Multipurpose Prevention Technologies *for* Reproductive Health

2011 SYMPOSIUM

Executive Summary

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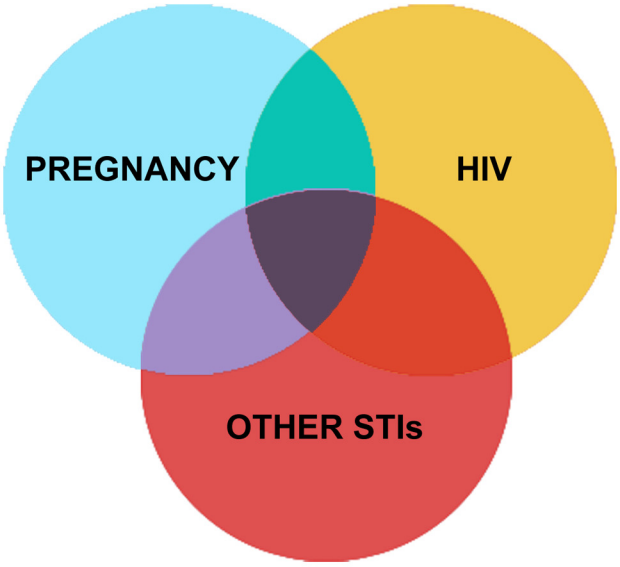

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The **Initiative for Multipurpose Prevention Technologies (IMPT)** for sexual and reproductive health was established in the spring of 2009 to unite reproductive health researchers, health care providers, policymakers, advocates, product developers, and donors behind a focused objective: to advance the development and introduction of products that can be used in various combinations to address multiple sexual and reproductive health needs, namely unintended pregnancy and STIs, including HIV.

The **mission** of IMPT is to raise awareness about and support for new and existing multipurpose prevention technologies that can be used in various combinations to address multiple sexual and reproductive health needs.

The IMPT's uniqueness is to focus on emerging technologies in combination with technologies that are currently available. While there are not many existing MPTs other than condoms, there are single purpose technologies that can be combined either with each other or with new technologies/drugs and other novel technologies are in development.

Our vision is to advance these promising technologies as quickly and efficiently as possible through an integrated development program from pre-clinical investigation to, clinical testing, regulatory approval, scale-up, public readiness, and product evaluation. The **IMPT** strives to:

1) Mobilize financial, scientific, and political resources to advance the development and access of MPTs;
2) Build synergy and cooperation between scientific disciplines that will help facilitate collaborations and expedite product development and implementation;
3) Develop a cross-disciplinary advocacy strategy and promote increased support for MPTs.

Multipurpose prevention technologies (MPTs) for sexual and reproductive health, also referred to as "combinations" or "dual" technologies include vaccines, microbicides and devices (e.g ., intravaginal rings, diaphragms, etc) and are designed to 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. **MPTs** that are acceptable, affordable, and widely available would greatly improve health and save resources across the globe.

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Executive Summary

Background: The consequences of unintended pregnancy, HIV, and other sexually transmitted infections (STIs) are among the great public health challenges of our time; women worldwide bear substantial social, health and economic burdens of unintended pregnancy and STIs. The Initiative on Multipurpose Prevention Technologies (IMPT) convened a Symposium in November 2011 to advance the agenda for technologies that could simultaneously address multiple sexual and reproductive health (SRH) needs. The Symposium brought together 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. The symposium provided a critical opportunity for researchers, advocates, donors, and other key constituents to take stock of progress on MPTs and look ahead to consolidate these gains as research continues.

Target Product Profiles: A number of previous discussions focused on identifying existing and emerging scientific approaches that could be applied to developing MPTs. They concluded that developing MPTs is challenging but feasible, and proposed a framework for MPT development to help assess and prioritize candidate products according to their development potential, likely impact, and market potential. Working groups formed to develop target product profiles (TPPs) for drug-drug, drug-device, and multipurpose vaccine combinations. The interplay among different attributes is complex and varies among product concepts, but general priority indications and formulations include: contraception and HIV; contraception and HSV; and long-acting reversible formulations like injectables and vaginal rings. This general approach is consistent with the Bill and Melinda Gates Foundation Dual Protection Strategy, which has prioritized contraception and HIV prevention through injectables or rings.

Incorporating Diverse Perspectives: Successful MPT development needs to both reflect and incorporate diverse perspectives of end-users, providers, regulators, donors and developers. Such products can help policymakers meet multiple health and development goals, which can foster political champions essential for public and private investment. Product development should be also informed by eventual introduction and roll out, which in turn can draw on experience with a range existing products and technologies.

Recommendations

The Symposium generated a number of recommendations related to developing and implementing MPTs in order to advance the field quickly and efficiently:

- **Target Product Profiles (TPPs).** Defining Target Product Profiles (TPPs) based on the most relevant MPT product attributes and parameters is essential, both to prioritize donor investments and to guide developer strategies. This process must be dynamic and regularly informed by emerging data, with the resulting TPPs specifically linked to regulatory pathways. MPT development should continue to pursue methods that use hormonal, non-hormonal and barrier contraceptive approaches to provide more options for women.

- **Pipeline.** A sufficient, sustainable pipeline of MPT scientific concepts and product approaches is needed and should include a range of approaches to allow for more product choice, flexibility in adapting and prioritizing products in response to new data, and greater responsiveness to women's needs. Potential regulatory pathways should be mapped for those MPT products that are furthest along in development.
- **MPT Vaccines.** MPT vaccine development can build on the history of successful multipurpose vaccines developed to prevent other diseases. Meaningful investment in the fundamental science associated with MPT vaccine approaches will be required to move this area of research forward.
- **Hormonal Contraception.** MPT development must continue to be informed by evidence around the interface between hormonal contraception and HIV and work to support the WHO guidance process and the development of a research agenda to further understand this interaction. MPT development should also continue efforts to include non-hormonal contraceptive approaches.
- **Acceptability and Use.** Product acceptability, potential for adherence, and eventual implementation must play a central role in MPT product design and development and should factor into the TPPs.
- **Regulatory Approaches.** Regulatory approaches should form a key component of TPPs, and should be mapped for those MPT products furthest along in development. The IMPT should also identify opportunities to engage regulatory authorities from diverse settings on MPT concepts and approaches, and so their perspectives can inform regulatory strategies for emerging products.
- **"Multipurpose Visits".** To provide critical services to meet current needs while new products are being developed, the IMPT and its allies can work to encourage "multipurpose visits" to provide women with ways to address the dual risks of unintended pregnancy and unwanted infection.
- **Diversity of "Users".** Successful development and implementation of MPT products will depend on a broad definition of 'users' to better understand and address the barriers and enabling factors that will affect product uptake and use within all relevant environments: policy, health systems, and end users.
- **Metrics for "Success".** New health products or innovations generally require a long time to become established, so it will be important to identify realistic metrics for "success" for new MPTs. These should include: 1) developing new approaches to allow for more realistic demand forecasts and more accurate linking of supply and demand, 2) an investment framework for introduction, and 3) strategies for ensuring adequate funding for introduction and roll-out.
- **Funding.** For the MPT pipeline to grow and advance, it will be crucial for donor agencies to maintain current levels of funding and increase those as budgets allow. The field will also need to explore new sources of funding and investment.

- **Advocacy.** The IMPT should work to expand the constituency for MPTs to form a cadre of new advocates in new sectors, and to advance the scientific and product development agendas.
- **Regional Constituencies.** Regional efforts to highlight and build strong constituencies for MPTs should explore establishing national MPT teams involving potential end users, community opinion makers and service providers.
- **Partnering.** MPT developers and advocates will need to seek and create innovative partnerships that bridge the for-profit sector and needs in low-resource countries with poorer populations

Looking Ahead

As work on MPTs advances, efforts to date, recent developments in reproductive health research, and the current economic climate signal three areas for priority emphasis:

- The MPT products currently in clinical testing are heavily dependent on a few combination products, which may or may not prove sufficiently safe and/or effective. Continued, timely funding for the advancement of these "first-generation" products will be essential to informing the potential of such strategies and to setting the stage for sound, strategic pipeline management and funding going forward.
- The IMPT's efforts to map the product should continue and diversify as the basis for fostering a full, frank, and well-informed understanding of the preclinical pipeline, its potential, and what fresh concepts might appropriately be drawn in to enrich and bolster it. Energy and craft are needed—and soon—to identify, analyze, and attract potential additions and creative approaches.
- After a decade of turmoil, there is much more real dialogue and collective support for HIV prevention research, for truly integrated reproductive health services, and for strategic, collaborative review and funding. These heartening and timely developments merit continuation and expansion to meet current economic and political challenges. This means that donors must keep talking, sharing, and seeking synergistic intellectual and financial engagement.

Developing a robust, diverse and sustainable pipeline for MPTs will require sustained and new resources – ideas and people, as well as funding. Opportunities for scientific exchange, innovative thinking and recruiting a range of new talent will build on existing approaches in new ways and attract fresh ideas and solutions. The IMPT is committed to continuing to this work, with long-time and a growing cadre of new partners that will offer the best chance of making these urgently needed technologies become reality.

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