Global Forum on Multipurpose Prevention Technologies for Reproductive Health

Advancing the MPT Agenda

EXECUTIVE SUMMARY

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Initiative for Multipurpose

Prevention Technologies











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.

This report was prepared by Elizabeth McGrory, Consultant to Population Council; Bethany Young Holt, CAMI/Public Health Institute; Judy Manning, US Agency for International Development (USAID); Alan Stone, Senior Consultant to CAMI; and Martha Brady, Population Council. It was made possible by the generous support of the Wellcome Trust and the American people through the USAID Cooperative Agreement # GPO-A-00-06-00005-00, the Mary Wohlford Foundation and the Population Council.

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.

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.

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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