Multipurpose Prevention Technologies for Reproductive Health

International Symposium on Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health

Final Report

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New Delhi, India
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The contents of the report are the responsibility of ICMR and CAMI/IMPT.
The Indian Council for Medical Research (ICMR), headquartered in New Delhi, is the apex body in India for the formulation, coordination and promotion of biomedical research. ICMR’s research priorities coincide with national health priorities such as family planning, maternal and child health, nutrition, and control and management of communicable diseases; developing alternative strategies for health care delivery; containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders; and mental health research (including both pharmaceutical and traditional remedies). All of these efforts are undertaken with a goal to reduce the total burden of disease and to promote the health and well-being of the population.

The Initiative for Multipurpose Prevention Technologies (IMPT) was established in 2009 to unite researchers, health care providers, policymakers, advocates, product developers, and funders 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 human immunodeficiency virus (HIV), and other reproductive tract infections (RTIs). 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 (PHI), Oakland, CA, USA.

Multipurpose prevention technologies (MPTs) for sexual and reproductive are single products which would simultaneously address two or more sexual and reproductive health needs, including prevention of unintended pregnancy; prevention of STIs, including HIV; and prevention of other RTIs, such as bacterial vaginosis. Safe and effective MPTs that are also acceptable, affordable, and made widely available would greatly improve health and save resources across the globe.

The International Symposium Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health was sponsored by ICMR, CAMI/IMPT, USAID, and WHO. Nomita Chandhiok (ICMR, New Delhi, India) organized all aspects of the meeting, along with Bethany Young Holt (CAMI/Public Health Institute, USA), Judy Manning (USAID, USA), and Alan Stone (Senior Consultant to CAMI and MEDSA, London, UK).

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FOREWORD

Many Reproductive and Sexual health outcomes in India have improved. However, women continue to be disadvantaged with high rates of unwanted and unintended pregnancy, unsafe abortion, unmet need for contraception, exposure to HIV and other sexually transmitted infections. There is an urgent need to improve the utilization of various existing technologies and accelerate the development and subsequent utilization of products that would simultaneously prevent unintended pregnancies, HIV and other STIs. These multipurpose prevention technologies would empower women to address their contraceptive and disease prevention needs.

In order to raise the awareness and sensitize key stakeholders, including biomedical researchers, policy makers, research managers, drug regulators and health providers about the potential of MPTs to address India-specific SRH issues, identify the primary indications of most concern and the priority research questions relevant to India, a symposium was organized in December 2012 in Delhi, India along with the Coalition Advancing Multipurpose Innovations (CAMI), the US Agency for International Development (USAID), and World Health Organization (WHO). It is hoped that the proceedings and deliberations of this symposium would stimulate early and mid-stage translational milestone driven research that will lead to the development of multipurpose prevention strategies, taking into account local health practices, safety, effectiveness, acceptability, cost and promoting reproductive health rights within the target population.

(V. M. Katoch)
Executive Summary:

Multipurpose prevention technologies (MPTs) are some of the most innovative sexual and reproductive health (SRH) products currently under development, with the potential to simultaneously prevent unintended pregnancy, sexually transmitted infections (STIs) including the human immunodeficiency virus (HIV), and reproductive tract infections (RTIs).

The newly emerging field of MPT research and development (R&D) builds upon more than two decades of research on dual protection products, and came together with the creation of the Initiative for Multipurpose Prevention Technologies (IMPT) in 2009. The IMPT is comprised of researchers, product developers, advocates and providers working to promote innovative prevention strategies for SRH around the globe. The Coalition Advancing Multipurpose Innovations (CAMI) serves as the neutral organizing body and Secretariat for the IMPT, with no conflicts of interest related to advancing certain MPT products. CAMI is a project of the Public Health Institute (PHI), headquartered in California, USA. CAMI serves as the central leadership and coordinating body for the IMPT, convenes technical meetings, maintains a forum for multidisciplinary collaboration, sponsors an on-line MPT Resource Hub, provides technical coordination to MPT stakeholders, and facilitates funding agency coordination and collaboration with regards to specific investments related to MPT product priorities. Since the launching of the IMPT in 2009, CAMI has convened a series of nearly a dozen international meetings on MPTs which have advanced the MPT field.

The *International Symposium on Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health* was convened on 11-12 December 2012 in New Delhi, India. The meeting was organized by the Indian Council for Medical Research (ICMR), along with CAMI. This meeting was the first-ever regional symposium on MPTs, bringing together SRH experts from across India and worldwide to raise awareness and support for MPTs.

The objectives of the 11-12 December 2012 India MPT symposium were to:

* Review the current status of MPT development and highlight needs and potential challenges, including increasing the utilization of existing dual protection products;
* Expand multisectoral input into possible product development plans, including the perspectives of product developers, end users and providers; and
* Identify research priorities relevant to India, and define a clear agenda for MPT R&D that would provide both the scientific rationale as well as concrete information for developers, scientists, regulators, funding agencies and advocates.

The summary of the discussion around each session is described in the following pages.
Session I: The need for MPTs: Overview of epidemiological trends and the rationale for MPTs

As the world progresses toward the Millennium Development Goals (MDGs), special attention needs to be paid to the unmet need for contraception, maternal mortality rates and the incidence of STIs, including HIV. MPTs have the potential to simultaneously address at least two SRH prevention needs: unintended pregnancy, STIs, including HIV and other RTIs. MPTs address these challenges in a single, comprehensive technology that offers an integrated, potentially cost effective approach. However, given the differences in SRH risks across regions and within specific countries, a suite of MPT products would better meet the needs of women as their SRH concerns change over time. As evidenced by the epidemiological data in India, unintended pregnancies and STIs are major causes of morbidity and death. Thus, prevention of unintended pregnancy and STIs are the two prioritized attributes for designing the target product profile (TPP) for the Indian population.

Session II: The use of existing reproductive health (RH) prevention technologies: challenges and potential approaches to increased utilization

Despite the availability of male and female condoms as effective options for preventing unintended pregnancy, HIV, and other STIs, these outcomes continue to occur. Efforts should be made to improve uptake of male and female condoms by expanding opportunities to increase their use, and by learning from past experience. Improving uptake and use of these existing technologies will require individual behaviour change as well as changes to the health care system. Communication messages for providers and end users should take into account the diverse populations that would benefit from greater condom use.

Session III: Status of MPT R&D

A number of MPTs with different combinations of indications are under development, with a focus on on-demand and sustained release products. These first-generation MPTs have the potential to greatly expand prevention options for women, and meet different needs as women’s SRH concerns change over time. Of particular importance to Indian women would be MPT products that prevent pregnancy and STIs. The availability of several of the first generation MPTs is largely dependent on the results of the FACTS 001 confirmatory study of TFV gel for prevention of HIV and HSV-2, which should be available in 2014.

Session IV: Effective communication and its impact on R&D

Well-planned communication strategies and tailored messages can help motivate funding agencies to advance MPT research specific to Indian needs. At the same time, these communication strategies have the potential to create awareness among policy makers who will play an important role in the eventual incorporation of MPTs into SRH programmes.
Session V: Product prioritization

Country-specific product prioritization exercises can help to inform the development of a TPP; however, the path to R&D and introduction is still challenging. Modelling projections and lateral thinking is crucial for predicting the future need for MPTs in different regions, given that the first generation of MPTs will not be available for at least several years.

Session VI: Challenges in the R&D pathway for MPTs: Limitations, gaps and opportunities

Developing a TPP for MPTs using different permutations and combinations helps to prioritize product development. There are limitations to currently available prevention products, and the development of MPT intravaginal rings (IVRs) will face a number of challenges – chief of which will be the simultaneous release/bio-availability of two or three different active pharmaceutical ingredients (APIs) for different indications. There will also pose regulatory challenges, since there are no international or national guidelines for the development of MPTs. Finally, investment by the pharmaceutical industry in MPT R&D will require early consideration of key aspects to potential marketing and product uptake, including the potential for public health impact.

Session VII: Involving the end-users and providers in the development of and access to MPTs

Knowledge and support of the providers and involvement of end-users are the key components for successful introduction and uptake of MPTs. Innovative strategies will have to be developed, taking into account the challenges faced by providers in increasing utilization of existing RH technologies.

Session VIII: Availability and access of MPTs: Implementation issues

What are the lessons learned?

Integration of MPTs into the existing SRH programmes will have to be strategically planned, and take into account lessons learned from the introduction and uptake of existing prevention products.

The complexity of the MPT R&D pathway is sobering given the various possible combinations of indications, mechanisms of action, formulations, and modes of delivery that must be considered. Furthermore, there are pharmacokinetic actions, drug interaction and bioavailability issues that must be considered for two or three APIs combined in one MPT product. The eventual introduction and use of MPTs, however, could very well lead to marked declines in both unintended pregnancies and sexually transmitted diseases, particularly in areas of the world where these health burdens are greatest. Knowledge and support of the providers and involvement of end-users are the key components for successful introduction and uptake of MPTs. Innovative strategies will have to be developed, taking into account the challenges faced by providers in increasing utilization of existing RH technologies. By targeting multiple SRH needs simultaneously, MPTs offer an efficient approach to addressing important public health needs, which could result in social and economic benefits to women and their families worldwide.
The International Symposium on *Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health* provided Indian scientists with updated knowledge in the area of MPT R&D and the global effort to advance these new technologies. Introduction of MPTs will have to be strategically planned to maximize use and integration of programmes will help in cost effective delivery.

**Introduction and Background**

This report summarizes the presentations, discussions and outcomes from the *International Symposium on Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health* convened on 11-12 December 2012 in New Delhi, India. The meeting was organized by the Indian Council for Medical Research (ICMR), along with the Coalition Advancing Multipurpose Innovations (CAMI), Secretariat to the Initiative for Multipurpose Prevention Technologies (IMPT). This meeting was the first-ever regional symposium on multipurpose prevention technologies (MPTs), bringing together sexual and reproductive health (SRH) experts from across India and around the globe to raise awareness and support for MPTs.

MPTs are some of the most innovative SRH products currently under development, with the potential to simultaneously prevent unintended pregnancy, sexually transmitted infections (STIs) including the human immunodeficiency virus (HIV), and reproductive tract infections (RTIs) in a single product. The complexity of the MPT research and development (R&D) pathway is sobering, given the various possible combinations of indications, mechanisms of action, formulations, and modes of delivery that must be considered. Furthermore, there are pharmacokinetic actions, drug interaction and bioavailability issues that must be considered for two or three active pharmaceutical ingredients (APIs) combined in one MPT product. The eventual introduction and use of MPTs, however, could very well lead to marked declines in both unintended pregnancies and STIs, particularly in areas of the world where these health burdens are greatest. By targeting multiple SRH needs simultaneously, MPTs offer an efficient approach to addressing important public health needs, which could result in social and economic benefits to women and their families worldwide.

The newly emerging field of MPT R&D builds upon more than two decades of research on dual protection products, and came together with the creation of the IMPT in 2009. The IMPT is comprised of researchers, product developers, advocates and providers working to promote innovative prevention strategies for SRH around the globe. CAMI serves as the neutral organizing body and Secretariat for the IMPT, with no conflicts of interest related to advancing certain MPT products. CAMI is a project of the Public Health Institute (PHI), headquartered in California, USA.

This first-ever regional MPT symposium held in India, *Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health*, builds upon a series of nearly a dozen meetings convened by CAMI focused on advancing the MPT field. These include a 2009 meeting held in Berkeley, California, USA that focused on assessing the challenges and opportunities of developing MPTs; the IMPT was formed as an outcome of this meeting. In May 2011, an “MPT Think Tank” convened some 30 scientists in Washington, DC, USA who determined that while challenging, the development of MPTs was scientifically feasible. Subsequently, larger international MPT forums were held in Washington, DC, USA.
and in London, UK – convening a multidisciplinary cadre of experts from around the world working in the areas of family planning, and HIV/AIDS and STI prevention, including product developers, scientists, regulators, policy makers, health care providers, advocates, and funding agencies.

The objectives of the 11-12 December 2012 MPT Symposium held in India, were to:

- Review the current status of MPT development and highlight needs and potential challenges, including increasing the utilization of existing dual protection products;
- Expand multi-sectorial input into possible product development plans, including the perspectives of product developers, end users and providers; and
- Identify research priorities relevant to India, and define a clear agenda for MPT R&D that would provide both the scientific rationale as well as concrete information for developers, scientists, regulators, funding agencies and advocates.

This meeting brought together nearly 100 participants – regional experts, ICMR representatives and international stakeholders. Meeting attendants were charged to consider the current status of MPT development internationally, and discuss opportunities to advance MPT research and support within India with representatives from reproductive health and HIV prevention research, product development, funding agency, advocacy, and policy entities within India. Session presentations and thoughtful discussion provided an essential information exchange and laid the foundation for further, multisectorial discussions on MPT R&D in India.

**Need for MPTs in India**

In India there is still ignorance, apathy, and a lack of risk perception about SRH matters among the general population – particularly the prevention of STIs and unintended pregnancies. As India is striving to reach the Millennium Development Goals (MDGs), especially the maternal health indicators, the government is taking steps to reach key populations in urban and rural settings. Although the prevalence of HIV and other STIs in India is declining, the high rate of unintended pregnancies in many regions directly affects maternal and infant mortality rates. Currently, female sterilization remains the most accepted method of contraception, even among younger women, and it is frequently performed as soon as women believe they have completed their families (traditionally after two or three children). Thus, while a large number of adult women are unlikely to be at risk of unintended pregnancy, they may still be at risk for contracting STIs, including HIV. With or without a contraceptive component, MPTs that prevent STIs would benefit women in discordant couples, at-risk single women, married women who are at risk because of the behaviour of their husbands (a small percentage of the population), and female sex workers (FSWs). Different combinations of MPTs, therefore, would enable women to meet their changing needs during different stages of their lives.

Lessons learned from the introduction of other health technologies can help plan for and eventually introduce MPTs. Different communication messages will be required at different stages of MPT R&D, as well as during initial introduction and scale up. These messages will need to be tailored for different
audiences, including scientists, politicians, advocates, mass media and, most importantly, the end-users. Education and awareness-raising, in addition to generating demand, may actually accelerate development of MPTs and also help to ensure their eventual uptake and use.

**Session Summaries**

During the two days of the conference, attendants participated in ten sessions aimed at addressing the meeting’s three objectives. Day one addressed the need for MPTs, the use of existing reproductive health prevention technologies, the current status of MPT R&D, effective communication and its impact on R&D, along with product prioritization. Day two addressed challenges in the R&D pathway, involving end users and providers in product development, implementation issues and a final, round table discussion on advancing support for MPT R&D in India. As summarized below, each session and discussion contributed to the advancement of MPT research and support within India.

**Session 1: The need for MPTs: Overview of epidemiological trends and the rationale for MPTs**

The objective for this session was to examine the public health need for MPTs in different regions of the world.

Dr. Manjula Lusti-Narasimham, from the World Health Organization (WHO), provided a **global overview of the need for MPTs**.

WHO’s reproductive health (RH) strategy aims to promote and strengthen SRH services by

- improving antenatal care, safe delivery, safe postpartum period and newborn care;
- providing family planning services, including infertility services, and eliminating unsafe abortion; and
- combating STIs, including HIV, RTIs, cervical cancer and other gynaecological morbidities and promoting sexual health.

Effective contraceptive prevalence varies from <10% to >70% across the globe, with very low usage in many countries in sub-Saharan Africa, and high usage in North America, parts of South America and Russia. Similarly, there is wide variation in the unmet need for family planning in developed and developing countries. More than 215 million women in developing countries have an unmet need for family planning, which translates annually to 53 million unintended pregnancies, 25 million abortions, 590,000 newborn deaths and 90,000 pregnancy-related deaths. Maternal mortality rates are strikingly high in some countries in southern Africa, such as Chad and Somalia with >1000 maternal deaths per 100,000 live births.
Globally, approximately 34 million people were living with HIV at the end of 2010, as per UNAIDS estimates. Access to antiretroviral therapy (ART) has improved considerably in the past 10 years, with greater than 70% access to treatment achieved in Botswana, Namibia and Rwanda, Swaziland and Zambia. However, for every person put on ART, two people are newly infected. As a result, 20 million more people are predicted to acquire HIV by 2031, and the resulting cost to health care systems and communities is predicted to be extremely high.

STIs are a major global cause of acute illness, infertility, long-term disability and death, with serious medical and psychological consequences of millions of men, women and infants. There were nearly 500 million new cases of four common non-HIV STIs in 2008 in adults between the ages of 15 and 49: 105.7 million cases of C. trachomatis, 106.1 million cases of N. gonorrhoea, 10.6 million cases of syphilis and 276.4 million cases of T. vaginalis.

Considering the potential to simultaneously address unintended pregnancy, HIV and other STIs, MPTs fit within the synergised approach of the WHO for improving reproductive health.

Overview from China: Need for MPTs from Dr. Allen Wu of the Center for Public Health Research, Nanjing University, China.

The estimated HIV prevalence in China was 0.058% in 2011, with an estimated 48,000 new HIV infections. Although the overall HIV prevalence remains low in China, the epidemic is quite concentrated in certain regions. Sexual transmission is the primary route of HIV transmission, and the proportion of people living with HIV continues to grow. In 2009, there were five provinces (Yunnan, Guangxi, Henan, Sichuan, Xinjiang and Guangdong) with HIV prevalence higher than the national average. These five provinces accounted for 77.1% of the total cases in China. China’s epidemic is diverse and evolving; by the end of 2011, about 780,000 people (28.6% of which were women) were estimated to be living with HIV, of which 154,000 had AIDS.

The STI epidemiological profile in China has been very dynamic. Before the mid-1990s, gonorrhea and genital warts (i.e., Human Papillomavirus- HPV) were the most common STIs. From the late 1990s to 2005, non-gonococcal urethritis (NGU) was the most common STI, but gonorrhea, HPV and syphilis were also widely spread. After 2006, syphilis became the predominant STI, with chlamydia, gonorrhea, and HPV infection being almost equally as prevalent. The regions in China with high HIV prevalence also have high numbers of syphilis infection. In 2008, China had 278,215 officially reported syphilis cases – a threefold rise in the number of reported cases compared to 2004, and a tenfold increase over the past decade.

Despite a generally slow population growth rate in China – due to education, affluence and the government’s one-child policy – it remains the most populous in the world. China’s coastal regions have the highest population growth rate, while the central regions are experiencing population decline. Most of the population growth in China is occurring in the economically developed provinces, and there is a large floating population of economic migrants that are of particular concern when it comes to the spread of HIV and other STIs. In 2009, there were 211 million migrants who were mostly
sexually active young adults. Additionally, young adults constitute a significant proportion of the population in many cities. Contraceptive usage is high in China, with intrauterine devices and sterilization being the dominant methods, but condom use relatively low. Although condom use is increasing with urbanization, improved access and easy availability, sexually active young adults still constitute most of the floating population who have the greatest need for prevention options for HIV, STIs, and unintended pregnancy.

**Overview from India: Need for MPTs** presented by Dr. Badri Saxena of the Centre for Policy Research (CPR), New Delhi, India.

In India, at the end of 2009 approximately 2.4 million people were living with HIV and the adult HIV prevalence rate had declined from 0.41% in 2002 to 0.31% in 2009. Recently, there has been a decline in the number of new HIV infections in India and an increase in the number of AIDS patients accessing ART, with corresponding decline in annual deaths. This success has occurred through targeted interventions among the high-risk groups such as FSWs, men who have sex with men (MSM), transgenders (TGs), and injection drug users (IDUs), as well as with the bridge population such as those with other STIs.

It is estimated that the annual STI incidence in India is about 5% in the adult population, with approximately 40 million new cases of STIs each year. However, reliable nationwide prevalence and incidence estimates of STIs in India are still lacking. A recent study from India shows Herpes Simplex Virus-2 (HSV-2) prevalence among general population to be about 10%. The overall HPV prevalence among women with normal cytology in India varies from 7.9%-18% in different regions. Although India has one fourth of the global burden of cervical cancer (which caused by chronic persistent infection with high-risk HPVs), as estimated by the International Agency for Research on Cancer (IARC) of WHO, cervical cancer screening and/or HPV vaccination is not yet incorporated into the public health system.

The most recent data on contraceptive prevalence rates (CPRs) in India comes from the Indian National Family Health Survey-3 (NFHS-3) of 2005-06, with a CPR for currently married women at 56 percent. The rate of unintended pregnancies has not changed over time and is still 25-30%. Contraceptive use was highest in Himachal Pradesh (73%) and West Bengal (71%), and lowest in Meghalaya (24%). Overall, female sterilization accounted for two-thirds of contraceptive use, and is the preferred method of women who have had two to three children, and thus have reached their ideal family size. Widespread use of female sterilization for contraception has led to very low use of condoms, even though sexually active women need protection against HIV and other STIs. The age-adjusted maternal mortality ratio in India is 200 per 100,000 live births, which met the 2007 target for maternal mortality ratio under the MDGs, but is far from the target of 109 for 2015. India is a large country that is demographically diverse, with variable fertility rates and HIV infection rates across the states. While India represents a small world in and of itself, it may also represent global patterns of various RH indicators with a diverse need for MPTs.

**Session 1 Summary:**
Given the differences in SRH risks across regions and within specific countries, a suite of MPT products would meet the needs of women as their SRH concerns change over time, and as risks differ across
countries and around the globe. MPTs have the potential to improve the quality of life of many thousands of women by simultaneously preventing unintended pregnancy, HIV, and other STIs. In addition, a single comprehensive technology that offers an integrated approach could be more cost effective.

Session II: The use of existing RH prevention technologies: challenges and potential approaches to increased utilization

The objective of this session was to assess the challenges and opportunities for increasing the utilization of existing RH prevention technologies.

Global overview: The use of existing RH preventive technologies presented by Martha Brady of the Population Council in New York City, USA.

In spite of the availability of some effective RH technologies, unintended pregnancies and infection from HIV and other STIs continue to pose a substantial global burden. Many women who do not want to become pregnant do not use a contraceptive for a host of reasons, including concerns about side effects, infrequent sex, false sense of security during the post-partum period, partner’s opposition, women’s opposition, high cost, lack of access, perceived sub-fecundity, and lack of awareness about available methods. Although Africa has the greatest percentage of women with unmet need for family planning, the largest absolute number of women with unmet need is in South and West Asia. This session reviewed the challenges and potential approaches to increasing utilization of existing technologies through the use of five case studies: female condoms (FCs), emergency contraceptives (ECs), contraceptive vaginal rings (CVRs), vaginal gels, and antiretroviral drugs (ARVs).

FCs are an existing MPT, given their potential to prevent HIV, others STIs, and unintended pregnancy. This technology has certain advantages, including availability over-the-counter (OTC) without a prescription, user-controlled, use on demand, short duration of use and little or no local effects. However, FCs do not possess widespread popularity due to strong provider and policy bias. Low demand has led to product costs remaining high, which creates a vicious cycle that hinders increasing access and use. Additionally, there is a learning curve for using FCs, with acceptability increasing over time with repeated use. Education surrounding sexuality, communication and negotiation skills would also help to improve uptake and continuation of use, and decrease partner opposition to this method. Strategies for increasing demand for FCs may be achieved by highlighting its potential to enhance the sexual pleasure of both partners, positioning it as an alternative to the male condom, and underscoring its value in enabling women to negotiate use of protection during sex.

The second case study focused on ECs. Depending on specific country requirements, ECs are either available OTC or by prescription. Advantages of this method are that they can be used on demand, they are user-controlled, and they have a short duration of action. Although effective methods are available, women who express interest in methods that can be used during or immediately after sex often choose ECs. Thus, there is good demand for ECs, and more than 30 brands are currently available in the market. In those countries where ECs are not available OTC, easing restrictions to access would likely increase demand. However, providing this method OTC has some disadvantages, including increased
difficulty of safety and quality monitoring, reduced counseling opportunities, and the need for women to
pay out of pocket for the product, rather than receiving it free through private health insurance or a public
sector programme.

The third case study focused on CVRs. There are currently several types of CVRs on the market;
however these are mostly available in developed countries and require a prescription. CVRs are coitally
independent, have durations of action between one month and one year, and do not require daily action
(use protocol differ by ring type and duration of action). Many types of CVRs are quite popular in the US
and Europe; their introduction into countries in Sub-Saharan Africa and South Asia will require initial
acceptability studies in settings with different sanitary conditions, toileting and hygiene practices, and
levels of urbanization. Since full or partial expulsion of CVRs can occur, there is a need to document and
address such expulsions in order to prepare for introduction and uptake in other regions of the world.

The fourth case study focused on vaginal gels, which are used on demand, are user-controlled, and have
few to no side effects. When vaginal gels were first studied in microbicide trials for HIV prevention during
the 2000’s, there were many negative assumptions about the acceptability of gel use. Since then, the
acceptability of many different types of vaginal gels has been well documented, with many women
reporting that they found sex less painful and sometimes more pleasurable with use of the gel.

The final case study focused on adherence to ARVs for treatment of HIV. Experience from the
introduction of ARVs repeatedly documents high levels of adherence at the start of treatment that
unfortunately decrease over time, thus dissipating the long-term effects of the intervention. Achieving
sustained adherence will likely require the use of cognitive-behavioral interventions, social support
interventions, and new types of marketing and product introduction schemes.

**Overview from India: The use of existing RH preventive technologies** by Dr. S.K. Sikdar of the
Ministry of Health and Family Welfare (MOHFW), New Delhi, India.

There are three prime indicators in the field of family planning: total fertility rate (TFR, the average
number of children that would be born to a woman over her reproductive span), CPR, and unmet need
(the percentage of women who do not want to have a child but are not using any contraception). In India
in 2012, the TFR was 2.5, the CPR was 54% and unmet need was 21.3%. Female sterilization is the
most common contraceptive method used (34%), with limited availability, preference or use of other
methods such as condoms, oral contraceptive pills or the intrauterine device (IUD).

Family planning is a central component of the Indian government’s commitment to ensure universal
access to health, a part of its 12th Five Year Plan. Family planning policy in India has undergone a
paradigm shift, changing its focus from population control to one of improving maternal and child health.
The Indian government has expanded its family planning policy and programme to include birth spacing
methods such as IUDs and post-partum family planning services, and by increasing the workforce of
Accredited Social Health Activists (ASHAs) and Auxiliary Nurse Midwives (ANMs). Under the National
Rural Health Mission, the government of India has contracted approximately 860,000 ASHAs to serve as
catalysts for delaying age at first birth and ensuring healthy spacing between births by providing
information, services, and commodities to their clients. ASHAs provide contraceptive options such as condoms, oral pills and ECs to village women in their homes. Additionally, approximately 200,000 ANMs provide IUD services on fixed days at sub-centers in close proximity to communities. ASHAs are paid fixed remuneration when clients delay the first childbirth, demonstrate healthy spacing after childbirth, opt for permanent methods of contraception after two children, or choose institutional delivery. Initial assessment results of the performance of ASHAs indicate an unqualified success, with 95% satisfaction self-reported. The ASHAs state that they feel good about their work and that it allows them to develop relationships with the women and later provide other services. Additionally, the ASHAs have been able to break down communication barriers and now distribute condoms freely to male members of the population.

**Overview from UNFPA in India: The use of existing RH preventive technologies** presented by Dr. Dinesh Aggarwal of the National Programme Officer Reproductive Health, UNFPA, India.

During 2011 alone, the condom market grew from 1.6 billion to 2.7 billion in India (including 639 million condoms distributed for free). Condom uptake has increased in both the public and private sectors, and there are now 1.3 million retail outlets that sell condoms. Despite this level of popularity, there are still challenges to uptake and use: condoms are not aggressively promoted, not yet readily available in clinics, and there are often delays in placing orders. However, implementation of performance-based social marketing contracting and funding has strengthened the national monitoring system, and is an easy and inexpensive way to reach the male population. Uniform messaging across all media and communication platforms (mass media and mid-media) has been achieved with the vision of the National AIDS Control Program IV to protect every “unsafe” sex act with a condom. Messaging about use of condoms for dual protection can be further strengthened by linking women who visit ART clinics and integrated HIV counseling and testing centres with local family planning centres.

FCs have been introduced in India in targeted interventions, but they have not yet been introduced into the general population. A recent feasibility study by Hindustan Latex Family Planning Promotion Trust (HLFPPT) yielded highly encouraging results in terms of reducing the cost by adding a latex-based FC to the market mix. Reducing unit cost will help to increase marketability, access and uptake.

**Session II Summary:**

Despite the availability of male and female condoms as effective options for preventing unintended pregnancy, HIV, and other STIs, these outcomes continue to occur. Efforts should be made to improve uptake of male and female condoms by expanding opportunities to increase their use, and by learning from past experience. Improving uptake and use of these existing technologies will require individual behaviour change as well as changes to the health care system. Communication messages for providers and end users should take into account the diverse populations that would benefit from greater condom use.

**Session III: Status of MPT R&D**

The objective of this session was to review the MPTs in the product development pipeline.
Dr. Judy Manning of the United States Agency for International Development (USAID) presented the **Global overview: Status of MPT R&D.**

The primary challenge for MPT R&D is a product with a single delivery mechanism that will simultaneously prevent pregnancy and STIs, including HIV. The various options for combined indications, mechanisms of action, formulations and delivery mechanisms, and dosing regimens all add to the complexity of creating a single MPT product, as illustrated in the figure below.

Given the possible permutations involved in MPTs, a target product profile (TPP) has been developed to prioritize key characteristics and parameters, taking into account the potential public health impact in the hardest hit regions of the world. The highest priority combination of indications for many of these regions is contraception and HIV prevention. In other regions with lower HIV prevalence, the priority combination of indications is contraception and prevention of other STIs, particularly HSV and HPV. Product formulation for MPTs is focusing on long acting reversible formulations such as injectables and vaginal rings that would also increase adherence. This general approach is consistent with the Bill and Melinda Gates Foundation’s Dual Protection Strategy, which has prioritized contraception and HIV prevention through injectables or rings.

The first generation MPTs currently under development are primarily products that could be used on-demand, and sustained release devices such as intravaginal rings (IVRs).
On-demand products such as those pictured to the right (e.g., tablets, gels, films and FCs) are used at the time of intercourse and are appropriate for women who have intermittent sex, or who would like more direct control over their own protection.

Sustained release devices, such as the IVRs pictured to the right, are user initiated but do not require daily action. They can improve adherence, and therefore overall effectiveness.

MPTs in the product development pipeline:

1. **SILCS + Tenofovir (TFV) Gel**: TFV gel (developed by CONRAD) is the first-ever vaginal microbicide shown to reduce HIV acquisition by an estimated 39% overall, and by 54% in women with high gel adherence. Additionally, a significant 51% reduction of the risk of acquisition of HSV-2 was observed, making TFV gel a true dual prevention product. SILCS (developed by PATH and CONRAD) is a “one size fits most” silicone diaphragm that does not need to be fitted by a clinician. It is intended for OTC provision, and over the typical use period (six months), pregnancy rates are comparable to the standard fitted diaphragm when used with a contraceptive gel (10.4%). SILCS has a five-year shelf life and can be reused for up to three years. The SILCS diaphragm used in combination with Tenofovir gel would provide both contraception and STI prevention.

2. **MZL Gel and MZL IVR**: These products (developed by the Population Council) combine MIV-150 (an ARV with activity against HIV) + Zinc Acetate (a mineral with activity against HIV and HSV-2) + the progestin Levonorgestrel (LNG, a contraceptive). The MZL gel uses a carrageenan base (carrageenan shows activity against HPV). In vivo studies indicate that the MZL gel can prevent pregnancy, HIV, HSV-2 and HPV, with a single dose providing protection for up to 24 hours. Currently, optimization and initial in vivo pharmacokinetic evaluation of the MZL gel is underway. The MZL vaginal ring is intended to release all three active pharmaceutical agents for at least one month’s duration, with the potential to prevent pregnancy, HIV and HSV-2.

3. **Dapivirine (DPV) + LNG IVR**: This IVR (developed by IPM) combines DPV (an ARV) + the contraceptive LNG. It is currently undergoing formulation and testing. Ultimately, the DPV+LNG IVR could prevent pregnancy and HIV.

4. **TFV + LNG IVR**: This IVR (developed by CONRAD) is designed to last for three months, and prevent pregnancy, HIV and HSV-2. Clinical studies are expected to begin in 2013.

5. **Bioring**: This IVR contains non-hormonal contraceptives (Ferrous gluconate, Ascorbic acid and Pharmalytes) and microbicides (Boc–Lysinated Betulonic Acid and TFV). It has the potential to prevent pregnancy, HIV and HSV-2. The BioRing is likely to enter clinical trials soon, as discussions with US Food and Drug Administration are underway. (Presented by Dr. Mukul Singh, Bioring LLC)

**The Indian initiative and the progress regarding MPTs** was presented by Dr. Satish Gupta of National
Institute of Immunology. Research is ongoing for developing a contraceptive vaccine using different antigens like recombinant beta HCG, human sperm antigen and human seminal plasma inhibin. Clinical trials on RISUG – a non-hormonal intravasal injectable male contraceptive – indicates that it is safe and effective. Indian scientists are working on various synthetic compounds, herbal extracts, anti-microbial peptides identified from rabbit vaginal lavage, and haemolymph of Indian mud crab. These products have anti-HIV/STI or contraceptive activity, and in vitro / in vivo testing is underway. The challenges faced by Indian scientists include lack of expertise in a given academic/research organization to formulate research leads into products and lack of enthusiasm from industry to take these research leads forward into making MPTs. Dr. Gupta suggested that there should be early involvement of industry and research should be carried out through a consortium approach among various academic groups and industry with protection of scientific/commercial interests.

Session III Summary:
A number of MPTs with different combinations of indications are under development, with a focus on on-demand and sustained release products. These first-generation MPTs have the potential to greatly expand prevention options for women, and meet different needs as sexual and reproductive health concerns change over time. Of particular importance would be MPTs that prevent pregnancy and STIs, including HIV. The availability of several of the first generation MPTs is largely dependent on the results of the FACTS 001 confirmatory study of TFV gel for prevention of HIV and HSV-2, which should be available in 2014.

Session IV: Effective communication and its impact on R&D

The objective for this session was to provide a messaging framework to coordinate MPT advocacy.

Communication Tools to Advance MPT Support in India, presented by Jessica Cohen of PATH.

The IMPT has three priority areas: a) advancing the scientific agenda; b) strengthening communications, outreach and advocacy; and c) ensuring acceptability and access. The purpose of the IMPT’s Communication and Advocacy Working Group (CAWG) is to create awareness and build support for the development of MPTs, to support the goals of the Scientific Agenda Working Group (SAWG) and the Acceptability and Access Working Group (AAWG), and to build a coordinated network of IMPT advocates around the world to maximize synergies for MPT advocacy and development.

Communication strategies enable advocates to speak with a common voice and shared terminology. Such strategies provide greater coordination and reach for MPT advocacy, and strengthen the ‘call to action’ when the messages are clear and consistent.

Since MPTs are still in the early stages of development, there is
an opportunity to develop a messaging framework that enables scientists, leaders, advocates and communities to understand the need for MPTs and to foster support for their development and introduction.

The IMPT’s CAWG in collaboration with Indian communication and scientific experts developed key messages that can be used to advance awareness and build support for MPTs in India, an effort which involved many Indian and international partners. Through this effort, consensus was achieved on communication goals, a communication framework was developed, and messages were tested and finalized for use in India. Target audiences for these messages were researchers, policy makers, programme managers for family planning/reproductive health programmes and science administrators.

The draft messages for India were developed for the following areas:

• The need for SRH prevention options
• Why MPTs?
• Products and technologies
• Call to action to accelerate the MPT agenda

The messages for India were finalised after a series of interviews with the target audiences. Indian IMPT partners can use this messaging framework and incorporate them into IMPT advocacy materials for key audiences that can advance research, policy, and funding support for MPTs. Proper messaging can also help in reaching the target audiences, and could be specific to the needs of Indian women.

*Session IV Summary:*
Well-planned communication strategies and tailored messages can help motivate funding agencies to advance MPT research specific to Indian needs, and at the same time create awareness among policy makers who will play an important role in the eventual incorporation of MPTs into SRH programmes.

*Session V: Product prioritization*

The objectives of this session were to:

1) *Review and discuss the preliminary recommendations from the IMPT’s Scientific Agenda Working Group.*

2) *Review and seek consensus on MPT pipeline gaps for India.*

**MPT pipeline preliminary priority recommendations** presented by Dr. Judy Manning of USAID.

The goal of developing a TPP is to identify key attributes and parameters for MPT products that would lead to the highest potential public health impact. It is clear that any MPT TPP has to take into account the many permutations that can occur when combining different indications, mechanisms of action, formulations, and dosing strategies in a single delivery mechanism.
The IMPT’s SAWG developed a general TPP for MPTs, which can be further refined with specific input from regional and country experts. In 2011, the SAWG surveyed 593 US providers who were members of the US-based organization, Association of Reproductive Health Professionals (ARHP), and 289 African providers attending the 2011 International Conference on Family Planning in Dakar, Senegal, to identify key priority attributes for MPTs as per regional needs. Participants attending the MPT symposium in India were surveyed during this session. African providers ranked unintended pregnancy + HIV as the highest (65.7%) priority combination of indications for MPTs, while US providers ranked unintended pregnancy + other STIs as highest (66.3%). Indian providers also ranked unintended pregnancy + other STIs as the priority combination of indications. HPV was the priority non-HIV STI of all providers surveyed, US, African and Indian alike. African providers preferred MPTs delivered in the form of injection or sustained release devices, compared to US providers who showed a preference for oral pills. The majority of Indian participants surveyed during the meeting were in favor of a sustained release device.

In 2012, the SAWG used the general MPT TPP to conduct a landscape analysis of MPTs in the product development pipeline, and develop preliminary recommendations regarding product prioritization for funding agencies and researchers. The SAWG considered three priority areas for APIs: ARVs for HIV prevention, HCs for pregnancy prevention, and compounds to prevent STIs. The SAWG also identified a number of gaps in the MPT product development pipeline. First, since reverse transcriptase inhibitors (RTIs) are a type of ARV used in frontline treatment of HIV infection, their use for prevention may lead to the development of resistant virus; thus, alternative ARVs would be better suited for MPTs. Second, with regards to contraception, use of HCs on-demand will likely disrupt the menstrual cycle, which would be culturally unacceptable in many settings; thus, non-hormonal contraceptives are needed. Given that the potential relationship between specific forms of HCs (e.g., injectable DMPA) and increased risk of HIV acquisition is currently not sufficiently understood, non-hormonal contraceptives could be an alternative option. Third, with regards to STI prevention, there are few STI-specific products currently under development; thus, pathogen-specific APIs are needed. Finally, the SAWG pipeline analysis recommended the development of a suite of MPT products that would include vaginal rings, long acting injectables and on-demand products, to meet women’s needs as they change over time.

The MPT product prioritization process relies on available demographic and epidemiological data for unintended pregnancies, new STIs and HIV; however, many developing countries where MPTs are most needed do not have robust surveillance systems. Furthermore, the epidemiology of HIV and other STIs has changed significantly over the last decade, with trends suggesting that it could change even further over the next decade. Given that the first-generation MPTs are at least five years away from regulatory approval and initial introduction, demographic and epidemiological modelling studies to help predict such trends would enable focused product prioritization to provide optimum public health benefits in five to ten years. Additionally, considering the huge costs and logistics involved in conducting Phase III trials, funders are likely to invest more in MPTs that include prevention components that have already demonstrated efficacy. One such product, TFV gel, is currently in its second Phase III confirmatory trial, and is a key component in several of the first-generation MPTs. In addition to product attributes and parameters, user access and acceptability must also be considered in the R&D of MPTs, with prioritization on improving the quality of life of affected populations.
Session V Summary:
Country-specific product prioritization exercises can help to inform the development of a TPP; however, the path to R&D and introduction is still challenging. Modelling projections and lateral thinking is crucial for predicting the future need for MPTs in different regions, given that the first generation of MPTs will not be available for at least five years.

Session VI: Challenges in the R&D pathway for MPTs: Limitations, gaps and opportunities

The objective of this session was to examine the limitations, gaps and opportunities for MPT development and discuss priorities for next steps.

Challenges in MPT research: limitations, gaps and opportunities presented by Dr. Alan Stone of MEDSA, consultant to CAMI.

The most important challenge for researchers is the selection and development of MPTs with the greatest potential for public health impact, which promise to be achievable within an acceptable timeframe. The IMPT SAWG has held consultations on the MPT TPPs, and on their preliminary prioritization of the product R&D pipeline. It is clear that there is a diversity of regionally-specific needs, due to varied epidemiology across and within countries (e.g. pockets of high HIV incidence in India), as well as cultural differences that may affect acceptability. Thus, a suite of MPTs is needed to address different situations, and also to provide more choice in prevention options for women.

Limitations of currently available products:

Contraceptives: A wide range of drugs, devices, drug-device combinations and vaccines are currently available prevention options for one or more SRH indications. HCs for prevention of unintended pregnancy are an effective and well-tried approach. HCs are available in the form of oral tablets, injectables, implants, and IVRs, but they often have undesirable side effects; therefore, non-hormonal contraceptive agents deserve further attention. Spermicidal contraceptives used on-demand may be particularly useful for women who have sex fairly infrequently, who wish to avoid the side-effects of HCs and who want immediate yet quickly reversible contraception. Unfortunately, currently available spermicides use Nonoxynol-9, Octoxynol-9 or benzalkonium chloride, all of which have inflammatory properties. In a large HIV prevention trial, Nonoxynol-9 actually increased HIV acquisition in women who used it during sex three or more times a day. There is thus a strong case for a focused effort to develop contraceptive agents that are free from both hormones and surfactants.

Pre-exposure prophylaxis (PrEP): On July 16, 2012, the U.S. Food and Drug Administration approved Truvada (emtricitabine/tenofovir disoproxil fumarate) for PrEP in uninfected high-risk individuals in combination with safer sex practices to reduce the risk of sexually-acquired HIV infection. Effectiveness of PrEP has been demonstrated in three clinical trials, including the 6-country iPrEx trial, a study in Botswana in heterosexual men and women and the Partners PrEP trial conducted in Kenya and Uganda. In July 2012, WHO published guidance on use of oral PrEP by serodiscordant couples, men, and
transgender women who have sex with high risk men, and has recommended demonstration projects in countries. Despite the success of PrEP in clinical trials, more data needs to be collected on its long term safety and adherence.

**Challenges associated with the development of IVRs:**

IVRs are an attractive option for an MPT, however, there are many challenges to their development. APIs will have to be incorporated in sufficient quantity into the ring material or into reservoirs within the IVR. The APIs will have to be eluted from the ring and enter the epithelial tissue at a fairly constant and sufficient rate in order to ensure the presence of a sufficient amount of effective drugs over time. Therefore, both laboratory and clinical studies will need to include pharmacokinetics and pharmacodynamics (PK/PD) measurements of the APIs, by assaying drug levels in vaginal secretions and tissue biopsy samples. For an IVR that contains two or more APIs (e.g. a contraceptive plus an ARV), developers will need to assess the possibility of drug-drug incompatibility, interference, or toxicity when combined or released simultaneously. This will be particularly important for those APIs, which are still considered experimental by regulatory authorities.

**Regulatory Challenges: global perspective** presented by Dr. Cara Chrisman of USAID.

Since the concept of MPTs has been recently introduced, there are currently no international guidelines for their development. There are critical steps to consider in the pathway of MPT development (see illustration), and regulators’ advice should be sought early and often to ensure product approval.
**Regulatory Challenges: Indian perspective** presented by Mr. Ashish Rai of Central Drugs Standard Control Organisation (CDSCO) in New Delhi, India.

In India, the import, manufacturing, sale and distribution of medical devices is regulated under the Drugs and Cosmetics Act and Rules. At present, medical devices approved by Central Government are regulated under this Act. A list of notified medical devices is available on the CDSCO website: [www.cdSCO nic.in](http://www.cdSCO nic.in). The CDSCO has published a guidance document on the "Requirements for Conducting Clinical Trial(s) of Medical Devices", where devices are classified into low, moderate, and high risk; the regulations and licensing of foreign products are considered as per the regulations in the country of origin. These guidelines are still evolving, and the licensing authority may consider any product with significant public health impact by a special process.

Dr. Jaideep Gogtay of CIPLA, Mumbai, India presented: **Industry Perspective on R&D of MPTs**.

Indian pharmaceutical companies have a very strong background and reputation for high-quality products that are exported to many African and Asian countries. Additionally, the industry has the capacity to manufacture drugs and other products in large quantities. The Indian pharmaceutical industry considers several aspects before investing in product R&D, including potential product demand, target populations, marketing, intellectual property rights, and changing health priorities. The Indian pharmaceutical industry also considers responsibility towards society and the opportunity to make a difference in the country/world, and, as a result, focuses on ‘return of investment’ rather than ‘return on investment’.

**Session VI Summary:**
Developing a TPP for MPTs using different permutations and combinations helps to prioritize product development. There are limitations to currently available prevention products, and the development of MPT IVRs will face a number of challenges, chief of which will be the simultaneous release/bio-availability of two or three different APIs for different indications. There will also be regulatory challenges, since there are no international or national guidelines for the development of MPTs. Finally, investment by the pharmaceutical industry in MPT R&D will require early consideration of key aspects to potential marketing and product uptake, including the potential for public health impact.

**Session VII: Involving the end-users and providers in the development of and access to MPTs**

The objective of this session was to assess ways to ensure that the perspectives of end-users and providers are integrated into the critical path for MPT development.

**Global perspectives on MPTs: What do we know, and what do we need to know?** Presented by Martha Brady of the Population Council, New York City, USA.

The need to involve end-users in the development of MPTs is evident from the under-utilization of the existing RH technologies. Globally, women need RH information, and a support system that can educate them. Women’s perceptions of actual vs. relative risk, and how those may influence product use, are key
questions that can be addressed through end-user involvement. Providers at all levels need skills and training for proper messaging when counseling their clients. Clinic-based health care providers play an important role in determining access to many types of RH products, and in helping women make informed choices; their skills and knowledge base require regular updating to stay current on issues and changing guidelines. In many countries, pharmacies are key providers of many OTC RH products (including oral pills, ECs, and condoms), and a basic knowledge base is essential to providing accurate information. Community awareness and support for research should begin at the clinical trial stage. Involvement of policy makers can help them to develop an introduction/implementation plan, involve key stakeholders, and develop guidelines. One example of community development is the voucher financing model developed by the Government of Kenya, supported by its German development partners BMZ (Federal Ministry for Economic Cooperation and Development) and KfW Banking Group. They are currently piloting a new model to help the poor access good quality RH care called ‘Output Based Aid’ (OBA) or ‘Vouchers for Health’. We know from experience in FP programming that when women’s solidarity groups and community health workers are provided appropriate information, education, training and counseling materials, they can directly meet the needs of end-users and improve uptake and utilization of SRH prevention options.

The **Indian perspective** was presented by Dr. Shalini Bharat of the Tata Institute of Social Sciences (TISS) located in Mumbai, India.

The focus of MPTs will be on women of reproductive age living in diverse cultural settings, and Indian women are not a homogenous entity. The challenges of involving end-users include understanding their risk perceptions, making them aware of the risks, and sensitizing and motivating them in culturally appropriate ways. MPTs could be delivered at FP clinics, STI clinics, HIV counseling and testing clinics, HIV treatment centers, and general integrated (e.g., FP/MNCH) health clinics. There is also a critical need to reach out to and accommodate adolescents. Messages about MPTs will have to be tailored to specific groups of end-users to improve uptake and sustain utilization.

**Session VII Summary:**
Knowledge and support of the providers and involvement of end-users are the key components for successful introduction and uptake of MPTs. Innovative strategies will have to be developed, taking into account the challenges faced by providers in increasing utilization of existing RH technologies.

**Session VIII: Availability and access of MPTs: Implementation issues**

*What are the lessons learned?*

The objectives of this session were to comment on potential issues and challenges associated with delivery of MPT products in India, and discuss necessary actions to achieve MPT product delivery.

**Integration with existing technologies in the programme** was presented by Dr. D. Bachani of Lady Hardinge Medical College (LHMC), New Delhi, India.
The challenges of integration include maintaining capacity for distribution and logistics management, including the supply chain in different states. Providers’ adoption of a product and client’s participation in decision-making for a health product adoption is often weak in the Indian context. Decision-making at the provider level is fairly centralized, and is mostly the responsibility of doctors. Factors that affect end-user adoption of currently available prevention products include knowledge of and perceived benefit from the product, side effects of the product, quality of counseling offered to the client, and the “social” image of the product. A positive environment prepared by information, education and counseling can greatly affect initial product uptake.

Dr. Bulbul Sood of JHIEPGO addressed the **Non-Governmental Organization (NGO) Perspective**.

An ideal MPT would prevent unintended pregnancy, HIV and other STIs, be affordable and easily available, be designed for specific needs and preferences, and ensure women's privacy and safety. Improving the utilization of existing RH technologies in India will help to ensure the integration of new MPTs when they become available. Such integration will need to include communication interventions, capacity building of health care providers, addressing specific target population groups through counseling and informed choices, and mobilizing and empowering health workers, community leaders, NGOs and other stakeholders. An adequate and uninterrupted supply of MPTs through social and commercial marketing will be essential. Introduction of MPTs will have to converge with various national programmes simultaneously, such as Reproductive & Child Health Program, National AIDS Control Program, Adolescent Reproductive & Sexual Health, Integrated Child Development Services and the National Cancer Control Program.

Dr. Reynold Washington of the Karnataka Health Promotion Trust, Bangalore discussed **Innovative Partnerships and Business Models**.

Knowing the needs of the end-users, their risk perception, community engagement and rapid scale up to achieve wide coverage will help in introduction and acceptance of MPTs. Dr. Washington presented the following model for systematic community engagement for introduction of MPTs.

**Systematic community engagement and introduction:**
There is also a need of convergence of programmes of National Rural Health Mission (NRHM), NACO and District Health Services (DHS) to comprehensively address pregnancy prevention and prevention of STIs and HIV.

Session VIII Summary:
Integration of MPTs into the existing SRH programmes will have to be strategically planned, and take into account lessons learned from the introduction and uptake of existing prevention products.

Round Table on advancing support for MPTs R&D in India

The closing session was a round table discussion wherein the opinion of key national and international stakeholders was obtained with regard to the next steps for advancing MPT R&D in India. The stakeholders included research managers from the premier Indian research organizations, regulators, programme managers, SRH advocates, international funding and normative agencies like USAID and WHO as well as professional societies.

Dr. Nomita Chandhiok, from ICMR, moderated the session and reiterated that the major goal of this meeting was to raise awareness, energize and activate key Indian stakeholders on MPT development and access. The science for developing of MPTs is challenging and it is important that future investments in research should be efficient, effective and complementary to research being carried out elsewhere in India and worldwide. Furthermore, research should be carried out in a coordinated and collaborative manner in order to avoid duplication. The benefit should be derived from capabilities available elsewhere, rather than making additional local investments to re-establish new capabilities. We need to draw up a road map of activities that should be taken up in the next 1-5 years so that tangible results are obtained.

Research Managers

Dr. Malabika Roy stated that ICMR is a 100 year old organization with a focus on addressing nationally relevant issues. The challenges and gaps for MPT R&D have been identified and ICMR needs to take forward what is most visible and benefits the end user. She suggested efforts to increase the utilization of existing products, bridging studies, basic research for development of new molecules and mode of delivery that should be acceptable, accessible and available. The ICMR funds through several ways including Task Force mission mode where the priority areas are identified. ICMR has collaborative agreements with several national and international organizations through which joint projects are carried out.

Dr. Sandeep Sarin reported that the Department of Biotechnology (DBT) has several ongoing collaborative partnerships with other ministries and departments, including ICMR/DHR. The ICMR-DBT collaboration on HIV/AIDS and Microbicides is in its second phase and had successfully supported several projects. The DBT has several funding mechanisms including Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Program (BIPP) which fund industry through soft loans, grants, etc. This funding promotes industry-academia partnership on identified priority
areas from pre-conceptual stage to later development and clinical trials. Several other schemes are also available under which scientific institutions can source funds for research. The priority areas/issues identified for MPTs R&D could be jointly supported with ICMR or under the various other schemes of DBT.

Advocacy

Mr. Bobby Ramakant clarified that advocacy efforts need to be taken up to keep the momentum on MPTs ongoing. While this meeting represented a diverse array of stakeholders (i.e., RH, STI, HIV, regulators, biomedical researchers and civil society) it will be important to engage other stakeholders as well. There is a need to prioritise and strategize on what is relevant for India, maximising public health, social justice and ensuring women’s rights. Coherent messages should be developed on available MPTs. These messages should be incorporated into existing RH and HIV messages and delivered up to to the district level. They should also be included in the ongoing training and capacity building of providers under different government programmes like RCH, NACO, ARSH. Information on existing and new MPTs should be imparted at conferences, meetings and other scientific events. An Indian advocacy group can be constituted to inform and engage key stakeholders and the public about recent scientific advances and they could play a critical role in moving MPT R&D forward. Similar advocacy work was done for the HIV vaccine in which Indian parliamentarians were brought on board.

Also, in response to next steps with regard to advocacy, Jessica Cohen from PATH replied that India has vast expertise and capacity available with pharmaceutical companies. Engaging them early in the development process is important. The synergies of advocacy groups working in different countries like China, South Africa, Europe and USA need to be built upon – including sharing the lessons learned and identifying the priority issues on an ongoing basis. The IMPT provides an umbrella to do that through continuous engagement and communication.

Program Managers

Dr. Sunil Khaparde stated that the efforts were ongoing at NACO to set mechanisms for obtaining STI surveillance data along with the ongoing HIV sentinel surveillance. This information is important for designing and evaluating the programme. There is also a dichotomy under the programme as syndromic case management is advocated, whereas STI prevalence estimation will be on etiological basis leading to a disconnect between actual estimation and what health care providers sees in the clinic setting. The programme is also focusing on management of RTIs as they lead to high reproductive morbidity. Products like MPTs can play a vital role in reducing morbidity and could be included in the programme after proven safety, efficacy and regulatory approval. They can easily be distributed through the ongoing, targeted interventions to high-risk groups after feasibility and cost effective studies have been completed.

Regulators

Dr. G.N Singh of DCGI reiterated that the government is committed to the health of women. Products/technologies that impact the health of women would be reviewed in fast track mode through a stringent regulatory pathway, ensuring their safety and effectiveness. In particular, the benefits of science
should reach women from rural and remote areas. Presently, processes are not fully developed. Drugs and devices are considered together and there are no clear cut separate regulatory guidelines for medical devices. While considering regulatory approval of drugs/devices, it is preferred that Indian data should be available. If the safety, efficacy and quality requirements of Indian government are satisfied, sometimes they are considered even without clinical trials held in India. A new drug regulation bill is proposed to be introduced shortly in which medical devices will get special emphasis based on global regulation and amendments. Interaction of regulators with experts in forums (like the present one) are necessary and appreciated as it informs about the advances in science. Currently there is no systemic pathways for regulatory approval of herbal products. However, the revised Schedule ‘Y’ with a special window for herbal products has been approved by the Drugs Technical Advisory Board (DTAB) and draft notification will be shortly released. After its formalization, there will be opportunities for regulatory approval of herbal products.

Professional Societies

Dr. N.K. Lohiya stated that ISSRF with more than 1100 members from diverse disciplines is committed to supporting all issues pertaining to reproductive health. It could be a platform for encouraging young researchers to get involved in MPT research. To increase awareness about MPTs amongst the scientific fraternity, a dedicated session would be held during their annual conference and other meetings and information would also be put up on their website for wider circulation.

International Funding and Normative Agencies

Dr. Judy Manning from USAID expressed her appreciation for the motivation and commitment of the participants for improving the health of women in India. Key Indian stakeholders discussed the challenges, obstacles and opportunities for MPT development and the enthusiasm for working in this area and moving it forward was tremendous. USAID would continue to help keep this initiative going and through it provide support for communication, advocacy and collaboration with other funding agencies and international agencies like WHO, NIH etc. to get a groundswell of support.

Dr. Manjula Lushi-Narasimhan reiterated the interest of WHO in MPTs and informed that they have been included in the future work of the Department of Reproductive Health and Research at WHO. WHO would continue to give technical support and normative guidance to the Ministry of Health of the Government of India, and provide support wherever possible. The need for MPTs clearly came out during the meeting. The challenges, linkages and synergies amongst the different agencies need to be integrated together. The WHO has developed several integration tools that can be adapted to the Indian context.

In his closing remarks, Dr. V.M. Katokh, Director General of ICMR, reiterated the commitment of ICMR in coordinating and galvanizing all key stakeholders together to move this forward. To be acted upon, the priorities for research should be well defined and aligned with the country’s needs. MPTs, however, have the potential to address many health issues that Indian women face. Research priorities identified during this meeting would go through ICMR’s review process. Due to finite budgets, the focus of ICMR would
be on operational research and feasibility studies with available products/technologies for the more promising leads in India and globally. Concurrently, development science would continue. He wished all the success to this endeavor.

**Conclusion**

While the MPT development pathway is complex, the eventual introduction and use of MPTs, however, could very well lead to marked declines in both unintended pregnancies and sexually transmitted diseases, particularly in areas of the world where these health burdens are greatest. The *International Symposium on Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health* brought together over seventy key Indian stakeholders and international experts who, over a period of two days, shared their experiences and vision for MPTs in various settings. Their inputs contributed to a rich discussion that resulted in an identification of gaps, challenges, and strengths for MPT development, as well as the evaluation and implementation of MPTs in different health care delivery settings. The success of the symposium was evident in the agreement amongst all stakeholders that MPTs would empower women to address their sexual and reproductive health needs with a focus on prevention. Finally, the symposium successfully focused on priority indications for MPTs in India and charged key stakeholders with developing a road map for MPT R&D, including fostering potential partnerships with the Indian pharmaceutical industry.
Acknowledgement

We would like to thank all of the international and national participants who spared their valuable time and came from long distances to attend the Symposium. Their constructive inputs not only contributed immensely to the success of the meeting, but also effectively moved the MPT research and advocacy agenda forward in India.

The contribution of scientific and administrative colleagues from the Division of Reproductive and Child Health, ICMR are duly acknowledged for their technical support and for arranging all the logistics for this meeting. The tireless contribution of Devesh Lodhy towards the success of the meeting is especially acknowledged. We would also like to acknowledge the contributions of Diane Royal of CAMI towards the meeting and the final report.
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Glossary of Terms (in alphabetical order)

AAWG – Acceptability and Access Working Group
ANMs – Auxiliary Nurse Midwives
APIs – active pharmaceutical ingredients
ARHP – Association of Reproductive Health Professionals
ART – Antiretroviral therapy
ARVs – antiretroviral drugs
ASHAs – Accredited Social Health Activists
BIPP – Biotechnology Industry Partnership Program
CAMI – Coalition Advancing Multipurpose Prevention Technologies
CAWG – Communication and Advocacy Working Group
CDSCO – Central Drugs Standard Control Organisation
CPR – Centre for Policy Research
CPRs – contraceptive prevalence rates
CVRs – contraceptive vaginal rings
DBT – Department of Biology
DHS – District Health Services
DTAB – Drugs Technical Advisory Board
ECs – emergency contraceptives
FCs – female condoms
FSWs – female sex workers
HCs – hormonal contraceptives
HIV – human immunodeficiency virus
HLFPPT – Hindustan Latex Family Planning Promotion Trust
HPV – human papillomavirus
HSV-2 – Herpes Simplex Virus-2
IARC – International Agency for Research on Cancer
ICMR – Indian Council for Medical Research
IDUs – injection drug users
IMPT – Initiative for Multipurpose Prevention Technologies
IUD – intrauterine device
IVRs – intervaginal rings
LHMC – Lady Hardinge Medical College
MDGs – millennium development goals
MPHW – Ministry of Health and Family Welfare
MPTs – Multipurpose Prevention Technologies
MSM – men who have sex with men
NFHS-3 – Indian National Family Health Survey-3
NGO – Non-Governmental Organization
NGU – non-gonococcal urethritis
NRHM – National Rural Health Mission
Glossary of Terms (cont...)

OBA – Output Based Aid  
OTC – over the counter  
PK/PD – pharmacokinetics and pharmacodynamics  
PrEP – pre-exposure prophylaxis  
R&D – research and development  
RH – reproductive health  
RTIs – Reproductive Tract Infections  
RTIs – reverse transcriptase inhibitors  
SAWG – Scientific Agenda Working Group  
SBIRI – Small Business Innovation Research Initiative  
SRH – Sexual and reproductive health  
STIs – Sexually Transmitted Infections  
TFR – total fertility rate  
TGs – Transgenders  
TISS – Tata Institute of Social Sciences  
TPP – target product profile  
USAID – United States Agency for International Development  
WHO – World Health Organization