Supporting Agency Coordination and Cooperation in the Development of Contraceptive Methods Appropriate for Provision and Use in Low Resource Settings

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Panel Session: From Bench to Bedside: Perspectives on the Challenges and Opportunities for Introducing New Contraceptives

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Despite more than 50 years of success in the development, introduction and use of FP, more than 222 million women in low resource countries still have an unmet need*.

Method-related reasons account for 70% of unmet need:

- Concerns about side effects: 22%
- Appropriate for infrequent use: 21%
- Appropriate for use by post-partum or breast-feeding women: 17%
- Partner opposes the method: 10%

* Guttmacher Institute, 2012. *Adding it up: Costs and benefits of contraceptive services.*
There is also a great need for women-centered methods that prevent HIV and other sexually transmitted infections (STIs). Each year, more than two million women die of AIDS, and cervical cancer caused by Human Papillomavirus (HPV)*.


- Each year, 1.8 million women die of AIDS...
- ... and 2.7 million more become infected with HIV

- Annually, 275,000 women die of cervical cancer
- New vaccines against HPV infection could ultimately prevent ~500,000 new cases of cervical cancer every year in resource-poor settings
Governments, foundations, private sector and civil society organizations from around the world came together and committed more than $2.6 billion to the goal of assuring access to voluntary FP to 120 million additional women by 2020.

New and refined FP products designed to address the method-related reasons for unmet need, and that also prevent HIV and other STIs, could help to contribute to reaching the FP Summit goal.

Recommendations: USAID’s contraceptive R&D program should focus on the following critical unmet needs: non-hormonal methods, dual protection (pregnancy/HIV) methods, male contraception, and non-surgical sterilization. Any new method should be appropriate for delivery and use in low resource settings.

Bill & Melinda Gates Foundation Landscape Analysis (2010)

Outcomes: BMGF prioritized support for methods for women in three discovery areas: pericoital, non-hormonal, and permanent; and five late-stage technologies with high-impact potential: pericoital “on demand” pill; long-acting injectable; vaginal rings; Sino-Implant (II); and Sayana Press.

US Institute of Medicine “Future of Contraceptive R&D” meeting (2012)

Recommendations: The recently-established Contraceptive Technology Donors Working Group should expand to include other donors and foundations, and establish and prioritize a contraceptive R&D agenda that addresses gaps that need to be filled.


Recommendations: 1) Donors and developers strongly encouraged to reach consensus on development objectives; 2) Important to identify single MPT leads through common R&D pathways; 3) Coordinated investment and collaborative development is critical.
Supporting Agency Collaboration on FP/RH R&D

Contraceptive Technology Donor Working Group (CT-DWG)

established in 2010
as a result of the Gates Foundation FP/RH Biomedical R&D landscape analysis,
and subsequent donor mapping exercise

ORGANIZATION

Secretariat: Gates Foundation

Membership:

- US NIH / National Institute of Child Health & Human Development (NICHD)
  - USAID, Office of Population & Reproductive Health
    - Other donors as identified

Schedule of meetings: face-to-face bi-annually,
and by teleconference as needed
Prevention products that better meet the needs of women and girls as their reproductive health concerns change over time:

- **Refined FP methods** that are more effective, acceptable, affordable, and easier to provide and/or use
- **New FP methods** that fill “duration of effectiveness” gaps in the existing method mix, or that address other barriers to use
- **Multipurpose prevention technologies (MPTs)** for unintended pregnancy, HIV and other STIs
Leveraging Supporting Agencies’ Strengths to Enhance Collaboration on FP/RH R&D

**CT-DWG Members’ Respective Focus:**

- **NICHD** -- Leads on R&D of new contraceptive methods for men and women. Early products undergo biological testing and preclinical toxicology. Qualified products are evaluated for safety and effectiveness in the NICHD Contraceptive Clinical Trials Network.

- **USAID** -- Leads on R&D of contraceptives and MPTs for women that are appropriate for provision and use in low resource settings.

- **Gates Foundation** -- Leads on efforts to reduce the risk of introducing new contraceptive products; takes on longer term, higher risk investments in contraceptive discovery, research and development.
FP/RH R&D and Introduction: What it Takes

R&D Total $$: $\sim 250M$

Clinical Testing

- Discovery
  - High-throughput screening

- Pre-clinical
  - Laboratory & animal testing

- Phase I
  - 20-100 volunteers: safety & dosage
  - 1-5% success rate

- Phase II
  - 100-500 volunteers: efficacy & side-effects
  - 40-60% success rate

- Phase III
  - 1,000-1,500 volunteers: long-term use study
  - 60-80% success rate

- RA review

Product Intro
Total $$: $\sim 75M$

Time: $\sim 7$ years

Total time: $\geq 15$ years

- Product Intro
  - $\sim 5-20 \times 10^6$

- Ongoing
  - $\sim 50-100 \times 10^6$
FP/RH R&D and Introduction: the Essential Role of Supporting Agency Coordination

Discovery
- High-throughput screening
  - 10,000 compounds
  - 1-5% success rate
  - 5 years

Pre-clinical
- Laboratory & animal testing
  - 250 compounds
  - 1 year

Phase I
- 20-100 volunteers: safety & dosage
  - 5 volunteers
  - 1.5 years

Phase II
- 100-500 volunteers: efficacy & side effects
  - $5-20 \cdot 10^6
  - 50-70% success rate
  - 2 years

Phase III
- 1,000-1,500 volunteers: long-term use study
  - $80-100 \cdot 10^6
  - 60-80% success rate
  - 2.5 years

RA review
- $1.2 \cdot 10^6
- 20% success rate

Product Intro
- Ongoing
- $50-100 \cdot 10^6
Future Aims of Supporting Agency Coordination on FP/RH R&D

- Further address the method-related reasons for unmet need by developing contraceptive products that are:
  - Non-hormonal
  - Appropriate for use by post-partum and breast-feeding women
  - Appropriate for occasional use by women who have infrequent sex
  - Discreet (can be used without the partner’s knowledge or consent)

- Expand research on new technologies with high impact potential:
  - Nonsurgical permanent contraception for women and men
  - Long-acting, reversible contraceptive methods

- Support “flagship” contraceptive R&D projects that provide:
  - Long term commitment to the full product development and innovation process
  - Flexibility to incorporate scientific break-throughs and other opportunities
  - Responsiveness to method-related concerns as they arise from the field

Thank you!