New Developments in Barrier Contraception: Implications for Multipurpose Prevention Technologies (MPTs)

Association of Reproductive Health Professionals
www.arhp.org
Disclosures

• Michelle Forcier
  – Consultant Planned Parenthood, Merck
  – Board Member Trans Youth Equality Foundation, Physicians for Reproductive Health

• Bethany Young Holt
  – No disclosures
Session Overview

- New developments in barrier methods
- Overview of the MPT pipeline and field
Women’s Sexual & Reproductive Health Risks are Interlinked

- Unintended Pregnancy
- HIV
- Other Sexually Transmitted Infections (STIs)

Women need better protection.
Case Study

- Age 31 G3P2
- Single parent who feels like she has completed childbearing
- Doesn’t always use a condom with her regular partner
- Worried about recent diagnosis of chlamydia
- Wants a method she can control
Diaphragm Before 2014

Important woman controlled option, acceptable low resource settings... Low use in US women <1% US

**PROS**

- Excellent efficacy as dual method
- Effective consistently correctly used
- Perfect use pregnancy rate 6%
- STI reduction potential
- Resusable

**CONS**

- Anticipatory motivation
- Correct use coitus
  - 6 hrs before & 6 hrs after
  - + spermicide
- Use every coitus typical use pregnancy rate 12%
- Requires MD to purchase, fit
- Before 2014 2 US diaphragms
  - Milex Wide-Seal Arcing Style & Omniflex Diaphragm (CooperSurgical)

http://www.theatlantic.com/Making a More Modern Diaphragm
How the new, very purple “Caya” is trying to make an old-fashioned birth-control option relevant again
Aug 20 2015 Heather Hansman
SILCS diaphragm - Caya®

- Program for Appropriate Technology in Health (PATH)
  - With support of Contraceptive Research and Development program (CONRAD) + USAID
  - Kessel German Family Planning Organization PRO FAMILIA & HPSRx Enterprises Inc
  - FDA approved September 2014

- Single size reusable, covers cervix
  - Easier to supply
  - No provider or fit training
  - Easier insert & use

- Well accepted & tolerated
  - Insertion, removal
  - Awareness- before, during, after sex

Medical-grade silicone molded over a single piece polymer spring core
Contoured spring allows gentle compression of rim for easy insertion/removal
SILCS

Device:
- Flexible rim
- Silicone membrane 2
- 2 cup structures + flat area
  - Larger cup fits loosely over cervix
  - Smaller cup aids in hooking rim for removal

Insertion:
- Squeeze rim at point of opposing sets of grip dimples
- Push deeply as possible, tip anterior rim up behind pubic bone
Case Study

- 20 yro G0P0
- Intermittently sexually active
- Likes condoms but worries that her partners do not always want to use them
- Wants to delay childbearing while finishes school
- Interested in a method that protects her from pregnancy and STIs

Angie
Overview: Additional Barriers

FemCap (FemCap, Inc) silicone cap, removal strap, brim holds spermicide/trap sperm (3 sizes: 22, 26, 30mm) US & Europe

Protectaid® Pirri Pharma, Canada contraceptive sponge polyurethane foam impregnated with F-5 Gel (N9, BKC, NACOL) Canada & Europe

Seminia Diaphragm, Semina Industries, Commerce Ltd. Silicone diaphragm, coil spring, 60-85mm (5mm increments) in Brazil

Shanghai Lily SL Life Rubber Product Co., Ltd, latex 4 sizes: 54, 58, 62, 66mm; China

Duet™ single size 3 layers of protection vaginal-side gel, barrier film, cervical-side gel

Lea Contraceptivum Biovision 1 size silicone barrier, removal loop, valve for fluid, 48 hours of continuous use. No longer being manufactured
Overview Condoms

FC2, Female Health Company, nitrile polymer, inner ring insertion and helps to secure, softer outer ring; US & world

Reddy Female Condom Medtech Health Products latex, polyurethane sponge insertion, flexible outer ring; Europe, Africa, South America, Brazil, Europe, India

Woman's Condom Shanghai Dahua Medical Apparatus Company (PATH) polyurethane pouch, dissolving capsule for insertion, foam shapes for stability, water based lubricant

Cupid Limited, India, natural latex rubber, polyurethane foam internal retainer; India, Brazil, Indonesia, South Africa, Mozambique

Panty Condom Innova Quality SAS, panty liner, polyethylene w lube sheath inserted by penis; Columbia

Phoenurse Tianjin Kangdunbao Co polyurethane sheath, insertion tool, water-based lubricant; China, Brazil
**Origamic Internal Condom (OIC)**

*Origamic Condoms, United States*

Partner-initiated, internal condom, inserted intercourse, before designed to enhance sensation for both partners, improve ease of use, improve safety, provide direct tactile sensation, minimize slipping and breaking, and to accommodate a range of penis sizes. It replicates a fluid environment for the penis consistent with natural intercourse performance.

Unlike a conventional nitrile female condom, the transparent OIC is molded with anatomy-specific design. Its unique material tested 100% biocompatible and non-allergenic in independent preclinical lab testing.

**The OIC is expected to reach the market in late 2016, pending regulatory premarket reviews with the CE Mark (EU), WHO, and the United States FDA.**
Upcoming Trends in Condoms

**S.T.EYE Condom** which glows green due to layers of molecules detect bacteria/STIs

green=chlamydia, yellow=herpes, purple=HPV, blue=syphilis

by TeenTech awards students at Isaac Newton Academy in Ilford


**Skyn Condom** - thin polyisoprene self lubricating biodegradable


**Hydrogel Condom** - ultra-strong, skin-like prosthetics tissue makers

Australia's University of Wollongong, Project Geldom improved naturalistic feel, building in automatically released internal lube or Viagra
Gates Foundation Awards Grants...New Generation Condoms

- **Durable and Sensitive Tough Hydrogel Condoms** Robert Gorkin, University of Wollongong, Wollongong, Australia 24 APR 2014
- **Nanotextured Condoms: Surface Engineering for Better Safe Sex** Charles Chung, UbiQ World, San Francisco, United States 23 APR 2014
- **Development and Testing of the Female Pleasure Condom** Debby Herbenick, Indiana University, Bloomington, United States 22 APR 2014
- **Condom Materials to Increase Pleasure and Enhance Erection** Shengxi Chen, Arizona State University Foundation for A New American University, Tempe, United States 22 APR 2014
- **Flavonoid Antioxidant Embedded Solid Hydropolymer Condom** Mahua Choudhury, Texas A&M Health Science Center, College Station, United States 16 APR 2014
- **Poly(glycerol sebacate)-Based Condoms** Lakshminarayanan Ragupathy, HLL Lifecare Ltd, Trivandrum, India 16 APR 2014
- **Making Condoms <30µm by Improving Properties of Natural Latex Emulsion** James Zhijun Lu, Regenex Pharmaceuticals Ltd, Guangzhou, China 14 APR 2014
- **Air-Infused Female Condom** Mache Seibel, HealthRock LLC, Newton, United States 10 APR 2014
- **Non-Gender Specific Internal Silicone Condom** Daniel Resnic, Origami Healthcare Products, Inc, Culver City, United States 10 APR 2014

SEATTLE (November 20, 2013) — The Bill & Melinda Gates Foundation today announced a new round of winners as part of its Grand Challenges Explorations (GCE) initiative.
Multipurpose Prevention Technologies

MPTs combine protection against:

- Unintended pregnancy
- HIV
- Other STIs
MPT Products Currently Available

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

**Co-formulated:**
Multiple API formulated into a single dose

**Co-administered:**
Two independent products used together

**Co-packaged:**
Two different doses packaged together in a single product for simultaneous co-use
Implications for Barriers as MPTs

- New barriers as MPTs
  - Novel designs & materials
  - Nanofibers as barriers

- Delivery system for gels or other drugs preventing STIs/HIV
SILCS (Caya®) as MPT

- Silicone barrier contraceptive
- Reusable delivery system for a microbicide gel
- Controlled release delivery system with an ARV drug loaded into the spring
MPTs in the R&D Pipeline

- Vaginal rings
- Innovative vaginal delivery products
- Injectables and implant technologies
- Other novel technologies and platforms
# MPTs in Clinical Trials

## HIV + Other STIs

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0% Tenofovir Vaginal Gel</td>
<td>III</td>
</tr>
<tr>
<td>mapp66 (mAb) Vaginal Film</td>
<td>I</td>
</tr>
<tr>
<td>MIV-150 + Zinc acetate + Carrageenan Vaginal Gel</td>
<td>I</td>
</tr>
<tr>
<td>Tenofovir + Acyclovir Intravaginal Ring</td>
<td>I</td>
</tr>
<tr>
<td>Tenofovir Disopropxil Fumerate Intravaginal Ring</td>
<td>I</td>
</tr>
<tr>
<td>Tenofovir Vaginal Film</td>
<td>I</td>
</tr>
<tr>
<td>Tenofovir Intravaginal</td>
<td>I</td>
</tr>
<tr>
<td>Tenofovir Vaginal Tablet</td>
<td>I</td>
</tr>
<tr>
<td>TFV/FTC Vaginal Tablet</td>
<td>I</td>
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</tbody>
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## Pregnancy, HIV & Other STIs

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Phase</th>
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</thead>
<tbody>
<tr>
<td>Origami Female Condom</td>
<td>III</td>
</tr>
<tr>
<td>Tenofovir + Levonorgestrel Intravaginal Ring</td>
<td>I</td>
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</table>

## Pregnancy & Non-HIV STIs

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Amphora Gel</td>
<td>I</td>
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**Plus products in preclinical development for:**

- HIV + Pregnancy
- HIV + Other STIs
- Pregnancy, HIV & Other STIs
- Pregnancy + Non-HIV STIs
Initiative for MPTs

- Contraception
- HIV Prevention
- STI Prevention

- Science
- Funder Collaboration
- Advocacy & Market Development

- Women’s Voices & Access
HIV, HSV-2, HPV, and Unmet Need for Modern Contraception among Women


*Principal component 1: HSV-2, HIV, and HPV by country and region.
**Principal component 2: Unmet need for modern contraception by country. See manuscript for full description of principal components analysis and methods.
A Suite of Products is Needed

Contraception + HIV & STI Prevention

Contraception + HIV Prevention

Contraception + STI Prevention

HIV + STI Prevention
MPT Concepts: Short Term Possibilities

- Co-packaged Oral MPT Concept
  - Oral Truvada + Oral Contraceptives

- HPV Vaccine
  - STI + Cancer prevention
MPT Product Development Database

This database includes MPT products that are currently available, as well as MPT products in active development. In addition, a number of existing products and products in development for single indications are also included. The database outlines detailed product information and can be searched to display products by desired criteria as selected from the drop-down boxes or by entering a keyword in the search box. Click on the product name to access detailed information on each product. Click here to learn more about the inclusion criteria and information update methodology.

Links to Summary Tables outlining (1) MPT Products in Development, (2) Existing Single Indication Products or (3) Candidate Single Indication Products that could serve as potential components of future MPTs can be found below.

Check out the MPT products in the development pipeline — view an MPT Pipeline Table by Indication Combination.

http://mpts101.org/mpt-database
Health & Social Impact of MPTs

- Women’s Health
  - SDG 3 & 5

- Child & Family Health
  - SDG 3 & 5

- Educational Attainment
  - SDG 4 & 5

- Employment & Economic Benefits
  - SDG 1, 5 & 8
What you can do to move the MPT field forward:

- Inform MPT science
- Assist with data collection and dissemination
- Advocate & get involved with current research
- Join the Network of Experts (NoE) and IMPT working groups
Acknowledgements

• Kathryn Stewart
• Wayne Shields
Learn more at www.cami-health.org
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 the IMPT and its partners and do not necessarily reflect the views of USAID or the US Government. The IMPT is a project of CAMI Health, an organization dedicated women’s reproductive health and empowerment, housed at the Public Health Institute.
Q & A
ARHP Resources

- Additional ARHP webinars and *Clinical Minutes* available on-demand on [www.arhp.org](http://www.arhp.org)

- Educational slide decks on [http://core.arhp.org/](http://core.arhp.org/)

Core (Curricula Organizer for Reproductive Health Education)
Resources

- http://gcgh.grandchallenges.org/grants?f[0]=field_challenge%253Afield_short_title%3ANext%20Generation%20Condom&items_per_page=100