Putting hindsight to use:
Applying lessons learned from family planning to new HIV prevention products and multipurpose prevention technologies

Session organizers:
Initiative for MPTs (IMPT) &
International Partnership for Microbicides (IPM)

Moderator:
Amy Lin (Center for Innovation and Impact | USAID)
13 October, 2016
Session Objectives

• Enhance participants’ understanding about the progress and challenges of the MPT field

• Leverage participants’ expertise in identifying key lessons learned that may be applied to the MPT context
Session Format

• What are the most important lessons learned from family planning and/or HIV prevention work with regard to product acceptability and adherence among young women and adolescent end-users?

• What do we wish we knew then that we can use now?

• How can these lessons inform activities and introduction planning for the HIV prevention and MPT fields?
Multipurpose Prevention Technologies

MPTs combine protection against:

- Unintended pregnancy
- HIV
- Other STIs
Applying lessons learned from family planning to inform the development of new HIV prevention products and MPTs: What do we know about acceptability and adherence for young women?

Tabitha Sripipatana, Office of Population & Reproductive Health (PRH) | USAID
Judy Manning, PRH | USAID
October 13, 2016
What can we learn from 50 Years of Family Planning R&D and Program Experience?

- USAID’s FP program supports women and couples to make informed, voluntary decisions about whether to have children and, for those who would like children, when and how many to have

- Contraceptives are used by the majority of married or in-union women in almost all regions of the world
  - In 2015, 64 per cent of married or in-union women of reproductive age worldwide were using some form of contraception

Source: UN Dep of Economic and Social Affairs, Population Division. 2015, Trends in Contraceptive Use Worldwide
However...

Despite more than 50 years of success in the development, introduction and use of FP, more than 225 million women in low resource countries who would like to avoid getting pregnant are not using contraception.

- Unmet need is much higher for adolescents than for women overall
- The proportion of adolescent women in need who are not using contraception is higher in Asia (69%) and Africa (68%) than in Latin America and the Caribbean (36%)

**Reasons cited for non-use:**

- Concerns about side effects: 26%
- Infrequent sex (not warranting contraceptive use): 24%
- Post-partum or breast-feeding (not menstruating): 23%
- Opposition: 20%
- Lack of access: 5%


## Choices: How the most common FP methods compare

<table>
<thead>
<tr>
<th>Main Reason for non-use</th>
<th>Standard Days Method (SDM)</th>
<th>Lactational Amenorrhea Method (LAM)</th>
<th>Condoms (Male/Female)</th>
<th>Pills</th>
<th>Injectables</th>
<th>Implants</th>
<th>IUDs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Concerns about side effects</strong></td>
<td>none</td>
<td>none</td>
<td>none</td>
<td>few</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Infrequent sex</strong> (= need for user-controlled method)</td>
<td>yes* (requires partner involvement)</td>
<td>yes</td>
<td>yes* (requires partner involvement)</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Post-partum / Breast feeding</strong></td>
<td>no (must be cycling)</td>
<td>z</td>
<td>yes</td>
<td>Yes* (POPs)</td>
<td>Yes* (after 6 wks)</td>
<td>Yes</td>
<td>Yes* (&lt; 48 hrs or &gt; 4wks)</td>
</tr>
<tr>
<td><strong>Opposition</strong> (= possible need for a discreet method)</td>
<td>no</td>
<td>yes* (up to 6 mos)</td>
<td>no</td>
<td>maybe</td>
<td>yes</td>
<td>yes</td>
<td>maybe</td>
</tr>
</tbody>
</table>

- Importance of a range of methods and opportunities to switch
- Need for adolescence user preference data for early MPT R&D
How does 50 years of FP provision and research inform MPT development?

Across Products, Geographies, and Time, Women Want to Know...

- **Will the product be effective?**
  (and some sense of how well in an understandable format)

- **Will it cause harm?**
  (to me, my partner, my baby if I'm breastfeeding)

- **Will it jeopardize my future fertility?**
  (will I be able to get pregnant in the future, if I want to?)

- **Will it affect my relationship with my partner?**
  (issues of trust, pleasure, secrecy, social cost)

FP Product Characteristics and Introduction Strategies to Consider for Young Women

**Adherence**
- User-controlled vs. user-independent
- Coitally-dependent vs. user-independent

**Access**
- By prescription (Rx) vs. Over-the-counter (OTC)
- Skilled clinician involvement vs. limited or none

**Distribution**
- *Scientific and safety profile* of product determines regulatory status
- *Regulatory status* determines opportunities for service delivery:
  - Facility-based vs. pharmacy distribution vs. social marketing
  - Point of use, “high risk” vs. “mainstream”
  - OTC status gains access, but loses ability to monitor
- *Target Multiple Channels*: Public sector, private sector; sequencing and timing
- *Integration/linkages* with other health delivery and prevention strategies

Sources: M. Brady, 2009: Advancing Prevention Technology for SRH Strategy Symposium, Berkeley, CA
2011: WHO/UNAIDS Consultation on Introducing 1% TVF gel, South Africa.
Access Challenge: lessons learned from adolescent FP services

HIV Testing as a Gateway to MPT Use

- Periodic testing will be a unique, difficult feature for ARV-based MPTs

Proven Service Delivery Approaches for Young People:

- Trained providers are nonjudgmental and friendly to adolescent clients
- Health facilities are welcoming and appealing
- Communication and outreach activities inform adolescents about services and encourage their use
- Community members support the importance of providing health services to adolescents

Source: Chandra-Mouli V. 2015. What does not work in adolescent sexual and RH health. Global Health Science and Practice
Applicability of FP High Impact Practices (HIPs):

Evidence-based practices to help focus FP resources and efforts

Will these be applicable to the introduction of MPTs? YES!

- Community Health Workers: Bringing FP services to where people live and work
- Drug Shops and Pharmacies: Sources for commodities and information
- FP and Immunization Integration: Reaching post-partum women
- Mobile Outreach Services: Expanding access
- Postabortion FP: Strengthening RH services of postabortion care
- Social Marketing: Leveraging the private sector to improve contraceptive access, choice and use
- Vouchers: Addressing inequities in access to contraceptive services
- Adolescent-friendly services: Pay attention to the FP data on what doesn’t work...

More to consider around enabling environment.... another presentation

https://www.fphighimpactpractices.org
Thank you!
Hindsight to use: Applying lessons learned from family planning to new HIV prevention products and MPTs

Sharyn Tenn, Senior Director of External Affairs
International Partnership for Microbicides (IPM)

October 13, 2016
The International Partnership for Microbicides (IPM)

To develop HIV prevention products and new sexual and reproductive health solutions for women in developing countries

About us

• Nonprofit product developer
• Founded in 2002
• Offices in the United States and South Africa
HIV Prevention Toolkit

Existing Options

- Male and female condoms
- Behavior change
- Prevention of mother-to-child transmission (PMTCT)
- Voluntary medical male circumcision
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
- Oral pre-exposure prophylaxis (PrEP)
HIV Prevention Toolkit

Potential new options:

• Microbicide vaginal rings
• Rectal microbicides
• Injectable ARVs
• HIV vaccines
What are Microbicides?

- Products being developed to help prevent HIV during sex
- Most contain ARVs, already used successfully to treat HIV
- Could offer convenience, options
- Monthly or longer, around time of sex
- Potential to combine ARVs, other drugs
- Ideally safe, effective, low cost, user-friendly
Monthly Dapivirine Ring

- Flexible silicone vaginal ring developed by IPM
- Woman-controlled:
  - *Self-inserted* monthly
  - *Discreet*
- Slowly releases ARV drug dapivirine
  - Worldwide rights through Janssen Sciences Ireland UC
- *Two parallel efficacy studies:* The Ring Study and ASPIRE
Why the Ring for HIV Prevention?

• Puts power of prevention in women’s hands
• First long-acting method
  90-day ring in development
• Good safety profile
• Effective, and higher efficacy possible with consistent use
Phase III Study Questions

- Will the ring prevent HIV?
- Is the ring acceptable?
- Is the ring safe?
- Will women use the ring?
### The Ring Study and the ASPIRE Study

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of Sites</th>
<th>Total Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa:</td>
<td>9</td>
<td>1,426</td>
</tr>
<tr>
<td>Western Cape</td>
<td>1</td>
<td>97</td>
</tr>
<tr>
<td>Kwa-Zulu Natal</td>
<td>7</td>
<td>1,064</td>
</tr>
<tr>
<td>Gauteng</td>
<td>1</td>
<td>119</td>
</tr>
<tr>
<td>Uganda:</td>
<td>1</td>
<td>253</td>
</tr>
<tr>
<td>Kampala</td>
<td>1</td>
<td>197</td>
</tr>
<tr>
<td>Zimbabwe:</td>
<td>3</td>
<td>678</td>
</tr>
<tr>
<td>Harare</td>
<td>3</td>
<td>678</td>
</tr>
<tr>
<td>Malawi:</td>
<td>2</td>
<td>272</td>
</tr>
<tr>
<td>Blantyre</td>
<td>1</td>
<td>130</td>
</tr>
<tr>
<td>Lilongwe</td>
<td>1</td>
<td>142</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>2,629</td>
</tr>
</tbody>
</table>

### Notes
- The image includes a map of Africa with marked locations indicating study sites.
- The map highlights the distribution of study sites across South Africa, Uganda, Zimbabwe, and Malawi.
Phase III Results Summary

- The monthly dapivirine ring safely and effectively reduced risk of HIV infection by approximately 30% overall.

- Higher protection seen in women older than 21.

- Higher efficacy seen with more consistent use - at least 56% in ASPIRE with potential for greater protection. Additional analyses strongly even higher efficacy levels found with more consistent use.

- More research needed to understand prevention needs of younger women.
What’s Next for the Ring?

PUBLIC HEALTH PATHWAY
Two open-label extension studies and a Human-Centered Design Market Research project to better understand and support end-users and consistent use

REGULATORY PATHWAY
Apply for regulatory approval mid-2017H
Planning for Dapivirine Ring Access: 10 Lessons from the Introduction of Contraceptive Technologies

1. Beware the “magic bullet syndrome.”
2. Cost matters.
3. Choice matters.
4. Understanding the end-user’s lifestyle, needs and preferences is critical.
5. Perseverance is key.
6. Ensure strong, sustained stakeholder support.
7. Strong procurement and logistics systems are essential.
8. Every country and cultural setting is different.
9. Build on existing health structures.

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#11: It Takes a Village

- Advocates
- Procurement Agencies, Distributors, Health Care Workers and Clinics
- Civil Society
- Women, End-Users, Communities
- Regulatory Authorities
- Implementing Organizations
- Policymakers and Government Agencies
- Industry
- Donors
- Advocates
- HIV & SRH Prevention Programs
- Health Care Workers and Clinics

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A Path Forward for MPT Development and Introduction

Bethany Young Holt, PhD MPH
Director, Initiative for MPTs

13 October 2016
Initiative for MPTs

- Contraception
- HIV Prevention
- STI Prevention

- Science
- Funder Collaboration
- Advocacy & Market Development
- Women’s Voices & Access

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IMPT strategic approach: market access in tandem with MPT R&D

R&D
To achieve safe and efficacious products

Social-Behavioral & Market Research
To achieve widespread, sustained & consistent use

Public Health Impact
IMPT builds the field

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

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

Delivery & Distribution
IMPT Priority Areas

1) R&D
   • Understand hormonal contraceptive (HC) knowledge gaps in the context of MPT development.
   • Assess challenges and other issues related to MPT clinical trial design.
   • Develop a process for achieving a more robust product development pathway for non-HIV STI MPTs.

2) Market Access
   • Assess the gaps in social-behavioral knowledge for MPT development and MPT commercialization potential.
   • Engage modeling efforts to robustly assess public health impact and cost effectiveness of MPT product options in specific target populations.
Strategic Roadmap for MPT Field

- Market demand and understanding
- Epidemiology
- APIs, dosage targets, dosage forms, product design
- Impact and cost effectiveness modeling
- Regulatory pathways
- Bioequivalence
- Policy and advocacy
- CMC and scale up capacity

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Technical Meetings on Key Challenges & Questions for MPT Field

Clinical Trial Evaluation Workshop for MPTs

Technical Meeting on HC in MPTs
Select Outcomes & Lessons Learned from Technical Meetings

- Urgent need for **strategic decision-making** given limited resources and time.

- Identification and prioritization of **target population**.

- Establishment of technical and market/socio-behavioral **standards and data requirements**.
Learn more about MPTs at www.theIMPT.org
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Against the backdrop of the Sustainable Development Goals, the need for improved, affordable and more ‘fit for purpose’ reproductive health technologies has been highlighted.

-- Helen Rees
Discussion

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Thank you!