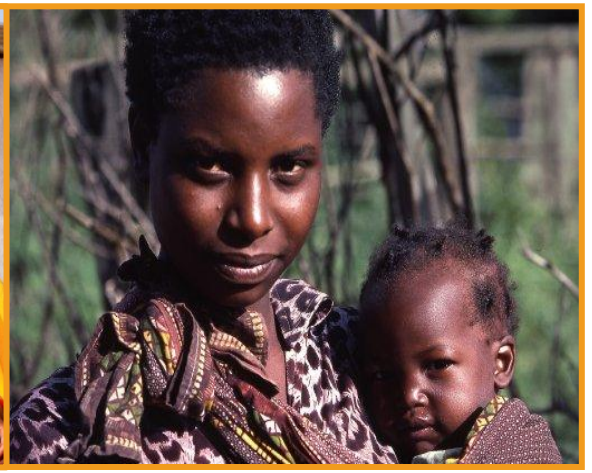


MULTIPURPOSE PREVENTION TECHNOLOGIES (MPTS) *FOR* SEXUAL AND REPRODUCTIVE HEALTH

Bethany Young Holt, PhD MPH

Executive Director, CAMI

Initiative for Multipurpose Prevention Technologies *for* Reproductive Health

USAID FROM THE AMERICAN PEOPLE

Association of Reproductive Health Professionals

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Reproductive Health 2013

21 September 2013 – Denver, CO

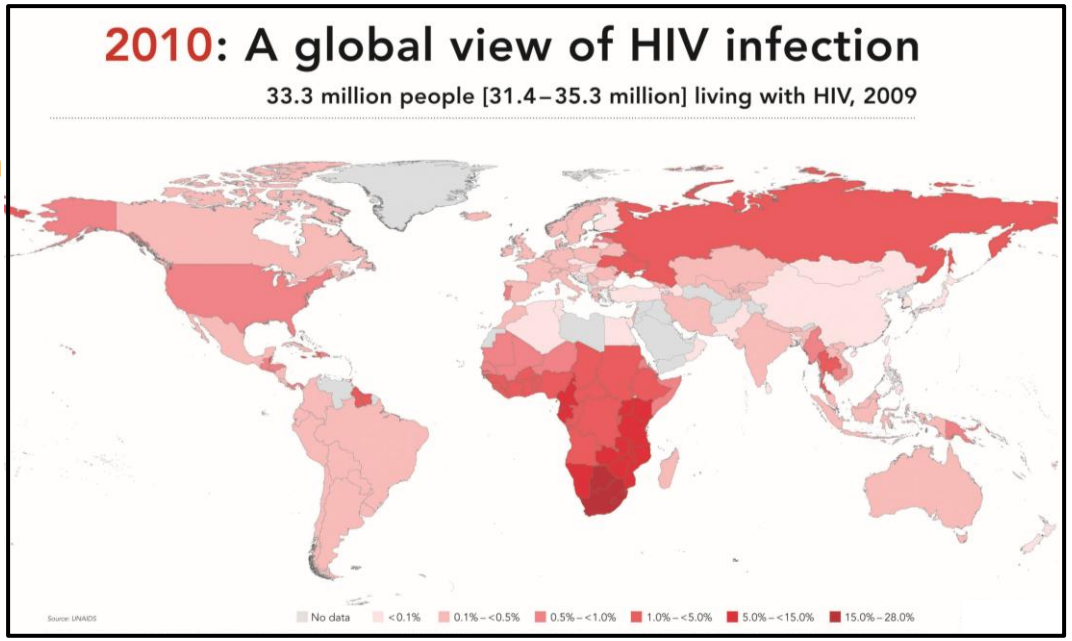
Session Objectives

This session is designed to help you do the following:

- Define multipurpose prevention technologies (MPTs)
- Describe existing MPTs in use globally
- Describe the range of MPT delivery systems in development
- Describe the challenges and timeline for MPTs development
- Provide your input on MPTs that are in development

Global Need… *HIV & STIs*

- In 2010, **1.8 million people died of AIDS**… in 2009 an estimated **2.6 million become infected with HIV.**[1]
- **Young, married women** are the **fastest growing group of HIV+** people worldwide.[2]



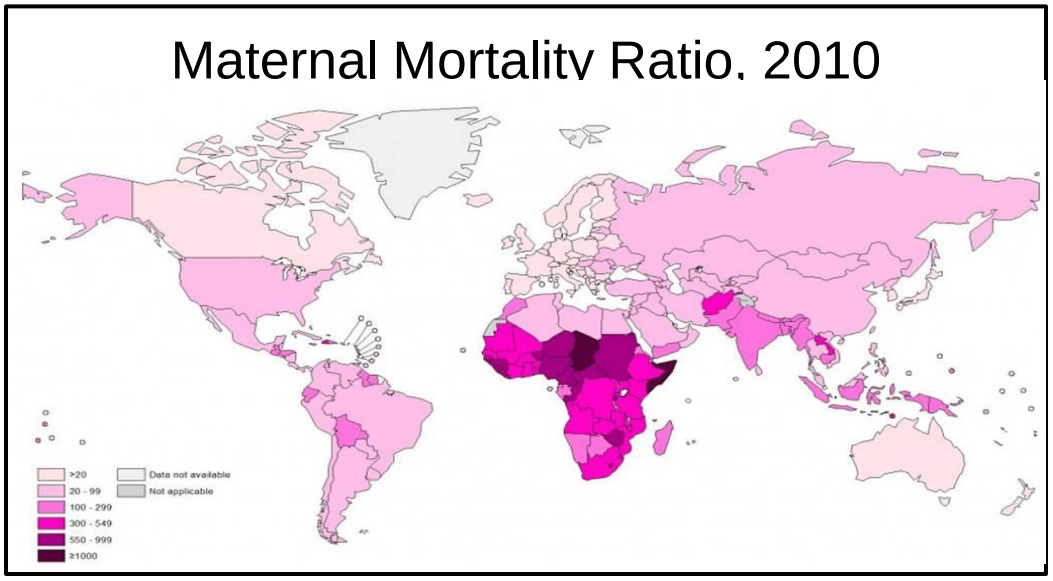
4

- Worldwide, **women are 5 times more likely to get sexually transmitted infections** than men.[3]
- Each day, about **500,000 young people, mostly women, contract an STI.**[3]

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Global Need… *family planning*



[8]

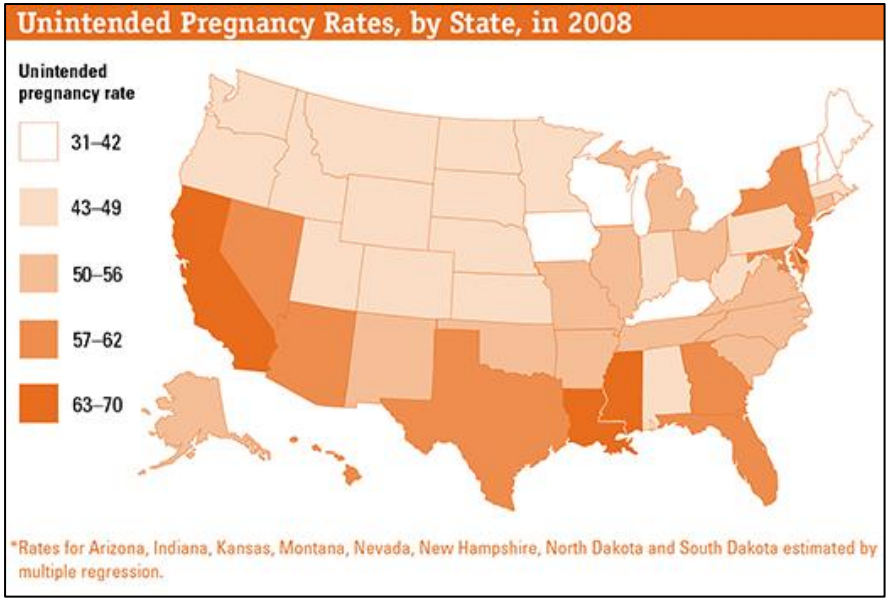
- **222 million women** have an **unmet need for modern contraception.**[7]
- There are approximately **80 million unintended pregnancies** in the developing world[7]
  - Resulting in **40 million abortions**, **30 million unplanned births**, 10 million miscarriages.[7]

- Each day, close to **800** women in developing countries die from complications related to pregnancy and childbirth.[5]
- An additional **15 to 20 million** women suffer debilitating consequences of pregnancy.[6]

Initiative for Multipurpose Prevention Technologies for Reproductive Health

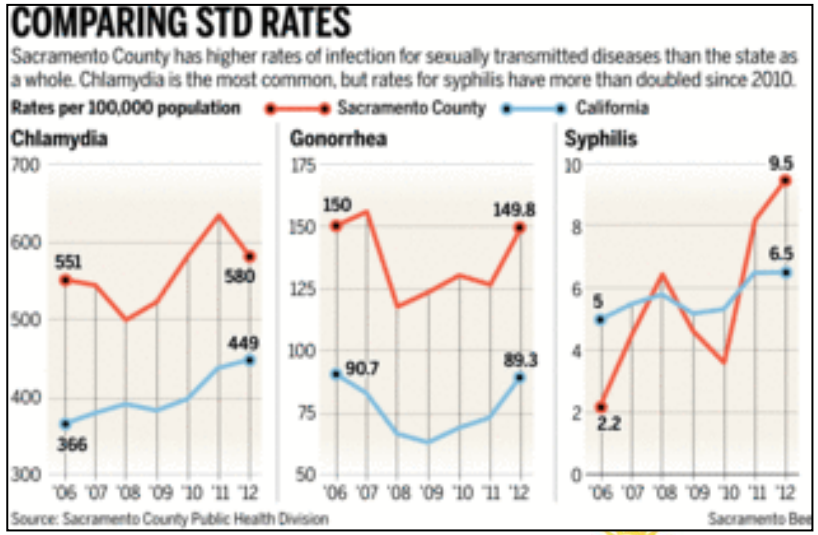
CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

In the United States



13

- Nearly **half of all pregnancies** among American women are **unintended**, and four in ten of these end in abortion.[9]
- An estimated **750,000 women** aged 15-19 in US **become pregnant annually**, of which over **80% are unintended**.[10,11]



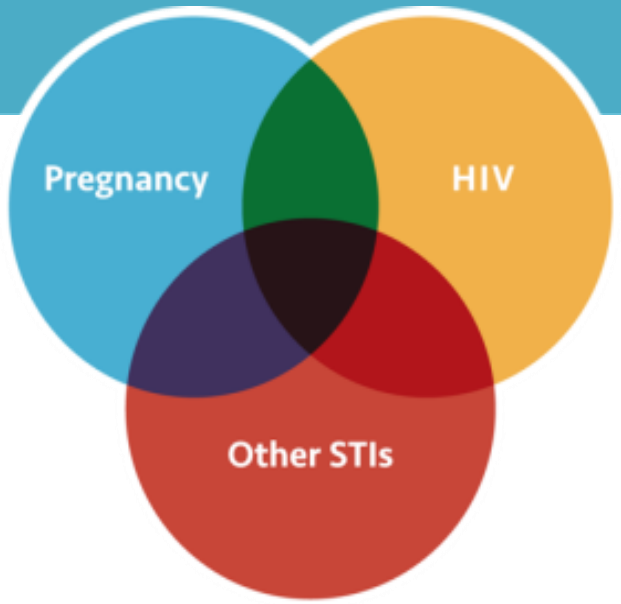
- **STIs are the most commonly reported communicable diseases** in the US.[12]
- Of the **18.9 million new cases of STIs** each year in the US, **9.1 million (48%) occur among 15-24 year olds**.[12]

14

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

What are Multipurpose Prevention Technologies (MPTs)?



A single product or strategy, configured for <u>at least two</u> SRH prevention indications:

- ✓ **Unintended pregnancy**
- ✓ **HIV**
- ✓ **Other STIs**

WHY **MPTs?**

- ❑ Greater ***efficiency*** in terms of cost, access and delivery of SRH prevention products
- ❑ Capitalize on the demand in populations using one product type to achieve uptake and use of a second "product"

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

MPTs: Historical Precedents

H_2O + flouride	The pill + iron	Grains + folic acid

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Why do women need MPTs?

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

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

MPT products currently available

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

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

MPTs in the Pipeline

Drug Combinations	Drug/Device Combinations	Multipurpose Vaccines	Bacterial Therapeutics	Nanoparticles

Initiative for Multipurpose Prevention Technologies for Reproductive Health

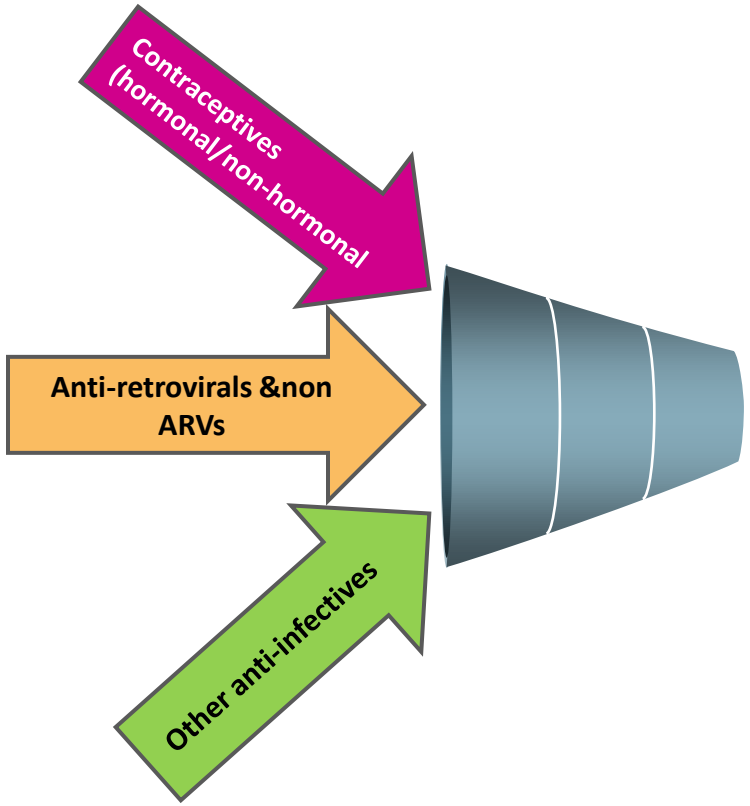
CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Successful products means listening to what women want…

Technology Filter

Product Prioritization and Gap analysis

Ideal MPT Products Supported

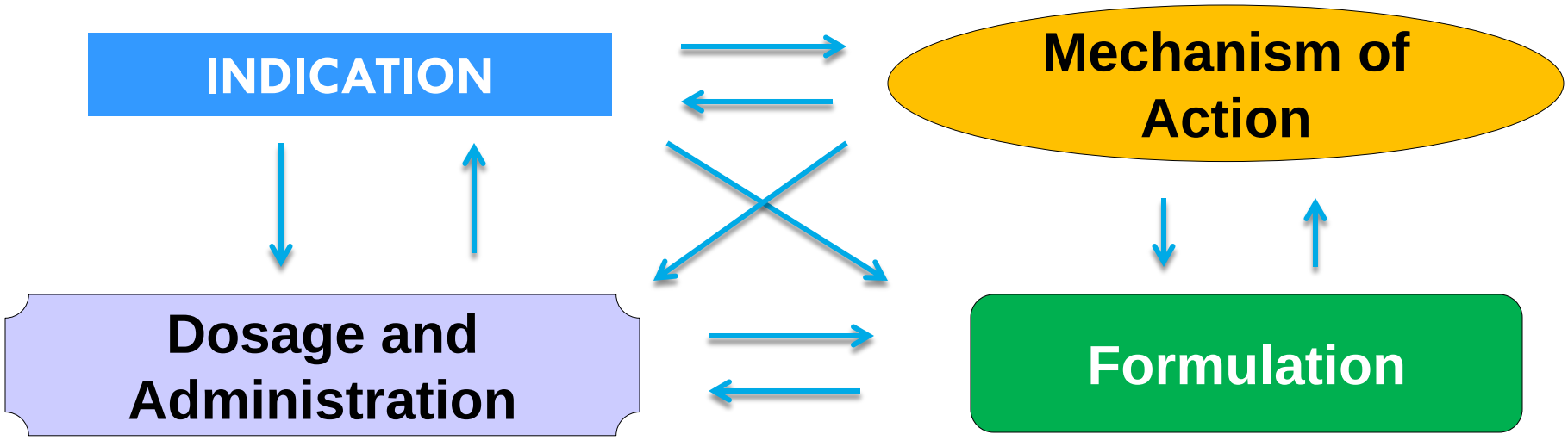


Candidate MPTs

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Complexity of developing MPTs



10 MPT IVR	10 Single Indication IVR	31 HIV Entry Inhibitors
3 On-Demand MPT	12 On-Demand HIV Only	11 Enzyme Inhibitors
2 Barrier MPT	2 Injectable HIV Only	7 Other HIV Inhibitors
23 HC products	2 Lacto-based Products	29 non-HC products

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

MPT Product Profile: Working Group Recommendations

MPT PRODUCTS

HIV/STI Prevention

Contraception

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

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

Initiative for Multipurpose Prevention Technologies for Reproductive Health

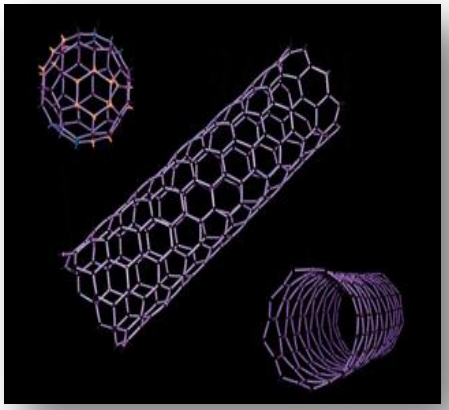
CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

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

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

On-Demand Products: Devices + Active Agents

SILCS (PATH, CONRAD, NICHD)

- "One size fits most" silicone diaphragm
- Intended for OTC pregnancy prevention
- 5-yr shelf life, re-use up to 3 yrs

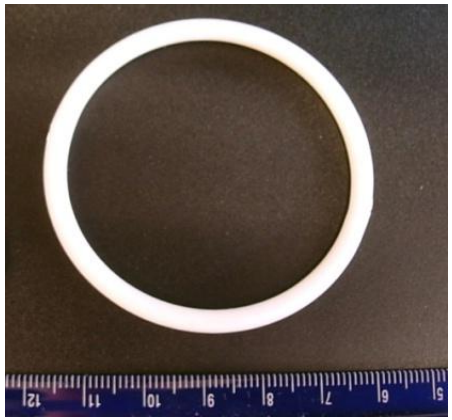
+ TFV Gel (CONRAD)

- SILCS barrier = delivery device
- Non-hormonal MPT protection: pregnancy, HIV, HSV2 up to 24 hrs

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Sustained Release Devices: Combination Intravaginal Rings

30-day MZL Combo (Population Council)	60-day Dapivirine + LNG (IPM)	90-day TFV + LNG (CONRAD)
		
■ MIV-150 + Zinc Acetate + LNG ■ Demonstrated single-API success ■ Pregnancy, HIV, HSV2	■ DPV + LNG ■ Testing underway, clinical studies 2013 ■ Pregnancy, HIV	■ TFV + LNG ■ Testing underway, clinical studies 2013 ■ HIV, HSV2

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

MPT Target Product Profiles (TPPs)
MPT Product Priority and Gap Analysis

- ✓ Priority Indications (Regional Differences):
  - Pregnancy + HIV
  - HIV + STI
  - Pregnancy + STI
- ✓ Dosage Forms: "Suite of Products"
  - Sustained release (IVR), LA Injectable, On-Demand
- ✓ Drugs:
  - ARV for HIV, HC for pregnancy, STI specific drugs (GAP!)
    - Non-ARV/non-HC options are longer term (GAP!)
- ✓ Other Product Attributes:
  - Stability, shelf life, safety and efficacy targets, COST, scale-up, user preferences, adherence potential, market demand…

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Single & Multipurpose Vaccines

Today

- *Single purpose* vaccines (e.g. HPV)
- *Multipurpose* vaccines that include HBV (e.g. Twinrix)

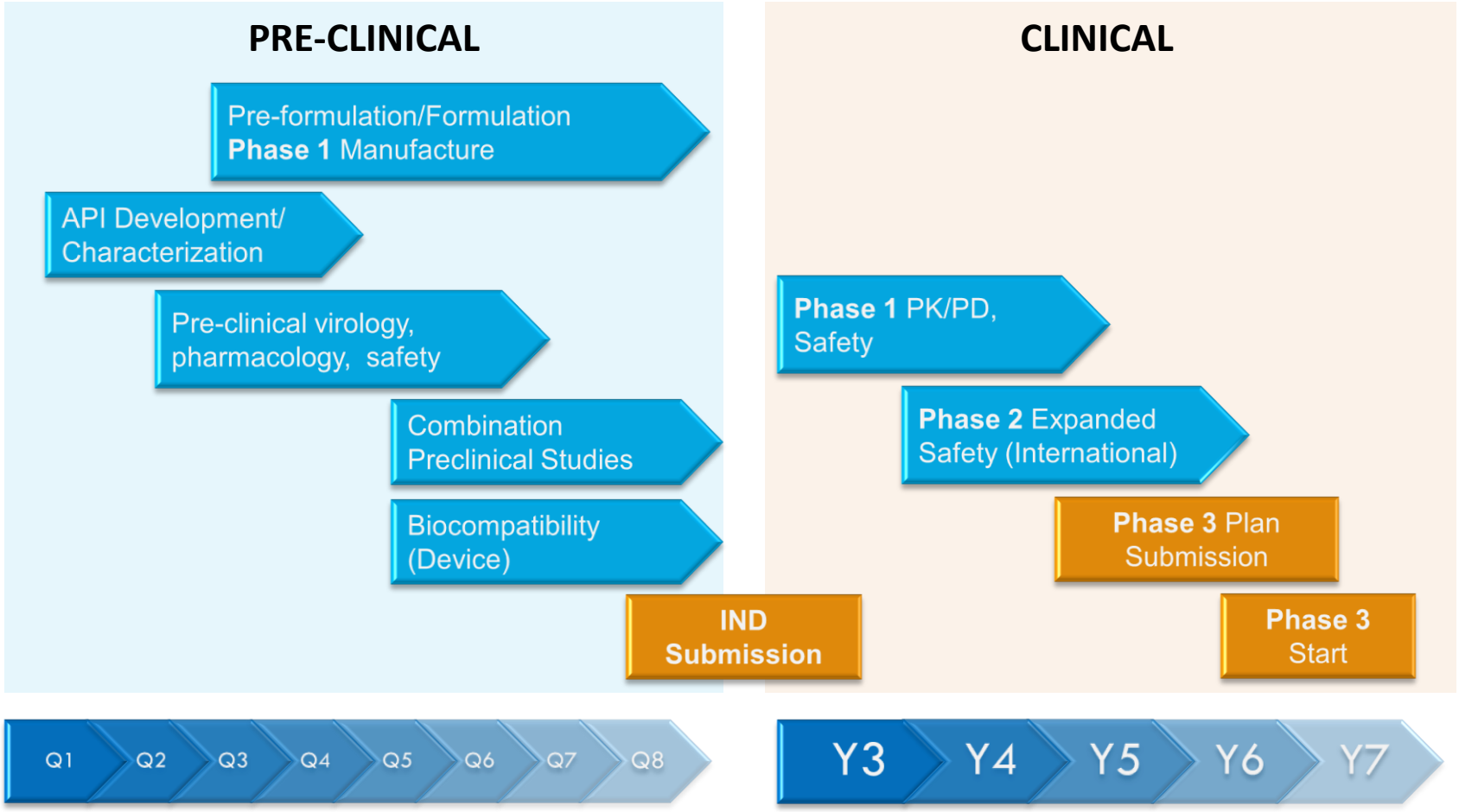
Future

- *Multipurpose* STI vaccines (HSV, HIV, Gonorrhea, Chlamydia, Trichomonos, other STIs)
- Reversible immunocontraceptives (e.g. anti-sperm)
- What would ***your*** patients want in a multipurpose vaccine?

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

MPT Product Development Timeline



CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

The Initiative for Multipurpose Prevention Technologies

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Barriers to progress on MPTs

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Initiative for Multipurpose Prevention Technologies (IMPT)

Scientific Agenda

Acceptability and Access

Communications and Advocacy

Funding Coordination

Secretariat:

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

part of the Public Health Institute

National & Int'l Funding Agencies
BMGF, ICMR, IPPF, USAID, USFDA, US National Institutes of Health, WHO, Wellcome Trust

Research & Public Health Orgs
California Family Health Council, CONRAD, IPM, Jhpiego, PATH, IPPF, Population Council, Public Health Institute, RTI International

SRH Policy and Advocacy Orgs
AVAC, ARHP, Guttmacher Institute

Biotechnology Companies & Orgs
Auritec, Mapp Biopharmaceutical, Medicines360, Osel, ReProtect, Teva, WomanCare Global

Universities
China, India, Kenya, Nigeria, South Africa, UK, USA

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

MPT: Conclusions and the Future

So Far…

- ✓ MPT Products can potentially address major unmet medical needs for women globally
  - Key advantages over current strategies
- ✓ The IMPT has defined product attributes for an MPT TPP
  - Product specific MPT development is ongoing with partners
- ✓ The IMPT has defined MPT pipeline priorities and gaps
  - Helps set the R&D agenda for the future

Next…

- ✓ Informing/interacting with regulatory agencies and local country stakeholders will be crucial going forward
- ✓ Understanding market/commercialization issues for MPT is crucial to GO/NO GO decision making
- ✓ Consensus agreement on product priorities is crucial to achieve coordinated investment among funding organizations in MPT

Initiative for Multipurpose Prevention Technologies for Reproductive Health

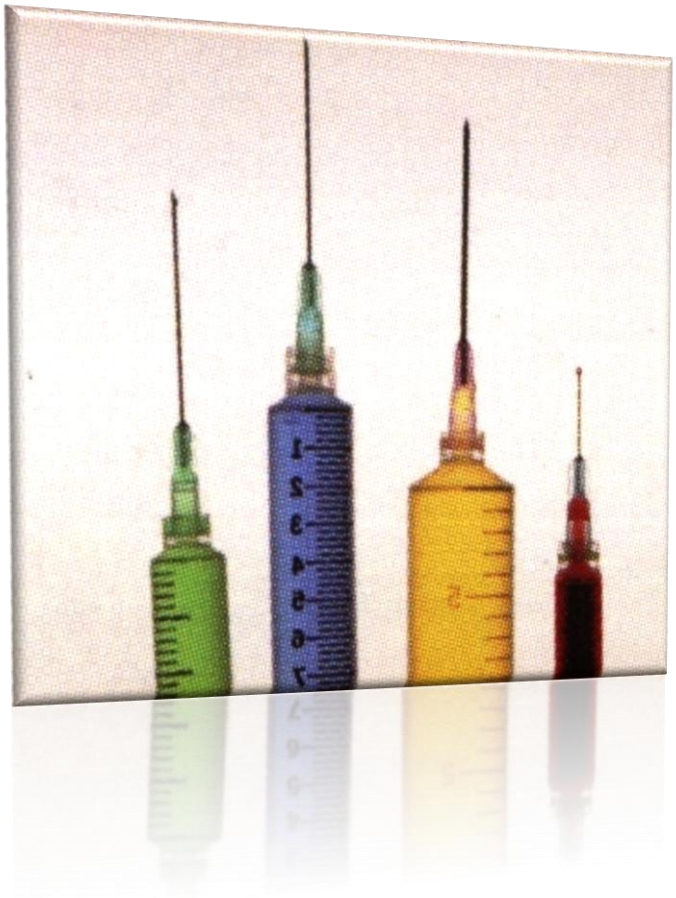
CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Make MPTs a reality!

Your Insights can help ensure *acceptable* and *successful* MPT development

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS



MULTIPURPOSE VACCINES FOR SEXUAL AND REPRODUCTIVE HEALTH

Q1

Which of the following vaccine combinations do you believe would be most useful for your clients?

(a) HSV (genital herpes) + HIV (AIDS)

(b) HSV + HIV + HPV (genital warts/cervical cancer)

(c) HSV + HPV

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Q2

What do you believe is the minimum acceptable efficacy rate (for all the pathogens targeted) of a MPT vaccine?

(a) 30 – 49%

(b) 50 – 69%

(c) 70 – 89%

(d) 90% +

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Q3 Which type of vaccine administration do you believe your clients prefer?

(a) Injection (by provider)

(b) Mucosal (needle-free and self-administered)

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Q4

How much do you believe most of your clients would be willing to pay for the entire series of an injectable MPT vaccine?

(a) $50 – $99

(b) $100 – $149

(c) $150 – $199

(d) $200 – $249

(e) $250 – $300

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Q5

Would adding a reversible contraceptive vaccine to a multipurpose STI vaccine lead to an overall increase in uptake by your clients?

(a) Yes

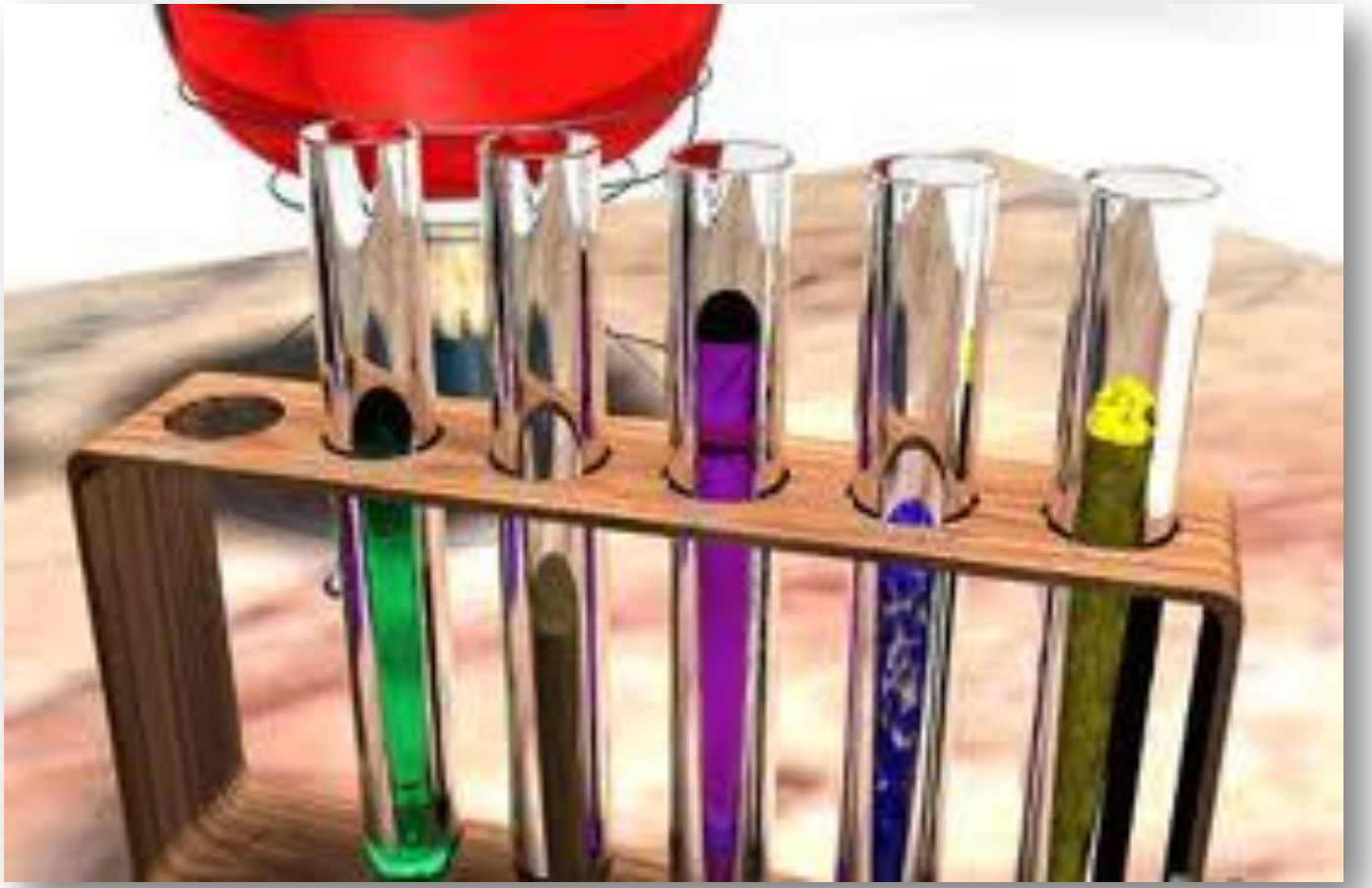
(b) No

(c) No difference

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

The time for MPTs is now



Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI
COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Acknowledgements

Thanks to the following individuals for their contributions to this effort:

- Joseph Romano (NWJ Group)
- Judy Manning (USAID)
- Wayne Shields (ARHP)
- Kathryn Stewart (CAMI)
- Susan Rosenthal (Columbia U)
- Diane Royal (CAMI)
- Kevin Whaley (Mapp Biopharmaceutical)
- Greg Zimmet (Indian U)

… and the following organizations for their critical support:

- Association for Reproductive Health Professionals
- Bill & Melinda Gates Foundation
- Mary Wohlford Foundation
- Microbicide Trials Network
- National Institutes of Health
- Public Health Institute
- US Agency for International Development
- Wellcome Trust

Learn more! www.mpts101.org

Initiative for Multipurpose Prevention Technologies for Reproductive Health

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

Thank you!

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 CAMI/PHI and its partners and do not necessarily reflect the views of USAID or the US Government.

Initiative for Multipurpose Prevention Technologies for Reproductive Health

USAID FROM THE AMERICAN PEOPLE

CAMI COALITION ADVANCING MULTIPURPOSE INNOVATIONS

References

Global Need: HIV & STIs

1. UNAIDS. Global Report: UNAIDS Summary of the AIDS Epidemic, 2010. http://www.unaids.org/globalreport/global_report.htm
2. PATH, UNFPA. Female Condom: A Powerful Tool for Protection. Seattle: UNFPA, PATH; 2006.
3. UNFPA. Reproductive Health: Breaking the Cycle of Sexually Transmitted Infections, 2009. http://www.unfpa.org/rh/stis.htm
4. UNAIDS. 2010: A Global View of HIV Infection. http://www.unaids.org/documents/20101123_2010_hiv_prevalence_map_em.pdf

Global Need: Family Planning

5. WHO. May 2012. Fact Sheet No. 348: Maternal Mortality. Media Centre. http://www.who.int/mediacentre/factsheets/fs348/en/index.html
6. Ashford L. Hidden Suffering: Disabilities From Pregnancy and Childbirth in Less Developed Countries. Population Reference Bureau, 2002. http://www.prb.org/pdf/HiddenSufferingEng.pdf
7. Singh S. and Darroch J.E. Adding It Up: Costs and Benefits of Contraceptive Services—Estimates for 2012. New York, NY: Guttmacher Institute and United Nations Population Fund (UNFPA), 2012. http://www.guttmacher.org/pubs/AIU-2012-estimates.pdf
8. WHO. 2010: Maternal Mortality Ratio. http://gamapserver.who.int/gho/interactive_charts/mdg5_mm/atlas.html

In the United States

9. Finer L.B. and Zolna M.R. Unintended pregnancy in the United States: incidence and disparities, 2006. *Contraception*, 2011: doi: 10.1016/j.contraception.2011.07.013.
10. Kost K., et al. U.S. Teenage pregnancies, births and abortions: National and state trends and trends by race and ethnicity. Guttmacher Institute, 2010.
11. Finer L.B. et al. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. *Perspectives on Sexual and Reproductive Health*, 2006: 38(2):90–96.
12. Centers for Disease Control and Prevention (CDC). Sexually Transmitted Disease Surveillance, 2009. Atlanta, GA: U.S. Department of Health and Human Services, 2010.
13. Kost K. Unintended Pregnancy Rates at the State Level: Estimates for 2002, 2004, 2006 and 2008, New York: Guttmacher Institute, 2013. http://www.guttmacher.org/pubs/StateUP08.pdf
14. Craft C. Sacramento County one of state's hotbeds for sexually transmitted diseases. Sacramento Bee, July 9, 2013. http://www.sacbee.com/2013/07/19/5577880/sacramento-county-one-of-states.html#storylink=cpy