

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



GENERAL MEMBERSHIP MEETING
of the
REPRODUCTIVE HEALTH
SUPPLIES COALITION

10-14 OCTOBER 2016

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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

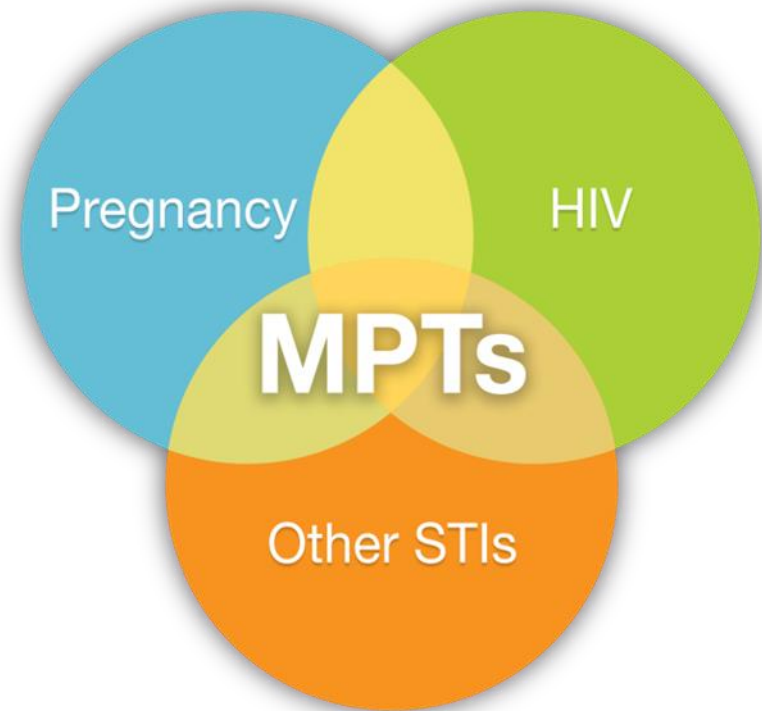
- What are the most important lessons learned from family planning and/or HIV prevention work with regard to product acceptability and adherence among young women and adolescent end-users?
- What do we wish we knew then that we can use now?
- How can these lessons inform activities and introduction planning 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



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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%**

Source: Darroch JE et al, 2016. *Adding it up: Costs and benefits of meeting the contraceptive needs of adolescents.* Guttmacher Institute.

Source: Sedgh, Ashford and Hussain, 2016. *Unmet Need for Contraception in Developing Countries: Examining Women's Reasons For Not Using a Method.* Guttmacher Institute.

Choices: How the most common FP methods compare

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

- ✓ 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)



Source: M. Brady, 2012. *Shaping the Operations Research Agenda for Women-centered ARV-based Prevention: Gel and Rings Consultation*, Population Council, New York

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.

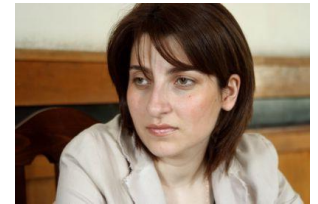
Access Challenge: lessons learned from adolescent FP services

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!



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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



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The International Partnership for Microbicides (IPM)



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

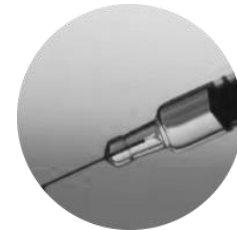
About us

- Nonprofit product developer
- Founded in 2002
- Offices in the United States and South Africa

HIV Prevention Toolkit

Existing Options

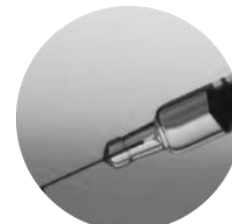
- Male and female condoms
- Behavior change
- Prevention of mother-to-child transmission (PMTCT)
- Voluntary medical male circumcision
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
- Oral pre-exposure prophylaxis (PrEP)



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



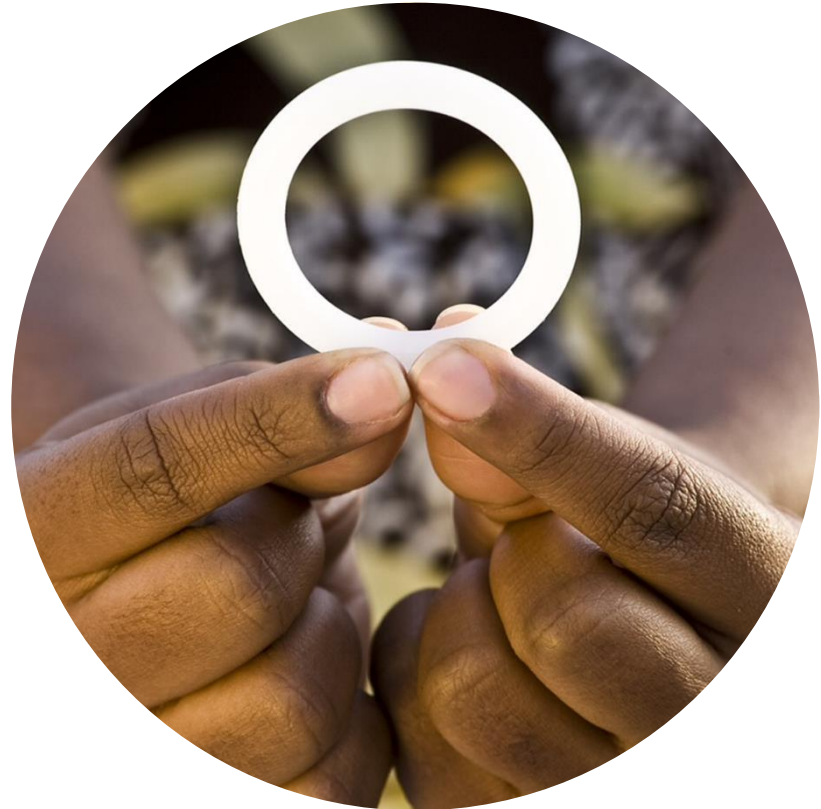
Monthly Dapivirine Ring




- 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 safe?

Is the ring acceptable?

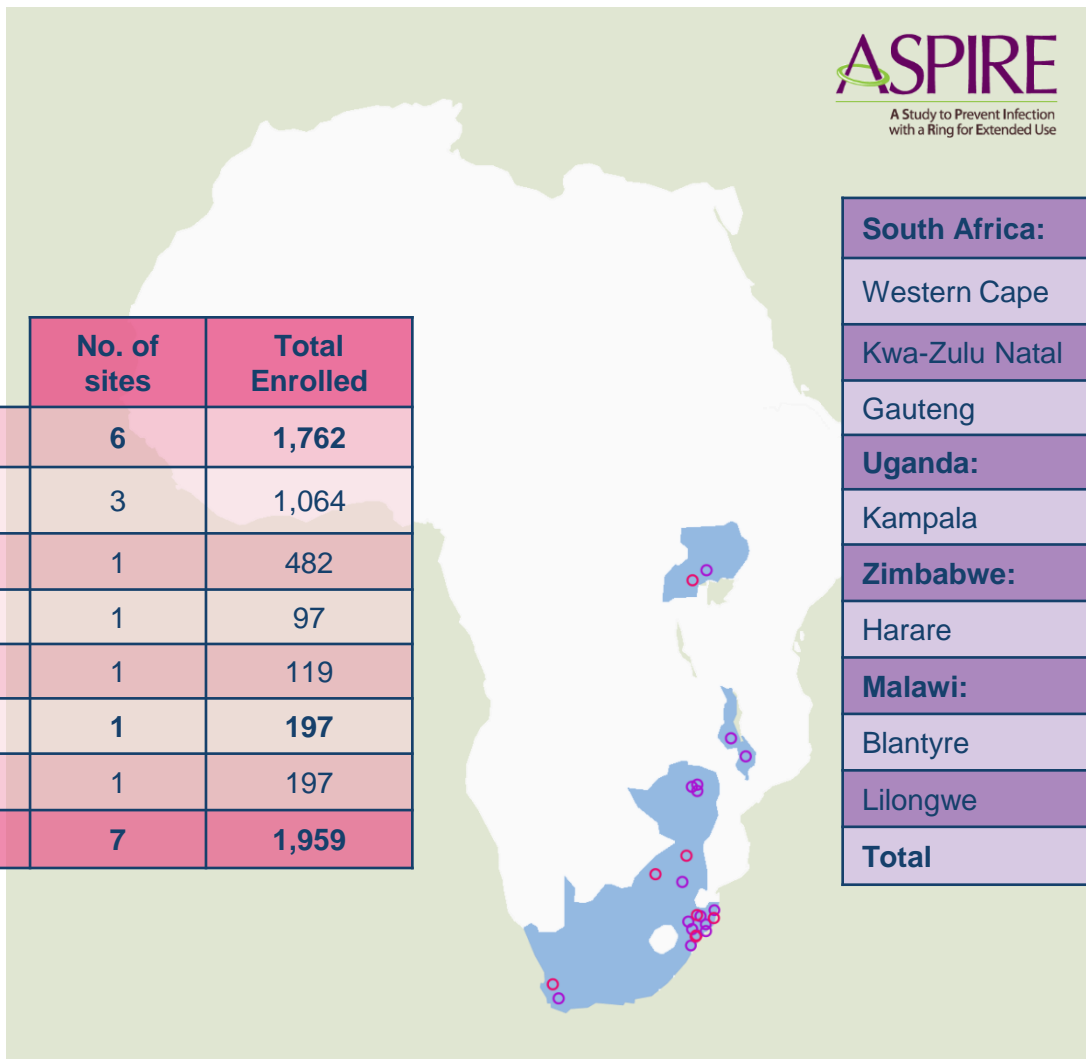
Will women use the ring?



The Ring Study and the ASPIRE Study



	No. of sites	Total Enrolled
South Africa:	6	1,762
Kwa-Zulu Natal	3	1,064
North West	1	482
Western Cape	1	97
Limpopo	1	119
Uganda:	1	197
Masaka	1	197
Total	7	1,959



	No. of sites	Total Enrolled
South Africa:	9	1,426
Western Cape	1	97
Kwa-Zulu Natal	7	1,064
Gauteng	1	119
Uganda:	1	253
Kampala	1	197
Zimbabwe:	3	678
Harare	3	678
Malawi:	2	272
Blantyre	1	130
Lilongwe	1	142
Total	12	2,629

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



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ASPIRE
A Study to Prevent Infection
with a Ring for Extended Use

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

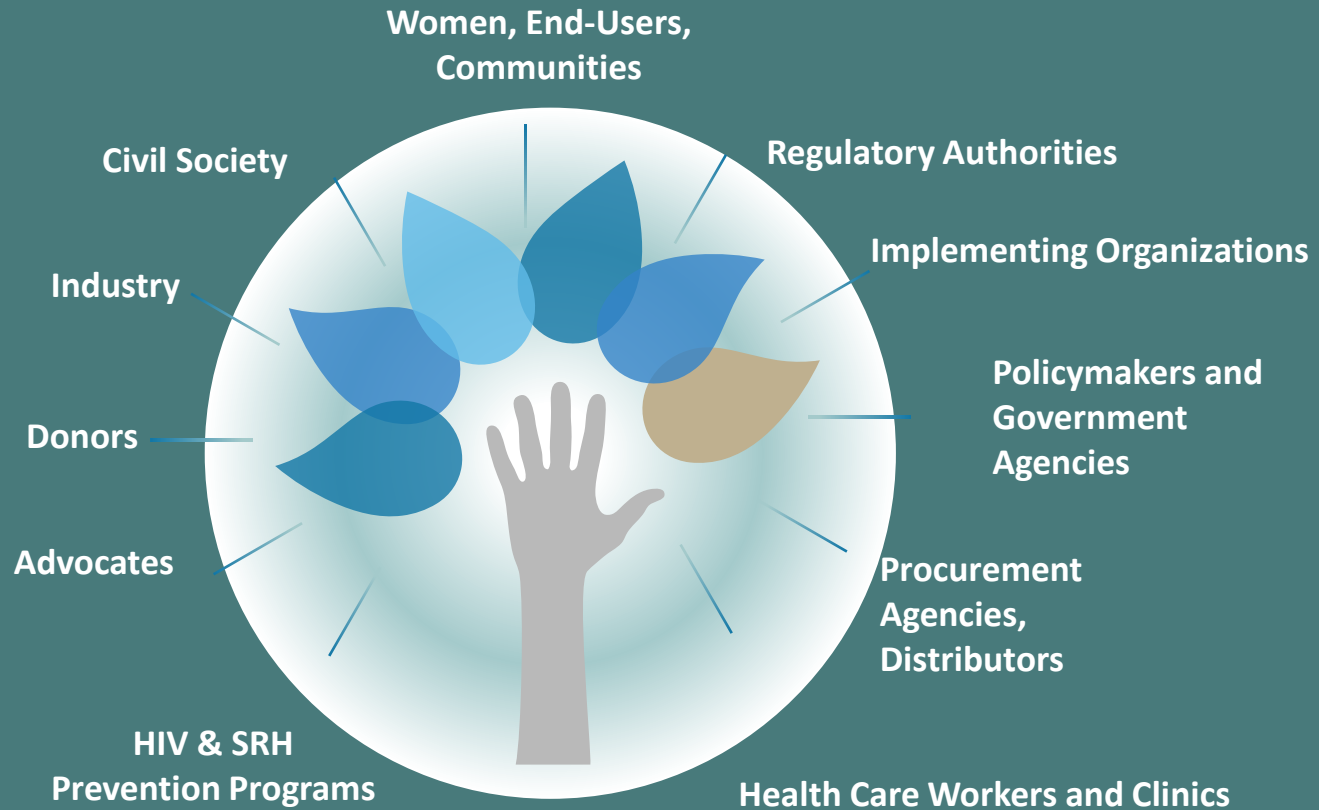
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Planning for Dapivirine Ring Access: 10 Lessons from the Introduction of Contraceptive Technologies



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.
10. Plan for scale-up.

#11: It Takes a Village



A Path Forward for MPT Development and Introduction

Bethany Young Holt, PhD MPH
Director, Initiative for MPTs

13 October 2016



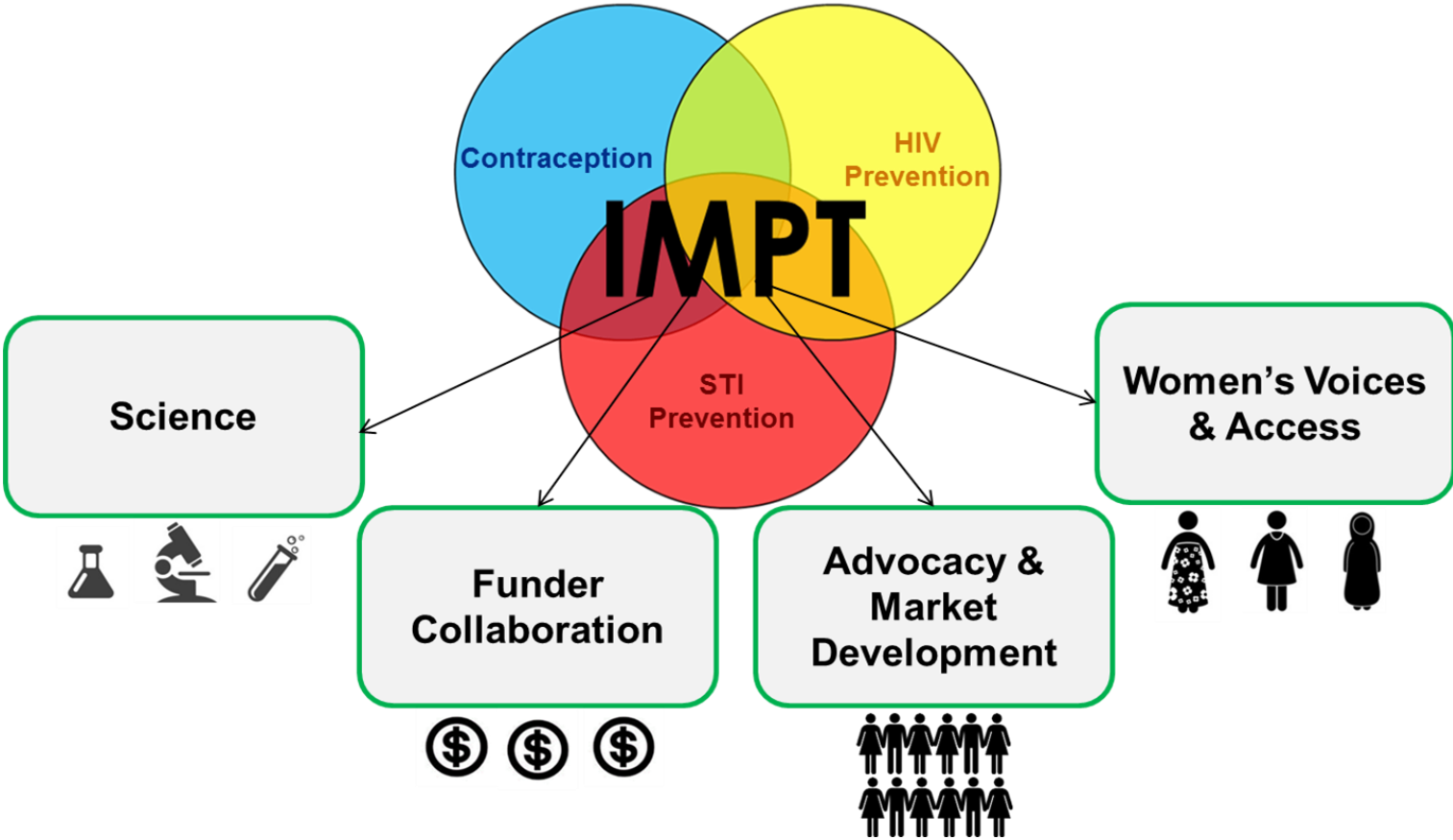
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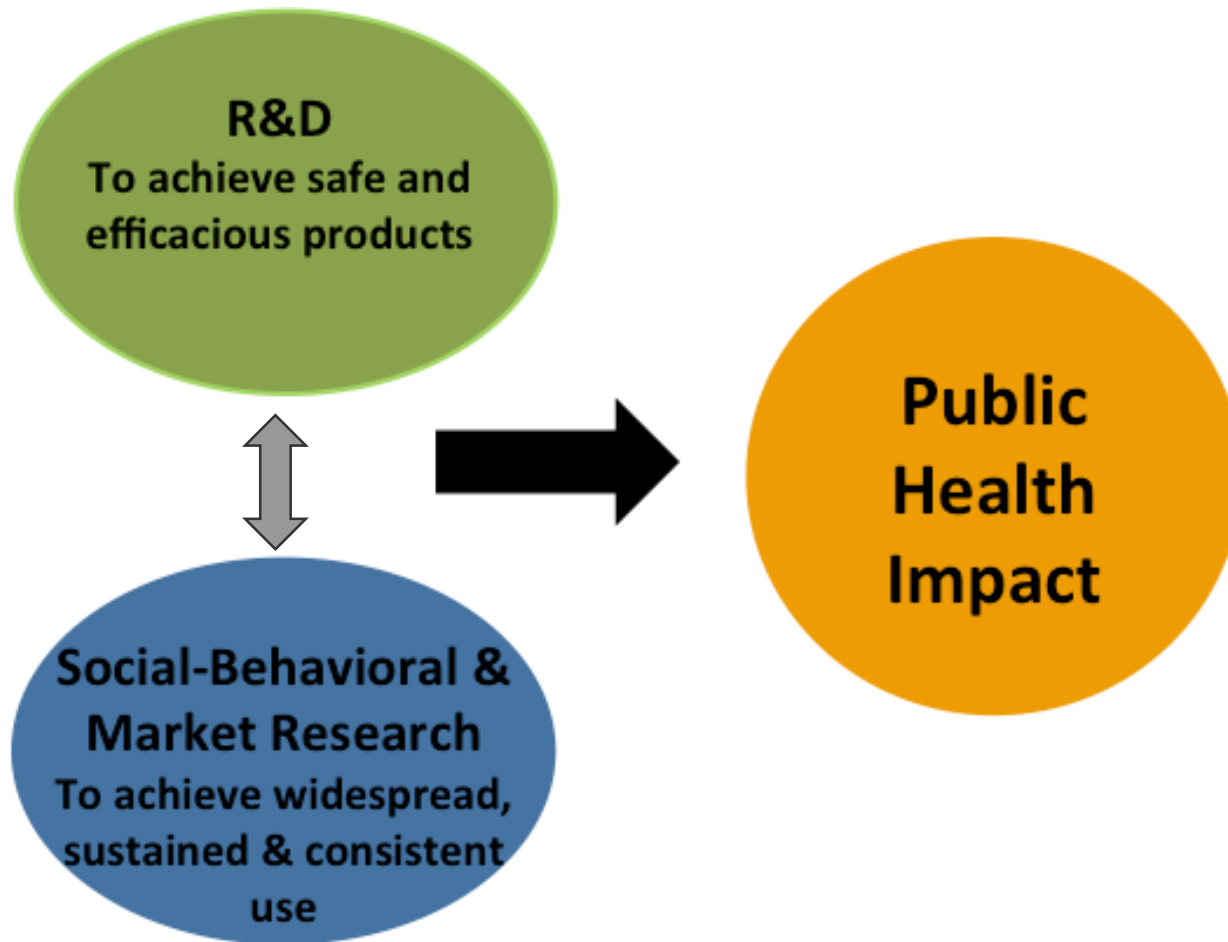
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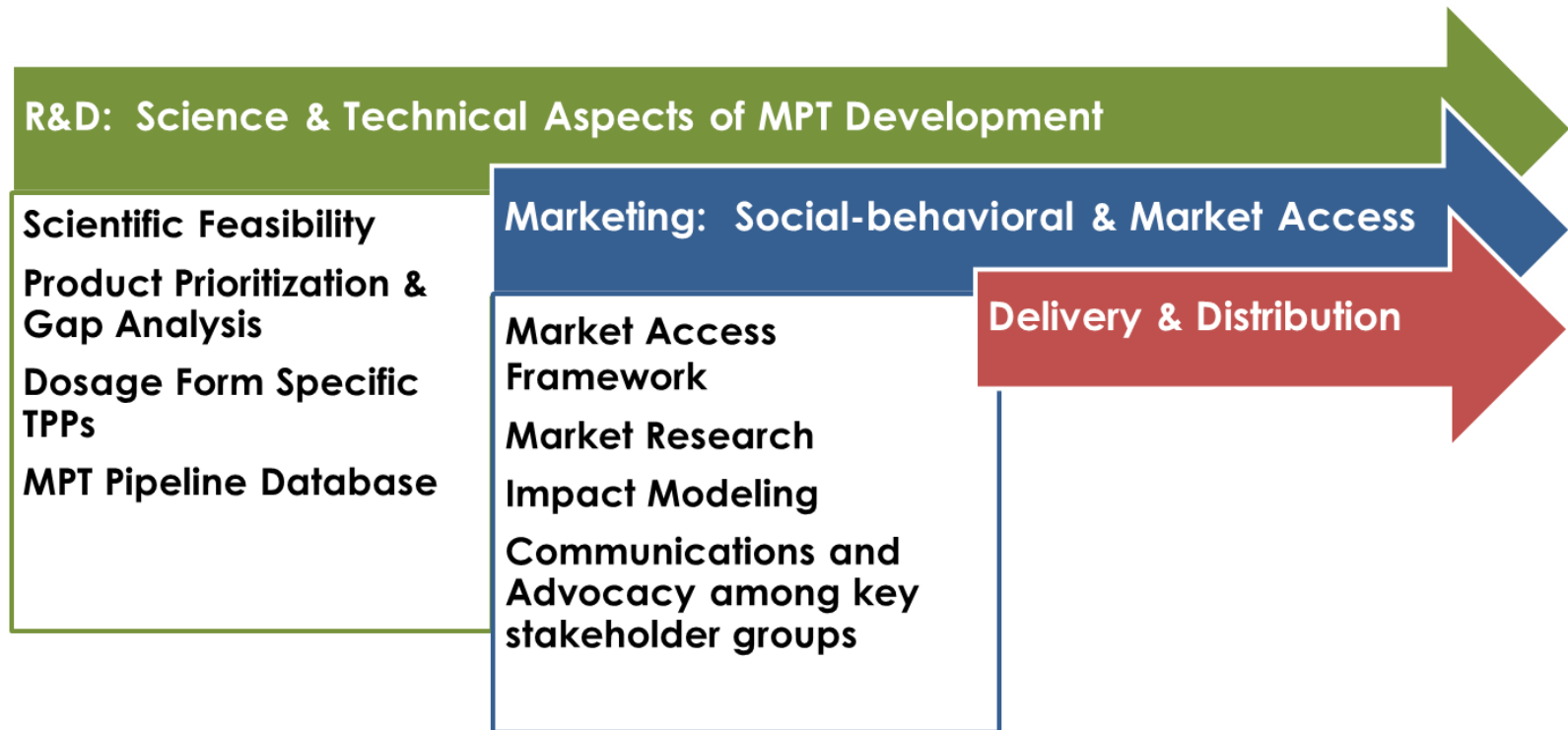
Initiative for MPTs



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



IMPT builds the field



IMPT Priority Areas

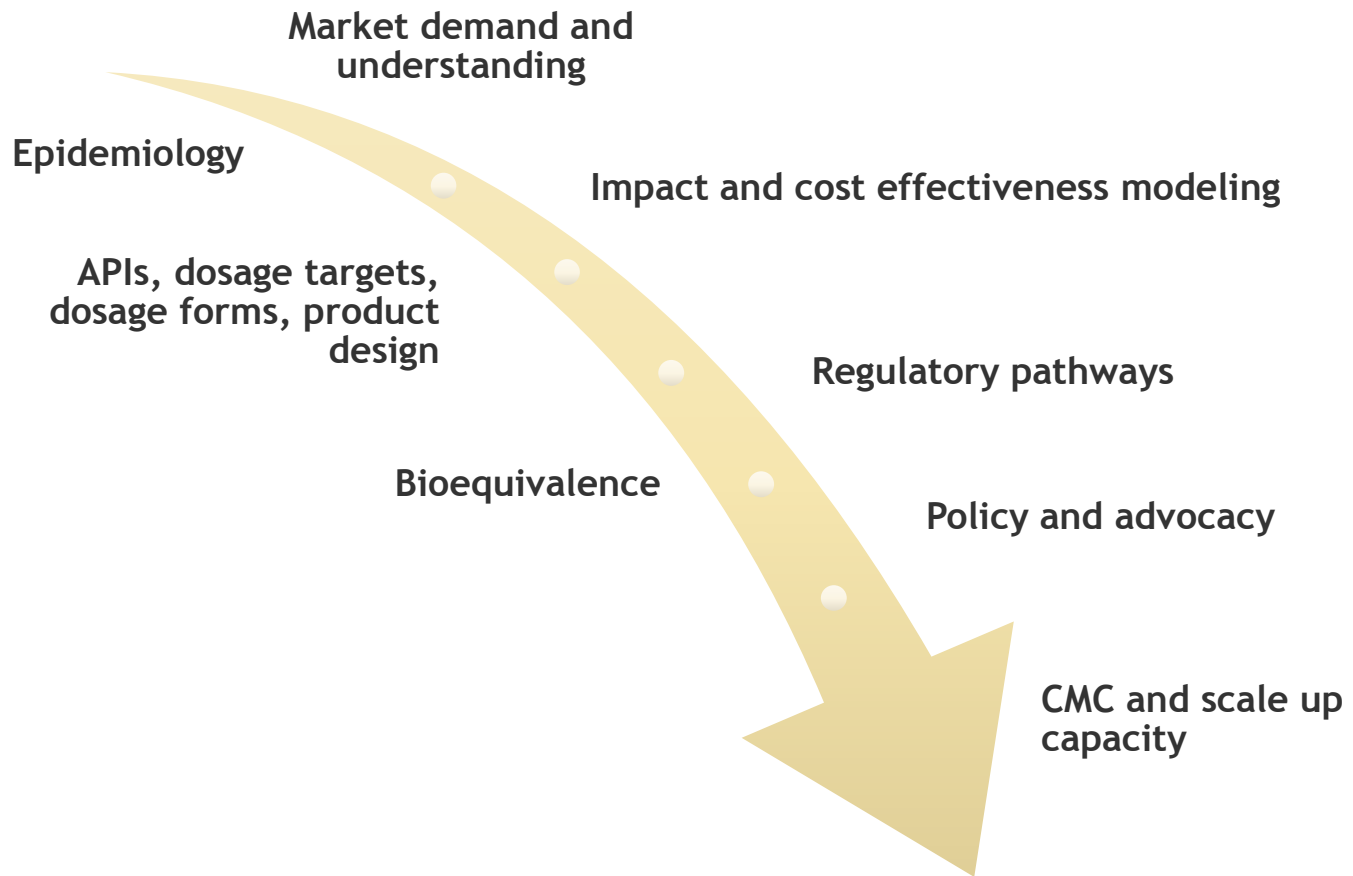
1) R&D

- 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



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





Thank You!

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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

- 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?
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