



**Report of a Symposium
Berkeley, California, USA
24-25 March 2009**

Rapporteur

Alan Stone, MEDSA Limited, London, UK

Supporting Organizations:

Alliance for Microbicide Development; California Microbicide Initiative/ Public Health Institute; CONRAD; International Partnership for Microbicides; Mary Wohlford Foundation; National Institutes of Health/Division of Microbiology and Infectious Diseases; PATH; Population Council; University of California, Berkeley; University of California (Discovery Grant); University of California, San Francisco; United Nations Population Fund; US Agency for International Development; Venture Strategies for Health and Development; World Health Organization; and Mapp Biopharmaceutical.

This report presents the collective views of an international group of experts (see Annex 2) and does not necessarily reflect the decisions or stated policies of any of the institutions whose staff participated in the discussions or of the organizations which supported the symposium.



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* *Members of Symposium Planning Committee (Chair: Bethany Young Holt)*

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Executive Summary

The urgent need for effective methods to prevent infection with HIV, the massive global burden of other sexually transmitted infections (STIs), and the scale of the unmet need for contraception all highlight the need for a range of preventive technologies that are acceptable, affordable, accessible, and easy to use and that can meet the varying needs and intentions of individuals.

In the broad field of sexual and reproductive health, there is a great deal of activity aimed at developing methods for the prevention of unintended pregnancy, HIV, other STIs and reproductive tract infections (RTIs). However, the manner in which this agenda has evolved has led to the major emphasis being on protection against single indications, either pregnancy, HIV, or other infections. It does not adequately embrace the urgent need to increase the range and availability of *multi-purpose* technologies that can protect individuals from several or all of these.

Providing people with suitable protection is a continuing challenge, especially in settings where access to health services is limited, and the availability of technologies that address more than one indication would be a significant improvement in terms of efficiency and convenience. The provider would be able to stock, supply, and advise on a more compact range of products, and the user would need to purchase, understand, store, and use fewer products. A further advantage is that users would be protected automatically against more than one indication even if they had obtained the product with regard to a single perceived risk.

To achieve the important goal of developing and deploying effective, acceptable, and affordable multi-purpose prevention technologies will require a determined, well-coordinated, and innovative effort.

In recognition of this, an international symposium was convened in Berkeley, California, USA, in March 2009 with the goal of accelerating the development and deployment of relevant multi-purpose technologies and strategies. In view of the unusual breadth of the topics that necessarily impinge on this aim, invited delegates (*see Annex 2*) were drawn from a wide range of relevant disciplines, from the basic sciences to family planning, sociology, public health, and international development.

The meeting agenda was designed to maximize the opportunity for this group of international experts to share diverse kinds of information and discuss ideas over a period of two days. The first session set the scene by defining multi-purpose technologies in the context of sexual and reproductive health and illustrating the need for them. This was followed by sessions devoted to exploring strategies for developing, respectively, multi-purpose devices, preventive vaccines, microbicides, and other relevant multi-purpose preventive technologies. In each session delegates considered existing and evolving technologies and related services, and priorities for developing multi-purpose technologies. The main challenges were identified in both the development and deployment of these new technologies, and measures were discussed that might help to overcome obstacles to progress.

These technical discussions were followed by a session devoted to the integration of multi-purpose technologies into prevention strategies and service delivery. This began with an expert panel whose aim was to identify the biomedical, social science, regulatory, advocacy, and programmatic strategies needed in order to achieve this. Delegates then broke into five working groups which focused in more detail on priorities for advancing appropriate scientific strategies and policy requirements.



Priorities identified by the group:

Microbicides and combination devices

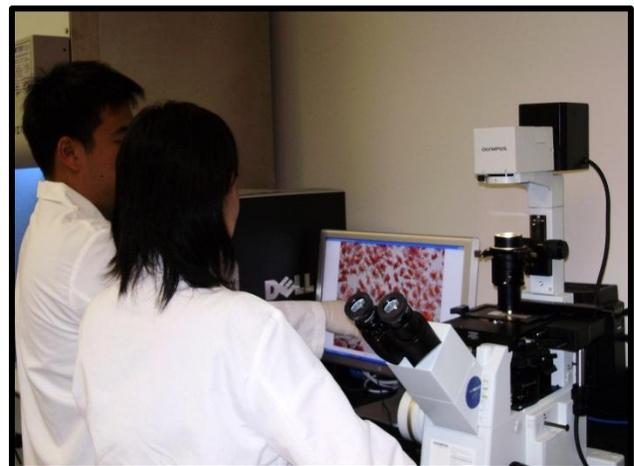
- Increase understanding of cervical, vaginal, and rectal physiology and of the effects of the product on mucosal safety in terms of increasing the risk of infection
- Investigate the estrogenization of the vaginal epithelium and its significance regarding susceptibility to infection
- Expand the pipeline of product leads to include agents active against other STI pathogens as well as HIV
- Explore alternative dosage forms in terms of pre-clinical/clinical assessments of safety and efficacy, effects on PK/PD level. Develop more informative animal models for such studies
- Enhance regulatory involvement in product development from an early stage, especially the development of combination products
- Strengthen manufacturing capacity.



Source: http://www.cami-health.com/APT2009/PDFs/Manning_Mar09.pdf

Vaccines

- Increase understanding of how to generate an effective immune response in the genital tract, including by mucosal immunization, especially studies in humans (children and adults). The potential role of mucosal immune tolerance
- Identify immune correlates of protection for each infectious agent prior to advancing products into Phase III trials
- Expand basic knowledge of the male and female genital tracts and of the rectum, and the effects of changes related to pregnancy, aging, and HIV infection
- Develop improved pre-clinical animal models for safety and efficacy, for vaccines against HIV and against other STIs, and for immune adjuvants
- Develop univalent vaccines in preparation for the development of multivalent vaccines
- Explore more intensively the use of monoclonal antibodies, including the use of animal models.
- Encourage investigator-initiated proposals for studies on samples from clinical trials
- Support the creation and improvement of centers of excellence that bring together diverse kinds of expertise.



Source: Osel, Inc.



Social and behavioral science

- Support stand-alone research as well as integrated approaches for collecting data within and independently of clinical trials
- Integrate social and behavioral science early in the product development process
- Explore societal norms in sexual and reproductive health in terms of partner types, sexual practices, pleasure, communication, the prevention of pregnancy and infections, and the use of intravaginal devices
- Product acceptability with respect to users, health practitioners, community and policy leaders
- Adherence: studies of how to measure and improve it (including triangulation models)
- The use of behavior change models in research and program development
- How to optimize the use of information in policy development, in ethical considerations (for example subsequent to a clinical trial; public health ethics) and in programmatic development
- Improve research methodology in terms of rigorous design, better data collection and analysis, and building capacity in developing countries.



Source: http://www.cami-health.com/APT2009/PDFs/justman_3.09.pdf

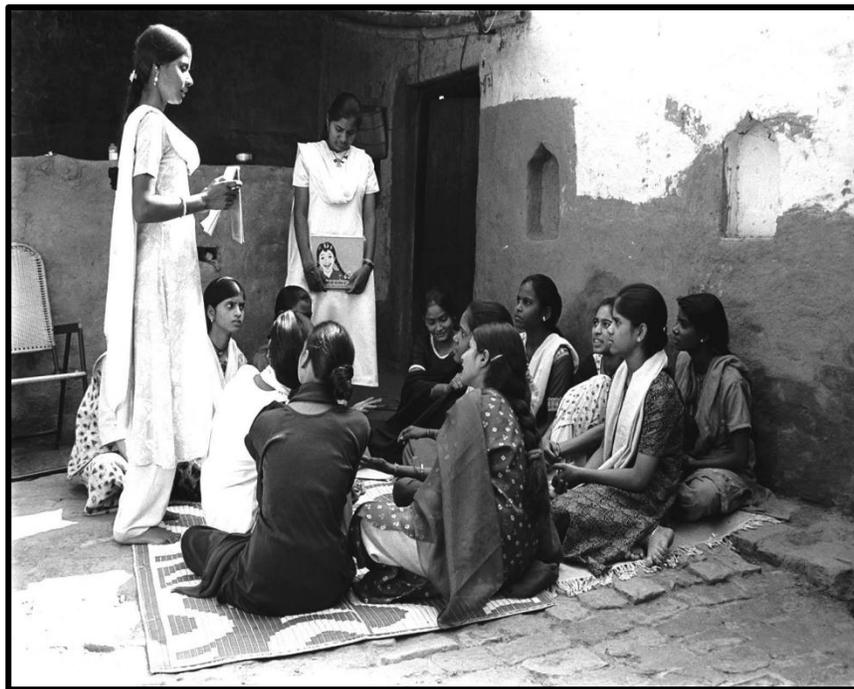
Advocacy

- Develop multiple communication strategies
- Consider ways and means for ensuring access to new products (especially for those who participated in the clinical trials)
- Address issues of quality of care for research participants and the community, including issues of training, confidentiality and health promotion and education
- Sustainability of support after the trial has completed
- Creation of demand for new products, balanced with supply.



Programmatic

- Consider how *existing* sexual and reproductive health technologies can help to fill gaps given appropriate advocacy efforts
- Stimulate the demand for new technologies, bearing in mind the need to avoid creating unrealistic expectations
- Share information on product acceptability, efficacy, and cost to individuals and organizations that need to know
- Bring the cost down of new technologies by encouraging open sourcing and competition, developing a market-driven approach (need to align supply and demand), and encouraging task-shifting to enhance efficiency and scalability
- Increase literacy about health matters and support the development of cultural competence consistent with benefiting from new technologies
- Integrate new approaches into existing strategies.



Source: <http://www.cami-health.com/APT2009/PDFs/Brady.pdf>



Next Steps

The main symposium was followed by a more focused Strategy Meeting whose aim was to sustain the initiative by identifying appropriate strategies for addressing scientific priorities and policy needs and laying out the steps for moving the work forward. It was agreed that a document would be prepared to draw the attention of donors and others to the urgent need for multi-purpose prevention technologies in sexual and reproductive health, and to provide a case for securing the funds necessary for advancing this agenda.

With this objective in mind, three Working Groups were established, respectively (i) to develop appropriate messaging and a suitable Mission Statement; (ii) to consider the detailed position regarding existing multi-purpose technologies; and (iii) to consider the status of technologies still under development, including microbicides, PrEP, methods for the post-coital prevention of infections and pregnancy, and vaccines for a broad range of indications including HIV. Information will also be collated on the relevant technical and programming activities of major agencies and institutions internationally. Delegates agreed that these activities would be crucial to achieving the important objective of getting multi-purpose technologies firmly on the agendas of such organizations.

[The complete report can be found at: www.cami-health.com]



Speakers and Presentations

Welcoming Remarks: Bethany Young Holt, CAMI/Public Health Institute/ UC Berkeley

Plenary 1: Defining Multi-Purpose Technologies in the Context of Sexual and Reproductive Health

Moderator: Jeff Spieler, US Agency for International Development

Why we need multi-purpose prevention technologies: the USAID perspective

Presenter: Judy Manning, US Agency for International Development

Critical linkages: HIV, other sexually transmitted infections (STI), and their shared need and potential for prevention

Presenter: Jessica Justman, Columbia University

Contraception as a component of multi-purpose sexual and reproductive health technologies

Ward Cates, Family Health International

Session 1: Strategies for Developing Multi-Purpose Devices

Moderator: Jessica Cohen, PATH

The condom conundrum: lessons learned from promoting the male and female condom as "dual protection" methods

Presenter: Bidia Deperthes, United Nations Population Fund

Deconstructing the MIRA trial: what has been learned and how might remaining questions be answered

Presenter: Nancy Padian, RTI International

Update on approaches to advancing cervical barriers for pregnancy and disease prevention

Presenter: Marianne Callahan, CONRAD

Advancing female condoms: product status, regulatory challenges, and commercialization opportunities

Presenter: Maggie Kilbourne-Brook, PATH

The potential of vaginal rings as multi-purpose SRH prevention devices

Presenter: Meredith Clark (for Patrick Kiser), University of Utah



Session 2: Strategies for Developing Multi-Purpose Preventive Vaccines

Moderator: Kevin Whaley, Mapp Biopharmaceutical

Multi-purpose vaccines: safety, efficacy, and acceptability

Presenter: Kevin Whaley, Mapp Biopharmaceutical, Inc.

Deployment of multi-purpose pediatric vaccines and STI vaccines (HPV, HBV)

Presenter: Eileen Yamada, California Department of Health

Developing vaccines that prevent cervicovaginal transmission

Presenter: Jiri Mestecky, University of Alabama, Birmingham

Industrialization of multi-purpose vaccines

Presenter: Charlie Arntzen, Arizona State University

Plenary 2: Obstacles and Opportunities for Accelerating Development of New SRH Prevention Technologies and Integrating Them into Existing Service Delivery

Moderator: Jeff Spieler, US Agency for International Development

Obstacles and opportunities for accelerating development of new SRH technologies: evidence from experience

Presenter: Sharon Camp, Guttmacher Institute

HIV/STI, family planning, and reproductive health: integrating service delivery on the ground in the United States

Presenter: Vanessa Cullins, Planned Parenthood Federation of America

Responding to women's multiple SRH needs with multi-purpose technologies: matching users' needs, technologies, and service delivery platforms

Presenter: Martha Brady, Population Council



Jeff Spieler, Ward Cates, Judy Manning, and Jessica Justman



Session 3: Strategies for Developing Multi-Purpose Microbicides and Other Relevant Multi-Purpose Technologies

Moderator: Polly Harrison, Alliance for Microbicide Development

Surveying the microbicide pipeline for potential combinations

Presenter: Charles Kelly, King's College London

Explicit combination development programs and translational tools for multi-purpose technologies

Presenter: Gustavo Doncel, CONRAD

Versatile platforms for manufacturing and delivery of multi-purpose microbicides

Presenter: Jim Turpin, US National Institutes of Health

Other technologies with multi-purpose potential

Presenter: Daniel Halperin, Harvard School of Public Health

Learning from trials: STIs as secondary endpoints

Presenter: Sharon Hillier, University of Pittsburgh, Magee Women's Hospital

Session 4: Integrating Multi-Purpose SRH Technologies into Prevention Strategies (A Strategy Panel)

Moderator: Wayne Shields, Association of Reproductive Health Professionals

Social Science: Cynthia Woodsong, International Partnership for Microbicides

Biomedical: Deborah Anderson, Boston University

Biomedical: Joe Romano, International Partnership for Microbicides

Regulatory: Bob Russell, RJR Consulting

Programmatic: Melodie Holden, Venture Strategies for Health and Development

Programmatic: Heidi Bauer, California Department of Public Health, STD Control Branch

Advocacy: Angelina Namiba, International Community of Women Living with HIV

Presentations are available in PDF format at <http://www.cami-health.com/APT2009/speakers.html>.