MULTIPURPOSE PREVENTION TECHNOLOGIES (MPTS) FOR SEXUAL AND REPRODUCTIVE HEALTH

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Session Objectives

This session is designed to help you do the following:

- Define multipurpose prevention technologies (MPTs)
- Describe existing MPTs in use globally
- Describe the range of MPT delivery systems in development
- Describe the challenges and timeline for MPTs development
- Provide your input on MPTs that are in development
Global Need... *HIV & STIs*

- In 2010, **1.8 million people died of AIDS**... in 2009 an estimated **2.6 million** become infected with HIV.¹

- **Young, married women** are the fastest growing group of HIV+ people worldwide.²

- **Worldwide, women are 5 times more likely to get sexually transmitted infections than men.**³

- Each day, about **500,000 young people, mostly women, contract an STI.**³
Global Need... family planning

- Each day, close to 800 women in developing countries die from complications related to pregnancy and childbirth.\(^5\)
- An additional 15 to 20 million women suffer debilitating consequences of pregnancy.\(^6\)
- 222 million women have an unmet need for modern contraception.\(^7\)
- There are approximately 80 million unintended pregnancies in the developing world\(^7\)
  - Resulting in 40 million abortions, 30 million unplanned births, 10 million miscarriages.\(^7\)
In the United States

- Nearly half of all pregnancies among American women are unintended, and four in ten of these end in abortion.\(^9\)
- An estimated 750,000 women aged 15-19 in US become pregnant annually, of which over 80% are unintended.\(^{10,11}\)

- STIs are the most commonly reported communicable diseases in the US.\(^{12}\)
- Of the 18.9 million new cases of STIs each year in the US, 9.1 million (48%) occur among 15-24 year olds.\(^{12}\)
What are Multipurpose Prevention Technologies (MPTs)?

A single product or strategy, configured for at least two SRH prevention indications:

- Unintended pregnancy
- HIV
- Other STIs

**WHY MPTs?**

- Greater **efficiency** in terms of cost, access and delivery of SRH prevention products
- Capitalize on the demand in populations using one product type to achieve uptake and use of a second “product”
MPTs: Historical Precedents

- $\text{H}_2\text{O} + \text{fluoride}$
- The pill + iron
- Grains + folic acid
Why do women need MPTs?

- Healthy timing & spacing of intended pregnancies
- Protection against HIV
- Protection against other STIs
MPT products currently available

= Male and female condoms are the only currently available methods for prevention of multiple SRH risks
MPTs in the Pipeline

Drug Combinations

Drug/Device Combinations

Multipurpose Vaccines

Bacterial Therapeutics

Nanoparticles
Successful products means listening to what women want...

- **Technology Filter**
- **Product Prioritization and Gap analysis**
- **Ideal MPT Products Supported**

- **Candidate MPTs**

  - **Contraceptives** (hormonal/non-hormonal)
  - **Anti-retrovirals & non-ARVs**
  - **Other anti-infectives**
Complexity of developing MPTs

- **Indication**
  - 10 MPT IVR
  - 3 On-Demand MPT
  - 2 Barrier MPT
  - 23 HC products

- **Mechanism of Action**
  - 10 Single Indication IVR
  - 12 On-Demand HIV Only
  - 2 Injectable HIV Only
  - 2 Lacto-based Products

- **Dosage and Administration**
  - 31 HIV Entry Inhibitors
  - 11 Enzyme Inhibitors
  - 7 Other HIV Inhibitors
  - 29 non-HC products
MPT Product Profile:
Working Group Recommendations

MPT PRODUCTS

HIV/STI Prevention
Contraception
Priorities for 1\textsuperscript{st} Generation MPTs

- Used around time of intercourse
- For women who have intermittent sex or want more direct control over their protection
- User-initiated, does not require daily action
- Should increase adherence and effectiveness

“On Demand”

Sustained release
On-Demand Products: Gels, NFDs

**Tenofovir Gel (CONRAD)**
- 1\textsuperscript{st} proof-of-concept vaginal microbicide
- Coitally-dependent
- Confirmation trial underway for 2014

**MZL Combo NFD (Pop Council)**
- MIV-150 + Zinc Acetate + LNG in NFD
- Prevents pregnancy, HIV, HSV-2, HPV
- Up to 24-hrs protection
On-Demand Products: Devices + Active Agents

SILCS (PATH, CONRAD, NICHD) + TFV Gel (CONRAD)

- "One size fits most" silicone diaphragm
- Intended for OTC pregnancy prevention
- 5-yr shelf life, re-use up to 3 yrs
- SILCS barrier = delivery device
- Non-hormonal MPT protection: pregnancy, HIV, HSV2 up to 24 hrs
### Sustained Release Devices: Combination Intravaginal Rings

<table>
<thead>
<tr>
<th>30-day MZL Combo (Population Council)</th>
<th>60-day Dapivirine + LNG (IPM)</th>
<th>90-day TFV + LNG (CONRAD)</th>
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<tbody>
<tr>
<td>MIV-150 + Zinc Acetate + LNG</td>
<td>DPV + LNG</td>
<td>TFV + LNG</td>
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<td>Demonstrated single-API success</td>
<td>Testing underway, clinical studies 2013</td>
<td>Testing underway, clinical studies 2013</td>
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<tr>
<td>Pregnancy, HIV, HSV2</td>
<td>Pregnancy, HIV</td>
<td>HIV, HSV2</td>
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MPT Target Product Profiles (TPPs)
MPT Product Priority and Gap Analysis

✓ Priority Indications (Regional Differences):
  • Pregnancy + HIV
  • HIV + STI
  • Pregnancy + STI

✓ Dosage Forms: “Suite of Products”
  • Sustained release (IVR), LA Injectable, On-Demand

✓ Drugs:
  • ARV for HIV, HC for pregnancy, STI specific drugs (GAP!)
    • Non-ARV/non-HC options are longer term (GAP!)

✓ Other Product Attributes:
  • Stability, shelf life, safety and efficacy targets, COST, scale-up, user preferences, adherence potential, market demand…
Single & Multipurpose Vaccines

Today

- Single purpose vaccines (e.g. HPV)
- Multipurpose vaccines that include HBV (e.g. Twinrix)

Future

- Multipurpose STI vaccines (HSV, HIV, Gonorrhea, Chlamydia, Trichomonos, other STIs)
- Reversible immunocontraceptives (e.g. anti-sperm)
- What would your patients want in a multipurpose vaccine?
MPT Product Development Timeline

**PRE-CLINICAL**
- Pre-formulation/Formulation
  - Phase 1 Manufacture
- API Development/Characterization
- Pre-clinical virology, pharmacology, safety
- Combination Preclinical Studies
- Biocompatibility (Device)

**CLINICAL**
- Phase 1 PK/PD, Safety
- Phase 2 Expanded Safety (International)
- Phase 3 Plan Submission
- Phase 3 Start

**IND Submission**

Q1 Q2 Q3 Q4 Q5 Q6 Q7 Q8

Y3 Y4 Y5 Y6 Y7

NWJ Group, LLC
Barriers to progress on MPTs
Initiative for Multipurpose Prevention Technologies (IMPT)

Scientific Agenda

Acceptability and Access

Communications and Advocacy

Funding Coordination

Secretariat:

National & Int’l Funding Agencies
BMGF, ICMR, IPPF, USAID, USFDA, US National Institutes of Health, WHO, Wellcome Trust

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part of the Public Health Institute
MPT: Conclusions and the Future

So Far...
✓ MPT Products can potentially address major unmet medical needs for women globally
  • Key advantages over current strategies
✓ The IMPT has defined product attributes for an MPT TPP
  • Product specific MPT development is ongoing with partners
✓ The IMPT has defined MPT pipeline priorities and gaps
  • Helps set the R&D agenda for the future

Next...
✓ Informing/interacting with regulatory agencies and local country stakeholders will be crucial going forward
✓ Understanding market/commercialization issues for MPT is crucial to GO/NO GO decision making
✓ Consensus agreement on product priorities is crucial to achieve coordinated investment among funding organizations in MPT
Make MPTs a reality!

Your Insights can help ensure *acceptable* and *successful* MPT development
MULTIPURPOSE VACCINES FOR SEXUAL AND REPRODUCTIVE HEALTH
Q1 Which of the following vaccine combinations do you believe would be most useful for your clients?

(a) HSV (genital herpes) + HIV (AIDS)
(b) HSV + HIV + HPV (genital warts/cervical cancer)
(c) HSV + HPV
Q2 What do you believe is the minimum acceptable efficacy rate (for all the pathogens targeted) of a MPT vaccine?

(a) 30 – 49%
(b) 50 – 69%
(c) 70 – 89%
(d) 90% +
Q3

Which type of vaccine administration do you believe your clients prefer?

(a) Injection (by provider)
(b) Mucosal (needle-free and self-administered)
Q4
How much do you believe most of your clients would be willing to pay for the entire series of an injectable MPT vaccine?

(a) $50 – $99
(b) $100 – $149
(c) $150 – $199
(d) $200 – $249
(e) $250 – $300
Would adding a reversible contraceptive vaccine to a multipurpose STI vaccine lead to an overall increase in uptake by your clients?

(a) Yes
(b) No
(c) No difference
The time for MPTs is now
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Learn more! www.mpts101.org
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References

Global Need: HIV & STIs
2. PATH, UNFPA. Female Condom: A Powerful Tool for Protection. Seattle: UNFPA, PATH; 2006.

Global Need: Family Planning

In the United States