Multipurpose prevention technologies (MPTs): a promising response to current challenges around hormonal contraceptive methods and HIV

27 January 2016
10:30 - 11:50 AM
Kintamani 1
Multipurpose prevention technologies (MPTs): a promising response to current challenges around hormonal contraceptive methods and HIV

Moderator:
Kirsten Vogelsong (Bill & Melinda Gates Foundation)

Presenters:
Chelsea Polis (Guttmacher Institute)
Anke Hemmerling (IMPT/UCSF)
Laura Dellplain (IMPT)
MPTs combine protection against:

- Unintended pregnancy
- HIV
- Other STIs
Hormonal contraceptive methods: do they increase HIV acquisition risk & do they interact with antiretroviral drugs?

Chelsea B. Polis, PhD

March 8, 2016 IMPT Secretariat Webinar Recap of Presentation Made on January 27, 2016 at the International Conference on Family Planning
Women & girls face overlapping SRH risks, and MPTs could simultaneously address these risks.
Hormonal contraceptive methods & HIV risk: a motivating example for MPTs

Possible HIV acquisition risk with injectables

Uncertainty in data

Life-saving benefits of hormonal contraceptives

Public health conundrum
Do specific methods of hormonal contraception increase risk of:

1. HIV acquisition in uninfected women?
2. Interactions with antiretroviral therapy?
3. HIV disease progression in HIV-infected women?
4. HIV transmission to uninfected male partners?
Causal vs. confounded associations: condom use example

Use of a hormonal contraceptive (exposure) → Higher risk of HIV acquisition (outcome)
Causal vs. confounded associations: condom use example

Use of a hormonal contraceptive (exposure) \[\rightarrow\] Higher risk of HIV acquisition (outcome)

OBSERVED ASSOCIATION IS CAUSAL
Causal vs. confounded associations: condom use example

Use of a hormonal contraceptive (exposure) → Less consistent condom use → Higher risk of HIV acquisition (outcome)

OBSERVED ASSOCIATION IS DUE TO CONFOUNDING
Previously published (2014) systematic review on HC and HIV acquisition

- 22 relevant studies published by Jan 15, 2014
- Most assessed OC pills or injectables (DMPA, NET-EN)
- We rated studies either:
  - Severely flawed and “unlikely to inform the primary question”, or
  - “Informative, but with important limitations”
    - All were observational & vulnerable to confounding

Observational studies of oral contraceptive pills and HIV acquisition

Studies rated “informative but with important limitations” (2014)
Observational studies of (mostly) DMPA and HIV acquisition
Studies rated “informative but with important limitations” (2014)

Observational studies of **NET-EN** and HIV acquisition

Studies rated “informative but with important limitations” (2014)

Summary of previously published (2014) systematic review: HC for HIV-uninfected women
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- **OCPs**: data do not suggest an increased risk
Summary of previously published (2014) systematic review: HC for HIV-uninfected women

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- **Implants**: limited data do not suggest increased risk
Summary of previously published (2014) systematic review: HC for HIV-uninfected women

- **OCPs**: data do not suggest an increased risk
- **NET-EN**: limited data, mild uncertainty
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- **Patches, rings, hormonal IUDs**: no data
Summary of previously published (2014) systematic review: HC for HIV-uninfected women

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- **DMPA**: substantial uncertainty; some higher quality studies suggest increased risk, others do not
Summary of previously published (2014) systematic review: HC for HIV-uninfected women

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- **NET-EN**: limited data, mild uncertainty
- **Implants**: limited data do not suggest increased risk
- **Patches, rings, hormonal IUDs**: no data
- **DMPA**: substantial uncertainty; some higher quality studies suggest increased risk, others do not
  - If association is causal, magnitude could range from a modest effect to a doubling in risk
“Unless the true effect size approaches a relative risk of 2.19, unlikely that reducing IHC could result in public health benefit, with possible exception of countries in S. Africa with the largest HIV epidemics.”

2016 systematic review (in progress): search strategy

- Kept all references identified in previous review
- Searched PubMed & Embase between Jan 15, 2014 and Jan 15, 2016
- Retrieved 312 new references
- 10 contain information relevant to our review
  - 8 new HC vs. non-use of HC analyses
  - 1 DMPA vs. NET-EN analysis
  - 1 meta-analysis with previously unpublished data
2016 systematic review (in progress): 10 studies newly included

- 5 “Unlikely to inform the primary question”
- 5 studies “Informative but with important limitations”
  - 2 studies: no sig ↑ in risk with injectables
  - 2 studies: ↑ risk with DMPA
    - 49% and 41% (vs. no HC and vs. NET-EN, respectively)
  - 1 meta-analysis:
    - All studies: 50% ↑ in risk for DMPA
    - “Higher-quality studies”: ↑ no longer significant (22%)
- Where OCPs or implants assessed: no sig ↑ risk
ECHO: a randomized trial to assess hormonal contraception & HIV risk

- Randomizes 7,800 women to one of three arms: DMPA, Jadelle, Copper-T IUD
  - Outcomes: HIV infection, pregnancy, SAEs, continuation
- Study sites in: South Africa (9), Kenya (1), Zambia (1), Swaziland (1)
- Recruitment began Dec 2015; results by 2018
- Research consortium includes FHI 360, University of Washington, Wits RHI, and WHO
  - More info at http://echo-consortium.com/
Some ARVs may reduce efficacy of certain HC methods, including COCs and implants

- Some NNRTIs (esp. efavirenz)
- Some PIs (esp. ritonavir-boosted PIs)
- Some integrase inhibitors
- No interactions expected with DMPA

ART efficacy does not appear to be impacted by use of any HC tested
Efavirenz reduces implant effectiveness; implants still more effective than other HC
Efavirenz reduces implant effectiveness; implants still more effective than other HC

Where do burdens of HIV & unmet need for modern contraception overlap the most?

Closing thoughts

• Questions on DMPA & risk of HIV acquisition may not achieve complete clarity for some time.

• Drug-drug (HC-ART) interactions must be considered in MPT development.

• Women need access to safe, effective, acceptable, accessible MPTs to simultaneously prevent multiple health risks.

• Let’s get to work!
Bigger than the sum of the parts:
Bringing together the silos of HC and ART research
to solve challenges for MPT development

Anke Hemmerling
Universities of California, San Francisco & Berkeley
IMPT

Multipurpose prevention technologies (MPTs): a promising response to current challenges around hormonal contraceptive methods and HIV

2016 International Conference on Family Planning
27 January 2016 – Nusa Dua, Indonesia
MPTs: Many Possibilities

Indications
- Pregnancy, HSV, HPV, HIV, BV, Chlamydia, Gonorrhea, Syphilis, Candida, Trichomonas

Delivery Methods
- Topical daily, Topical pericoital, Systemic sustained, Topical sustained, Oral daily, Oral pericoital

Active Pharmaceutical Ingredients
- HC, Non-HC, Barrier, Probiotic, Antimicrobial, Antifungal, Antiviral

Product Types
- Vaginal film, Vaginal tablet, Oral tablet, Vaginal ring, Non-IVR device, Vaginal gel, Injectable, Implantable

MPT Product Possibilities
Potential MPT Product Types

<table>
<thead>
<tr>
<th>Drug combinations</th>
<th>Drug/device combinations</th>
<th>Multipurpose vaccines</th>
<th>Bacterial therapeutics</th>
<th>Nanoparticles</th>
</tr>
</thead>
</table>

MPTs: a promising response to current challenges around hormonal contraceptive methods and HIV
2016 International Conference on Family Planning - 27 January 2016 – Nusa Dua, Indonesia
# MPTs in development: Gels and Films

## HIV + Other STIs

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Phase</th>
<th>Conditions</th>
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<tbody>
<tr>
<td>1.0% Tenofovir Vaginal Gel</td>
<td>Phase III</td>
<td>HIV, HSV</td>
</tr>
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<td>mapp66 (mAb) Vaginal Film</td>
<td>Phase I</td>
<td>HIV, HSV</td>
</tr>
<tr>
<td>MIV-150 + Zinc acetate + Carrageenan Vag Gel</td>
<td>Phase I</td>
<td>HIV, HSV, HPV</td>
</tr>
<tr>
<td>Tenofovir Vaginal Film, Tablet</td>
<td>Phase I</td>
<td>HIV, HSV</td>
</tr>
<tr>
<td>TFV/FTC Vaginal Tablet</td>
<td>Phase I</td>
<td>HIV, HSV</td>
</tr>
<tr>
<td>VivaGel</td>
<td>Phase I</td>
<td>HIV, HSV, BV</td>
</tr>
<tr>
<td>SILCS Diaphragm + MIV-150 + Zinc acetate + Carrageenan Vag Gel</td>
<td>Advanced Pre-clinical</td>
<td>HIV, HSV, HPV, Pregnancy</td>
</tr>
<tr>
<td>Griffithsin vaginal insert/gel</td>
<td>Early Pre-clinical</td>
<td>HIV, HSV, HPV</td>
</tr>
<tr>
<td>SR-2P Gel</td>
<td>Early Pre-clinical</td>
<td>HIV, HSV</td>
</tr>
</tbody>
</table>

## Pregnancy, HIV & Other STIs

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<tr>
<th>Product Name</th>
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<tbody>
<tr>
<td>Amphora gel</td>
<td>Phase I</td>
<td>BV, Gon, Pregnancy</td>
</tr>
<tr>
<td>PPMC SAMMA gel</td>
<td>Pre-clinical</td>
<td>HIV, HSV, HPV, Chl, Gon, Pregnancy</td>
</tr>
</tbody>
</table>
**MPTs in development: Intravaginal Rings**

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<th>HIV + Pregnancy &amp; Other STIs</th>
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<tbody>
<tr>
<td>Tenofovir + Levonorgestrel IVR</td>
<td>Phase I</td>
<td>HIV, HSV, Pregnancy</td>
</tr>
<tr>
<td>Dapivirine + Levonorgestrel IVR</td>
<td>Advanced Preclinical</td>
<td>HIV, Pregnancy</td>
</tr>
<tr>
<td>MIV-150 + Zinc acetate + Carrageenan + LNG IVR</td>
<td>Early Preclinical</td>
<td>HIV, HSV, HPV, Pregnancy</td>
</tr>
<tr>
<td>BioRings IVR</td>
<td>Early Preclinical</td>
<td>HIV, Pregnancy</td>
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<td>Tenofovir + Acyclovir IVR</td>
<td>Phase I</td>
<td>HIV, HSV</td>
</tr>
<tr>
<td>Tenofovir Disoproxil Fumerate (TDF) IVR</td>
<td>Phase I</td>
<td>HIV, HSV</td>
</tr>
<tr>
<td>Zinc acetate + Carrageenan IVR</td>
<td>Advanced Preclinical</td>
<td>HIV, HSV, HPV</td>
</tr>
<tr>
<td>Tenofovir + IQP-0528 IVR</td>
<td>Advanced Preclinical</td>
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<td>Griffithsin IVR</td>
<td>Early Preclinical</td>
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Priorities for 1st Generation MPTs

“On demand”
- Used at time of intercourse
- For intermittent sex
- Oral or topical

Sustained release
- Vaginal ring or long-acting injectable
- No daily administration required
- Potential for increases adherence and effectiveness
### Sustained Release Devices: MPT IVRs

<table>
<thead>
<tr>
<th>90-day MIV-150 + ZA +C + LNG (Pop Council)</th>
<th>90-day Dapivirine + LNG (IPM)</th>
<th>90-day TFV + LNG (CONRAD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Image of MIV-150 + ZA +C + LNG" /></td>
<td><img src="image2" alt="Image of Dapivirine + LNG" /></td>
<td><img src="image3" alt="Image of TFV + LNG" /></td>
</tr>
<tr>
<td>• EVA matrix with reservoir core</td>
<td>• Silicone matrix ring</td>
<td>• Segmented PU ring</td>
</tr>
<tr>
<td>• Pre-clinical stages</td>
<td>• Advanced pre-clinical stages</td>
<td>• Phase I clinical study</td>
</tr>
<tr>
<td>• Pregnancy, HIV, HSV-2, HPV</td>
<td>• Pregnancy, HIV</td>
<td>• Pregnancy, HIV, HSV-2</td>
</tr>
</tbody>
</table>
MPTs in the Development Pipeline

- Long acting vaginal rings
- Fast dissolving films and tablets
- Innovative gels
- Injectables
- Nanofiber delivery systems
- Biotherapeutics
Unite experts in contraception and MPT development to discuss MPT research

Review gaps and challenges, identify research priorities for including HC into MPTs

Expert recommendations for developers and funders
Uniting researchers and developers in contraception & HIV prevention

- **Technical Meeting on Hormonal Contraceptives in MPTs** (09/2014)
- **Priority Survey for the Field** (02/2015)
- **Stakeholder Round Table on Hormonal Contraceptives in MPTs** (05/2015)

**Participants:** USAID, BMGF. Contraceptive Clinical Trials Network (CCTN), National Institutes of Health (NICHD, NIAID, NIH OAR), CONRAD, International Partnership for Microbicides, Population Council, FHI 360, Guttmacher Institute, California Family Health Council, Planned Parenthood, Gilead, Merck
The Contraception Side of MPTs
Topical effects:
Creating unfavorable conditions for implantation and sperm capacitation (despite ovulation).

Systemic effects:
Suppressing ovulation.
What we know about hormonal contraception

- Foundational HC research in 1960-1990s
  - Limited measures of PK and PD
  - Limited surrogate markers for effectiveness
  - High HC plasma levels that prevent ovulation have best contraceptive efficacy
  - complete ovulation suppression not needed (e.g. IUDs)
Contraceptive Pharmacokinetics: threshold for contraceptive efficacy

Contraceptive efficacy

Achilles, SL. 2014
Drug-Drug-Interactions can impact metabolism

CYP3A4 inducers: Efavirenz, Nevirapine

Potential Sequelae from Sub-Therapeutic Dose: Pregnancy

Courtesy of Shannon Achilles
HC candidates for MPTs

- **Levonorgestrel**
  - to date progestin with most available data
  - oral contraceptives, Jadelle, Norplant, Skyla, Mirena, WHO IVR
  - Possible drug-drug-interaction with selected NNRTIs

Newer progestins or combinations of LNG with estrogen may have advantages such as better bleeding profiles:

- **Etonogestrel**
  - Implanon, Nexplanon, Nuvaring (with ethinyl estradiol)
  - Possible drug-drug-interaction with selected NNRTIs

- **Desogestrel**
  - Prodrug to etonogestrel, in oral contraceptives
What we **DO NOT** know about hormonal contraception: Research Priorities #1

1. **Systemic effects of HC**
   - Exact plasma levels needed for preventing ovulation and reaching contraceptive efficacy for each HC

2. **Topical effects of HC**
   - Systematic investigation of MoA other than ovulation

3. **Impact of drug-drug-interactions of HC with other APIs**
   - Impact HC concentrations and efficacy
What we DO NOT know about hormonal contraception: Research Priorities #2

4. Which **HCs** are suitable for MPTs?

5. Which HCs best used for **on-demand MPTs**?

6. Understanding **relationship between bleeding patterns and acceptability** of HC options in different cultural settings

7. **Contraceptive efficacy** of standard HC dosing in women with **high BMI**
Conclusions

- Researchers, developers and supporting agencies should partner
  - to systematically identify and fill critical research gaps
  - develop streamlined “Go/No Go" criteria

- Collaborative process
  - avoids duplication of efforts
  - ensures most pressing questions are prioritized
  - most effective use of limited resources

- MPT field needs to follow developments in the larger fields of HIV and family planning
Keeping up to date with MPT R&D

http://mpts101.org/mpt-database

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Delivery Route</th>
<th>Delivery Method</th>
<th>Development Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Show All Product Types</td>
<td>Show All Delivery Routes</td>
<td>Show All Delivery Methods</td>
<td>Show All Stages</td>
</tr>
<tr>
<td>Indication</td>
<td>Product Developer</td>
<td>Product Sponsor/Funding</td>
<td>Active Ingredient</td>
</tr>
<tr>
<td>Show All Indications</td>
<td>Show All Developers</td>
<td>Show All Sponsors</td>
<td>Show All Active Ingredients</td>
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If we build it, will they come? Investigating the complex market access contexts relevant to developing successful MPTs

Laura Dellplain and Bethany Young Holt (IMPT); Joseph Romano (NWJ Group/IMPT); Moushira El-Sahn (Routes-2-Results/IMPT)

Multipurpose prevention technologies (MPTs): a promising response to current challenges around hormonal contraceptive methods and HIV

2016 International Conference on Family Planning
27 January 2016 – Nusa Dua, Indonesia
Initiative for MPTs [IMPT]

MPTs: a promising response to current challenges around hormonal contraceptive methods and HIV
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# MPTs in Clinical Trials

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<table>
<thead>
<tr>
<th>Pregnancy, HIV &amp; Other STIs</th>
</tr>
</thead>
</table>
| Origami Female Condom | Phase III  
| Tenofovir + Levonorgestrel Intravaginal Ring | Phase I  

<table>
<thead>
<tr>
<th>Pregnancy &amp; Non-HIV STIs</th>
</tr>
</thead>
</table>
| Amphora Gel | Phase I  

Plus products in preclinical development for:
- HIV + Pregnancy
- HIV + Other STIs
- Pregnancy, HIV & Other STIs
- Pregnancy + Non-HIV STIs

Source: MPTs101.org/mpt-database
Expansion of focus

2009

Science & Technical Aspects of MPT Development
- Scientific Feasibility
- Product Prioritization & Gap Analysis
- Dosage Form Specific TPPs
- MPT Pipeline Database

2014

Social-behavioral & Market Access
- Market Access Framework
- Market Research
- Impact Modeling
- Communications and Advocacy among key stakeholder groups

2020

Delivery & Distribution
Underscored by recent microbicide trials

VOICE

- None of the products tested proved to be effective among the women enrolled in the trial; most participants did not use them daily as recommended.
- “Urgent need for safe, effective and practical HIV prevention methods that young, unmarried women will actually use.”

FACTS 001

- “For most of this population of young, unmarried women, the majority of whom still live with their parents, using the gel consistently proved to be very challenging.”
- “More end-user centered research is needed to understand barriers and motivators of product use, as well as preferred methods and dosage forms.”

http://www.mtnstopshiv.org/node/2003
IMPT Market Access Activity

**Goal:** MPT products in development will be desired, acceptable, and accessible to women and adolescent girls once introduced and commercially available.

**Objective:** Facilitate the convening of relevant stakeholders and develop resources that will support the integration of priority market access related activities into the MPT development process.
IMPT Market Access Activity Methods

- Convening of sub-group of IMPT technical advisors
- Development of draft framework
- Vetting of framework with experts from IMPT network
- Finalization of framework
- Prioritization of key activities through stakeholder convenings
Preclinical Studies (Critical Path)

Discovery Candidate Identification → Preclinical Virology → Preclinical Studies (Critical Path)

In vitro & Ex vivo Testing

Animal Safety Toxicology & Pharmacology
- Acute
- Chronic
- Reproductive
- Carcinogenesis

Chemistry, Manufacturing & Control (CMC) → Scale-up → Commercial Supply

Clinical Studies

Pre-IND → IND → NDA

Phase I Initial Safety → Phase II Expanded Safety → Phase III Safety & Efficacy → Phase IV Additional Monitoring

Behavioral & Social Sciences

Perceptibility: Individual preferences for Physical & Rheological Properties: target population

Initial Acceptability → Expanded Acceptability → Marketing Research

Confirmation Perceptibility

Identification of population specific issues

Creating population specific approaches

Development of use instructions

Source: Jim Turpin (NIAID)
MPTs: a promising response to current challenges around hormonal contraceptive methods and HIV

2016 International Conference on Family Planning – 27 January 2016 – Nusa Dua, Indonesia

Inspired by: Jim Turpin (NIAID)
IMPT Market Access Activity Methods

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- Finalization of framework
- Prioritization of key activities through stakeholder convenings
Idea to Impact Guide

- Practical guidance to plan for the launch of global health innovations from beginning of development
- Adapted to fit specific needs of MPT field

# Market Access Framework for MPT Development and Introduction

<table>
<thead>
<tr>
<th>Clinical and Regulatory</th>
<th>Policy and Advocacy</th>
<th>Manufacturing and Distribution</th>
<th>Market and User Understanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Define the Target Product Profile (TPP)</td>
<td>- Conduct global policy assessment relevant to MPT development, manufacture, and distribution</td>
<td>- Perform manufacturability assessment and landscape</td>
<td>- Identify target end-user populations and settings based on epidemiologic assessment of need.</td>
</tr>
<tr>
<td>- Develop quantitative biomedical measures of adherence</td>
<td>- Conduct stakeholder engagement strategy</td>
<td>- Conduct intellectual property evaluation</td>
<td>- Conduct situation/market assessment</td>
</tr>
<tr>
<td>- Develop trial participant recruitment strategy</td>
<td>- Conduct cost-effectiveness analysis of TPP</td>
<td>- Identify partnership opportunities</td>
<td>- Evaluate attitudes of and develop value proposition for user, sexual partner, healthcare provider, policymaker, market, and other stakeholder audiences</td>
</tr>
</tbody>
</table>

**Product Development**

<table>
<thead>
<tr>
<th>Phases 1 &amp; 2 (Preclinical)</th>
<th>- Develop and execute clinical plan with clearly defined endpoints</th>
<th>- Develop communications, advocacy, and key stakeholder engagement strategy</th>
<th>- Develop manufacturing strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Conduct regulatory landscape assessment</td>
<td>- Conduct cost-effectiveness analysis of TPP</td>
<td>- Develop distribution strategy</td>
<td>- Develop strategic launch plan with uptake targets</td>
</tr>
<tr>
<td>- Support inclusion in treatment guidelines and on country-level essential medicines lists</td>
<td>- Establish manufacturing strategy</td>
<td>- Continue to identify partnership opportunities</td>
<td>- Develop bottleneck analysis</td>
</tr>
<tr>
<td>- Execute communications, advocacy, and key stakeholder engagement strategy</td>
<td>- Establish distribution strategy</td>
<td>- Finalize product and packaging designs</td>
<td>- Update end-user needs and acceptability assessments</td>
</tr>
<tr>
<td>- Update cost-effectiveness analysis</td>
<td>- Continue to identify partnership opportunities</td>
<td>- Develop pricing strategy</td>
<td>- Develop demand generation strategies and create marketing materials</td>
</tr>
</tbody>
</table>

**Phases 3 & 4 (User Clinical)**

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<th>- Complete clinical trials</th>
<th>- Support inclusion in treatment guidelines and on country-level essential medicines lists for new markets</th>
<th>- Validate impact and cost-effectiveness analyses</th>
<th>- Develop strategic launch plan progress and achievement of uptake targets</th>
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<tr>
<td>- Obtain national regulatory authority approvals</td>
<td>- Develop appropriate advocacy strategy to minimize counterfeit and sub-standard MPT products</td>
<td>- Evaluate manufacturing and distribution footprint and adjust as necessary</td>
<td>- Evaluate progress against prioritized barriers and update bottleneck analysis</td>
</tr>
<tr>
<td>- Continue with national regulatory authority approval(s) for new markets</td>
<td>- Evaluate and optimize product and/or packaging if necessary</td>
<td></td>
<td>- Introduce into new markets and to new user segments</td>
</tr>
<tr>
<td>- Conduct post-market surveillance</td>
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<td>- Expand demand generation campaigns for new markets and user segments</td>
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**Product Introduction**

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**Full Commercialization**

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<td>- Conduct post-market surveillance</td>
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<td>- Expand demand generation campaigns for new markets and user segments</td>
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MPTs: a promising response to current challenges around hormonal contraceptive methods and HIV
2016 International Conference on Family Planning - 27 January 2016 – Nusa Dua, Indonesia

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IMPT Market Access Activity Methods

- Convening of sub-group of IMPT technical advisors
- Development of draft framework
- Vetting of framework with experts from IMPT network
- Finalization of framework
- Prioritization of key activities through stakeholder convenings
MPTs: a promising response to current challenges around hormonal contraceptive methods and HIV
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Preliminary Results: Key Questions

- Would MPTs be best presented and marketed primarily as a contraceptive, or clearly as a combination of contraception and HIV prevention?
- What is the most appropriate service delivery setting for MPTs?
- What will be the most effective strategies to engage appropriate stakeholders to support MPT delivery, distribution, and access?
Next Steps

- Continued stakeholder convenings to identify priority questions and issues to address from this framework

- Development of strategic evaluation framework in partnership with USAID – Office of HIV/AIDS
The Initiative for Multipurpose Prevention Technologies (IMPT) is a project of CAMI Health, an organization dedicated to women’s reproductive health and empowerment.
Support for this project is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the HealthTech Cooperative Agreement #AID-OAA-A-11-00051, managed by PATH. The contents are the responsibility of CAMI/PHI and its partners and do not necessarily reflect the views of USAID or the US Government.