working with MPTs may, for example, have commercial potential, or provide opportunities to demonstrate social responsibility, to gain experience with a new technology that could be a platform technology for other work, explore a new market, or to develop scientific skills. For example, Cipla, Ltd has done well in innovative generic markets such as combination ARVs. The company worked with the Indian Council for Medical Research to develop pediatric HIV treatment formulations to meet an urgent public health need, although the market held little commercial potential.
- A number of PPP models have been developed in recent years to commercialize health products, many focused on delivering these products to resource-poor settings at an affordable price. Some, like Medicines 360, are based on a model of cross-subsidization where profits from commercial sales help subsidize and offset costs to supply the public sector. Both are dynamic and complex arenas, and PPPs must be powered and structured to operate effectively within this complex milieu. Medicines 360 currently focuses on bringing an affordable LNG-containing intrauterine system (IUS) to women in the public sector in the US, with an aim to expand this to low-resource settings in the future. The company maintains that it has a number of commercial partners interested in this product, and by leveraging philanthropic funds it can remove some of the risk for these commercial entities. This model may be applicable in the future once an MPT product is developed, and those

working on MPTs should continue to explore the different models of PPPs and what they can offer. Given the many diverse roles and issues outlined above, more than one PPP or entity may be needed to address all the different elements of commercializing and delivering an MPT.

- Partnerships will also be needed with service delivery systems to conduct pre-introductory studies and explore the best approaches to providing MPTs. MSI has experience with a number of new technologies, including current work with FHI360 to register and distribute the hormonal implant Femplant in key countries. MSI's experience echoes a number of the overall challenges with product introduction, including difficulties in forecasting, uncertainty about timelines for registration, extensive up-front costs, and inhibition of uptake due to high initial pricing. For MPTs, groups like MSI that provide integrated services can serve as natural partners for product introduction and roll out.
- Attracting private sector interest for MPTs is difficult but important. Although many of the components of MPTs under development have come from the private sector, it is the public sector that is driving MPT product development, and bearing the cost and risk of clinical trials for these products. In the field of contraception, most of the innovation is in refining and adapting existing combinations or technologies, as fear of litigation has caused most private companies to abandon the development of novel contraceptives.
- A range of different partnerships with organizations like the ones above – and likely others – may offer innovative approaches to meeting the diverse challenges of developing and introducing MPTs. Key actors working on MPTs should continue to explore what these and other models may offer for product manufacturing, registration, and implementation.

## Policy considerations of MPTs

The global health policies of donors and national governments play an important role in determining how products for resource limited settings are developed and prioritized, and ultimately in shaping intended markets. Speakers from several donor agencies and other global health organizations--including DFID, USAID, WHO, The Wellcome Trust and the Guttmacher Institute--described their priorities and perspectives as they relate to MPTs:

- As donors consider investments, for many, limited budgets can mean direct tradeoffs between research and development for the future, and supporting programs that benefit people directly now. In noting this dilemma, the speaker from **DFID** suggested that MPTs are appealing in that they potentially offer efficiencies and value for money by meeting multiple needs for individuals and at a policy level. MPTs also dovetail with DFID's focus on innovation. At the same time, the uncertainty around new product development and the complexity of navigating among the different scientific approaches and leads may make it difficult to determine whether and where to invest.
- MPTs and the approach to developing them fit within several of the priorities outlined by the **Wellcome Trust** and **USAID**. The Wellcome Trust's approach is informed by public engagement and dialogue with diverse communities involved in or affected by the research; technology transfer to help bridge the gap between fundamental research and commercial application; understanding how the social aspects of health interventions or biomedical research impact their effectiveness; broadening the research base for scientific endeavor in under-resourced environments; and

supporting international networks and partnerships focused on problems of resource-poor countries. USAID is a key funder of MPT advocacy and development, consistent with two of the core principles of the US Government's Global Health Initiative (GHI): promoting women, girls and gender equality; and promoting research and innovation. Two of the GHI's technical focus areas, HIV/AIDS and family planning and reproductive health, are the main health concerns that MPTs aim to address. USAID's support for MPT product research and development, clarifying regulatory pathways for MPTs, and raising awareness and support through technical meetings, are reflected and documented throughout this report.

- **WHO** is charged with developing and maintaining global norms, international standards, and guidelines for the quality, safety and efficacy of drugs, and for providing guidance in harmonization efforts. The pre-qualification system is a service to assess and certify pharmaceutical quality through compliance with good manufacturing processes. WHO guidance documents in family planning, SRH, HIV prevention and integration could be brought to bear on MPTs. WHO may also issue formal guidelines on use of a new health innovation like an MPT following a formal process of assessment. As MPT research moves forward, it will be important to ensure that sufficient evidence exists or is being generated to inform WHO guidelines.
- Several speakers noted that potential delivery and impact need to be aligned with product development in order to build support for MPTs among donors, national governments, and other key decision makers. "Making the case" for MPTs may require documenting a more active demand rather than citing the more passive "unmet need."
- It would be useful to continue and strengthen efforts to ensure coordination among donors and organizations supporting MPT development. One proposed project is to develop a clear roadmap to outline what is happening in the field, future activities and needs, and key gaps. Such a roadmap would assist donors and others in the field to prioritize which candidate products move forward in development. With the high cost of Phase 3 trials, coupled with the tightening of global health budgets and lack of private sector investment in MPTs, it is more important than ever to ensure that only the most promising candidates are supported through regulatory approval and introduction.

## Next Steps

*The Global Forum on Multipurpose Prevention Technologies for Reproductive Health* helped to consolidate and advance the field of MPTs, especially in more fully engaging colleagues in different regions of the world, and developing strategies to carry forward work in this area. The Global Forum included side meetings for participants from different regions to brainstorm ideas for advancing work on MPTs. During the final session, several speakers proposed concrete next steps they will take in the different settings where they live and work. Emerging from the Global Forum were the following key actions and commitments:

### **CREATE A ROADMAP FOR MPT DEVELOPMENT AND DELIVERY**

Consolidating the work to date on MPTs in an overall research and development roadmap was identified repeatedly during the Global Forum as a key priority. This roadmap would be used to characterize the pipeline from discovery through approval, analyze the pipeline against the MPT Target Product Profiles,

and link both with the potential regulatory pathways to identify opportunities and gaps. In doing so, this roadmap would provide an important framework for researchers and donors to prioritize development actions and investments. The key US government donors at the Global Forum—USAID, NIAID and the NIH Office of AIDS Research --agreed to work together on the roadmap process via an interagency working group to be coordinated by the IMPT.

### ***STRENGTHEN AND EXPAND COORDINATION***

One outcome of the Global Forum will be heightened coordination among researchers, donors, and global health advocates interested in MPTs. A number of donors are already supporting the work of CAMI as Secretariat for the IMPT to provide a forum for exchanging information and ideas across basic science, research and development, stakeholder engagement, and potential delivery of MPTs. The IMPT is currently working on a strategic plan for the next five years, and will continue its work to support and coordinate novel approaches for multi-disciplinary collaboration, facilitate funding for research and development, expand US and global funding and support, and assist with efforts to create a MPT Roadmap and clarify regulatory pathways.

### ***ENCOURAGE HARMONIZED REGULATORY PATHWAYS***

The Global Forum brought together experts with experience working in and with diverse regulatory authorities. Following the regulatory session at the November 2011 MPT Symposium, which focused mainly on the USFDA, the Global Forum offered a chance for other regulators to reflect on the processes that will be needed for regulatory review of MPTs. This included a discussion of terminology that focused especially on clarifying “combination products” and “multiple indications”, and most of the regulatory experts present concurred that the definitions put forward by the USFDA would provide a useful framework for considering MPTs. In a number of settings, ongoing efforts at regulatory harmonization are creating a climate conducive to addressing public health problems. Participants agreed that there are opportunities to build upon these harmonization efforts and enable smaller regulatory authorities to work with others that have more experience with novel products. The Population Council will continue to encourage this dialogue and information sharing about regulatory processes as part of its role in the IMPT.

### ***FOSTER NEW PARTNERSHIPS***

The Global Forum drew a number of representatives from the private sector and public-private partnerships, key actors in the global health arena that provide important complementary perspectives to the scientific and advocacy focus of the MPT field to date. The IMPT will continue to work with these and similar partners to explore appropriate approaches to MPT technology transfer, production, and distribution in key markets, in order to ensure that these critical perspectives are fully incorporated into the MPT development process.

### ***INITIATE NATIONAL AND REGIONAL COMMUNICATIONS***

Recognizing that MPTs have the potential to meet the goals and priorities already articulated by national governments, much of the initial work proposed for national and regional settings focused on raising

awareness among key stakeholders to the potential and progress of MPTs in their specific territories, including the following:

- India: Relevant officers at the Indian Council for Medical Research and the Centre for Policy Studies will work with colleagues at the Federation of Obstetricians and Gynecologists and other groups to convene a workshop on MPTs in late 2012 or early 2013. The purpose of the workshop will be (a) to raise awareness of MPTs in India and to advocate for investment in priority R&D activities aimed at the creation of novel MPTs; and (b) to identify opportunities for strengthening the use of existing SRH technologies, especially in selected demographically vulnerable states. These efforts will be pursued with national and international collaborators. The protagonists will also work to familiarize government officials, scientific groups and pharmaceutical companies in an effort to draw new actors into the field of MPTs.
- Kenya: Brief symposia on MPTs will be organized for existing SRH meetings of key stakeholders, such as biomedical researchers, OB/GYN groups and midwifery associations. Further steps will be based on specific needs and interests.
- Southern Africa: Discussions will ensue on how best to engage key stakeholders in that region, and also ensure that the products developed will meet the most urgent unmet SRH needs. Initial priorities will focus on communication, consultation and advocacy, followed by strategies to engage Pharma and other new collaborators.
- China: The current environment is conducive to supporting research and development, especially in technology innovation like MPTs that meet clear national needs. There are numerous opportunities for advancing biomedical research related to MPTs in China. Forming a consortium and identifying international collaborations are important initial steps.

Building upon the partnerships forged at the Global Forum, the IMPT will work with colleagues in these regions to develop and implement communications and advocacy plans that build awareness and interest of MPTs among key constituencies, and provide mechanisms to integrate their perspectives into overall MPT strategies.

## **Conclusion**

The Global Forum's success reflected not only the wealth of experience embodied in the more than 60 invited delegates but also their readiness to participate in vigorous debate throughout the two days of the meeting. The presentations, panels and discussion forcefully highlighted the universal need for MPTs and the importance of continuing to push forward the scientific and policy agenda despite challenges and the complexity inherent in such efforts. At the same time, attendees also acknowledged that priorities and emphasis may differ across regions and among population groups. Participants identified a number of clear actions and concrete next steps to be taken forward by research groups and emerging regional networks. Finally, the Forum underscored the potential of MPTs that meet multiple sexual and reproductive health needs to facilitate efficient delivery of and access to health innovations and services to improve women's health and lives around the world.

## **Acknowledgement**

The Global Forum on Multipurpose Prevention Technologies for Reproductive Health could not have happened were it not for the generosity of the Wellcome Trust in hosting the Forum, and the collegial and conducive environment that the Trust provided. It is clear that the objectives of the Global Forum are entirely consistent with the Wellcome Trust's policy of affording high priority to the alleviation of reproductive health concerns on a global level, and it is to be hoped that future collaboration between the MPT field and the Trust will ensure that we will continue to contribute positively to that policy.

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