Multipurpose Prevention Technologies
for Sexual & Reproductive Health

MPTs Available Now and in the Future

Wayne C. Shields, ARHP President & CEO
Session Objectives

This session is designed to help you do the following

- Define multipurpose prevention technologies
- Describe existing MPTs in use globally
- Describe the range of MPT delivery systems in development
- Describe the challenges and timeline for MPTs development
Multipurpose Prevention Technologies

- Prevent at least 2 of the following: unintended pregnancy, HIV/AIDS, STIs
- Ensure women’s privacy & autonomy
- Are safe & easily available
- Are designed by women for their specific needs & preferences
Global need, regional priorities
MPTs: Historical Precedents

- H₂O + fluoride
- The pill + iron
- Grains + folic acid
Currently Available MPTs

| Female Condom | Male Condom |

**Advantage:** Available now

**Disadvantages:** Use rates are low, can be difficult to negotiate
Complex Factors = Many Possibilities

- **Conditions**: Pregnancy, HSV, HPV, HIV, BV, Chlamydia, Gonorrhea, Syphilis, Candida, Trich
- **Product Types**: Vaginal film, Vaginal tablet, Oral tablet, Vaginal ring, Non-IVR device, Vaginal gel, Injectable, Implantable
- **Delivery Methods**: Topical daily, Topical pericoital, Systemic sustained, Topical sustained, Oral daily, Oral pericoital
- **Actions**: HC, Non-HC, Barrier, Pro-biotic, Antimicrobial, Antifungal, Antiviral

NWJ Group, LLC
## Potential MPT Delivery Methods

<table>
<thead>
<tr>
<th>Devices</th>
<th>Vaginal Rings</th>
<th>Vaginal Tablets</th>
<th>Vaginal Films</th>
</tr>
</thead>
</table>

[Image of vaginal devices]
### MPTs in the Pipeline

<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>

[Images of various MPTs]

- **Drug combinations**
- **Drug/device combinations**
- **Multipurpose vaccines**
- **Bacterial therapeutics**
- **Nanoparticles**
Single & Multipurpose Vaccines

- **Today:** Single purpose vaccines (HPV & HBV)
- **20 years:** Multivalent vaccines (HSV, HIV, Gonorrhea, Chlamydia, Trichomonas, other STIs)
- Contraceptive vaccines not likely
MPT Product Profile: Working Group Recommendations

MPT PRODUCTS

HIV/STI Prevention

Contraception
Priorities for 1st Generation MPTs

“On demand”
- Used around time of intercourse
- For women who have intermittent sex or want more direct control over their protection

Sustained release
- User-initiated, does not require daily action
- Should increase adherence and effectiveness
On-Demand Products: Gels, NFDs

**Tenofovir Gel (CONRAD)**
- 1st 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 (Pop Council)</th>
<th>60-day Dapivirine + LNG (IPM)</th>
<th>90-day TFV + LNG (CONRAD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MIV-150 + Zinc Acetate + LNG</strong></td>
<td><strong>DPV + LNG</strong></td>
<td><strong>TFV + LNG</strong></td>
</tr>
<tr>
<td><strong>Demonstrated single-API success</strong></td>
<td><strong>Testing underway, clinical studies 2013</strong></td>
<td><strong>Testing underway, clinical studies 2013</strong></td>
</tr>
<tr>
<td><strong>Pregnancy, HIV, HSV2</strong></td>
<td><strong>Pregnancy, HIV</strong></td>
<td><strong>HIV, HSV2</strong></td>
</tr>
</tbody>
</table>
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

Q1 Q2 Q3 Q4 Q5 Q6 Q7 Q8

Y3 Y4 Y5 Y6 Y7

NWJ Group, LLC
MPTs roadmap is not linear
The Initiative for Multipurpose Prevention Technologies
Barriers to progress on MPTs
The time for MPTs is now
Acknowledgments

INDIVIDUALS
- Heather Boonstra (Guttmacher Institute)
- Martha Brady (Population Council)
- Nomita Chadhiok (ICMR)
- Jessica Cohen (PATH)
- Polly Harrison (CAMI/AVAC)
- Anke Hemmerling (UCSF/CAMI)
- Annette Larkin (CONRAD)
- Judy Manning (USAID)
- Helen Rees (Univ. of Witwatersrand)
- Joseph Romano (RWJ Group)
- Wayne Shields (ARHP)
- Kathryn Stewart (CAMI)
- Alan Stone (CAMI/MEDSA)
- Kevin Whaley (Mapp Biopharmaceutical)
- Allen Wu (Nanjing University)

SUPPORTERS
- Bill & Melinda Gates Foundation
- Boston Consulting Group
- Mary Wohlford Foundation
- Microbicide Trials Network
- National Institutes of Health
- Public Health Institute
- US Agency for International Development
- Wellcome Trust
Questions?