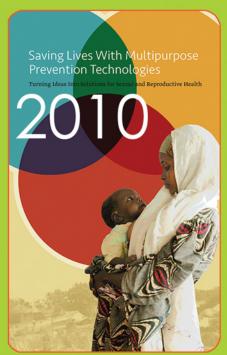
"It's all in a decade's work"









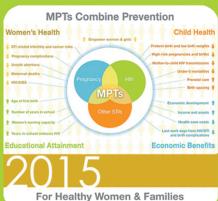


















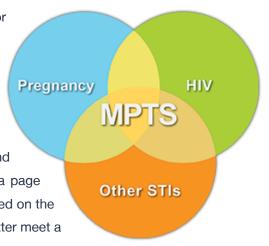


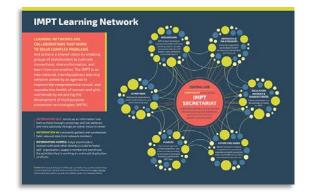
Introduction

A decade of the MPT Field: Where we are now

Ten years ago, the field of multipurpose prevention technologies (MPTs) was born. This new field was conceptualized to build upon decades of foundational research in contraception and microbicides for HIV prevention in women; but 2009 marked a recognition of the urgent need to bridge the silos between the fields of contraception, HIV, and other STIs, while simultaneously leveraging resources and expertise, to prepare for a meaningful fieldwide push toward MPT development and introduction. What was previously just an idea to work toward creating a novel suite of products to help women protect themselves from HIV, other STIs and unintended pregnancy, became a reality.

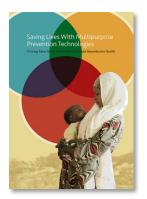
MPTs are safe, effective, accessible, and acceptable tools for women that combine prevention of at least two sexual and reproductive health (SRH) risks, including HIV, other STIs, and unintended pregnancy. Despite important advances in the family planning, STI prevention, and HIV prevention fields, condoms were the only available method for comprehensive SRH protection at the founding of the MPT field in 2009, and remain a critical component of the method mix today. Taking a page from the family planning field, however, the MPT field was founded on the idea that a 'suite' of multipurpose prevention products would better meet a woman's needs throughout her life course.





In the early days of the MPT field, it was acknowledged that developing such comprehensive products required reconciling technical challenges with the complex realities of women's lives through a determined, well-coordinated effort. Launched in tandem with the MPT field, the <u>Initiative for MPTs</u> (IMPT) was founded in 2009 to facilitate this momentous effort. The product-neutral IMPT <u>learning network</u> continues to be a key driving force behind this nascent industry, with the IMPT Secretariat at its helm.

In order to jumpstart the field, in 2009 the IMPT Secretariat collaborated with a core group of network partners to write a brief entitled: "Saving Lives with Multipurpose Prevention Technologies: Turning Ideas into Solutions for Sexual and Reproductive Health" published in 2010. Reconciling the inherent complexities of combining prevention against multiple SRH indications into a single product with the promise of such products to improve the lives of women worldwide, the brief outlined the following recommendations for the MPT field:



- 1) Increase collaboration and resources across disciplines;
- 2) Plan deliberately and early for the research and development of MPTs; and
- 3) Increase awareness of and support for MPTs.

With the IMPT leading the charge, the MPT field has seen tremendous progress in the past decade. This retrospective report will utilize each of the three recommendations from the "Saving Lives" brief-first published close to ten years ago-to reflect on the ways in which the IMPT has facilitated progress in the MPT field; bringing an innovative suite of MPTs continually closer to reality.

Today, thanks to the collaborative efforts of product developers, funders, researchers, and advocates, over two dozen MPTs are in <u>development</u>-including intravaginal rings, fast-dissolving vaginal films, gels, implants, IUDs, and co-encapsulated tablets. Through <u>technical consultations and think tank meetings</u> with partners in HIV and STI prevention as well as family planning, the IMPT remains committed to identifying and prioritizing key technical and market challenges as well as research gaps, while simultaneously garnering increased and sustainable financial support for the MPT field.

A summary of key activities undertaken by the IMPT over the past decade that align with the three key recommendations for the launching of the MPT field, as outlined in the "Saving Lives' brief, can be found within this report.

Increase collaboration and resources across disciplines

Substantial collaboration, particularly across disciplines, will be needed to bring this new class of products forward. Scientists, developers, and advocates will need to draw on relevant research findings from across disciplines. Researchers will need to work with end-users and health providers to ensure that emerging products truly reflect stakeholders' needs. Nongovernmental organizations, funders, industry groups, and regulatory authorities will need to work together to address regulatory approvals, manufacturability, supply, and plans for market access. –Excerpt from "Saving Lives" brief, 2010

The IMPT was established to bridge existing silos in a wide range of relevant disciplines including HIV and other STI prevention and contraception, as well as to unite experts from pre-clinical research, product development, socio-behavioral and market research, policymaking, funding, and advocacy around the shared goal of advancing the development of MPTs. What started as a small core group has grown to be a vast global network over the past ten years. Having evolved from a model based on a 'collective impact' approach into a full 'learning network,' collaborations have varied over the years in order to best meet current demands from the field. From high level working groups to now more specific ad hoc task groups focused on specific technical issues—the operational thrust of the IMPT has remained cross-disciplinary collaboration.

IMPT working groups: A brief history

At its founding in 2009, the IMPT's first task was to determine if the MPT concept was technically feasible. To do so, the IMPT Secretariat formed the first IMPT network sub-group: the <u>Scientific Agenda Working Group (SAWG)</u> comprised of technical experts from across various fields. Over thirty members contributed to a series of meetings that, in the end, reached <u>consensus</u> that the development of MPTs, despite its challenges, was scientifically feasible.



In parallel to work around the scientific agenda, the Secretariat also facilitated the formation and management of additional working groups to develop and implement complementary strategies to advance the MPT field. This included a communications and advocacy working group and in-country task forces in Kenya, South Africa, China, and India. The Communications and Advocacy Working Group (CAWG) developed messaging and strategic communications to help raise awareness about MPTs as a concept, as well as about the IMPT network. They also worked closely with regional communications working groups in Kenya, India, and South Africa on country-specific communications and messaging.

Moreover, the Secretariat established a Steering Committee to continually refine the overarching vision and priorities of the IMPT network. In 2013, the Bill & Melinda Gates Foundation provided complementary support alongside the United States Agency for International Development's (USAID) ongoing funds to establish a committee to facilitate collaboration and investment optimization among MPT funding organizations, referred to as the Supporting Agency Collaboration Committee (SACC).

In 2016, a new phase of the MPT field began. There were nearly a dozen MPT products in various stages of clinical development, and the term 'MPT' had become more widely recognized as a new class of comprehensive prevention products in sexual and reproductive health as demonstrated by inclusion of MPTs in a growing number of international HIV prevention conferences and in Requests for Applications (RFAs)—more on MPTs in RFAs in section two. The IMPT Secretariat, intentionally structured to be lean, nimble, and adaptive to the evolving needs of the MPT field, thus shifted its priorities to focus on ensuring that MPT products would achieve the maximum public health impact once introduced and that support to the MPT field was sustainable. Toward these new priorities, the IMPT itself also evolved in its operating approach.

First, in 2017 the Steering Committee was phased out which facilitated the formation of the IMPT Advisory Council. This shift marked a broader change within the IMPT network. In its role during the IMPT's early days, the Steering Committee provided guidance to Secretariat staff, ensuring that Secretariat activities aligned with the broader network's priorities. To this end, the Steering Committee helped develop the IMPT Strategic Plan, provided guidance on network membership and positioning, among other issues as necessary. In this way, the Steering Committee directly fostered the growth of the IMPT network–and further solidified the role of the Secretariat. With the momentum and promise of MPTs mounting, alongside the now more established IMPT network and Secretariat, the Steering

Committee made way for an Advisory Council with a particular focus on the network's sustainability. Drawing on members who work in related fields, an overall objective of the Advisory Council is to enhance fundraising efforts for the MPT field, expand stakeholder engagement within the IMPT, and provide strategic guidance on work plan activities managed by the Secretariat.

In alignment with the ideal progression of networks over time, the IMPT shifted to a model of increasingly ad hoc groups convened around more specific areas of study. For example, in 2017 a task group was created to facilitate the inclusion of end-user perspectives into the MPT product development process to maximize public health impact, including identifying the primary MPT target population. With the insights gained from this group, two webinars aimed at the broader IMPT network occurred later that same year. The <u>first</u> provided a general update to the field around MPT end-user work currently being done, highlighting new research exploring the acceptability of and preference between potential MPT product types, drivers of future product use, and other important end-user considerations. The <u>second</u> webinar aimed to engage new stakeholders in MPT end-user research by bringing together experts for a dynamic discussion around lessons learned from conducting end-user research in the fields of contraception, HIV, and MPTs, and to share best practices for MPT product development and introduction. This working group and the subsequent two webinars helped facilitate a timely engagement with the MPT end-user space that remains ongoing. More about the IMPT's technical work in section two.

Membership within the larger IMPT learning network, while inclusive of subgroups like the SACC or Advisory Council, has always been more informal. This was done, by design, to be inclusive. Members remain connected through a variety of mechanisms, including strategic communications within the network, network virtual convenings and regular updates, in-person technical meetings convened around identified priority topics critical to the field, and the creation of an MPT online resource hub (see section three). In all these ways a wide variety of stakeholders are brought together to learn about and work on key issues, and to collaborate to address critical gaps and challenges in the MPT field.

Interested in connecting with the IMPT network? Visit us at http://mpts101.org/membership!

MPT resources and investments

Over the past ten years continuous funding support for the IMPT Secretariat has included: USAID, the National Institutes of Health (NIH), and the Mary Wohlford Foundation, along with several individual donors. From 2013-2016, the Bill & Melinda Gates Foundation also funded Secretariat work.

Funding for the broader MPT field–including investments in product research and development (R&D)–stems from a more diverse funder base and is tracked annually by the Secretariat. The objective of the MPT investment tracking activity is to monitor investments on an annual basis and help inform investment priorities and gaps for the field. Since 2013, the Secretariat has noted steady growth in investments in R&D. In 2018, there were 64.8 million US dollars invested in the MPT field–19% increase from 2017, when 54.5 million US dollars were invested in the field; and an overall 144% increase from 2013, when the Secretariat first began tracking investments in MPT related work.

The vast majority of work being done on MPTs is supported through the US Government, as seen in a number of projects being supported through grants of varying sizes and accounts for approximately 75%, or more, of the pipeline. Worth noting is that this does not translate in the total amount of dollars invested because investment in a single product accounted for 67% of the total invested in the full field in 2018. If this outlier is removed from the portfolio, the percentage of MPT related work supported by US Government funding would increase from 21% to 65% in 2018, 43% to 76% in 2017, and 53% to 71% in 2016.

The total combined investment from non-US funders accounted for less than 1% of the fieldwide total and included MPT project support from the United Kingdom, France and Canada. Non-US support of MPT related work fell only slightly, as it was just above 1% in 2017.

Alongside fieldwide investments, the Secretariat also tracks and messages around Requests for Applications (RFAs) set by organizations such as the NIH or USAID. Since 2011, there have been twenty RFAs calling specifically for MPTs. Previous RFAs dating back to the founding of the MPT field spoke to "combined" or "integrated" strategies. By setting a technical agenda for the field, the IMPT has also worked over the past decade to inform RFAs—including several RFAs released by the NIH in 2017 that were explicitly in alignment with IMPT-identified priorities for the MPT field.

Also tasked with promoting MPT R&D both within and beyond the IMPT network, in 2017 for example, a two-page brief aimed to recruit new product developers into the MPT space. This brief defined MPTs,

gave an update on the field, and described the market for MPTs as well as the challenges associated with MPT product development. Finally, it discussed funding opportunities and pointed toward other relevant tools developed by the Secretariat for the broader network. This two-page brief was widely circulated beyond the IMPT network and is an example of the ways in which the Secretariat and broader IMPT network collaborate in order to widen the scope of the MPT field–continually working to increase both resources and investments for MPT R&D.

As US Government (USG) funding makes up the vast majority of MPT investment over the past decade, it remains a priority to engage with other potential funders in order to diversify funding sources and advance the MPT field. In this vein, it is exciting to see interest in MPTs from funders outside of the purview. As part of the early efforts made by the IMPT to establish scientific feasibility and advance the MPT field, non-USG support was central. For example, in 2012 the Indian Council for Medical Research

(ICMR) and IMPT Secretariat co-hosted an international symposium in New Delhi, India on "Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health." Earlier that same year, the Wellcome Trust and IMPT Secretariat co-hosted a "Global Forum on MPTs"—a small convening held in London, United Kingdom comprised of international stakeholders brought together to help shape the evolving strategy for accelerating the development of MPTs, with a focus on regions in Africa and parts of Asia. Moreover, direct contributions to MPT R&D from non-USG funders have increased over the past five years. Most recently, announced in November 2018, the Children's Investment Fund Foundation (CIFF) is supporting the development of an MPT–a Dual Purpose Prevention Pill aimed at preventing unintended pregnancy and HIV.

Beyond financial infusions into the MPT field, since 2009 MPTs have been integrated as priority focus areas for numerous organizations working across SRH fields. In 2016, MPTs were prioritized in the strategies of IMPT partners NIH and the World Health Organization (WHO). This increased commitment to MPTs, in tandem with steady growth in MPT R&D investment, has propelled the MPT movement forward over the past decade–better establishing the multipurpose concept, the 'MPT' term itself, and thus facilitating the journey of MPTs from inspired idea to marketable product.

Despite the exciting growth in the MPT field over the past ten years, current investments are not sufficient to ensure the value potential of MPTs. Nearly one decade since the launch of the MPT field, the IMPT remains focused on finding and creating opportunities to diversify and optimize funding for appropriate technical and market investments by leveraging existing MPT support and identifying new partnerships. In this way, the IMPT will continue to prioritize galvanizing current members of the IMPT network as well as engaging with new audiences—all in the interest of curating sustainable, long-term funding for MPT research, development, and thoughtful introduction.

Plan deliberately and early

To ensure efficient and effective research and development, researchers and developers must use systematic evaluation and rigorous product-development planning and implementation processes. As the product-development cycle progresses [...] development plans should be refined to incorporate emerging information. –Excerpt from "Saving Lives" brief, 2010

A key role of the IMPT is to advance a larger fieldwide strategy to ensure effective and efficient MPT R&D. As such, the IMPT network-led by the Secretariat-works to continuously assess the status of the MPT field, identify priority areas, and accelerate action around those areas through objective guidance and tools, as well as convene technical experts. Over the past decade this effort has been iterative, enabling the IMPT to adapt as the MPT field evolves. A wide range of tools and guidance have been developed in collaboration with experts within the IMPT network to inform the strategic direction of the MPT field. These include:

Early stage assessments to clarify product role and intended context.

In the early years of the IMPT, the SAWG worked to critically examine scientific and technical issues facing the development of MPTs (see section one). Outcomes from the "Global Forum on MPTs" helped shape the agenda of the SAWG as they tapped into multidisciplinary experts from across the globe. As part of this early work, the IMPT initiated an MPT product prioritization and gap analysis exercise to clarify objectives and lay a firm foundation for the strategic development of MPTs, including which indications to prioritize. Recommendations were vetted at the Product Prioritization Stakeholder Meeting, held in October 2012, which brought together technical experts to review preliminary recommendations, including those on product profile, priority candidates, and gaps.

The resulting meeting report summarized key recommendations and suggestions in three priority areas:

- 1) Active Pharmaceutical Ingredients (APIs);
- 2) Formulation and Delivery; and
- 3) Coordination and Process.

Overall, the expert group noted a few key takeaways: The need for "good basic science" that can inform MPT R&D; the inclusion of young women aged 14-17 in research studies; the incorporation of "deliverability" and "access" planning as key factors guiding MPT prioritization and investment; continued exploration of approaches to working across HIV, STI, and family planning programming; as

well as planning ahead for anticipated complex regulatory processes for MPT R&D; and finally, meeting participants recommended that MPT development must balance advancing products with the most near-term potential, while also continuing to work toward concepts and products that best meet the parameters specified in the prioritization exercises. As noted in the meeting report, "Those working on MPTs should 'dream big' rather than only settling for working on and refining what is already in the near-term pipeline." Seven years later, despite the MPT field's advancement toward specific recommendations from the 2012 Product Prioritization Stakeholder Meeting, many of the 'takeaways' described above remain at the core of the IMPT's efforts.

Clear go/no go decisions for safety, efficacy, acceptability, and costeffectiveness parameters.

In the two years following the October 2012 meeting that worked to define general target attributes for MPT products, the IMPT also worked to inform standard-setting in MPT product development. In 2014, the MPT Product Prioritization and Gap Analysis exercise was released—a summary of survey findings intended to inform network efforts to support strategic focus on MPT priority product development strategies among funders and product developers. This exercise provided a basis for target product profile (TPP) development, described below, among other efforts such as better understanding social-behavioral and commercialization issues relevant to achieving high-impact MPT products.

In this way, two years after the 2012 Product Prioritization Stakeholder Meeting, the IMPT had evolved beyond simply prioritizing specific MPT product dosage forms and general MPT product attributes to the development of more specific TPPs focused on each type of prioritized product dosage form. These dosage-form specific TPPs, published in 2014, worked to define the necessary attributes and required supporting data for the successful development of impactful MPT products. At the time, two TPPs with dosage-form specifics were published. One on the MPT Intravaginal Ring, the second on the MPT Long-Acting Injectable.

Building off of this work, in 2015 the IMPT determined that a Strategic Evaluation Framework (SEF) would be a useful tool for funding agencies to work with their product developers and other implementing partner grantees to help fill identified research gaps and break from the limitations of the current clinical research paradigm. The brief entitled, "Laying the Groundwork for a Strategic Evaluation Framework (SEF) for HIV Prevention and MPT Product Development," outlined the three key components of an SEF: the Target Market Profile (TMP), the Strategic Target Profile (STP), and the Target Product Profile (TPP). With the TPPs having already been completed, in 2015, the IMPT led research to support the development of a generalized TMP and STP for ARV-based prevention and MPT

products. The eventual <u>SEF for MPT development</u>-published in 2016-aimed to inform design and development decisions in a way that maximize market success and impact of potential products aligned with the market drivers for MPT target populations.

More recently, an emergent key challenge for MPT R&D is that investment in the MPT field stems primarily from the US Government, including NIH and USAID, as well as smaller non-profit and for-profit entities that often do not have resources for end-user research-not to mention the capacity and expertise for manufacturing, and scale-up. Large scale pharmaceutical companies typically boast the necessary infrastructure for end-user and other 'end stage' considerations into their early stage R&D investment decisions, for example. But this is not the scenario for how current MPTs in the pipeline are funded and developed.

With this in mind, in order to help guide decisions for prioritizing investments and integrating end-user research early and throughout the biomedical HIV prevention product development process, the IMPT, in close collaboration with USAID's Office of HIV/AIDS (OHA), developed a framework designed to inform investment decisions that integrate user perspectives at various stages of product development for USAID's Microbicide Program. The content of this framework was generated through consultations with experts representing global pharmaceutical organizations with experience in standard R&D as well as public-private partnerships, smaller biotechnology companies, and non-profit product developers.

Highlighted in this framework is the importance of end-user considerations being recognized as a critical part of the HIV prevention product development process, as well as guidance on what type of user and market data to incorporate at which stage (from R&D to launch) that would increase the potential success of new biomedical HIV prevention products in the highest risk populations. The final published framework will be available in available soon.

Reviews of feasibility, sources of supply, and manufacturability to identify issues that will affect MPT product specifications.

The complexity of developing MPT products includes numerous factors beyond combining indications. As such, the IMPT has taken a closer look at a number of areas identified as critical gaps or key research areas. Following the 2015 Priority Issues Identification Exercise, the IMPT Secretariat convened three technical meetings examining the challenges of combining hormonal contraceptives (HCs) with antiretrovirals (ARVs) in MPTs and also hosted a summary webinar on the topic. The work around this topic also resulted in the peer-reviewed publication of a Strategic Action Framework on HC MPTs.

Also in 2016, the IMPT hosted a <u>two-day workshop</u> focused on clinical trial evaluation for MPTs with the goal of informing an overall strategy for the successful clinical evaluation of MPTs. Meeting participants outlined strategies for successfully addressing challenges and risks, and identified critical market issues

that can be addressed through clinical evaluations of MPTs, or through the study of intended target populations. Similarly, in 2017, the IMPT hosted a <u>webinar</u> on bioavailability and bioequivalence strategies—a key issue for MPT R&D that emerged from the network. Other IMPT-hosted technical webinars under this topic area include the discussion of: <u>manufacturing issues for MPTs</u>; <u>opportunities and challenges in developing long-acting MPTs</u>; and the <u>development of MPTs to address STIs</u>.

Building off of findings from the HC MPT workstream, in 2018 the IMPT initiated a new work stream activity focused on novel female-initiated non-hormonal contraceptive (non-HC) approaches, including approaches that may be combined with agents that prevent STIs, including HIV, that can help advance the development of non-HC MPTs. To identify priorities and gaps that can inform product development and investment decisions in this area, in 2019 the IMPT conducted an extensive literature review of work conducted in the area of non-HC over the past forty years, as well as conducted interviews with technical experts working on male and female non-HCs. Outcomes from this activity will be a white paper outlining recommended action areas to advance this area of MPTs to be vetted as part of the annual Contraceptive Development Meeting hosted by the Contraception Research Branch of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) in November 2019. This meeting is inclusive of all NICHD's Contraceptive Development Branch awardees that are developing new and improved methods of non-hormonal contraception, including MPTs. Stay tuned!

Evaluations to ensure that the needs of end-users, health care providers, and other stakeholders are incorporated throughout the development process.

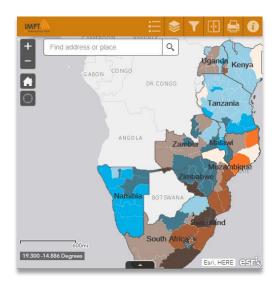
The IMPT has long recognized that developing a successful and impactful MPT depends on factors beyond success in the lab. A key focus of the IMPT has been on activities that are critical to ensuring that MPTs in development are not only efficacious in clinical trials, but also desired, acceptable, and accessible once commercially available. Toward this end, the IMPT collaborated with experts from across the field for several years–first starting in 2016–to develop a Market Access Framework, which serves as a roadmap for user evaluations.

Similar to MPT investment tracking, a task of the IMPT Secretariat is to annually track end-user research within the MPT field. To better understand this landscape, the IMPT has conducted a methods analysis looking at different types of research in this space and released a report comparing socio-behavioral research with human-centered design (HCD) and convened two technical webinars on the topic–also described in section one. The <u>first</u> highlighted new research exploring the acceptability of and preference between potential MPT product types, drivers of future product use, and other important end-user considerations. The <u>second</u> engaged new stakeholders in the end-user space by bringing together experts for a dynamic discussion of lessons learned from conducting end-user research in the

fields of contraception, HIV, and MPTs to synthesize and share best practices for MPT product development and introduction. Developing MPTs that put women at the center of product R&D was a core premise in the founding of the IMPT, and the network is working to enhance its end-user portfolio as more products move through clinical trial phases and inch closer to reality.

Business and financial analysis plans for sustainability.

In a landscape of limited funding to support product development and introduction, it is necessary to take a close look at financial and market considerations to support the pursuit of products with the best chance to make an impact. To this end, the IMPT developed an online interactive target population mapping tool—launched in 2018—that overlays HIV prevalence and the total addressable market for contraception to illustrate the 'hot spots' where an MPT that combines HIV prevention with contraception might have the greatest impact. The contraceptive method mix was also added to the map to further illustrate key factors for



consideration when looking at the target population. Previously, the IMPT looked at impact modelling around MPTs-publishing a <u>landscape review report</u> as well as a <u>technical webinar</u> around the topic. This provided the foundation for current work to develop an investment case for MPTs, but certainly more work to help ensure the market success of MPTs is needed. Moreover, the SACC has prioritized public-private partnerships in order to ensure MPT product supply and financing. MPT product developers have worked hard to foster these partnerships-but more work needs to be done to better engage the private sector and help ensure the future of MPT product development and introduction.

With over two dozen products in varying stages of development in the MPT product development pipeline, there has been great progress over the past decade. Still, there is much work to do, including: focused research for pressing questions around MPT market, facilitating public-private partnerships, supporting rigorous and feasible clinical trials, and ensuring a robust manufacturing infrastructure. Further, given limited resources and the high cost of clinical trials, rigorous standards to guide product investment decisions that can help ensure product success are critical.

Increase awareness and support for MPTs

Stakeholders must raise awareness, build support, and mainstream the concept of multipurpose prevention. By building a cadre of stakeholders across disciplines, for example, the global health community can foster a new generation of researchers, developers, advocates, providers, and policymakers who will incorporate multipurpose prevention options into health programs. [...] To build momentum, it will be critical to communicate progress, which will likely include strengthened collaboration across sectors, new multidisciplinary approaches, greater cost efficiencies, and accelerated impact. Now is the time to stimulate discussion, debate, and action on multipurpose prevention technologies.

-Excerpt from "Saving Lives" brief, 2010

Over the past ten years, a central aim for the IMPT has been to increase awareness around, and support for, MPTs. Many MPT-focused articles have been published in the mainstream media and popular press, including the Guardian, Ms. Magazine, the New York Times, and Women in the World. In 2014, the World Health Organization and IMPT were guest editors for a special issue on MPTs in the BJOG: An International Journal of Obstetrics and Gynaecology, featuring a wide array of research, policy, and advocacy articles on MPTs from global IMPT stakeholders. Also in 2014, the IMPT launched the "With an MPT I Can" Campaign. This ongoing campaign was a first step toward encouraging women to imagine the possibilities of the ways in which an MPT could impact their lives. Tremendous strides have been made in the awareness space. Only a decade ago the term 'MPT' was just being discussed into existence. Fast forward to 2017 where the keynote speaker at the International AIDS Society conference had a slide about the promise of MPTs!



In the early days of the IMPT, most external presentations given by the IMPT Secretariat and network partners were dedicated to explaining the MPT concept as such. Ten years later the MPT concept is well

established within the broader fields of sexual and reproductive health, as well as within the HIV prevention space; and although raising awareness around MPTs remains at the core of the IMPT network, external discussions have shifted to technical specifics and fieldwide updates, as opposed to the 'MPTs 101' format. In this way, as described in section one, the IMPT has shifted to focus on awareness efforts around solidifying sustainable support for a now more recognizable field.

Grounded in the <u>learning network framework</u>, over the past decade the IMPT has mobilized resources to further expand awareness around and support for MPTs guided by three component parts: 1) information in; 2) information out; and 3) information across. These components have increased the MPT field knowledge base, but also strengthened the methods in which innovative discussions and actions are showcased among a collection of stakeholders driven to improve women's sexual and reproductive health.

1) Information in

To gather information from the field, learning networks must stay connected with participants, have a clear process to ask for and collect information, and have a functional technological infrastructure to organize, archive, and deliver the information back to the field. –Excerpt from "Learn Before You Leap," 2018

A primary function of the IMPT is to serve as the information hub for the MPT field. In order to "gather information" the Secretariat conducts ad hoc conversations with IMPT network partners, hosts network webinars, attends conferences and meetings, regularly surveys product developers for the most up to date R&D information, and conducts ongoing stakeholder surveys in order to determine priority action areas and/or gaps, among other items. As a known leader of the field, partners turn to the IMPT to share news about their work, which the Secretariat helps promote out to the worldwide network. To this end, the Secretariat curates an online resource center for all MPT-related material.



2) Information out

Learning networks get information out to the field through webinars, calls, newsletters, learning opportunities, and other means of distribution. By aligning messaging from across the field, learning networks help fields build a sense of shared purpose and identity. –Excerpt from –Excerpt from "Learn Before You Leap," 2018

Over the past decade the IMPT website-hosted and managed by the Secretariat-has undergone several redesigns with network stakeholders' input. As described above, the <u>resource center</u> houses a searchable resource database that has grown tremendously over the past ten years as the Secretariat aims to synthesize all available MPT information into one easy-to-navigate location. The resource center hosts a collection of research and data findings from companion fields collected through ongoing conversations with MPT stakeholders and partners in compatible fields, and other resources as part of an ongoing landscape review. Moreover, as communications efforts are best when they leverage the broader IMPT network, the resource center hosts an <u>outreach toolkit</u> with templates for the public to openly utilize when communicating about MPTs in any setting. Separate from the IMPT website, in 2013 the Secretariat built and launched the <u>MPTs101</u> website with feedback from network members as a basic landing page for information about MPTs.

Academic publications as well as media pieces about MPTs have been collected since the field's inception as part of an ongoing tracking effort within the communications space. Dating back to 2014, an 'Articles from the Field' e-blast is circulated monthly to the IMPT network. Since tracking began in 2009, MPT-relevant academic publications have evolved from simply considering MPTs as prevention options, to conceptualizing non-hormonal MPTs, to considering end-user input throughout MPT R&D. In the early days, key pieces in the International Journal of Obstetrics and Gynaecology (BJOG) and Journal of Antiviral Research were critical in establishing the field and making MPTs known to a greater audience as they each demonstrated the feasibility of these products to provide comprehensive prevention and advocate for investment prioritization. Moreover, the BJOG article solidified the "innovative partner approach" of the IMPT.

As MPT product ideation has transformed, the use of MPT terminology in scientific contexts as well as within the broader media context has also increased from occasional 'mentions' to now more consistent, deliberate integration. The IMPT as a 'learning network' was recently highlighted in the <u>Stanford Social Innovation Review</u> as an essential actor for strengthening the interconnectivity of efforts in the sexual and reproductive health arena. In 2017, <u>Women in the World</u> showcased influential female leaders in the

MPT field; highlighting MPTs as a burgeoning option for women–particularly those with high unmet need. In 2014, the magazine Women's Health called attention to IMPT Executive Director Bethany Young Holt's work in advocating for MPTs calling her the "safe-sex empowerer."

In tandem with the evolution of published pieces, conferences and presentations featuring MPTs no longer address feasibility, as the industry focus has shifted to technical specifics and path to market strategies for several MPTs in later stages of development. Increasingly recognized at conferences and meetings around the world, MPTs and the IMPT are also often made visible through representation at these meetings by partners who are equipped with the knowledge and materials to engage myriad audiences. The IMPT has long used large international conferences as a space to further ignite enthusiasm for MPTs-by participating in side convenings, or satellite sessions in order to highlight MPTs both as part of the primary conference, but to also branch out with select stakeholders and spread the word about MPTs to those working in adjacent spaces.

The IMPT blog, a new addition to the Secretariat's communications activities, was launched in November 2017 and plays a vital role in highlighting the potential of MPTs in a fresh, more informal format. The blog now consists of two series. Initiated in February 2018, the 'From the Pipeline' series features posts from product developers about MPTs in the pipeline. The second series, 'Meet the Secretariat Staff' showcases staff members, their passionate beginnings, and ongoing dedication to improving women's health and lives with MPTs.



A final component to IMPT communications work is getting information 'out' to the IMPT network using social media. The Secretariat has long worked to shape a platform to communicate about MPTs on social media including Facebook, Twitter, LinkedIn, and Instagram. These platforms provide a space where the IMPT can share information about MPT innovations aimed at improving women's sexual and reproductive health. Social media has played an important role in discussing topics in real time and interacting with a virtual network. To this end, social media has been a significant factor in developing the IMPT's accessibility and relevance to existing and new audiences alike.

3) Information across

Collecting and disseminating information is a valuable service, but it is not sufficient. Learning networks must also help stakeholders connect with each other directly so that information can flow freely, unrestrained from the bottleneck of a central hub. By actively weaving connections across the network and providing mechanisms for network members to connect with one another, learning networks can foster self-organization, support members to coordinate the activities they're working on, and avoid duplication of efforts.

-Excerpt from "Learn Before You Leap," 2018

As described in section one, membership within the IMPT has always remained more informal than that of the working groups. This was done, by design, to be inclusive of members with varying availability and needs. Although members have a variety of ways to remain connected through mechanisms hosted or managed by the Secretariat, the IMPT learning network structure naturally encourages member connections beyond this. With a small, core staff the Secretariat functions best in its role as a facilitator of network connections—with its primary aim to foster growth within the MPT space.

Launched in 2013, the 'IMPT Network' [then called the 'Network of Experts (NoE)]—members receive MPT-relevant information from the Secretariat in the form of e-mail updates (e.g. 'Articles from the Field') as well as have the opportunity to participate in biannual webinars. As described in section two, the IMPT hosts technical webinars based on relevant topic 'trends.' Additionally, the biannual IMPT Network webinars are a platform to facilitate member engagement, as well as for the Secretariat and network members to provide MPT-relevant updates. All webinars provide participants opportunities to discusseither within the webinar presentation structure, or offline in small groups.

More recently, the Secretariat has been tasked with organizing large scale tailored communications outreach efforts around specific technical topics of interest to select network members. While personalized updates from Executive Director, Bethany Young Holt, and other Secretariat staff have long been prioritized as part of the 'information out' component to the IMPT learning network, the recent tailored communications outreach further aims to facilitate connections 'across' the network.

Finally, in early 2017, the IMPT launched a <u>Wikipedia page</u> about MPTs. This page openly invites contributors from all over the world to file their knowledge in an easy-to-find location and update information about MPTs. It also allows the IMPT to track MPT knowledge and education efforts.

Critical next steps

As the IMPT looks toward the next ten years, we remain steadfast in our commitment to comprehensive sexual and reproductive health approaches for women around the world, and the promise of MPTs. For MPTs to reach their full potential, the IMPT remains committed to continued collaboration in order to galvanize new support and leverage additional resources for appropriate, high-impact MPT investments. This includes:

Engaging with new technical partners.

Making the IMPT more visible through informal outlets, building credibility and consistency in the field, and attracting new partners.

Integrating the work of researchers who are developing standalone contraceptive and sexually transmitted infection solutions.

In this way, the IMPT can connect with leaders in corresponding fields, request to share input, and collaborate on ways to join forces across disciplines.

Centering the end-user.

As a founding principle for the IMPT was ensuring that the end-user remained at the center of MPT product R&D, the network will remain committed to elevating project work in this space.

Rigorous standards to guide product investment decisions.

Of the over two dozen MPTs in development, the majority are in pre-clinical or early-stage development. Given limited resources and the high cost of clinical trials, rigorous standards to guide investment decisions with end-user perspectives can help ensure that the MPTs with highest potential impact can continue through the product development pipeline and into the hands of women.

Hosting a platform for ongoing funder collaborations.

Including facilitating strategic go/no go decisions for products in the MPT pipeline.

Continually working to raise sufficient funding.

Support continued growth within the MPT field, as well as a sustainable IMPT network, given the long time-horizon required for product development.

Highlighting the value the IMPT adds to the MPT field.

Given the IMPT's ability to connect collaborators from all over the world in an effort to advance MPTs using the learning network concept. As described above, the IMPT's current methods of getting the word out about MPTs consistently shows the progression of MPT R&D, and how public perception of MPTs is evolving. Continued collaborations will help to continually promote the upward growth of the field, and as more people join the effort, the greater the value output becomes.

Featuring ten years at a glance

This 10-year retrospective report highlights advances in the MPT field that have synergistically combined to bring MPTs continually closer to a reality that will improve the lives of women and girls worldwide.

2009

March 2009: The Advancing Prevention Technologies for Reproductive and Sexual Health Symposium gave rise to the international Initiative for Multipurpose Prevention Technologies (IMPT)

2010

2010: <u>Published "Saving Lives with Multipurpose Prevention Technologies: Turning Ideas into Solutions for Sexual and Reproductive Health," making "MPTs" the term to be used</u>

2011

February 2011: First NIH NICHD RFA calling for multipurpose prevention strategies

May 2011: <u>Multipurpose Prevention Technologies for Reproductive Health: Advancing the Scientific and Product Development Agenda</u>

November 2011: Multipurpose Prevention Technologies for Reproductive Health Symposium

2012

January 2012: The Global Forum on MPTs defined a global strategy, forming the Scientific Agenda Working Group (SAWG)

October 2012: MPT Product Prioritization Stakeholder Meeting

December 2012: IMPT launched the Communications and Advocacy Working Groups (CAWG) in Kenya, South Africa, China, and India raising awareness about MPTs as a concept and the IMPT network

December 2012: <u>Indian Council of Medical Research (ICMR)</u>, in collaboration with the IMPT, USAID and WHO, convenes International Symposium on Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health in Delhi, India

2013

January 2013: <u>Call for proposals from USAID's Office of Population and Reproductive Health with specific MPT objective listed-since then it has been ongoing</u>

March 2013: 1st NIH NIAID RFA calling for MPTs

May 2013: Session on MPTs at the <u>European Society of Contraception and Reproductive Health (ESC)</u>: <u>First Global Conference on Contraception, Reproductive and Sexual Health</u> in Copenhagen, Denmark

December 2013: <u>Journal of Antiviral Research: Prioritizing multipurpose prevention technology development and investments using a target product profile</u>

2014

January 2014: <u>Supplement was published in BJOG: Multipurpose prevention technologies: maximising positive synergies; Coordinated the webinar "MPT Product Development & Regulatory Issues 101"</u>

February 2014: Convening of "SAWG Sub-Working Group on Sexually Transmitted Infections" prioritizing MPTs

March 2014: Launched searchable online MPT product development database

April 2014: The MPT Supporting Agency Collaboration Meeting identified processes through which funders can leverage support for MPT development and introduction.

May 2014: Completed MPT dosage-form specific Target Product Profiles (TPPs)

September 2014: IPSOS: Assessing the Potential of MPTs in South Africa, Uganda and Nigeria; Convened the first "Technical Meeting on Hormonal Contraceptives in MPTs"; Panel at SOCAP, "Multipurpose Prevention Technologies: Impact Investing for Global Reproductive Health"

October 2014: Organized "Multipurpose Prevention Technology (MPT) Manufacturing Issues"

November 2014: Hosted IPSOS webinar, "MPT Acceptability in Uganda, Nigeria and South Africa"

<u>Launched the "With an MPT I Can" Campaign encouraging women to imagine the possibilities of the ways in which an MPT could impact their lives</u>

2015

January 2015: 1st ICFP conference track calling for MPTs

January 2015: 1st R4P conference track calling for MPTs

May 2015: Presented "Latin America and the Caribbean (LAC) Regional Webinar on MPTs"; Convened second

meeting on HC and MPTs

June 2015: Convened the joint in-person Steering Committee Meeting and SACC meeting

September 2015: Presented in the World STI & HIV Congress Symposium on MPTs

2016

February 2016: 1st IAS conference track calling for MPTs

WHO includes MPTs as their RH strategy

Nearly a dozen MPT products are now in various stages of clinical development

September 2016: <u>Published "Laying the Groundwork for a Strategic Evaluation Framework (SEF) for HIV Prevention</u> and MPT Product Development" informing design and development decisions to maximize impact potential of MPTs

September 2016: Secretariat convenes Clinical Trial Evaluation workshop for MPTs in Washington, DC

September 2016: Secretariat convenes Technical Meeting on Hormonal Contraceptive MPTs in Washington, DC

2017

March 2017: Op-ed raising awareness about MPTs featured in Our Bodies Our Selves

May 2017: Secretariat hosts live <u>webinar on Modelling the Potential of MPTs, building on the landscape review</u> of MPT impact and cost-effectiveness mathematical modelling projects completed earlier in 2017

September 2017: MPT end-user perspectives were discussed in a webinar exploring user acceptability and preferences

December 2017: Op-ed in Women in the World, in association with the New York Times, features MPTs and the 'Zena warrior princesses of women's health'

2018

May 2018: The IMPT Advisory Council was formalized

July 2018: Secretariat co-chairs MPT workshop at 2018 IAS Conference in Amsterdam

September 2018: Peer-reviewed publication of strategic action areas to advance anti-retroviral and hormonal contraceptive MPTs

2019

Close to 30 MPT products now in the MPT product development pipeline

Activities to prepare for product launch of the Dual Purpose Prevention Pill by 2022/2023–this would be the first MPT to be introduced into the market since the condom!

IMPT celebrates its 10-year anniversary!

The <u>Initiative for Multipurpose Prevention Technologies</u> (IMPT) is a project of <u>CAMI Health</u>, an organization dedicated to improving the health of women and girls worldwide. CAMI Health is housed at the <u>Public Health Institute</u> (PHI). This project is made possible by the generous support of the American people through the <u>United States Agency for International Development</u> (USAID) under the terms of Cooperative Agreement #AID-OAA-A-16-00045. The contents are the responsibility of the IMPT, CAMI Health, PHI, and its partners and do not necessarily reflect the views of USAID or the U.S. Government.









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