Multipurpose Prevention Technologies for Sexual and Reproductive Health: the New Horizon

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Multipurpose Prevention Technologies (MPTs): products that simultaneously address the primary sexual and reproductive health concerns of women

- pregnancy + HIV
- pregnancy + other STIs
- HIV + other STIs
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MPTs for women: the public health rationale (data from WHO, 2002-10)

- HIV prevalence rate
- Total fertility rate
- Cervical cancer incidence rate
- % Women’s deaths from communicable, maternal, perinatal, & nutritional conditions

Data sources:
- World Health Statistics 2005
- Map production: Public Health Mapping and GIS, Communicable Disease (CD) World Health Organization
**Initiative for Multipurpose Prevention Technologies (IMPT)**

- **Created in 2009** – builds upon more than two decades of work on dual protection for SRH
- **Secretariat:** Coalition Advancing Multipurpose Innovations (CAMI), part of the Public Health Institute
- **Support:** USAID (primary); Mary Wolford Foundation; NIH Office of AIDS Research (NIH/OAR)

**Three Aims:**
- Provide a neutral forum to foster global collaboration on the development of MPTs
- Convene technical meetings to advance late-stage product development and introduction
- Expand international awareness and support for MPTs

**Active participation by representatives of:**

- **Universities** in China, India, Kenya, Nigeria, South Africa, UK, US
- **National & international agencies and donors** [USAID, FDA, National Institutes of Health (NIAID, NICHD, NIH/OAR); IPPF; WHO; Bill and Melinda Gates Foundation; Wellcome Trust]
- **FP/SRH Research Organizations** (California Family Health Council, CONRAD, IPM, Jhpiego, PATH, Population Council, Public Health Institute, RTI International)
- **SRH Policy and Advocacy Organizations** (AVAC, ARHP, Guttmacher Institute)
- **Biotechnology companies and organizations** (Auritec, Mapp Biopharmaceutical, Medicines360, Osel, ReProtect, Teva, WomanCare Global)
USAID’s priorities for MPT development:

✓ Sustained release devices:
  - User-controlled, but do not require daily action
  - Should increase acceptability and adherence, and therefore overall effectiveness

✓ “On demand” products:
  - Used at the time of intercourse
  - Appropriate for women who have infrequent sex, or who would like more direct control over their own protection
USAID-supported MPT development activities, 1:
Sustained-Release Combination Intravaginal Rings (IVRs)

- **90-day Tenofovir + LNG IVR**
  (2010 award to CONRAD; 5 years, $5 million ceiling)

  Project Aim: combine the hormonal contraceptive LNG with tenofovir in a vaginal ring, for the prevention of pregnancy, HIV and HSV-2.
  **Deliverables**: optimal dosing, clinical safety, PK/PD, and contraceptive effectiveness (Phase IIb).

- **60-day Dapivirine + Contraceptive IVR**
  [2011 award to the International Partnership for Microbicides (IPM); 5 years, $2 million ceiling]

  Project Aim: combine a hormonal contraceptive with dapivirine in a vaginal ring, for the prevention of pregnancy and HIV. (The current dapivirine ring will begin Phase III efficacy testing for HIV in mid-2012.)
  **Deliverables**: analytical development and ring formulation.
USAID-supported MPT development activities, 2: On Demand Barriers and Gels

- **SILCS Diaphragm + Tenofovir Gel**
  (2011 award to CONRAD; 5 years, $2 million ceiling)
  Project Aim: test the SILCS “one size fits most” diaphragm as a delivery device for tenofovir gel, reformulated to enhance contraceptive activity. The objective is a non-hormonal method of preventing pregnancy, HIV and HSV-2, and that provides protection for up to 24 hours.
  Deliverables: clinical safety, PK/PD, and post-coital testing.

- **MZL Combination Topical Gel**
  (ongoing work with the Population Council)
  Develop a multipurpose vaginal gel that combines MIV-150 and Zinc Acetate with the progestin LNG for protection from pregnancy, HIV & HSV-2, and that lasts up to 24 hours. Current work focuses on gel formulation optimization and initial PK in vivo.
USAID-supported MPT Regulatory Activity:

- Facilitating Regulatory Approval of MPTs (Population Council)
  - review existing guidance on combination products from Regulatory Authorities (RAs) such as the FDA, EMA, and ICH
  - develop clarifying questions for the FDA and other RAs on approval pathways for MPTs
  - convene technical meetings to discuss possible streamlined pathways for approval
  - work with WHO to connect with other RAs in sub-Saharan Africa and south Asia on developing approval processes for MPTs
Our Ultimate Goal for Multipurpose Prevention Technologies:

Expand the range of Effective, Acceptable, and Accessible prevention options for women that meet different sexual and reproductive health needs as they change over time.

We want your input!

Please respond to a 2-minute survey on MPTs:

https://www.surveymonkey.com/s/MPTsDec1English

https://www.surveymonkey.com/s/MPTsDec1Francaise

Additional information will be presented at the MPT panel session this afternoon, 4:00 – 5:30pm, in Salon Vert.

THANK YOU!

Informations supplémentaires seront présentés lors de la session de panel MPT, cet après-midi de 16h00 à 17H30, qui aura lieu dans le Salon Vert.

MERCI!