Background

Unprotected sex puts women worldwide at simultaneous risk of HIV, other sexually transmitted infections (STIs), and unintended pregnancy, all of which can impose heavy burdens on morbidity and mortality. “Multipurpose Prevention Technologies” (MPTs) integrating contraception and prevention of HIV and other STIs would address these combined risks and, with potentially improved uptake, enhance public health impact.

Risks Worldwide...
- 36 million unintended pregnancies worldwide annually
- 222 million women in low-resource settings use no contraception
- 550,000 annual deaths due to complications from pregnancy and childbirth
- 2.7 million annual new HIV infections, many in Sub-Saharan Africa (SSA), young women
- 1.8 million annual AIDS deaths
- 20 million annual new genital herpes infections
- 340 million annual STI infections curable with antibiotics (chlamydia, gonorrhea, syphilis)

Methods and Research Strategy

**Hypothesis:** Different global regions have different epidemiological dynamics, reproductive health needs and public health priorities, so priorities for MPT research and development will also differ.

**Objectives**
- Identify MPT products with highest potential for public health impact
- Provide guidance for donors, product developers & regulators regarding strategies for MPT R&D and investment needs

**Materials and Methods**
- Established Target Product Profile (TPP) Working Groups
- Constructed TPPs defining ideal & minimally acceptable product attributes, critical technical parameters, considerations of costs, time, regulatory complexity, manufacture & distribution
- Strategic sequence of quantitative surveys and qualitative interviews among sexual and reproductive health researchers and providers in Africa, Asia, and USA
- Expert review, consensus on common themes, capture of outlier positions
- Established Scientific Agenda Working Group (SAWG) to compile and describe integrated “pipelines” of candidates with contraceptive, anti-HIV & anti-STI activity, and relevant “platform” components
- Review of existing guidance on combination products, ongoing interaction with regulatory authorities, to clarify clinical path

Results: Key Findings & Actions

**Priority Indications**
1. HIV and pregnancy
2. HIV and STIs (HIV, HPV, BV)
3. STI and pregnancy
4. Other STIs, with contraception not a priority

**Dosage Forms**
- Sustained release
- Topical formulation over oral
- Parenteral formulation over daily
- Major determining factor: adherence
- Highest development priority: vaginal rings

**Efficacy Targets**
- HIV: 40-60%; STI: at least 40%
- Contraception: levels of currently available products (~95%)

**Solution:**
- **Multipurpose Prevention Technologies (MPTs)**
- Single products integrating contraception & prevention of HIV & other sexually transmitted infections

Conclusions

Promising innovations include multipurpose vaccines and gels, co-target vaginal rings and single-sized devices that may provide simultaneous protection against unintended pregnancy and infection, and have a major impact on the health of women and their families worldwide.

**Progress**
- Linked, interdisciplinary approach has built a framework for:
  - Identifying priorities needs & preferences
  - Analyzing MPT pipeline
  - Identifying gaps
  - Mapping a “plausible” critical path
  - Guiding investment
  - General development priorities & fundamental design targets for MPT products exist
  - MPT product development consistent with priorities & TPPs under way

**Challenges**
- Regional differences
- Unique, product-specific regulatory considerations
- Pipeline efficiency? Gaps!
- Hormonal contraception & HIV relationships relevance?
- Trial design (not efficacy without placebo control)
- Resources (money, trial capacity, participants, development partnerships)

Bottom Line... the path to an “ideal” MPT is not linear