

Advancing Prevention Technologies for Sexual and Reproductive Health

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Supporting Organizations

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**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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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.

The main priorities identified by the respective groups were:

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.

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.

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.

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.

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.

List of Acronyms

ARV	antiretroviral drug
CGMP	Current Good Manufacturing Practice
CT	<i>Chlamydia trachomatis</i>
HIV	human immunodeficiency virus
HBV	hepatitis B virus
HPV	human papillomavirus virus
HSV	herpes simplex virus
Ig	immunoglobulin
IUD	intrauterine device
IVR	intravaginal ring
NG	<i>Neisseria gonorrhoeae</i>
NNRTI	non-nucleotide reverse transcriptase inhibitor
NRTI	nucleotide reverse transcriptase inhibitor
OTC	over-the-counter
PrEP	pre-exposure prophylaxis
RTI	reproductive tract infection
STI	sexually transmitted infection
TV	<i>Trichomonas vaginalis</i>
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
VCT	voluntary counseling and testing

Introduction

Rationale

The stimulus for the symposium that is the subject of this report was a perceived and urgent need to develop and deploy safe, effective, accessible, and easy-to-use *multi-purpose* preventive technologies for sexual and reproductive health that will provide protection against two or more of the following: unintended pregnancy, HIV, STIs more broadly, and other common RTIs. Yet, despite its importance and broad potential benefit, this public health need has been only erratically and inadequately addressed and confronts a range of scientific and practical challenges. To redress this state of affairs will require determined, well-coordinated, and innovative effort.

While multi-purpose prevention technologies may benefit both men and women, it is women who, for complex physiological and societal reasons, are more vulnerable. While the preventive needs and preferences of women vary between individuals and over time as life circumstances change, their need to protect themselves is a continuing burden, especially in settings where access to health services in general and protective technologies in particular present challenges. Technologies that would address more than one indication would significantly improve efficiency and convenience for providers, who would be able to stock, supply, and advise on a more compact range of products, and users, who would need to purchase, understand, store, and use fewer products. A further important advantage in terms of individual protection and public health is that users would be protected automatically against more than one indication even if they had sought a given product to address just one perceived risk.

Male condoms are well known to offer a high level of protection against both pregnancy and sexually transmitted infections. Unfortunately, despite strenuous efforts to promote their use, condoms are often not used or are used inconsistently, especially between non-casual partners. This is reflected in the fact that unsafe sex is one of the highest risk factors for disability and death worldwide. Every year, 340 million people acquire at least one of the four primary curable STIs (*Neisseria gonorrhoeae*/NG), *Chlamydia trachomatis*/CT), *Trichomonas vaginalis*/TV), and syphilis, and just under 3 million become infected with the human immunodeficiency virus (HIV). In addition, untold numbers acquire chronic infections with pathogens such as the herpes simplex virus/HSV, a cause of genital ulcers, and the human papillomavirus virus/HPV, responsible for cervical cancer. In addition, recent research estimates that over 200 million women in developing countries have an unmet need for effective contraception (UNFPA 2005).

Even though there is much vitally important prevention work in each of these areas, that work tends to be focused on specific objectives: development of vaccines, microbicides, and Pre-exposure Oral Prophylaxis/PrEP with antiretroviral drugs for HIV prevention; implementation of male circumcision programs and behavioral interventions to reduce the spread of HIV; clinical trials of physical barriers such as diaphragms and of STI treatment [s a possible means of achieving this same aim; and vaccination of young girls against HPV infection. Yet the needs of individuals are generally broader than those being addressed by these targeted objectives, highly commendable as they are.

Goals and Objectives

The broad goal of the Symposium was to accelerate the development of multi-purpose technologies and strategies to prevent unintended pregnancy, sexually transmitted infections, and other common reproductive tract infections. Given the unusual breadth of the topics that necessarily impinge on this goal, the 140 invited delegates from 11 countries (*see Annex 2*) were drawn from a wide range of disciplines: basic sciences, 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 two-day period.

The three formal objectives of the symposium were to:

- Provide a forum to review the status of multi-purpose sexual and reproductive health prevention technologies
- Identify critical biomedical, social scientific, regulatory, programmatic, and advocacy priorities and challenges in the development and deployment of these technologies
- Explore strategies and best practices for further developing multi-purpose sexual and reproductive health prevention technologies and deploying them as they become available.

The symposium was followed by a small Strategy Meeting of 26 participants – funders, researchers and programmatic experts – charged with sustaining and advancing the initiative by identifying appropriate strategies for addressing gaps and taking the next necessary steps. The main conclusions and decisions reached at the Strategy Meeting appear at the end of this document following the report on the symposium itself.

Plenary 1. The need for multi-purpose prevention technologies

The main factors underlying the urgency of developing and deploying multi-purpose technologies for sexual and reproductive health were reviewed by *Judy Manning (US Agency for International Development, Washington, DC, USA)*. The targets for such technologies, from the perspective of USAID's Bureau for Global Health, are to achieve the healthy timing and spacing of pregnancies; safe birth for both mother and child; and protection against STIs, including especially HIV, HPV, HSV, gonorrhea, and chlamydia.

The unmet need for contraception is starkly illuminated by the degree of coincidence between the high fertility levels typical of many Sub-Saharan African nations and some parts of South Asia (often greater than 5 children per woman), low contraceptive prevalence (below 40%, compared with 75% and above in regions with fertility rates below 3 per woman), unacceptable levels of maternal mortality (over 500 – sometimes over 1,000 – deaths per 100,000 live births), under-five mortality (often over 150 per 1,000 live births), and the prevalence of underweight children (in many cases over 30%).

Wider implementation of voluntary family planning would not only mitigate these health deficits but would enable women to fulfill their potential for education, employment, and full participation in society. In the longer term, it would also mitigate the adverse effects of rapid population growth on natural resources, economic growth, and state stability.

The urgent need for effective methods to prevent infection with HIV (2.7 million new cases in 2007) is self-evident. The adult prevalence of HIV infection – incurable and manageable only where the relevant treatment facilities are available – is as high as 28% in some Sub-Saharan African countries and over 5% in parts of Asia and Eastern Europe. The massive global burden of other STIs (several hundred million cases each year) is associated with a high prevalence of morbidity and mortality. Untreated gonorrheal and chlamydial infections in women result in pelvic inflammatory disease in 40% of cases, with a quarter of those progressing to infertility. Cervical cancer results in

the untimely death of 240,000 women every year in resource-poor settings, yet most of these deaths could be prevented by efficient deployment of the new vaccines against HPV infection.

The challenge is to develop a range of multi-purpose products that are acceptable, affordable, and easy to use and that can meet the varying needs of individual women by addressing, in various combinations, the prevention of pregnancy and HIV; of pregnancy and other STIs; of HIV and other STIs; and of pregnancy, HIV and other STIs. Towards this aim, USAID, through partners, including CONRAD, the Population Council, PATH, International Partnership for Microbicides, and Family Health International, is supporting pre-clinical research, effectiveness trials and pre- and post-introduction studies on a range of products, both coitally-dependent and long-acting. These include semi-solid gels, gel capsules, films, intravaginal rings/IVR, sponges, compound-releasing intrauterine systems, diaphragms, and male and female condoms with and without spermicidal or anti-infective agents. It is of course fully recognized that these technologies will not by themselves achieve all the desired goals and that they will need to be introduced with care, with their deployment preceded and accompanied by well-designed educational programs.

Jessica Justman (Columbia University, New York, NY, USA) compared the pathophysiology and epidemiology of HIV with those of other STIs and discussed approaches to preventing these infections. HIV targets intraepithelial CD4 + cells in the vagina, in part through breaks in the epithelium. Viral replication and infection of other susceptible lymphocytes lead to widespread infection, deterioration of the immune response and, eventually, to opportunistic infections and death. In contrast, NG, for example, attacks columnar epithelial cells, followed 1-2 days later by submucosal infection. Purulent cervicitis may occur, but this rarely becomes systemic and the infection generally resolves. For both these pathogens and for CT, infections are common in Sub-Saharan Africa as a result of unprotected sex, multiple partners, and sexual networks. “Hot spots” showing this joint prevalence are also seen in other areas, including in New York City.

The global mortality rates associated with HIV and other STIs are, however, quite different: 2 million per year for HIV compared with under 300,000 for HPV-induced cervical cancer and far fewer for other STIs. The transmission rates are also very different, estimated as 0.008 per coital act in acute HIV infection and over 0.4 for CT and NG. HIV infection can be treated with antiretroviral drugs but it cannot at present be cured and neither can the other viral STI pathogens, HPV and HSV. On the other hand, chancroid, CT, NG, syphilis, and TV chancroid are curable.

Turning to prevention, male condoms have been shown to reduce HIV infection by 80% and to reduce acquisition rates for CT, HSV, NG, and syphilis in both men and women. Evidence regarding the ability of male condoms to reduce women’s acquisition of HPV and TV is less clear. Female condoms have not yet been shown to prevent HIV but appear to be as effective as male condoms against CT, NG, and TV. Clinical trials have shown that male circumcision reduces female-to-male HIV transmission by 50-76% but does not reduce male-to-female HIV transmission; and protects men from acquisition of the other viral STI pathogens, HSV-2 and HPV, but does not prevent transmission of other STIs (CT, NG, syphilis, or TV) in either direction. Community-level interventions to reduce HIV acquisition by use of antibiotics to treat STIs have had mixed success. A reduction of 38% was observed in a region where the HIV epidemic was still evolving, yet no significant effect was seen where the epidemic was more stable.

With the exception of 0.5% PRO 2000 gel, none of the microbicides that have so far completed effectiveness trials, i.e., BufferGel, carrageenan, cellulose sulphate, and nonoxynol-9, have shown evidence of protection against HIV infection in effectiveness trials (*see section on Multi-purpose Microbicides, below*). Nor have any of these products, including 0.5% PRO 2000, demonstrated clinical

evidence of reduction of infection by any other STI pathogens, despite evidence of such activity *in vitro* and in animal models.

Several antiretroviral drugs are under development for use as microbicides, including inhibitors of HIV's reverse transcriptase and agents that prevent attachment and fusion of the virus to its target cell, but no effectiveness trial of such products has been completed. Because these are all specific anti-HIV agents, no activity against other STIs is anticipated. Clinical trials of PrEP are also underway, involving daily oral dosing with HIV reverse transcriptase inhibitors. A large trial of antiretroviral therapy in discordant couples is also currently enrolling, and the recent observation that this approach was successful among discordant couples in Rwanda and Zambia is encouraging. It is recognized that the use of ARVs for prevention may create problems related to drug-resistant HIV strains and research on this aspect is receiving due attention.

In summary, despite considerable evidence of causality between HIV and other STIs – for example, the substantial influence of HSV on HIV transmission and progression – no oral or topical prevention product has yet produced clinical evidence of efficacy against non-HIV STIs nor are new products that are tightly HIV-specific expected to do so.

The wider value of contraception as a multi-purpose sexual and reproductive health technology was discussed by *Ward Cates (Family Health International, Research Triangle Park, NC, USA)*. The majority of individuals who use some form of contraception are not infected by HIV or other STIs, even in high-prevalence regions, and despite earlier suggestions that hormonal contraception might increase HIV risk, more recent data indicate that this is not the case. It has been estimated that for discordant couples engaging in two acts of unprotected intercourse per week, very early transmission of syphilis and NG are likely, and CT soon after, followed by pregnancy several months later, and HIV perhaps six months after that. This time-scale would be extended by a factor of 20-40 if the same couples used male condoms correctly and consistently. Moreover, effective contraception for HIV-infected women who do not wish to become pregnant would significantly reduce the number of children born with HIV and also decrease the number of future orphans.

The effectiveness of any preventive technology is closely related to adherence, and the typical use of male and female condoms, spermicides, diaphragms, and oral contraceptives is generally far from perfect, so that their protective benefits are reduced accordingly. Conversely, long-acting contraceptive technologies that do not require a decision to be made prior to sex, such as intrauterine devices/IUD, male or female sterilization, and hormonal implants, are significantly more reliable. The same will certainly apply also to technologies for preventing infections. For programmatic purposes, key linkages are Voluntary Counseling and Testing/VCT, promotion of safer sex, close coordination between, or integration of, HIV/AIDS and STI services and maternal and infant health.

Discussion

In the discussion that followed, it was pointed out that effective communication between providers and users, and among users themselves, can help increase condom use, but it is critical to accompany condom introduction with the right messaging. For example, in some settings it may be more productive to promote a hierarchical approach than to warn people to use a condom for every sex act.

Session 1. Multi-purpose devices

Some lessons learned from experience in promoting condoms for dual-protection (against unintended pregnancy and infection) were reviewed by *Bidia Deperthes (United Nations Population Fund, New York, NY, USA)*. UNFPA plays a proactive leadership role in global policy discussions about male and female condoms, identifying gaps in provision of country-level support, establishing global and regional support mechanisms for delivery of country-level support, advising global and country-level stakeholders, and fundraising.

There is a strong upward trend in the global distribution of female condoms since the launch of the UNFPA Global Female Condom Initiative in 2005 to address the sexual and reproductive health needs of women by scaling up access to and use of the female condom. For the third consecutive year, access to female condoms has dramatically increased, reaching a record number of 33 million female condoms in 56 countries in 2008 (up from 13.5 million in 2005). Partnership between governments and technical agencies helped maximize access to male and female condoms through the public and private sectors, civil society, and social marketing. Efforts were made to reach remote and rural areas with targeted distribution programs for vulnerable and marginalized populations including those most at risk. For both male and female condoms, demand is being created by means of interpersonal communication, community-level activities, and augmenting distribution and counseling in health centers.

More can be done to generate demand in order to increase and sustain condom use by couples at risk, if training programs can be expanded, if there is a greater choice of condom brands, and if funding levels are increased. It is also important to invest in research to understand the preferences of present and potential users so as to target distribution to specific groups, including those most at risk. These lessons and the experience gained in programming for female condom distribution and use at the global and country levels can help lay the social and political foundations for introduction of other female-initiated prevention methods such as microbicides that are still in the pipeline.

Maggie Kilbourne-Brook (PATH, Seattle, WA, USA) outlined recent developments aimed at improving the availability and acceptability of female condoms – the only dual-protection method currently available for women. Despite the benefits that female condoms offer, they are not yet widely available in most countries for various reasons. Consultations have established that product choice needs to be expanded to suit individual preferences and the cost of the product needs to be reduced. Targeted programming should integrate the female condom into HIV/AIDS prevention and treatment programs, and stronger advocacy is needed to build a supportive environment for programming. Appropriate positioning and strategic promotion are critical for strengthening stakeholder perceptions of the female condom relative to other products.

In terms of product choice, the “FC1” (a polyurethane product) approved by the US Food and Drug Administration/USFDA in 1993, is still the most widely available product, by now introduced in over 100 countries. A lower-cost successor product made of nitrile, the “FC2”, received USFDA approval in early 2009. Other female condom products are available with CE (i.e., European Union/EU) approval. A latex condom pouch of Indian manufacture is attached to a V-shaped outer frame, with a polyurethane sponge at the distal end. It is marketed in Argentina, Brazil, Indonesia, the southern Africa region, and in some EU countries, primarily through the private sector. A “panty condom” made in Colombia comprises a polyethylene condom pouch and a re-usable cotton or nylon panty and is sold through the private sector in Colombia, Costa Rica, the Dominican Republic, Panama, Spain, the United Kingdom, and Venezuela. Still in clinical testing is a novel

“Woman’s Condom” developed jointly by PATH and CONRAD with USAID funding and designed to make insertion easier and provide greater stability and comfort during use. The pouch is compressed into a capsule made of film which aids insertion and dissolves on contact with vaginal secretions. Design validation studies in four countries reported high acceptability and the product performed well compared to the FC1 in a Phase I slippage and breakage study. Manufacture has been transferred to China and a clinical trial for product registration in China is anticipated in 2010.

With this diversity of products, considerable attention is being given to the important matter of regulatory requirements for product approval. In the United States, the FDA requires data from a contraceptive effectiveness study before market approval; such studies are challenging and costly, and consistent product use is not assured. An alternative study design, such as a slippage/breakage study combined with using biomarkers of semen, has been proposed to the scientific community as a way to collect high-quality data on product failures while remaining implementable at a lower cost.

Nancy Padian (RTI International, San Francisco, CA, USA) reviewed the outcome of the MIRA (Methods for Improving Reproductive Health in Africa) trial, whose aim had been to test the hypothesis that by protecting the cervix, risk of infection would be significantly reduced. MIRA was an open-label randomized controlled trial at sites in South Africa and Zimbabwe in HIV-negative sexually active women, who were allocated either to diaphragm + lubricant gel + male condoms or to male condoms alone. All women received risk-reduction counseling, free male condoms, and diagnosis and treatment of curable STIs.

The trial outcome was disappointing: the diaphragm + lubricant provided no additional protective benefit against infection with CT, HIV, or NG. However, many questions remain open, including whether the outcome would have been different if adherence had been greater, or if coitally-independent barriers had been used, or if a different trial design had been employed. It is still not known whether diaphragm + gel is better than nothing or as good as a condom alone, or whether a diaphragm used with a microbicide might be more effective than either alone. Thus the results of MIRA do not necessarily disprove the hypothesis that coverage of the cervix could be protective.

The use of cervical barriers combined with a spermicidal and potentially microbicidal product to protect against both pregnancy and infection was the subject of a presentation by *Marianne Callaban (CONRAD, Arlington, VA, USA)*. A clinical trial to evaluate the contraceptive effectiveness of the Ortho All-Flex diaphragm used with either BufferGel or nonoxynol-9 showed both approaches to be equally effective. A similar trial with the SILCS diaphragm is ongoing in six sites in the United States. Its primary objectives are to estimate the 6-month probability of pregnancy during typical use and the safety of the diaphragm used with gel. Colposcopic findings and effects on the vaginal microflora are secondary objectives in a subset of women.

A further trial, still in the planning stage, will assess the effectiveness of the diaphragm used continuously (as distinct from coitally-dependent use as in the MIRA trial) to prevent infection with NG and/or CT among sex workers at high risk for STI acquisition and at low risk for HIV. This trial is to be undertaken at sites in Madagascar where condom use and HIV prevalence are low and STI infection and re-infection rates are high. Several studies, in women and in couples, are looking at the feasibility and acceptability of using the SILCS diaphragm as a microbicide delivery system, including its potential use as a controlled delivery device. The single-use Duet device with BufferGel on both the cervical and vaginal sides has proved easy to insert and remove and has the potential for over-the-counter/OTC availability. A trial of safety and acceptability in Zimbabwe is currently

recruiting, with women randomized to use the device with intercourse (coital method) or once daily (continuous use) for 14 days.

Another approach under evaluation is the use of PATH's Woman's Condom with microbicide-loaded film in place of the dissolving film currently used as an insertion aid. Finally, Family Health International is developing a Device for Vaginal Drug Delivery/DVD2, based on simple, well-known technology that could deliver microbicides and contraceptive gels that has the potential for use in multiple sex acts, is readily disposable and biodegradable, and could cost less than US\$0.05 per unit.

A presentation by *Meredith Roberts Clark and Patrick Kiser (University of Utah, Salt Lake City, UT, USA)* explored the prospects for using intra-vaginal rings/IVR as multi-purpose prevention devices. Both "monolithic" rings, impregnated with drug throughout the matrix, and rings in which the drug is contained in a core element, are capable of sustained delivery. For pregnancy prevention, the ring has been shown to be as effective as the once-a-day contraceptive pill. IVRs are also being developed as anti-HIV devices, loaded with an appropriate ARV.

There are several ways in which multi-purpose combination rings could be designed, in which the active agents are held in separate components of the ring, with release profiles customized for the drug's required pharmacokinetic/PK profile. Such devices could be protective against pregnancy and/or HIV and/or HSV and/or bacterial vaginosis. However, success will depend on overcoming numerous challenges. In terms of the science, there are issues about the correlation of *in vitro* and *in vivo* release patterns, about drug transport processes, about the impact of one drug on the performance of another, and about product acceptability. There is also a lack of suitable animal models. Questions about the impact of hormonal contraception on susceptibility to infection with HIV, other STIs and *Candida albicans* need to be resolved. Materials suitable for IVR construction are in limited supply and facilities with the capacity to make IVRs are scarce. There are also regulatory issues, including the complexity of clinical trials designed to test multi-drug/multi-purpose products.

Session 2. Multi-purpose vaccines

Kevin Whaley (Mapp Biopharmaceutical Inc., San Diego, CA, USA) reviewed multi-purpose vaccines that are commercially available. These include: (a) measles, mumps and rubella (MMR) vaccine, a mixture of three live attenuated viruses; (b) diphtheria, tetanus, pertussis/DTP vaccine, widely used for 60 years; (c) pentavalent vaccine against diphtheria, tetanus, pertussis, polio, and *Hemophilus influenzae* type b (DTaP, IPV, Hib), used in Canada for 10 years; (d) and a related hexavalent vaccine which also includes hepatitis B (DTaP, IPV, Hib, HBV), available in some European countries. There are several reasons why combination vaccines – especially vaccines for children – are often the preferred option: they are convenient, reduce pain by decreasing the number of injections required, improve compliance with on-time immunization, and enhance parental and provider satisfaction.

At present there are few vaccines in the sexual and reproductive health arena; only vaccines against HBV and HPV are commercially available, and there are no contraceptive vaccines. A particular challenge in developing such vaccines that prevent transmission is the fact that the genital immune response is generally poor. An ideal multi-purpose vaccine would combine multiple antigens, would elicit both systemic and mucosal immunity, and would be amenable to boosting by self-administered mucosal immunizations (nasal or vaginal). It would also be heat-stable, affordable, and safe and effective in children and adults. In preparation for these multi-purpose vaccines, common adjuvant

and delivery systems should be co-developed for each of the versatile production platforms: recombinant subunit vaccines, DNA vaccines, and live/attenuated vaccines.

The steps that have to be taken before a vaccine may be widely deployed in the USA were outlined by *Eileen Yamada (California Department of Public Health, Richmond, CA, USA)*. First, an assessment is made as to whether the disease is significant such that it warrants the development of a preventive vaccine and whether it is feasible to produce such a vaccine. Progressively larger clinical trials are then undertaken to assess dose, dosing frequency, immunogenicity, efficacy, and safety of the vaccine. The USFDA then determines whether the vaccine is suitable for licensing in the US. After licensure, the National Advisory Committee on Immunization Practices/ACIP reviews all studies on the vaccine and makes recommendations for its use in the USA, including target populations, contraindications, and precautions. Cost-effectiveness is also carefully considered for each recommended vaccine, taking into account such factors as the population targeted, the cost of the vaccine and its administration, the vaccine's efficacy, the duration of the immunity it confers (and the potential for future booster doses), and the cost savings from disease prevented by the vaccine. Being certain that a newly licensed vaccine is safe is obviously critical, and systems are in place to assess this not only before licensure but also by careful post-licensure monitoring.

In this connection, there has been controversy around the HPV vaccine. As for other preventive vaccines, it is important to immunize *prior* to any potential sexual exposure; that is, in the pre-teen period, the time when other immunizations are also given. Many parents deny that their child could be sexually active before adulthood and are concerned about the duration of immunity and often also about the possibility that immunization may promote promiscuity. There are no data to support the latter claim.

Jiri Mestecky (University of Alabama, Birmingham, AL, USA) explained how features of the mucosal immune system of the genital tract are relevant to the design of vaccines to prevent infection with STIs. The genital tract has relatively low numbers of lymphoid cells and its response to antigens is localized and dependent on systemic humoral immunity. It produces more immunoglobulin (IgG) than immunoglobulin A (IgA), both originating mainly in the uterus and the cervix, and is regulated hormonally. A wide variety of bacterial and viral pathogens and other antigens elicit only a mild humoral immune response in the female genital tract and it is difficult to detect any cellular immune response. The genital tract does, however, produce a humoral response to antigens delivered nasally or by a combination of rectal and oral routes.

In contrast, the immune response of the intestinal tract – the body's largest lymphoid organ – is disseminated and is largely independent of systemic immunity. The intestine produces very substantially more IgA than IgG and the response is not regulated by hormones. Its immunological role is to prevent the uptake of foreign antigens and eliminate them.

Future research relevant to genital immunization should include an evaluation of the humoral and cellular responses as assessed in genital tract secretions, immune responses to antigens applied by various routes (including systemic, intranasal, and sublingual), studies on the effectiveness of immunization in the protection of the female and male genital tracts, and mechanisms of antibody-mediated protection. The possibility that vaginal-uterine exposure to antigen induces mucosal tolerance also needs to be investigated.

Various approaches for the industrialization of multi-purpose vaccines were illustrated by *Charles Arntzen (Arizona State University, Tempe, AZ, USA)*, who pointed out that it is now timely to rigorously explore methods for scaling up the production of key vaccine candidates (as well as

immune potentiators) and of antibodies suitable for passive protection, as well as identifying appropriate delivery systems for both products. Regulatory aspects are challenging and still evolving, and cost – for vaccines not only the cost of the antigen but also of syringes and needles – also must be taken into account.

The use of bioengineered organisms is one means of mass-producing antigens cost-effectively, as is the case for hepatitis B vaccine, which exploits yeast fermentation. The current cost of this vaccine in bulk-purchase agreements has fallen to about US\$0.27 per dose, but three needle-delivered doses over multiple months by health care professionals makes true immunization costs much higher. Emerging strategies for needle-free delivery of heat-stable vaccines, including plant-derived vaccines, gene-based (DNA) vaccines, and virus-like particles, are promising approaches to creating safer and more potent products that could be incorporated into global public health programs at lower delivery costs. Gene-based vaccines, which are inexpensive to manufacture, generally elicit a good cell-mediated immune response but a relatively poorer mucosal response which is what is likely to be needed for blocking STIs.

Vaccine formulation and route of delivery have a major influence on responses. A strong vaginal mucosal response can be produced by nasal immunization, a method which lends itself to self-administration and the use of dry powder formulations for long-term, heat-stable storage. The discovery of potentially suitable antigens for several STI pathogens is progressing, including CT, HIV, HSV, NG, and TV, but the question remains as to whether their production can be sufficiently cost-effective for widespread use against STI infections in developing countries with minimal health-care infrastructure and where vaccination may require repeat boosting to maintain protective responses. A new protein pharmaceutical facility in the United States may cost from US\$0.3-1 billion and take more than five years to complete, with time-consuming regulatory qualification required at each step. However, the capital cost of a facility for producing a subunit vaccine in plants, such as tobacco, has been estimated to be as low as US\$17 million to provide 75 million doses per year of a dry-powder oral formulation. Moreover, the cost of manufacture would decrease with time as demand increased, since plant-based manufacture is readily scalable as product demand grows.

Discussion

Several pivotal issues were raised in the discussion that followed Sessions 1 and 2. One was the cost of providing vaccines in quantities sufficient to make a major and widespread impact. For example, the cost of the HPV vaccine is currently US\$20 per dose. It has often been claimed that the private sector could heavily subsidize the cost of pharmaceuticals in resource-poor countries by charging premium prices in the industrialized West and among middle-class consumers in countries like India. This model was considered worth pursuing for multi-purpose vaccines.

The prospect of DNA vaccines also generated some side-bar discussion. While DNA vaccines are inexpensive to produce and easy to administer, genital tract response to them may be inadequate. In the case of a DNA vaccine for HIV, there could also be problems with ensuring that the corresponding protein produced following immunization is properly glycosylated where appropriate, that is, attached to sugar molecules so as to match the corresponding natural product where this is necessary, if it is to elicit an effective immune response.

Another difficult and central issue concerns prioritization. For example, although cervical cancer results in the death of 274,000 women annually, there are low-cost screening and treatment options for HPV-associated pre-cancerous lesions (acetic acid diagnosis and freeze-treatment), while at the same time several million children die of diseases caused by preventable infections that must command attention.

Plenary 2. Obstacles and opportunities for accelerating the development of new prevention technologies and their integration into service delivery

The purpose of this plenary panel was to explore in detail why current approaches to prevention fail to address women's needs adequately and to identify ways in which the situation can be ameliorated.

In introducing this topic, *Jeff Spieler (US Agency for International Development, Washington, DC, USA)* claimed that ever-increasing emphasis on HIV over the past two decades was one of the reasons why it has been difficult to access funding for family planning and other aspects of reproductive health. Nevertheless, USAID has a good record of providing funds to a range of cooperating agencies for the development of the field more broadly through technical leadership, research, innovation, and direct support to country programs. In furthering this broad aim, the Agency has used its core funding to leverage financing from the private sector, foundations, and other bodies. Its priorities are to integrate existing technologies, e.g., contraceptives and other methods, into the health services of developing countries; to improve existing technologies to make current methods safer and more effective, affordable, acceptable and easier to deliver and use; and to develop new methods that would be likely to have major impact, such as non-surgical sterilization and dual-purpose pregnancy and HIV/STI prevention. He pointed out that, on average, 40% of women in developing countries want to limit the size of their families but at present only a very small percent of women use long-acting or permanent methods for preventing unintended pregnancy.

Sharon Camp (Guttmacher Institute, New York, NY, USA) explained why current contraceptive methods, including the contraceptive pill and condoms, will not fill the unmet need for contraception. Many women find current methods difficult to use consistently and correctly, some are inappropriate for women with low coital frequency, and side effects are often a major barrier to long-term use.

In the United States, there are over 3 million unintended pregnancies each year. Of the 43 million US women at-risk of unintended pregnancy, 65% use contraception consistently and account for 5% of unintended pregnancies. The 19% who practice inconsistent use account for 43%, and the remaining 16% who do not use contraception account for 52%. Reasons given for non-use include infrequent sex, problems in accessing or using methods, perceived low risk of pregnancy, and not caring about becoming pregnant. Major life changes, such as ending or starting a relationship, job and school changes, moving house, and personal crises can impact on contraceptive use.

In the developing world, 66% of women experiencing an unintended pregnancy use no method of contraception and only 20% use modern methods. The overall unintended pregnancy rate is high: 67 per 1,000 women in the 15-44 age group (excluding eastern Asia). The main reasons for non-use include several which are also stated by US women and include perceived low risk of pregnancy, often due to infrequent sex; problems with contraceptive methods; side effects or fear of health risks; poor access to contraceptive supplies; and opposition to contraception in general.

The implications of these statistics are clear: women in both the global North and the global South want contraceptive methods that protect against both pregnancy and disease without unpleasant side-effects, that do not interfere with sex, require little or no medical supervision, and that are effective if used post-coitally.

Efforts being made by Planned Parenthood Federation of America to reach a greater number of US women in need of sexual and reproductive health care services were described by *Vanessa Cullins*

(Planned Parenthood Federation of America, New York, NY, USA). At present the organization serves 18% of the US women in need of family planning services, but a nationally representative survey of women seeking care from a variety of US health care providers reported that long waits to get an appointment, inconvenient office hours, the long time required with the doctor, and high costs are all obstacles to the timely provision of contraception. The Federation is currently implementing improvements aimed at alleviating these difficulties, which are found in all health care systems. Systems are being strengthened to provide a respectful environment that is welcoming to all and that makes access to care easier, thus enabling women and their partners to make timely private decisions on achieving their ideal family size. An important aspect of this system-strengthening effort is helping US family planning providers understand that periodic gynecological assessment (annual exam with pelvic exam) should not be automatically linked to initiation or continuation of contraception in healthy, asymptomatic women of reproductive age. Instead, the periodic “well-woman assessment”, which will often require a pelvic exam, can be done in a separate visit at times convenient for the woman.

Martha Brady (Population Council, New York, NY, USA) argued that women want and need a diversity of sexual and reproductive health technologies, including multi-purpose products that offer simultaneous protection from pregnancy and STIs and/or HIV.

Decision-making around product adoption and use is influenced by numerous factors: intrinsic product attributes, safety, efficacy, “ease” of use, specific user needs, and characteristics, social and economic costs, locus of control of the technology, and the service delivery platform and approaches used. Desires, needs, and intentions concerning pregnancy and the prevention of HIV and other STIs differ among individuals in any population and will change over time as life circumstances change.

Sexual and reproductive health/SRH services and HIV/AIDS services often function independently although, at least recently, program synergies to serve more than one need have been developed and tested. Identifying specific, strategic, and targeted areas for service integration remains an important challenge for sexual and reproductive health and HIV programs. Ultimately, new multi-purpose technologies will need to be incorporated into these existing program structures. Multiple marketing and distribution channels are desirable for existing and new methods, including various combinations of public-sector hospitals and clinics, commercial markets, private providers, on-governmental organizations, social marketing, and community networks, although regulatory status will determine what type of marketing approach is applicable and feasible for a particular product. The rate of adoption of a new product will depend upon several factors, including how much behavior change is required, type of service delivery approach, cost, and level of marketing investment. A new product category provides a unique opportunity to shape both that category and its market; thus social science and market research on optimal introduction and positioning strategies merit investment.

Session 3. Multi-purpose microbicides and other technologies with multi-purpose potential

Charles Kelly (King's College, London, UK) reviewed the outcomes of several clinical trials designed to evaluate the effectiveness of various microbicides that had demonstrated pre-clinical activity against both infection with HIV and certain other STIs. Overall, the results of these trials were not productive in this regard. In brief, the non-ionic surfactant nonoxynol-9 increased HIV risk, especially in frequent users; Savvy, a combination of two amphoteric surfactants, and BufferGel,

designed to keep the vaginal pH at its normal acidic level, showed no effect; and the polyanion attachment/fusion inhibitors Carraguard, cellulose sulphate, and 2% PRO 2000 were also ineffective. However, a recently-concluded clinical trial of 0.5% PRO 2000 gave encouraging signals with respect to activity against HIV transmission and a larger trial of this product is due to report in late 2009 (*see below*).

However, the microbicide development pipeline includes a wide range of other candidate microbicides and combinations of some of those. The use of HIV reverse transcriptase inhibitors (RTIs) as microbicides is being intensively researched. Tenofovir, a nucleotide reverse transcriptase inhibitor/NRTI, and TMC120, UC781, and MIV 150, all non-nucleotide reverse transcriptase inhibitors/NNRTIs, are highly potent, have excellent safety profiles, and exhibit reasonable barriers to resistance. They are also stable, can be formulated for sustained release, and are inexpensive. The lipophilicity of the NNRTIs may be advantageous for microbicide use since that characteristic makes it possible for them to accumulate mainly in cell membranes where they remain at inhibitory concentration for several days (“memory effect”). HIV integrase inhibitors such as raltegravir are also of interest in the microbicide context, and while the use of HIV protease inhibitors as microbicides is not an obvious choice because they act *after* the viral DNA copy has integrated into the host cell’s DNA, the possibility is being explored within the European Microbicides Project/EMPRO. Compounds which block the CCR5 co-receptor are also under investigation, including the drug maraviroc and several analogues of RANTES, the chemokine for which CCR5 is the natural receptor.

A potential problem with the ARV approach is the possibility that HIV from an infected partner is resistant to the ARV in question, so that the microbicide might not protect the user. It is also possible that drug-resistant HIV strains may emerge and be transmitted onwards if the user of the microbicide is already infected. As is now the norm in HIV therapy, combining different ARVs in a microbicide could provide greater efficacy against resistant virus and, in an infected user, could increase the barrier to the emergence of resistant virus. Several such combinations are under investigation, including maraviroc co-formulated with TMC-120 in an intravaginal ring.

One obvious limitation is the fact that microbicides reliant on ARVs cannot be expected to be active against other STIs and would thus not in themselves be multi-purpose products. These limitations could be overcome by combining an ARV with a compound with a broader spectrum of activity, and a good deal of effort by a number of groups is going into the development of such combination products (*see below*).

The question of bi-directional protection was raised in the context of microbicides based on RTIs. Insufficient PK data are available to judge whether the penis’s short exposure to an RTI microbicide present in the vagina of an infected woman would lead to sufficiently inhibitory concentrations of drug in the penile epithelium to prevent replication of HIV transmitted to her male partner.

The prospects for developing multi-purpose microbicides were also considered by *Gustavo Doncel* (CONRAD, Eastern Virginia Medical School, VA, USA). CONRAD has a long history of work on dual-purpose protection technologies, including vaginal spermicidal anti-infectives and physical barrier devices.

In principle, anti-infective and contraceptive microbicides could be based on a single drug with dual activity, a combination of a microbicidal compound with a contraceptive agent, and/or a combination of a drug with a device. Studies conducted by CONRAD and partners have shown that cellulose sulphate/CS works as a contraceptive by blocking the binding of the sperm to the ovum’s

zona pellucida and preventing fusion with the oolemma and is an effective contraceptive in both animals and humans. Unfortunately, though active against HIV in laboratory studies, CS failed to protect women against HIV when evaluated clinically as a microbicide.

Other multi-purpose protection technologies are under development at CONRAD. A contraceptive microbicide based on progestin formulated in a silicone IVR together with UC781, an NNRTI, exhibits controlled, long-term release of both agents. A gel containing a sperm-function inhibitor (Q-2/carbopol) and UC781 is at the preclinical stage of development and can be inserted either by vaginal applicator or loaded onto a diaphragm. An anti-HIV/HSV product in which UC781 is combined with acyclovir in an IVR is also under development. For all these products there is a need for thorough assessment of cervico-vaginal safety, and intensive efforts are being made to identify useful biomarkers, that is, molecular indicators of normal or abnormal function.

A presentation by *Jim A Turpin (National Institutes of Health, Bethesda, MD, USA)* explored the numerous practical challenges to be faced before we are able to provide quantities of multi-purpose microbicides. For example, a major obstacle to the development of protein-based microbicides is the difficulty of producing them in sufficient quantity. Production methods that exploit transgenic plants, yeast, or bacteria may be a way of overcoming this problem, with plant production methods the most promising. Bioanalytic assessments of plant-produced materials suggest that they can be of high purity and identical with their natural counterparts. Using transient transgenic tobacco plants in the sort of facility envisaged, a gram of monoclonal antibody could be produced in two weeks, as against 6-12 months using mammalian cell culture and over a year in stable transgenic plants. It has been estimated that to provide anti-CCR5 or HSVgD monoclonals, made under cGMP (current Good Manufacturing Practice) conditions sufficient for a Phase I clinical trial would cost US\$0.5-0.8 million using the transient transgenic tobacco approach compared to perhaps 10x this using mammalian cell culture. Recent studies have shown that it is possible to produce IgG and cyanovirin-N (a protein under investigation as a potential microbicide) from transgenically modified tobacco plants grown hydroponically, which offers greater control of the process and potentially much higher yields.

Novel delivery systems for protein microbicides are also being investigated. These include mucus-penetrating nanoparticles and non-phospholipid liposomes; the latter have already been used successfully to deliver protein-based vaccines. Bioresponsive gels have been developed which can release microbicides under specific physiological conditions, for example on interacting with semen at slightly alkaline pH at 37 degrees C. Vaginal lactobacilli are being evaluated as a potentially sustainable living delivery system for protein-based microbicides, including 2-domain CD4, cyanovirin, and various antibodies to entities required for HIV entry. If necessary, these organisms can be rapidly cleared by vaginal dosing with azithromycin (demonstrated in non-human primates), and the environmental impact of using them on a large scale should be minimal because they rapidly lose their viability in air or water. Yet there remain many unanswered questions about this approach, concerning the size of the vaginal inoculum, the durability of the engineered lactobacilli in the human vagina, whether sufficient microbicide will be produced to prevent infection with the respective pathogen, possible immunotoxicity, and regulatory issues.

New categories of microbicides are also being assessed. These include iRNAs (interfering RNAs) and glycerol monolaurate. The latter, although having surfactant properties at high concentrations, seems to work (in macaques) at lower concentrations by altering the vaginal environment, reducing the levels of certain chemokines which, in turn, decreases the influx of CD4+ T cells. Its *in vitro* cytotoxicity profile looks acceptable, as did its behavior in the rabbit vaginal irritation test.

Daniel Halperin (Harvard University School of Public Health, Boston, MA, USA) referred to the limited success of the “standard” approaches to HIV prevention in Africa: condom distribution/promotion programs, voluntary counseling and testing/VCT, treatment of other STIs, and abstinence-based programs for youth. While VCT is clearly important for treatment, care, and support, evidence from rigorous studies in Uganda, Zimbabwe, and elsewhere suggests that the procedure has little positive effect on HIV risk behavior.

There is now consensus among most researchers that the decline in adult HIV prevalence in Uganda, from about 15% in 1992 to 7% in 2005, was largely due to the breaking up of sexual networks in response to a potent "zero grazing" (partner-reduction) campaign, although the deaths of large numbers of infectious individuals was also a contributory factor. New approaches to HIV prevention are needed, as well as improvements in family planning and reproductive health services, which are frequently seriously under-funded, and various combinations of these approaches. Male circumcision programs should be expanded and accelerated for maximum impact on the HIV epidemic, as well as for the additional health benefits of male circumcision which include reduction in chancroid and syphilis, elimination of foreskin infections, major reductions in invasive penile cancer, substantially less cervical cancer among female partners, and fewer urinary tract infections in infants. In addition, promotion of exclusive breast feeding – particularly through warning of the dangers of mixed feeding practices – can reduce mother-to-child transmission of HIV by at least 50% compared to mixed feeding.

Sharon Hillier (University of Pittsburgh, Pittsburgh, PA, USA) outlined the main findings from the HPTN 035 trial, a 4-arm Phase IIb effectiveness and safety study which compared 0.05% PRO 2000 gel with BufferGel, placebo gel and a non-blinded arm in which no gel was provided. All four groups of women received safer-sex counseling and a supply of male condoms. Both microbicides were shown to be safe, although BufferGel failed to reduce HIV risk compared to placebo or the no-gel arm. However, women in the 0.5% PRO 2000 group had 30% fewer HIV infections in comparison with those in the placebo gel group ($p=0.10$) or no gel group ($p=0.06$). In the according-to-protocol analysis of women whose gel product was withheld because of pregnancy, the protective benefit of PRO 2000 reached statistical significance. The results of another larger trial of PRO 2000, MDP 301, will be reported late in 2009 and will provide a better estimate of product effectiveness.

That said, the HPTN 035 trial demonstrated that women randomized to BufferGel or PRO 2000 did not have a reduced incidence of CT, HSV-2, TV, bacterial vaginosis (all well-powered data), or syphilis. Indeed, none of the other microbicide effectiveness trials (of Carraguard, cellulose sulphate, nonoxynol-9, and Savvy) showed a protective benefit for any of these organisms, even though all had inhibitory effects on some or all of them in the laboratory. Therefore, it is hard to escape the conclusion that these pathogens are considerably more vulnerable in laboratory systems than they are in the human vagina. Current models, with the exception of the Patton pig-tailed macaque model of *C. trachomatis*, do not predict the effectiveness of microbicides against sexually transmitted infections. This has obvious implications for the development of multi-purpose microbicides, and a focused search for new broad-spectrum agents is merited.

Session 4. Strategy Panel: Integrating multi-purpose sexual and reproductive health technologies into prevention strategies

These presentations were followed by a panel session moderated by *Wayne Shields (Association of Reproductive Health Professionals, Washington, DC, USA)* who explained that the aim of this session was to analyze the challenges, opportunities, and priorities for developing multi-purpose devices,

microbicides, and vaccines, and for accelerating the transition of these developments into valuable public goods.

Key issues in social science

Cynthia Woodsong (International Partnership for Microbicides, Silver Spring, MD, USA) raised a number of key social science issues. Gender norms for decision-making about contraception and HIV/STI prevention are highly diverse. While there are cultural norms, each individual's decisions will depend to a great extent on specific circumstances at the time, including the type of sexual partner and the quality of communication. Within this context, the acceptability of a product to a given user will depend on individual preferences regarding formulation and delivery attributes, the kind of protection the product provides (e.g., HIV, STIs, pregnancy, bi-directionality), accessibility, and branding. In contrast, the health practitioner will be more concerned about the product's level of efficacy in ideal and typical use, clarity about type of protection provided, potential side effects, and how the product fits in with hierarchical counseling strategies.

In summary, the key social science issues for prevention technologies are gender norms and decision-making, sexual practices and their significance to the individuals concerned, product acceptability, behavior changes required for product use, adherence to product use, and methods for informing related policy and programmatic issues.

Biomedical research

Some priorities from the medical science perspective were discussed by *Deborah Anderson (Boston University, Boston, MA, USA)*. More intensive investigation is required regarding vaginal physiology and microflora, and inflammatory markers and innate immunity, especially in the early stages of clinical trials. Given that genital and rectal conditions are remarkably diverse, there needs to be more Phase 2 and 3 testing in high-risk populations. Products can have dramatically different effects in populations with high prevalence of STIs, bacterial vaginosis, and other chronic genital inflammatory conditions.

With respect to developing vaccines directed at the genital and rectal mucosa, more studies are needed on the mucosal immunity of the rectum, endocervix, and penile urethra; on mucosal adjuvants; and on the use of human monoclonal antibodies for passive mucosal immunization. For microbicides, more work is needed on products that target HIV transmission by cell-associated virus and on products that are effective if used post-coitally. The influence of methods used for post-coital hygiene (e.g., douching) also merits investigation.

The product development pathway

Joe Romano (International Partnership for Microbicides, Silver Spring, MD, USA) reviewed various design strategies for multi-purpose devices and microbicides, including multiple anti-infectives applied topically for one or more indications (e.g., HIV and HSV) and perhaps also for contraception. These could be delivered in several ways, e.g., gel-filled applicators, IVRs, or solid dosage forms such as tablets, capsules, and films. The product development pipeline needs to include contraceptive options and broad-spectrum anti-infectives that function topically to prevent infection by multiple pathogens.

However, there are several challenges in the development of topical options. The formulation of multiple actives must ensure their mutual physico-chemical compatibility, and drug-drug interactions and toxicity will need to be investigated both in the laboratory and in the clinic. There are also challenges in designing and implementing a single clinical trial to evaluate one drug or a combination of drugs where the end-points involve multiple indications. Manufacturing capacity will have to be

enhanced. For example, 10 million women using a monthly IVR would require 120 million IVRs, needing 1,000 metric tons of silicone per year, whereas at present there are only three facilities which jointly make fewer than 20 million IVRs per year.

Although combination microbicide products effective against multiple agents would represent a significant benefit to female-controlled reproductive health, the technical and development challenges are significant and may best be reduced via lessons learned from single-indication microbicide product development.

Product regulation

The importance of linking all stages of product development and post-marketing studies with regulatory compliance was stressed by *Bob Russell (RJR Consulting, Inc., Blacklick, OH, USA)*. The USFDA has separate categories for Medicinal Products or Biologics, Medical Devices, and Device/Medicinal Combinations. In deciding whether to approve a product for advancing into clinical trials or for marketing, the FDA takes accounts of such factors as the acuteness of the relevant indication and what information might reasonably be required for proceeding without unacceptable risks to trial participants or users of any product.

Programmatic considerations

Melodie Holden (Venture Strategies for Health and Development, Anaheim, CA, USA) discussed the implementation of large-scale new technology programs in developing countries. Her non-profit organization works to move research into practice and to increase the availability of low-cost health products at the community level. Venture Strategies works primarily in four areas: (a) product registration, (b) policy development, (c) training, and (4) demand generation. Product registration is the legal authority to import and sell a specific product, and the organization brings together generic drug manufacturers and distributors to accomplish this. The development of appropriate policies and the institutionalization of new technologies are achieved by updating clinical guidelines, the Essential Drug List, and training curricula. Training is given to providers and trainers of trainers. In low-resource settings it is particularly important to employ “task-shifting” as part of implementation plans: simple tasks should be allocated to whoever can carry them out so that expert personnel, e.g., doctors, can give unencumbered attention to more complex tasks. Product distribution is arranged through public- and private-sector channels, social marketing, and subsidization, and demand is generated by means of information, education, and communication programs. High prices are ameliorated through the use of generics, price competition, negotiation, policies, and providing an investment to cover startup costs.

Some major programmatic issues were reviewed by *Heidi Bauer (California Department of Public Health, STD Control Branch, Richmond, CA, USA)*. She explained that some approaches have been deployed in the absence of data showing effectiveness. For example, it would seem self-evident that safer-sex counseling would result in the avoidance of many HIV and other STI infections, but in many settings there is little evidence that this is the case. More funding is needed to support translational research aimed at finding out whether a particular technology or other approach would be effective in various real-world settings involving different populations, and at different times in a given setting. The case for more closely integrating family planning services with services for the prevention and treatment of infections also requires a creative approach.

Advocacy

Angelina Namiba (African HIV Policy Network, London, UK) referred to the importance of engaging communities in advocating for new prevention technologies. This helps ensure that, as science progresses, advocacy is forward-thinking, practicable, and well-informed about a range of current

issues. These include the safety and appropriateness of technologies, effective and smooth transfer of knowledge and expertise, access to care, and sustained health promotion and education within the community. Community involvement also provides a channel for handling questions about the long time needed to develop and deploy new technologies, about the role of HIV-positive women in trials, and managing expectations around the potential utility of new preventive technologies to HIV-positive people. Fears, exacerbated by the media, about the ethics of Phase III trials are another important issue requiring attention. To complement such activities, representative past and present trial participants should engage in meetings such as the present one.

Break-out sessions

At this point in the symposium, participants split into five working groups to focus on priorities for advancing scientific, societal, programmatic, advocacy, and industrialization strategies and influencing policy. The main priorities the groups identified are summarized below, with suggestions about what additional representation would be required to advance the initiative effectively.

Microbicides and combination devices (*facilitated by Joe Romano and Bob Russell*)

Priorities identified:

- 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 in 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 levels, and 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

Future discussions should include:

- Experts from the pharmaceutical industry, including expertise in pipeline management, combination products, and formulation science
- Regulators (early in the development process)
- Ethicists, investigators from the global South and potential users of products
- Social scientists and cultural anthropologists
- Market researchers.

Vaccines (*facilitated by Deborah Anderson and James Rooney*)

Priorities identified:

- 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), and 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 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 development of multivalent vaccines
- Explore more intensively the use of monoclonal antibodies, including use of animal models
- Encourage investigator-initiated proposals for studies on samples from clinical trials
- Support creation and improvement of centers of excellence that bring together diverse kinds of expertise.

Future discussions should include:

- Basic scientists in the fields of mucosal immunology, virology, vaccinology, and reproductive biology/medicine
- Representatives from industry (including from the emerging markets, e.g., India and China)
- Funders
- Regulators.

Social and behavioral science (*facilitated by Cynthia Woodson and Polly Harrison*)

Priorities identified:

- 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 (including triangulation models) and improve it
- The use of behavior change models in research and program development
- How to optimize use of information in policy development, ethical considerations (for example, subsequent to a clinical trial and public health ethics), and programmatic development
- Improve research methodology in terms of rigorous design, better data collection and analysis, and building such capacity in developing countries.

Future discussions should include:

- Representatives from the pharmaceutical industry
- Manufacturers of condoms and other contraceptive devices
- Market researchers
- Biomedical researchers
- Advocacy groups
- Community representatives.

Advocacy (*facilitated by Angelina Namiba and Liza Solomon*)

Priorities identified:

- 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, health promotion, and education
- Sustainability of support after the trial has completed
- Creation of demand for new products, balanced with supply.

Future discussions should include:

- Advocacy organizations and relevant NGOs and women's groups
- Community representatives (at an early stage)
- Biomedical, social science, and behavioral researchers
- Funders
- Users of the product
- Industry representatives
- Health providers and policy-makers.

Programmatic (facilitated by Melodie Holden and Heidi Bauer)

Priorities identified:

- Consider how *existing* sexual and reproductive health technologies can help to fill gaps given appropriate advocacy efforts
- Stimulate 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 down the cost 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 development of cultural competence consistent with benefiting from new technologies
- Integrate new approaches into existing strategies.

Future discussions should include:

- Funders
- Government representatives
- Policy-makers
- Health providers
- Insurers
- Users
- Advocates
- Educators
- Researchers.

Report of Post-symposium Strategy Meeting held on 26 March 2009, Berkeley, California, USA

The main symposium was followed by a Strategy Meeting whose aim was to sustain the initiative by identifying appropriate strategies for addressing scientific priorities and policy needs and laying out steps for moving the work forward. The formal goal of the Strategy Meeting was: “To accelerate multi-disciplinary strategies for advancing the development and programming of multi-purpose approaches and technologies that prevent unintended pregnancy, HIV infection, other STIs, and RTIs.” Subject to any subsequent amendments, this was accepted as the Mission Statement for the initiative. It was agreed that a document would be prepared which would inform donors and others about the urgent need for multi-purpose prevention technologies in sexual and reproductive health, and would provide a case for the funds necessary for advancing this agenda.

Next Steps

To help address the range of activities necessary for making this initiative a reality, three Working Groups were established, each with the following tasks:

1. Prepare a convincing case for increased investment in multi-purpose protection methods for pregnancy, STI prevention, and RTI prevention, highlighting key research questions that should be addressed in the immediate, short, and long term, and suggesting strategies for reaching key stakeholders.
2. Map the field of existing prevention technologies, including agencies and institutions involved in the promotion, distribution, education, and advocacy for the utilization and implementation of current technologies.
3. Map the status of multi-purpose protection methods still under development, including microbicides, PrEP, physical barriers, hormones, methods for 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 three activities would be essential to achieving the important objective of getting multi-purpose technologies firmly on the agendas of such organizations.

Annex 1. Symposium Agenda



A Strategy Symposium March 24–25, 2009 • Berkeley, California

Goal: Accelerate the development of multi-purpose technologies that prevent pregnancy, sexually transmitted infections, and other common reproductive tract infections.

Objectives:

1. Provide a forum to review the status of multi-purpose sexual and reproductive health (SRH) prevention technologies.
2. Identify critical biomedical, social science, regulatory, programmatic, and advocacy priorities and challenges in the development and deployment of these technologies.
3. Explore strategies and best practices for further developing multi-purpose SRH prevention technologies and deploying them as they become available.

DAY 1 – Tuesday, March 24, 2009

8:00–9:00 am	On-Site Registration and Breakfast	
8:30–8:40 am	Welcoming Remarks	Bethany Young Holt (CaMI/Public Health Institute/UC Berkeley)
8:40–10:35 am	Plenary 1	
8:40–8:45	Moderator: Jeff Spieler (US Agency for International Development) for Sharon Camp (Guttmacher Institute)	Defining “multi-purpose technologies” in the context of sexual and reproductive health
8:45–9:15	Judy Manning (US Agency for International Development)	Why we need multi-purpose prevention technologies: the USAID perspective
9:15–9:45	Jessica Justman (Columbia University)	Critical linkages: HIV, other sexually transmitted infections (STI), and their shared need and potential for prevention
9:45–10:15	Ward Cates (Family Health International)	Contraception as a component of multi-purpose sexual and reproductive health technologies
10:15–10:35	Discussion	

10:35–10:55	Break	
10:55 am–1:00 pm	Session 1: Strategies for Developing Multi-Purpose Devices	
	Goal: Present strategies, lessons learned, evolving technologies, and priorities for developing multi-purpose devices	
10:55–11:00	Moderator: Jessica Cohen (PATH)	
11:00–11:20	Bidia Deperthes (United Nations Population Fund)	The condom conundrum: lessons learned from promoting the male and female condom as “dual-protection” methods
11:20–11:40	Nancy Padian (RTI International)	Deconstructing the MIRA trial: what has been learned and how might remaining questions be answered
11:40–12:00	Marianne Callahan (CONRAD)	Update on approaches to advancing cervical barriers for pregnancy and disease prevention
12:00–12:20	Maggie Kilbourne-Brook (PATH)	Advancing female condoms: product status, regulatory challenges, and commercialization opportunities
12:20–12:40	Meredith Clark for Patrick Kiser (University of Utah)	The potential of vaginal rings as multi-purpose SRH prevention devices
12:40–1:00	Discussion	
1:00–2:15	Lunch and Poster Viewing	
2:15–4:00 pm	Session 2: Strategies for Developing Multi-Purpose Preventive Vaccines	
	Goal: Present strategies, lessons learned, evolving technologies, and priorities for developing multi-purpose vaccines for SRH	
2:15–2:20	Moderator: Kevin Whaley (Mapp Biopharmaceutical)	
2:20–2:40	Kevin Whaley (Mapp Biopharmaceutical)	Multi-purpose vaccines: safety, efficacy, and acceptability
2:40–3:00	Eileen Yamada (California Department of Public Health)	Deployment of multi-purpose pediatric vaccines and STI vaccines (HPV, HBV)
3:00–3:20	Jiri Mestecky (University of Alabama, Birmingham)	Developing vaccines that prevent cervicovaginal transmission
3:20–3:40	Charlie Arntzen (Arizona State University)	Industrialization of multi-purpose vaccines
3:40–4:00	Discussion	

4:00–6:00 Poster Session and Reception at Berkeley City Club

DAY 2 – Wednesday, March 25, 2009

8:30–8:40 am Welcoming Remarks Andrew Szeri (UCBerkeley Department of Engineering/Dean of Graduate Division)

8:40–10:35 am Plenary 2

8:40–8:45 Moderator: Jeff Spieler (US Agency for International Development) Obstacles and opportunities for accelerating development of new SRH prevention technologies and integrating them into existing service delivery

8:45–9:15 Sharon Camp (Guttmacher Institute) Obstacles and opportunities for accelerating development of new SRH technologies: evidence from experience

9:15–9:45 Vanessa Cullins (Planned Parenthood Federation of America) HIV/STI, family planning, and reproductive health: integrating service delivery on the ground in the United States

9:45–10:15 Martha Brady (Population Council) Responding to women's multiple SRH needs with multi-purpose technologies: matching users' needs, technologies, and service delivery platforms

10:15–10:35 Discussion

10:35–10:55 Break

10:55 am–1:00 pm Session 3: Strategies for Developing Multi-Purpose Microbicides and Other Relevant Multi-Purpose Technologies

Goal: Present strategies, lessons learned, evolving technologies, and priorities for developing multi-purpose microbicides and other multi-purpose prevention technologies for SRH

10:55–11:00 Moderator: Polly Harrison (Alliance for Microbicide Development)

11:00–11:20 Charles Kelly (King's College London) Surveying the microbicide pipeline for potential combinations

11:20–11:40 Gustavo Doncel (CONRAD) Explicit combination development programs and translational tools for multi-purpose technologies

11:40–12:00 Jim Turpin (US National Institutes of Health) Versatile platforms for manufacturing and delivery of multi-purpose microbicides

12:00–12:20 Daniel Halperin (Harvard School of Public Health) Other technologies with multi-purpose potential

12:20–12:40	Sharon Hillier (University of Pittsburgh, Magee Women’s Hospital)	Learning from trials: STIs as secondary endpoints
12:40–1:00	Discussion	
1:00–2:00	Lunch and Poster Viewing	
2:00–5:00 pm	Session 4: Integrating Multi-Purpose SRH Technologies Into Prevention Strategies	
	Goal: Action-oriented session to identify the social science, biomedical, regulatory, programmatic, and advocacy strategies needed to advance development of multi-purpose devices, microbicides, and vaccines, and integrate them into service delivery.	
2:00–3:10	Strategy Panel on Devices, Microbicides, Vaccines	
	Moderator: Wayne Shields (Association of Reproductive Health Professionals)	
	Cynthia Woodsong (International Partnership for Microbicides)	Social Science
	Deborah Anderson (Boston University)	Biomedical
	Joe Romano (International Partnership for Microbicides)	Biomedical
	Bob Russell (RJR Consulting)	Regulatory
	Melodie Holden (Venture Strategies for Health and Development)	Programmatic
	Heidi Bauer (California Department of Public Health, STD Control Branch)	Programmatic
	Angelina Namiba (International Community of Women Living with HIV)	Advocacy
3:10–4:10	Break into working groups to strategize ways to advance social science, biomedical, regulatory, programmatic, and advocacy strategies	
4:10–4:15	Reconvene	
4:15–4:50	Report back from working groups and discussion	
4:50–5:00	Concluding Remarks: Polly Harrison (Alliance for Microbicide Development) Adjournment	

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Annex 3. List of Poster Presentations



**A Strategy Symposium
March 24–25, 2009 • Berkeley, California**

Poster Presentations

Devices

Anthony Ham, ImQuest BioSciences, Inc.

Co-authors: Karen M. Watson, Lu Yang, Christa E. Buckheit, Alamelu Mahalingam, Todd J. Johnson, Patrick Kiser and Robert W. Buckheit, Jr.

[D-1] Formulation of IQP-0528 into Intravaginal Rings as a Topical Microbicide for the Prevention of HIV

United States

Integration

Caroline Agochukwu, Health Matters

[I-1] Promoting Behavioral Maintenance Strategies for Youth in Maidan Community, Lagos, Nigeria

Nigeria

Augustina Obiajulu Amuamuziam, New HIV Vaccine & Microbicide Advocacy Society

Co-authors: Olayide Akanni, Morenike Ukpong

[I-2] HIV and STI Education: An Integral Component of HIV Biomedical Prevention Efforts

Nigeria

Kadiri Audu, National Youth Network on HIV/AIDS, Nigeria

[I-3] Health Benefits to a Community Participating in HIV/AIDS Research Program Lagos, Nigeria

Nigeria

Cindra Feuer, AIDS Vaccine Advocacy Coalition (AVAC)

[I-4] Women's Perspectives on the Roll-Out of Male Circumcision as an HIV Prevention Tool

United States

Jaco Homsy, UCSF Global Health Science

[I-5] Reproductive Intentions and Outcomes among Women on Antiretroviral Therapy in Rural Uganda: A Prospective Cohort Study

United States

Bridget Hughes, WORLD (Women Organized to Respond to Life Threatening Diseases)

[I-6] WORLD's POWER Project (Prevention Outreach with Women Empowered to Reduce Risks)

United States

Caitlin Kennedy, John Hopkins Bloomberg School of Public Health

Co-Authors: Caitlin Kennedy, Alicen Spaulding, Debbie Bain Brickley, Lucy Almers, Joy Mirjahanger, Laura Packel, Gail Kennedy, Michael Mbizvo, Lynn Collins, Kevin Osborne

[I-7] Linking Sexual and Reproductive Health and HIV Interventions: A Systematic Review and Meta-Analysis

United States

Jacinta Mulatya, Stay Alive for Us All (SAFUS CBO)

[I-8] Advocacy in Advancing Prevention Technologies for Sexual and Reproductive Health

Kenya

Onyinye Belinda Ndubuisi, Economic and Social Empowerment of Rural Communities (ERERC)

Co-author: Comfort Ikechi Uzoho

[I-9] Economic and Social Empowerment of Rural Communities (ESERC)

Nigeria

Derven Patrick, UNFPA

[I-10] Introducing the Female Condom - Experiences from the English-Dutch Speaking Caribbean

Jamaica

Jean-Paul Ngueya, Afrique Avenir

[I-11] Promoting Sexual and Reproductive Health by the Regulation of Behavioral Attitudes and the Diversification of information

France

Olanrewaju Onigbogi, University College Hospital

[I-12] Involving Opinion Leaders in the Search for an Appropriate Vocabulary for HIV Vaccine Trials in Nigeria

Nigeria

Microbicides

Charles Arntzen, The Biodesign Institute at Arizona State University

Co-authors: Brooke Hjelm, Alice Berta, Cheryl Nickerson, Melissa Herbst-Kralovetz

[M-1] An *In Vitro* Human Vaginal Epithelial Cell Model for High-throughput Microbicide Screening

United States

Sanjay Garg, University of Auckland, School of Pharmacy
[M-2] Improving Solubility of Dapivirine by Using Nanotechnology
New Zealand

Obi Goodluck, Global Alert for Defence of Youth and the Less Privileged (GADYLP)
[M-3] Anal Sex Regarded as a TABOO in South West Nigeria Makes Rectal Microbicides Unacceptable: Human Rights Activities Comes with a Solution!
Nigeria

Zachary Kwena, Kenya Medical Research Institute
Co-authors: N.M. Sang, E.O. Omondi, C.R. Obuya, J.H. Ochieng, E. A Bukusi
[M-4] Evaluating the Potential for a Male Microbicide among Fishermen along Lake Victoria in Kisumu District, Kenya
Kenya

Bonnie E. Lai, Duke University
Co-authors: Marcus Henderson, Jennifer Peters, David Walmer, David Katz
[M-5] Transport Theory for HIV Migration Through *In Vivo* Distributions of Microbicide Epithelial Coating Layers
United States

Gareth Lewis, Starpharma Pty, Ltd.
Co-author: Jeremy Paull
[M-6] SPL7013, a Dendrimer-based Microbicide, Demonstrates a High Genetic Barrier for the Development of Drug-Resistant HIV-1 *In Vitro*
Australia

Xiaowen Liu, Osel Inc
Co-authors: Yang Liu, Rosa Yu, Laurel Lagenaur, Andrew Cheng, Letong Jia, Qing Xia, Dean Hamer, Brigitte Sanders, Peter Lee and Qiang Xu
[M-7] Vaginal Lactobacillus Bioengineered for Mucosal Delivery of the Anti-HIV Molecules
United States

Kathleen Morrow, Miriam Hospital and Brown Medical School
Co-authors: J.L. Fava, R.K. Rosen, P. Kiser, D. Katz
[M-8] Linking Biophysical Functions to User Perceptions and Acceptability in Preclinical Product Development
United States

Suchan Park, University of California, Berkeley
Co-authors: Andrew Szeri, Alex Gorham, David Katz
[M-9] Epithelial Coating Flow Biophysics for Microbicide Delivery
United States

Alfred Shihata, FernCap Inc
[M-10] Novel and Unique Dual Strategy for HIV Prevention
United States

Alan Stone, MEDSA, Ltd.

[M-11] Microbicide Vaginal Tablet Formulation

United Kingdom

Stephane Verguet, Institute for Health Metrics and Evaluation

Co-author: Julia Walsh

[M-12] Cost-Effectiveness of a Hypothetical Microbicide Intervention

United States

Stephane Verguet, Institute for Health Metrics and Evaluation

Co-authors: Bethany Young Holt, Andrew J. Szeri

[M-13] Reframing Behavioral Acceptability of Microbicide Gel Vehicles in Conjunction with Biophysical Constraints

United States

Kevin Whaley, MAPP Biopharmaceutical, Inc.

Co-authors: Larry Zeitlin, Natasha Bohorova, Andrew Hiatt, Michael Pauly, Do Kim, Andy Ho, Jesus Velasco

[M-14] Preventing Sexual Transmission: Mapp66, a Multi-purpose Vaginal Microbicide

United States

Vaccines

Karl Krupp, Public Health Research Institute

Co-author: Purnima Madhivanan

[V-1] Predictors of Physicians' Intention to Recommend HPV Vaccination in Mysore, India

India

Purnima Madhivanan, San Francisco Department of Public Health

Co-author: Karl Krupp

[V-2] A Qualitative Study on the Acceptability of HPV Vaccination in Mysore, India

United States

Papa Salif Sow, University of Dakar

[V-3] HPV Infections and Cervical Lesions in HIV-1 and HIV-2 Infected Senegalese Women

Senegal

Kevin Whaley, MAPP Biopharmaceutical, Inc.

Co-authors: Charles Arntzen, Melissa Herbst-Kralovetz, Hugh Mason, Carol Tacket, Niharika Khanna, Larry Zeitlin

[V-4] The Vaccine and Microbicide Alliance

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