Developing Technologies for Preventing Unintended Pregnancy & STIs
Dr. Marrazzo received research funding from Cepheid, Hologic/GenProbe, and Viamet Pharmaceuticals.
Session Objectives

This session is designed to help you:

- Define multipurpose prevention technologies (MPTs)
- Describe 3 benefits of MPTs for women
- Apply effective strategies to increase usage of existing MPTs for unintended pregnancy and STI prevention
Multipurpose Prevention Technologies

- **Prevent** at least 2 of the following: *unintended pregnancy, STIs, HIV/AIDS*
- Should be **safe & easily available**
- Are **designed with key input from women** for their specific needs & preferences
Why is there a Need for MPTs?

- Healthy timing & spacing of intended pregnancies
- Protection against HIV
- Protection against other STIs
Global Need…

- Each year **1.6 million people die from AIDS** and **2.3 million become infected**.
- Each day, about **500,000 young people, mostly women, contract an STI**.
- Women infected with an STI are **5 times more likely to acquire HIV**.
- **222 million women** have an **unmet need for modern contraception**.
- Each day, close to **800 women in developing countries die** from complications related to pregnancy and childbirth.
Consequences of STIs

- STIs enhance the biological risk for HIV infection and transmission and can impact how the disease progresses.

- Long-term health consequences of STIs include:
  - Cervical cancer
  - Pelvic inflammatory disease
  - Infertility
  - Tubal or ectopic pregnancy

- Infants born to infected mothers can suffer from perinatal or congenital infections
Global need, regional priorities
Case Study: “Kajiata”

- Age 33, married
- Already has 6 children
- Husband spends a significant amount of time out of the village and she accepts he is unfaithful
- Husband will not wear a condom

Young, married women are the fastest growing group of HIV+ people worldwide.
Barriers to progress on MPTs
Examples of Historical Precedents

- $\text{H}_2\text{O} + \text{fluoride}$
- The pill + iron
- Grains + folic acid
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

- **MPT Product Possibilities**
Potential MPT Delivery Methods

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

- Devices
- Vaginal Rings
- Vaginal Tablets
- Vaginal Films
MPTs in the Pipeline

- Drug Combinations
- Drug/Device Combinations
- Multipurpose Vaccines
- Bacterial Therapeutics
- Nanoparticles
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

Long-acting Injectable
- Co-administration of products targeting separate indications
- Equal duration of effectiveness for the co-administered products
On-Demand & Sustained Release Products

- A ‘one size fits all’ diaphragm combined with a microbicide gel

- *Easier to use vaginal rings* offer contraception + protection against STIs, including HIV.

- *Innovative and effective gels* protect against HIV and other STIs
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 (Population Council)</th>
<th>60-day Dapivirine + LNG (IPM)</th>
<th>90-day TFV + LNG (CONRAD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• MIV-150 + Zinc Acetate + LNG</td>
<td>• DPV + LNG</td>
<td>• TFV + LNG</td>
</tr>
<tr>
<td>• Demonstrated single-API success</td>
<td>• Testing underway, clinical studies 2013</td>
<td>• Testing underway, clinical studies 2013</td>
</tr>
<tr>
<td>• Pregnancy, HIV, HSV2</td>
<td>• Pregnancy, HIV</td>
<td>• HIV, HSV2</td>
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# CAPRISA 004: Impact of tenofovir gel on HSV-2 incidence

<table>
<thead>
<tr>
<th></th>
<th>Tenofovir gel n = 202*</th>
<th>Placebo gel n = 224*</th>
</tr>
</thead>
<tbody>
<tr>
<td># HSV-2 infections</td>
<td>29</td>
<td>58</td>
</tr>
<tr>
<td>Women-years of follow up</td>
<td>292.3</td>
<td>287.3</td>
</tr>
<tr>
<td>HSV-2 incidence per 100 wy (95% CI)</td>
<td>9.9 (6.6, 14.2)</td>
<td>20.2 (15.3, 26.1)</td>
</tr>
</tbody>
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*Note: Excludes equivocal HSV-2 results at study exit

**IRR = 0.49 (CI: 0.30, 0.78); P = .003**

51% protection against HSV-2 by tenofovir gel (CI: 22%-70%)

Single & Multipurpose Vaccines

- **Today:** Single purpose vaccines (HPV & HBV)
- **20 years:** Multivalent vaccines (HSV, HIV, Gonorrhea, Chlamydia, Trichomonas, other STIs)
- Contraceptive vaccines are not likely
In the United States

- Nearly half of all pregnancies among American women are unintended.
- STIs are the most commonly reported communicable diseases in the US.
- There are 18.9 million new cases of STIs each year in the US.
- An estimated 50,000 new HIV infections occur in the U.S. each year, 20% of which occur in women.
Case Study #3: “Ashley”

- Age 27
- Not in a committed relationship
- Currently using long acting contraception
- Doesn’t always use a condom
- Lives in a city with high prevalence of STIs

Worldwide, women are 5 times more likely to get sexually transmitted infections than men.
Currently Available MPTs

<table>
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<tr>
<th>Male Condom</th>
<th>Female Condom</th>
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**ADVANTAGES:**  Available now

**DISADVANTAGE:** Use rates are low, difficult to negotiate
Increasing Usage of Existing MPTs: Counseling Messages

- Effective counseling messages should include visual aids.
- Numerical messages to should be positively framed.

When communicating to patients about increasing condom use providers should:

- Promote sexual health in clinical practice environments
- Be able to listen and interpret patients’ sexual values, experiences, and concerns
- Be willing to reply honestly and clearly to patients’ sexual concerns
Increasing Usage of Existing MPTs: Improving Access

Female Condoms

Available at select Walgreens Stores and online at Conscious Contraceptives and Drugstore.com. Also available at Public Health Clinics and Planned Parenthood locations.

Male Condoms

Widely available at drug stores, supermarkets, and even some bars and clubs. Also available at Public Health Clinics and Planned Parenthood locations.

www.Besider.org; www.fc2femalecondom.com
Increasing Usage of Existing MPTs: Interventions

- Have male and female condoms available to your patients and make sure they know where to get them;
- Include female condoms in condom discussions;
- Educate on proper use of male and female condoms – you can never have too many condom demonstrations;
- Discuss risk with patients; and
- Encourage STI screening for your patient and their partners as part of standard health care.
Learn more about MPTs...

www.MPTs101.org
Thank you!

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