

#### BACKGROUND

Founded in 2009, the Initiative for Multipurpose Prevention Technologies (IMPT) is an international and interdisciplinary collaboration committed to advancing the development and commercialization of MPTs as quickly and efficiently as possible. As Secretariat, CAMI Health serves as the neutral convener and organizing body for the IMPT, facilitating the strategic planning process for the initiative to identify and address critical issues to the field. In this role, CAMI Health developed and distributed an online survey to identify emerging priority issues and challenges to help inform the MPT field and next steps for the IMPT for 2015-17. A sub-survey focused on the priorities and gaps related to hormonal contraceptives (HC) and MPTs was also developed and distributed. While CAMI Health works with IMPT Steering Committee and Supporting Agency Collaboration Committee (SACC) members on an ongoing basis to identify and refine priorities for the MPT field, this survey exercise engaged a wider range of MPT stakeholders through a more concerted and rigorous process.

#### METHODS

**Survey Development:** CAMI Health worked closely with the IMPT Steering Committee and SACC to identify and outline a series of possible priority issues and challenges for the IMPT and the MPT field. Eight broad priority areas were identified, several of which were broken down into more specific sub-issues. A Likert scale ranking was used in the survey instrument, and issues and challenges were ranked as either 'high priority,' 'medium priority,' 'low priority,' or 'no opinion.' A second survey focused on priority issues and challenges related to HC in MPTs was developed aiming to prioritize the research gaps identified during the September 2014 HC in MPTs meeting as well as assess the status of ongoing research.

**Survey Distribution & Response:** CAMI Health sent a request to complete the IMPT Priority Issues survey to members of the IMPT Network of Experts (NoE) and other key MPT stakeholders across the globe (n=118). There was a 36% response rate to the survey (43/118). The HC and MPTs Priority Issues survey was distributed to members of the NICHD-funded Contraceptive Clinical Trials Network (CCTN) who attended the September 2014 convening (n=16) and had a 44% response rate (7/16). [The raw data collected through this exercise is available for review upon request.]

**Survey Data Analysis:** A small, product neutral review committee was formed from members of the IMPT Steering Committee to analyze the survey data. Committee members were selected to represent expertise spanning HIV, STIs, family planning, policy, and social-behavioral issues. The review committee analyzed the quantitative and qualitative survey data and convened virtually to discuss results and develop recommendations for the 2015-2017 IMPT strategic plan.

Critically, the broader context of the MPT field, including feasibility, was also considered in the data analysis process. Thus, an issue may have been identified as a high priority through the survey, but de-prioritized by the review committee based on committee members' understanding of the broader field and its constraints. Conversely, an issue may have been identified as a medium or low priority through the survey, but raised as a higher priority by the review committee in the context of the broader field.

**IMPT Evaluation:** CAMI Health is also conducting an evaluation of the IMPT, including tracking of relevant metrics and key informant interviews with members of the IMPT Steering Committee, SACC, Scientific Agenda Working Group (SAWG), and other stakeholders able to speak to the IMPT's functionality and progress. While not necessarily the primary aim of this ongoing evaluation exercise, key informants have articulated their perspectives on field-wide priorities as part of the evaluation. This feedback was considered in the overarching priority issues identification process.

## RESULTS

Based on the survey data, product neutral review committee discussion, and other input from IMPT Steering Committee and SACC members, five field-wide priority issues to be highlighted by the IMPT in 2015 for further funding, research, and other follow-up action were identified:

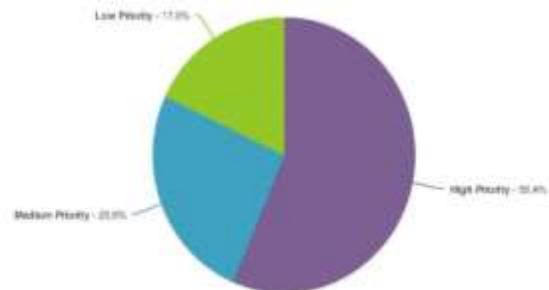
### 1) Assess the gaps in social-behavioral knowledge for MPT development and MPT commercialization potential.

*Description:* Broadly, an understanding and integration of the social-behavioral contexts and commercialization potential of MPTs during the product development process is critical to ensure that MPTs are desirable, deliverable, and accessible to end-users. To this end, the IMPT has developed a theoretical framework on these issues in the context of MPT development and has begun to convene relevant stakeholders to drill down on specific questions and challenges in this arena. Given the challenges related to product adherence in recent microbicide trials such as FACTS 001, work in this domain has been elevated to among the highest priorities for the field.

Critical areas for investigation include efforts to:

- Identify the most relevant MPT user groups (e.g., girls and young women, commercial sex workers, etc.) in priority settings, and define steps for robust assessment of acceptability and commercial feasibility in these groups.
- Assess whether we have adequate data and methods (e.g., placebo acceptability trials, discrete choice experiments, conjoint, demand forecasting, etc.) for collecting user preference data for product design.
- Understand end user/ community-level factors relevant to MPT market demand in populations with highest unmet need for MPTs (e.g., product related side effects, social norms, etc.).

*Rationale for Selection:* 56.4% of survey respondents ranked this as a *High Priority* issue. This priority ranking was supported in the neutral review committee discussion and feedback from several IMPT Steering Committee and SACC members during CAMI Health's evaluation key informant interviews.



*Next steps:* The IMPT will continue to organize and support small, in-person convenings in a variety of settings to better frame social-behavioral and commercialization contexts for MPT development, including articulating the appropriate research questions and identifying the best ways to answer these questions. This work will feed into the development of a detailed 'menu' of prioritized questions and activities to help guide the research landscape relevant to MPTs.

### 2) Understanding hormonal contraceptive (HC) knowledge gaps in the context of MPT development.

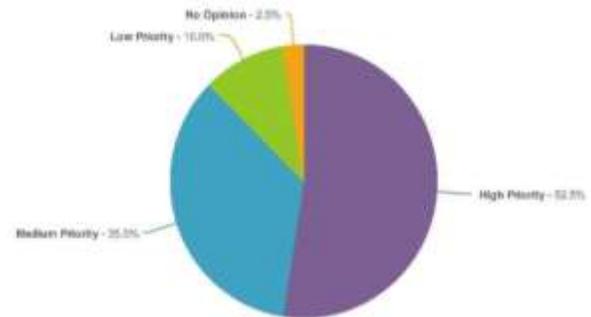
*Description:* A 2014 IMPT convening of HIV prevention researchers, MPT product developers, and researchers from the CCTN, organized in collaboration with the Bill & Melinda Gates Foundation, NICHD, and USAID, revealed a number of critical knowledge gaps that are critical to consider when combining HC and STI/HIV prevention active ingredients in a single product. These gaps are highlighted in a [summary of this 2014 convening](#) on the CAMI Health website.

Critical areas for investigation include efforts to:

- Determining dosage for HC and MPTs: Topical vs. systemic effects, mechanisms of action, BMI, and determination of appropriate surrogates of safety and efficacy (anovulation, etc.).

- Assess feasibility of dosage form options other than intravaginal rings (IVRs), including on-demand and long-acting formulations for MPTs.
- Assessment of non-HC options for MPTs.
- Understanding the pregnancy/fertility risk of MPTs.

*Rationale for selection:* 52.5% of survey respondents ranked this as a *High Priority* issue. This priority ranking was supported in the neutral review committee discussion and feedback from several IMPT Steering Committee and SACC members during CAMI Health's evaluation key informant interviews.



*Next steps:* A follow-up convening of HIV prevention, CCTN researchers, and product developers was held in May 2015 to drill down on the research agenda for HC in MPTs. A follow-up convening on HC in MPTs will be organized for the fall of 2015.

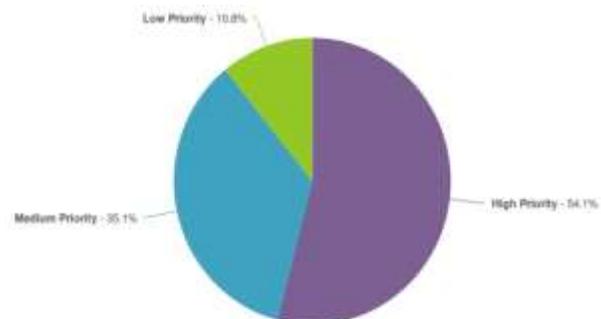
### 3) Assess challenges and other issues related to MPT clinical trial design.

*Description:* It is important for MPT funders, product developers, and researchers to understand feasibility and risk around clinical trial design issues to guide investment decisions, particularly in the wake of the challenges experienced during recent microbicide trials.

The IMPT has identified broad topics within clinical trials that warrant further thought and discussion, including efforts to:

- Analyze the following design issues: single trials per indication vs. combined indication per trial; placebo control or superiority/ non inferiority designs; bioequivalence options; and other specific ethical considerations (standard of care, stopping rules, pregnancy, appropriate follow up, etc.).
- Determine next strategies for obtaining PK/PD data and advancing research on drug-drug interactions of ART (NNRTIs, PIs) and HC (LNG, ENG).

*Rationale for Selection:* 54.1% of survey respondents ranked this as a *High Priority* issue. This priority ranking was supported in the neutral review committee discussion and feedback from several IMPT Steering Committee and SACC members during CAMI Health's evaluation key informant interviews.

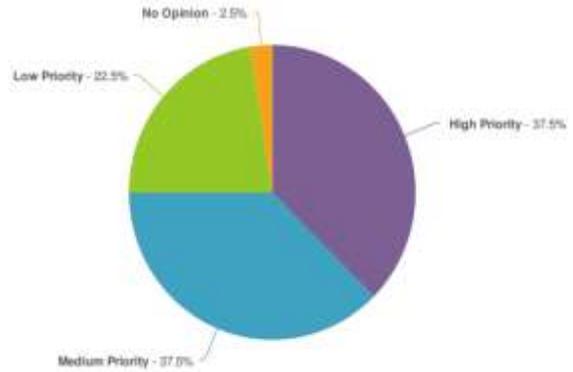


*Next steps:* The IMPT will organize a technical convening around identified priority MPT clinical trial design topics, planned for autumn of 2015.

### 4) Develop a process for achieving a more robust product development pathway for non-HIV STI MPTs.

*Description:* While perhaps difficult to tackle given the variability of STI epidemiology worldwide, the IMPT STI Working Group has begun work in this area by tracking compounds for STI indications. Critical gaps include the development of non-ARV MPTs, identification of candidate STI indications through products shelved due to non-efficacious non-STI primary indications, and additional data on STI epidemiology.

*Rationale for Selection:* The majority of survey respondents ranked this as a *Medium Priority* issue (37.5%); however, key IMPT scientific advisors have recommended that this issue be elevated to a high priority for the field, particularly due to high global rates of non-HIV STIs such as HSV.

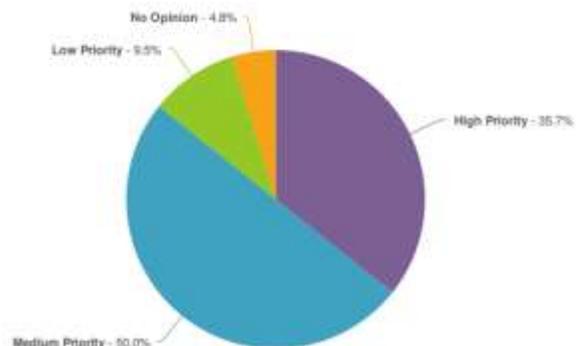


*Next steps:* The IMPT will engage additional STI experts through a variety of platforms, including convenings such as the ISSTD conference in Brisbane, Australia in September 2015 as well as outreach leveraged through ongoing work maintaining and expanding the online [MPT product development database](#). Overall, a critical first step to address this issue will be to build the case for STI MPTs and leverage support for further investment.

**5) Engage modeling efforts to robustly assess public health impact and cost effectiveness of MPT product options in specific target populations.**

*Description:* Data on the potential public health impact and cost effectiveness of MPTs are critical in building the case for MPT development, investment, commercialization, advocacy, and policy support. Given that MPTs are still largely undergoing clinical trials, however, the field does not have access to such data through robust surveillance efforts such as for products already on the market. Modeling is thus an important strategy in generating this evidence base. Moreover, modeling may be a useful tool in determining the appropriate balance of public health efficacy and cost effectiveness (though not mutually exclusive attributes) when developing and/or planning the introduction of a particular health intervention.

*Rationale for Selection:* The majority of survey respondents ranked this as a *Medium Priority* issue (50.0%); however, key IMPT scientific advisors and Steering Committee members have recommended that this issue be elevated to a high priority for the field. Modeling efforts, such as demand forecasting and cost effectiveness models, will also strengthen many other IMPT activities by supporting the field's operating assumptions with data.



*Next Steps:* CAMI Health and other IMPT partners will identify specific modeling activities and work to engage modeling experts in the related fields (family planning, HIV, non-HIV STI prevention, etc.) to explore the feasibility of and opportunities related to modeling projects to make the case for MPTs.

**NEXT STEPS**

CAMI Health, in collaboration with the IMPT Steering Committee, SACC and working group members, will **create a menu of fundable activities** based on the priorities identified through this exercise. These activities will be incorporated into the 2015-2017 IMPT Strategic Plan.