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# Partnership for prevention: A report of a meeting between women's health advocates, program planners, and scientists

Population Council

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**Partnership for Prevention:**

**A report of a meeting between women's health advocates,  
program planners, and scientists**

New York and Washington, DC  
3-12 May 1994

Organized by:

The Population Council

The Pacific Institute for Women's Health

The International Women's Health Coalition

The Population Council  
New York 1994

**The Population Council** seeks to improve the wellbeing and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources. The Council's *Robert H. Ebert Program on Critical Issues in Reproductive Health and Population* grew from an awareness that many important reproductive health problems, and the ways women experience them, have been neglected by policy makers, program planners and practitioners. Designing programs and promoting technology development that addresses sexually transmitted infections, including AIDS, within the larger context of women's reproductive health has been an important focus of the Program's activities since its inception. The Population Council's *Center for Biomedical Research (CBR)* has conducted important research regarding the mechanism of sexual transmission of the Human Immunodeficiency Virus (HIV) - the virus that causes AIDS. As an outgrowth of this work, CBR has identified several potentially microbicial compounds, which block the transmission of HIV when studied in the laboratory and is currently doing exploratory work on the formulation of these compounds into preparations that women could use intravaginally.

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**The Pacific Institute for Women's Health** is a not-for-profit research and advocacy organization dedicated to improving women's health status worldwide. The Pacific Institute works in partnership with women's organizations, health professionals, and researchers in both the North and the South to advance a broad, multidisciplinary analysis

of health grounded in the social, economic, and cultural realities of women's lives. Unlike other organizations that tend to stress either research or activism, the Pacific Institute aims to make high-quality, research-based activism its signature trademark. The organization also stands committed to helping community-based groups in the United States and abroad strengthen their ability to respond to the health needs of women in their communities.

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**The International Women's Health Coalition (IWHC)** is an independent organization working in alliance with feminists, women's organizations, health professionals, and officials in Southern countries and Northern institutions. IWHC promotes women's reproductive health and rights, and serves as a catalyst to change programs and policies that affect women's ability to manage their sexual health and attain their reproductive rights. IWHC's objectives are to enable women to remain free of disease, disability, fear, pain, or death associated with reproduction and sexuality; manage their own fertility safely and effectively; and bear and raise healthy children when they choose to do so. Providing professional and financial support to colleagues in eight countries of Asia, Africa, and Latin America, IWHC's programs are designed to facilitate contact among colleagues both within and across countries and regions. IWHC also initiates and convenes international conferences, collaborates with international agencies, and publishes issue papers.

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## Executive Summary

*From May 3-12, 1994, the Population Council, in conjunction with the Pacific Institute for Women's Health and the International Women's Health Coalition, hosted a meeting for women's health advocates from around the world to discuss the development of microbicides. Microbicides are pharmaceutical products that have the potential to prevent the transmission of HIV and other sexually transmitted infections when applied intravaginally. The group spent six working days in New York and two in Washington, DC and met with a wide range of scientists involved in microbicide research and development. We also met with senior staff from the U.S. Agency for International Development (USAID), the U.S. Food and Drug Administration (FDA), and the National Institutes of Health (NIH), as well as with women's congressional and lobbying groups. It was an intensive eight-day consultation and, although the itinerary was quite full, the women met frequently as a small group and discussed their emerging concerns and impressions. This process was the first step in building greater understanding and mutual respect among women's health advocates and Population Council staff and scientists in regard to the technology of microbicides. It is hoped that the recommendations resulting from this initiative will have a positive influence not only on the development of microbicides, but on all reproductive health technologies.*

*In producing a report of this consultative process, we decided as a group that rather than an exhaustive summary of our discussions, we would aim to reproduce some of the flavor of our deliberations by compiling short essays from most of the meeting participants. We felt that this format -- by allowing participants an opportunity to speak in their own voice -- would best capture the exploratory and often inconclusive nature of our initial discussions. The complexities of AIDS and its prevention belie the possibility of simple definitive recommendations, hence our emphasis on an on-going process of consultation and partnership.*

*As a group, we would like to acknowledge the considerable effort expended by Jennifer Grant in compiling and editing our individual contributions to this report. Jennifer also wrote the text that weaves the various pieces together into a coherent story.*

## **Background to the Meeting**

*Christiana Coggins  
Programs Division  
The Population Council*

*The Population Council, the Pacific Institute for Women's Health, and the International Women's Health Coalition share a commitment to women's reproductive health. In recent years, these institutions have called attention to women's exposure to reproductive tract infections (RTIs), including sexually transmitted diseases (STDs) and AIDS, within the broader context of reproductive and sexual health and cultural realities. Recognizing women's risk of infection points to an urgent need both to address the sociocultural aspects of women's sexual health and to develop woman-controlled prevention methods that will provide protection against sexually transmitted infection. Our three organizations, therefore, collaborated in May 1994 to initiate an ongoing consultative process between women's health advocates and scientists with regard to the technology of vaginal microbicides.*

*The term "vaginal microbicide" refers to any compound capable, when applied intravaginally, of preventing the transmission of sexually transmitted pathogens -- including bacteria, parasites, and/or viruses, such as HIV. Ideally, microbicidal products would be formulated and distributed in such a way as to ensure that they are truly woman-controlled and neither provider nor partner dependent. This advance would give women a tool they urgently want. The*

*PC/PI/IWHC initiative is committed to the timely development of safe and effective "microbicides" -- as opposed to the more narrow concept of a "virucide" -- because women require protection against the full range of sexually transmitted infections. Indeed, at present in many parts of the world these more common reproductive tract infections are responsible for greater amounts of morbidity and mortality than HIV/AIDS.*

*While the development of a microbicide is of critical importance, this technology alone will not redress the underlying conditions of women's lives that make them vulnerable to sexually transmitted disease. The global strategy to prevent STDs and AIDS has so far encouraged people to reduce their number of sexual partners and to use condoms. These strategies, however, most often do not confront the power imbalances that exist between men and women that make it virtually impossible for some women to refuse unwanted or unprotected sex. Gender power inequity also shapes the economic realities that necessitate the selling of sex by women and girls and the social perceptions that stigmatize women who use STD services.*

*The May meeting was designed to prepare participants for sophisticated debate on microbicide research, development, and introduction by reviewing detailed background information on science and policy issues; to consolidate a vision of the groups's collective goals over the next five-plus years; to expose Population Council staff and management to first-hand accounts of women's*

*views and concerns; to introduce participants to the politics, institutions and personalities that will shape the direction of microbicide development over the next five to ten years; and to develop a tentative three-year plan of action and funding proposal to support the future work of the consultative group.*

*These activities supported the general goals of the meeting, which were to:*

- *ensure that the Population Council's current commitment to microbicide development results in the availability of vaginal products that are safe, effective, and meets women's needs;*
- *develop a model for future reproductive health technology development that engages women as active partners in all aspects of the product development process;*
- *further dialogue between women's health advocates, scientists, and program planners on issues that affect women's sexual and reproductive lives, especially with respect to STD and HIV prevention;*
- *increase the ability of women to serve as effective advocates by increasing their understanding of and access to scientific information and to the institutions and decision makers that affect policy; and*
- *foster sensitivity and insight among scientists regarding the realities of women's lives that influence the introduction, safety, and effective use of reproductive health technologies, especially those seeking to prevent sexually transmitted infection.*

*The ideas, opinions and recommendations that emerged from the meeting will be instrumental in the Population Council's efforts to incorporate a women's health perspective into the range of activities that constitute new product development -- from formulation of products in the laboratory, through design of*

*study protocols, to the actual implementation of field research. This meeting was but the first step in building greater understanding and mutual trust and respect among women's health advocates and the Population Council's program planners and scientists. We hope that the changes resulting from this initiative will ultimately affect all future reproductive health technology development.*

*To achieve a balance of perspectives, similar numbers of women's health advocates, program planners, and scientists were asked to participate. Advocates from Latin America, Africa, Asia, Western Europe and the United States were invited to the consultation. The nucleus of the meeting was comprised of nine international women's health advocates and nine staff and scientists from the Pacific Institute, IWHC, and the Population Council's Programs Division and Center for Biomedical Research. A full agenda of our eight day consultation is attached, along with a complete list of participants. In planning the meeting we arranged for the group to spend six working days in New York and two in Washington, DC and to meet with a wide range of scientists involved in microbicide research and development. We also scheduled meetings with senior staff from the U.S. Agency for International Development (USAID), the U.S. Food and Drug Administration (FDA), and the National Institutes of Health (NIH), as well as with women's congressional and lobbying groups. Toward the end of the consultation the women's health advocates presented their concerns and recommendations to the senior staff of the*

*Population Council for consideration and discussion. These recommendations are attached to this report and have formed the basis for interim action on behalf of the Population Council. Progress on these recommendations will be discussed at the next meeting of the group, which is to be hosted by the Pacific Institute for Women's Health in Washington, DC in October, 1994.*

## ***Partnership for Prevention***

In her opening comments, Adrienne Germain (Vice-president, International Women's Health Coalition) called the consultation an historic event because it was one of the first efforts to bring together scientists, program planners, and women's health advocates to debate issues related to an important new reproductive health technology at an early stage in its development. Several years ago, the International Women's Health Coalition together with the World Health Organization sponsored a two-day dialogue concerning the need for earlier and more intensive exchange between scientists and advocates in the development of contraceptive technology. These discussions were summarized in their publication entitled Creating Common Ground. The May consultation was an excellent example of the type of early dialogue recommended by that report.

Historically, the Population Council has focused on the development of long-acting methods of contraception, as Christopher Elias (Senior Associate, Population Council) explained in his overview of the organization's work in technology development. For example, the Council was primarily responsible for development of the Copper T IUD and NORPLANT® subdermal implant system. Several years ago, however, David Phillips (Senior Scientist, Center for

Biomedical Research) and colleagues began to conduct experiments aimed at elucidating the precise mechanism of the sexual transmission of HIV across mucosal membranes. As an outgrowth of this work, several cell culture systems were developed for screening potentially microbicidal compounds, suggesting the possibility of developing a vaginal product capable of preventing HIV and other sexually transmitted infections.

Two and a half years ago, at the invitation of George Zeidenstein, then president of the Population Council, David and Chris made a joint presentation to the Population Council's Board of Trustees. They asserted that the expanding epidemic of sexually transmitted diseases (STDs) and AIDS mandated greater Council involvement in the development of barrier contraceptive methods, and suggested that vaginal formulations of products that women could use to protect themselves from STDs should be a priority for the Council's development program. They specifically requested and received the Board's permission to pursue both contraceptive and noncontraceptive microbicidal preparations, arguing that the latter are essential for promoting safe fertility choice among all women at risk of sexually transmitted infection. Subsequent to that approval, the Center for Biomedical Research and Programs Division have developed and implemented a detailed workplan that includes continuing basic research, as well as pursuing a critical path of microbicidal product development. This interdivisional collaboration has resulted in significant advances. Several

formulations of microbicial compounds are now in the preclinical stage of product evaluation and we anticipate beginning clinical testing of at least one of these products by the end of 1994. This progress has also been reflected in an exponential rise in the commitment of staff and financial resources to microbicide development within the Council over the past three years.

*Developing HIV Prevention Technologies for Women: The Need for Partnership*

*David M. Phillips, Senior Scientist  
Center for Biomedical Research  
The Population Council*

*The specific mandate of the Council's Center for Biomedical Research (CBR) is to carry out research that will serve as underpinnings for advances in the area of women's reproductive health. Traditionally CBR has focused on contraceptive development, but recently -- in the face of the growing need -- we have expanded into developing new ways for women to protect themselves against STDs, especially HIV/AIDS. At this juncture, it is important to identify mechanisms for receiving input from women who will be most affected by the development of microbicides.*

*Most of my own research on microbicides is still in a preclinical stage. When we began our work on HIV six years ago, it was generally believed that sexual transmission was initiated by the entrance of free-virus particles into tiny lesions in the epithelial cells that line the genital tract. Using cervix-derived cells that were grown in the laboratory, we demonstrated that HIV-infected white blood cells in genital tract secretions, or blood, are probably the vectors for HIV transmission. We have observed that infection is initiated by adhesion of these white blood cells to intact epithelia which line the genital tract. The laboratory cell cultures and assay systems that we developed to carry out this basic*

*research, have allowed us to identify several compounds that seem to block HIV infection of epithelial cells from the female genital tract. We have also found that the same compounds may inhibit chlamydial infection.*

*The Partnership for Prevention consultation confirmed for me that we are now at the stage where we need the advice of women "in the field" to determine how best to find out, 1) whether women are receptive to the use of such formulations, 2) whether other types of formulations may be better suited to their needs and lifestyles, 3) whether vaginal formulations containing such compounds can prevent the transmission of HIV and other sexually transmitted pathogens during the conditions of sexual intercourse in real-life situations, and 4) how to proceed with testing such formulations so as to learn how they can, and should, be introduced and used.*

*All research at the Population Council must be carried out with special understanding of the long-term effects that women might encounter when the product is put into use as well as the short-term effects on women involved in clinical trials. In my opinion, it is in this area that productive interaction with women's health advocates can be most helpful. The role of such advocates is especially critical in light of the great gulf that separates biomedical scientists of the western world from women of the developing world. Our interaction has great potential to be mutually beneficial: scientists will learn how best to test and deliver a new reproductive health product that is both safe and effective and*

*meets women's needs and women's health advocates will be provided with access to accurate scientific information to inform and propel the advocacy process. Along the way we all stand to gain from the development of mutual respect and the possibility of establishing partnership where, too often, there has been adversity.*

In 1992, the Council's Ebert Program on Critical Issues in Reproductive Health and Population decided to hold a seminar on microbicide development as a means of developing consensus within the scientific community regarding the need for and feasibility of developing such woman-controlled prevention technology. Lori Heise (Director, Pacific Institute for Women's Health, Washington, DC) worked with Chris Elias to organize a one day seminar in June 1992. Women's health advocates, scientists, and program planners were invited to discuss a range of issues including the need for a female-controlled microbicide and how such a product would fit into broader AIDS prevention strategies. Later that year, Chris and Lori wrote The Development of Microbicides: A New Method of HIV Prevention for Women which was printed in 1993 as a Population Council Working Paper. As a joint production of a scientist and an advocate, this working paper provided an explicitly feminist analysis of the need for microbicide development, as well as a pragmatic review of the principal challenges to be faced in advancing the development of safe, effective, and affordable microbicides.

## ***What Women Need in an HIV Prevention Method***

*Lori Heise*

*Director*

*The Pacific Institute for Women's Health, Washington DC*

*I came to the issue of microbicide research through my work on sexuality and violence against women. As I listened to women and to the frustrations of HIV prevention workers, it became increasingly clear that condoms simply were not an option for many women. Women told stories of being abandoned, ridiculed, or beaten for raising the issue of condom use with their partners. Others were afraid even to ask. It wasn't always violence they feared, however, but also the prospect of losing a relationship that was emotionally and/or economically important to them.*

*The AIDS mantra, "Always use a condom," seemed to ignore their realities and asked women to protect themselves by using a technology outside of their control. It also seemed particularly insensitive that the only option women had to protect themselves was one that also prevents pregnancy while, in many cultures, a woman's social status depends on her ability to bear children.*

*Given these dilemmas, I formulated a simple question and took it to every AIDS expert I could locate. I asked, "Is it scientifically **possible** to imagine a vaginal product that would kill or block HIV transmission but would not kill*

sperm?" The responses were enticing; I was frequently told that it was attainable. It was upsetting to learn then, from the same sources, that the idea was not being pursued.

The reasons why not could easily fill a scrapbook. "Women really aren't at risk of HIV. We have to invest our limited resources where they count." "If a woman wants a child, she should just stop using a condom for a while." And my favorite: "Such a product could be counterproductive in the long run because women would stop using condoms." This response, of course, ignores the reality that for many woman the choice is not be between a condom and a microbicide, but between a microbicide and nothing at all.

My initiation into the world of microbicide research has convinced me that the scientific community is often dangerously divorced from the reality of women's lives. I see the Partnership for Prevention consultation as a first step toward confronting this predicament and making sure that women's voices are heard.

As Chris and Lori's paper details, many questions remain regarding the reproductive biology associated with HIV transmission, such as identification of the specific infectious elements in semen, determination of the precise cells and tissues in the reproductive tract susceptible to infection, and the possible association of HIV with sperm. Other questions regard the local bacteriological, pH, and immune factors that comprise and sustain the ecology of the reproductive tract and the range of possible preventative mechanisms. This research, and the product development, testing, and registration of any new biotechnology takes up to seven to ten years. Thus, development of safe and effective microbicides will require a great deal of research effort. Testing of potentially microbicidal compounds is in its very early stages and, hence, the availability of new microbicidal vaginal products is still some time off -- time that is precious in the face of the global HIV epidemic. This reality further supports the need for close cooperation between scientists and advocates -- to expedite the development process as much as possible, but more importantly, to contextualize the work on new technologies so that we do not lose sight of the parallel need for concerted attention to other strategies for women's protection.

## ***The Role of Women's Health Advocates in Technology Research and Development***

*Amparo Claro  
Coordinator  
Latin American and Caribbean Women's Health Network*

*Having an open dialogue between scientists and women's advocates should be the first step in the research regarding women's reproductive health, including microbicide and contraceptive research. By involving women's groups in all phases of the process, reproductive health research will take a fundamental step forward and scientists, women's health advocates, and the technology under development will greatly benefit from the new alliance.*

*Carmen Barroso, (Director, Population Program, MacArthur Foundation), suggests several ways in which a scientific agenda is advanced by collaboration with women's health advocates. She points out that advocates work to:*

- counteract conservative forces that oppose the development and delivery of contraceptive methods;*
- gain the attention of policy makers who traditionally fail to give issues related to demographics and women's health due notice;*
- increase the ultimate effectiveness of the range of reproductive technologies by providing details of the complexity of women's lives affecting the acceptability of methods; and*
- help the scientific community in creating conditions for the implementation of high ethical standards.*

*Additionally, involving women's health advocates in clinical trials benefits both the study participants and the scientists. When researchers become allied with women's health advocates in the health centers where clinical trials are conducted, information about the product being tested is dispersed through local networks and members of the community. If involved in this process, women's health advocates would establish open and meaningful communication with the study participants which would provide, for the scientists, more accurate and complete reactions to the product. One way to accomplish this partnership would be for agencies to begin a dialogue with local networks by sending project lists to local organizations requesting input and collaboration. Additionally, a job position for a women's health advocate could be written into the original proposal. Taking these steps would serve to create a participatory, democratic, and respectful approach to the development of a new technology because the study participants and their communities would be regarded and employed as significant contributors to the research instead of passive participants.*

Many concerns have been expressed regarding the feasibility of designing clinical trials of microbicides that are both scientifically valid and ethically sound. Before entering human testing, a candidate compound would go through standard testing for toxicity in laboratory animals. With minor modification, the typical product-development sequence for a new vaginal contraceptive could be applied to the pursuit of new microbicidal compounds. The early evaluation of potential products will obviously require significant attention to the possible mutagenicity of vaginal compounds, especially those that are potentially noncontraceptive. Following successful testing in vitro and in animal models, a carefully selected group of potentially microbicidal compounds will be brought to human trials. Human trials typically involve three phases prior to drug registration: Phase I trials evaluate the safety, toxicity, and acceptability of a product in a small number of women; Phase II trials generally involve moderate numbers of women and are designed to establish some evidence of effectiveness; and Phase III trials expand the safety and effectiveness testing to large numbers of women. For a typical compound, completion of all three phases of human clinical trials can take at least five years, but may take longer for microbicide evaluation, given the sample size requirements and special characteristics of study populations.

## **A View from the Laboratory**

*Rachael Pearce-Pratt  
Center for Biomedical Research  
The Population Council*

*I viewed the meeting as an opportunity to discuss the basic science surrounding vaginal microbicide development with women's health advocates without oversimplifying the complex mechanisms involved in sexual transmission of HIV. The questions that the advocates raised regarding the relevance of the science to the "real-life situation" of heterosexual intercourse were well appreciated and fit in with our overall goal to make our laboratory systems as life-like as possible. Additionally, we benefited by hearing, first-hand, what were the realities of some of the women's lives for whom this product will be developed.*

*During the first session of the meeting, we discussed the idea that scientists and women's health advocates speak different languages and thus may not always be able to comprehend each other's approach to a new technology like microbicides. Our initial apprehension as to whether we could communicate as a group, however, was unfounded. In fact, the clarity and level of honesty in putting the issues that mattered most to us on the table had the effect of uniting all participants.*

*As scientists, we were surprised when the women's health advocates acknowledged that scientific research -- especially with respect to women's*

*reproductive health -- is often viewed suspiciously. Consequently, we were eager to reassure participants that we are concerned that any microbicide, once developed, will truly be woman-controlled and to insure this, we need women's health advocates to inform our work by expressing the global concerns of women about such a product. We need them to inform us about cultural practices that might make one formulation unacceptable in a certain society or necessitate that a microbicidal product be completely undetectable. Only by collaborating with women's health advocates do we learn both the realities of how clinical trials are actually implemented and that sometimes the way the design is interpreted "in the field" generates misleading results.*

*Women's health advocates are invaluable intermediates between the laboratory and the policy-making processes. We anticipate an essential relay of information as we go forward with the development of a female-controlled microbicide.*

The major challenge with respect to microbicide development is to design a Phase III effectiveness trial that is both scientifically rigorous and ethically defensible. From a scientific standpoint, the most rigorous, and therefore the most desirable, design is a randomized controlled trial, where trial participants are randomly assigned to receive either the compound under investigation or a placebo. Since it would be unethical to withhold a form of HIV prevention known to be protective, participants in a microbicide trial would also receive free supplies of condoms and be counseled to use both the vaginal product and a condom during each act of intercourse. Statistical techniques would be used to determine any incremental benefit offered by the experimental compound over condom use alone.

This type of trial design raises important ethical issues. An unfortunate reality to be faced in conducting such a trial is that, at best, some members of the comparison group will become infected with HIV while participating in the study. The critical ethical question, however, is whether all study participants will benefit from participation in the trial. Researchers have an obligation to minimize harm and to maximize the benefits to all trial participants. In the optimal design, therefore, all participants, including those in the control group, would benefit from receiving condoms, reproductive health care, and intensive HIV counseling. If the trial were performed properly the women in the control group should have a

lower HIV seroconversion rate than women not participating in the study.

Historical controls could be used to document improved use of condoms by all participants as a direct measure of the benefit of participating in the trial.

Attention to the ethics of clinical trial design is especially important because those groups of women who are at greatest risk of HIV and, hence, are often sought out by investigators for study participation (the greater the infection rate, the smaller the required sample size) are often extremely vulnerable to exploitation. Many of these women are sex workers. Given the economic, legal, and violent realities of many of these women's lives one must carefully examine the feasibility of actually obtaining informed consent, as well as the possibility of their further exploitation if the trial is not implemented as designed.

## **Research: Empowering or Exploitative?**

Liz Cameron  
Empower  
Chiang Mai, Thailand

*Women doing sex work in brothels are often referred to as a "vulnerable population". It is not, however, that the women themselves are "vulnerable", but instead their working conditions leave them unprotected from exploitation and abuse. The realities of their lives are such that they are not able to choose when to eat, bathe, sleep, or work. They cannot choose to whom they sell sex or where they will go when they are ill. The brothel owners make these decisions, along with those regarding their health care, wages, hours, and methods they use for prevention of pregnancy and STD. Sex workers are also vulnerable to exploitation from people conducting clinical trials; again the brothel owner decides whether the women will participate. "If we don't go for our interviews and tests, they contact our bosses and they tell us to go," explained one woman enrolled in a clinical trial.*

*The reality is that sex workers work extremely hard to support their families under the stress of financial hardship and the threat and effects of disease. In their limited free time, these women struggle to get education and improve their standard of living. One woman enrolled in a pre-clinical trial says, "Last night I didn't finish work until 4 a.m. I had to get up early to take my son to*

*school. I'm exhausted and would like to go to sleep but I have to go for an interview and test. I wish they would ask me what time is good for me." These women do not ask the outside world to solve their problems and, to a large extent, the rest of the global community seems content to leave these women to struggle alone.*

*Thai sex workers are distressed by the influx of reproductive health researchers from around the world. Social researchers intrude into their lives, and sex workers wonder whether the researchers are coming with the aim to address the needs and concerns of sex workers or to satisfy the agenda they came with. During a workshop on the ethics of research held by Empower, one woman asked, "Don't they have women doing sex work in other countries? Why come here where we have no rights?"*

*Both the researchers and the implementation of the study design don't meet these women's expectations. "I didn't know I would have to answer such personal questions. I was very embarrassed." Another says, "I thought it was important to be honest so I told him that I cannot always insist on condoms with every customer. I expected him to talk to me about the risks. Instead he just wrote it down, as he told me he was in a hurry to go and eat his lunch." Often women assume participation will in some way improve the conditions of their lives, even if explicit promises aren't made.*

*The medical community has been "doing research on sex workers"*

*instead of joining with the sex-worker community for mutually beneficial research.*

*The recruiting teams come into the women's homes and bedrooms after gaining consent to access by the brothel owners, not the women themselves. One woman who was enrolled in a pre-clinical trial explains, "I couldn't ask any questions or talk properly because I knew the owner was just outside and would hear everything."*

*The **realities of the lives** of the participants determine whether a clinical trial is ethical, regardless of how well it is intended or designed. Regardless of informed consent, use of women who work in brothels in clinical trials is unethical because the women themselves don't grant consent. If an organization seeks to conduct research on a "vulnerable population", they should first take the time truly to learn the realities of the women's lives. Doing this would take a researcher years, but would result in more ethical studies and scientifically valid results.*

The individual women who would participate in clinical trials will not necessarily benefit in the near term from the development of a vaginal microbicides. These women are at high risk of HIV infection and, in the seven to ten years it will take to develop, test, and register a microbicial product, many will probably already become infected with the virus. While pursuing the long term goal of developing new microbicial products, public health workers must also insist on more work to determine the safety and effectiveness of existing products, such as over-the-counter spermicides that may have some microbicial activity.

## ***Interim Prevention Strategies: The Debate over Nonoxynol-9***

*Vicki Legion*

*Community Health Worker Training Program*

*City College of San Francisco/San Francisco State University*

*Until recently, I worked at the Vida/SIDA (Life/AIDS) prevention project in a Puerto Rican neighborhood on the west side of Chicago. In this neighborhood, we experience the same trends reported from around the globe. Every day we hear women -- especially young women -- telling us loud and clear that condom use isn't relevant to their reality: "You can keep the condoms. My man will never go for it. Have you got anything else for me?"*

*The "anything else" that we have is a very slender thread: our practice of educating women with uncooperative partners about N-9 (nonoxynol-9) for partial protection against bacterial STDs. This lack of HIV prevention options is especially agonizing because it often seems that women at highest risk -- such as women in relationships with injection drug users and those who trade sex for money, drugs, or favors -- have the least likelihood of getting cooperation from their partners in the use of condoms.*

*What are we to do until a female-controlled microbicide is available? There is evidence to suggest that the spermicide nonoxynol-9 might provide some protection against STD, including HIV. N-9 is a biode detergent which has been used in the United States for 40 years as the contraceptive ingredient in*

*spermicidal jellies, creams, suppositories, foams, and films. A number of studies have shown N-9 to be partially effective in preventing common STDs, such as gonorrhea and chlamydia. Data is conflicting regarding the ability of N-9 to protect against HIV infection. No institution, however, has launched an aggressive research effort, nor even conducted a review of existing literature in order to craft an interim prevention message based on the available data, some of which is quite promising.*

*The result is that the prevention message for women is complete chaos: some sources advocate spermicide use for STD prevention, stressing that STD infection is a co-factor for HIV transmission while others send the message that N-9 creates lesions which are also considered co-factors for transmission. In the confusion, there is a deafening silence with respect to the critical situation facing the millions of women who are now unable to protect themselves.*

*In light of the public health crisis of HIV transmission, three issues emerge in the question of an interim message regarding N-9 use:*

- This is an emergency -- with a tidal wave of new infections bearing down on us, an imperfect, partial solution is better than a non-option.*
- Women are able to understand a hierarchical message that is more complicated than "condoms, condoms, condoms" and should be presented with available data, even if it is inconclusive.*
- The debate over N-9 should be kept open and studies on its effectiveness as a microbicide must be urgently pursued.*

The potentially microbicide spermicide nonoxynol-9 has been the focus of much controversy. Almost certainly, N-9 may have a lower *method* effectiveness as a prevention against HIV transmission than a physical barrier provided by a male or female condom. It may however, have the potential for higher *use* effectiveness because it is female-controlled and does not necessarily require the consent of a partner. *Use effectiveness* is the performance of a product in actual use while *method effectiveness* measures its performance under perfect use conditions. Regardless of its effectiveness as a microbicide, however, health workers face another problem when presenting N-9 as a possible female-controlled STD prevention method. As a spermicide, it -- like condoms -- prevents pregnancy.

## ***Practical Realities and Women's Protective Needs***

*Muriel J. Harris*

*Director*

*Society for Women and AIDS in Africa (Sierra Leone)*

*The place of a woman in the traditional African society makes her vulnerable to HIV infection. She is socially dependent on the man she marries, and although she contributes significantly to the income of the home, she is economically dependent on him as well. That it is generally accepted that men have multiple casual sexual partners also increases a woman's risk of STD and AIDS. Her husband may take a new wife when he chooses, and if a man dies, his wife is married to his brother.*

*The emphasis within traditional African culture on child-bearing makes existing prevention strategies including condoms inapplicable to women in that society. It is believed that a woman must produce all the children that God will give her and a woman must prove early on in her marriage, and irrespective of her age, that she is capable of bearing children. She must provide the husband's family with a son as soon as possible, even if it means having multiple pregnancies which compromise her health. The higher the number of sons, the higher the status of the mother. The total number of children she bears will determine her status in that community. Any use of contraceptives, then, are concealed from her husband.*

*The use of condoms is limited within the general population and this use is often related to sex within a casual relationship. A woman who requests condom use is often thought to have other sexual partners which can cause considerable problems of trust. Men believe that their ejaculate must have the potential to create a life and refuse to use condoms within their stable relationships.*

*It is clear, then, that a non-contraceptive vaginal microbicide that a woman could use without the consent of her partner is urgently needed in Africa. Available STD prevention methods including the condom or even potentially microbicidal products like N-9, prevent pregnancy and therefore are unacceptable to a woman whose status is wholly dependent on the number of children she produces. The woman's low status in traditional African society -- which compounds her vulnerability to STD -- needs also to be addressed in frank and non-judgmental terms, but a non-contraceptive microbicide may save her life long before societal change is realized.*

It is evident from above that an improved STD/AIDS prevention strategy must address both the longterm or *strategic* gender needs of women, i.e. efforts must challenge and alter the current power imbalances between women and men, as well as meet the immediate, *practical* need for woman-controlled technology. Such a strategy must emphasize the fact that all sexually active people are at risk of STD/AIDS. Without such efforts, microbicides are likely to be perceived only as a "technological fix" that at best by-passes, and at worst reinforces, gender power imbalances. In fact, behavioral and attitudinal factors make a "technological fix" for the STD/AIDS epidemic virtually impossible.

It is unlikely that, after a vaginal microbicide is developed, it will prove 100% effective in preventing the transmission of STD/HIV. It is more likely that a microbicide will offer limited protection against HIV and other STDs, and ideally would be used in addition to condoms when possible. This latter reality, among others, such as the safety and cost of microbicides, will be of tremendous importance when the time comes to consider introducing this new technology, and underscores the need for full participation of women's health advocates from the start.

## **No Quick Fix: Integrating Microbicides into an Overall AIDS Prevention**

### **Strategy**

Nicolien Wieringa  
Women's Health Action Foundation  
Amsterdam, The Netherlands

*The problem of women at high risk of STDs and AIDS is the result of many interrelated factors. These include multiple sexual partners, lack of knowledge about STDs, lack of condoms, lack of adequate medical services, inequity in power relationships between women and men, having other STDs, and the high prevalence of HIV in a community. Because of the complexity of these factors an integrated approach is needed to adequately address the situation of women at high risk for HIV. Looking in further detail at the influences that cause women to be at high risk for HIV transmission through heterosexual contacts, the following factors can be identified:*

- **Disease related factors** at the individual and community level; high prevalence of HIV infection and other sexually transmitted diseases (STDs).
- Factors related to the **political and socio-cultural context** in countries; multiple partners and sexual habits causing high risk of vaginal lesions; inequality in power relations between women and men.
- Factors related to the **quality of the health care system**: lack of medical care in the case of STDs, lack of knowledge about HIV transmission and preventive measures, lack of condom availability.

*These problems exist in developed and developing countries, although they appear in varying intensity and balance. The aim is to develop health policies based on a framework to control STDs and HIV wherein user's perspectives and needs are central.*

*Not only is a concomitant STD a factor leading to an increased risk of HIV transmission, it is a marker of a woman's risk and social vulnerability. This reality suggests that it is just not enough to develop a technological fix to prevent HIV. With the present high numbers of women and men already infected with STDs, major efforts are needed to give adequate care and treatment, especially in a time when economic constraints present a difficult challenge. The following issues should be included in a comprehensive strategy:*

- 1. Education, to encourage women to seek medical consultation when they experience vaginal complaints and to teach them the relationship between their complaints and the sexual transmission of diseases that cause them; to empower women to take care of their bodies.*
- 2. Treatment of STDs with antibiotics in order to reduce the number of people infected.*
- 3. Counselling and consultation to achieve treatment of sexual partners in case of STDs and to improve the acceptance of preventive measures.*
- 4. Preventive measures, providing condoms, other barrier methods and safe and effective microbicides. It is vital that condoms are not only*

*promoted through AIDS programs, but also in family planning services in order to make the connection between sexual behavior and contraception, STDs, personal care, and wellbeing.*

*5. Development of a medical infrastructure to provide adequate care for diagnosis and treatment of STDs. Ideally, this type of care needs to be integrated with reproductive health services, including access to different contraceptive methods and abortion services, along with services to prevent and treat infertility. Treatment, counselling and prevention of STDs are necessary elements of easily accessible medical care.*

*Developing and introducing microbicides needs to go hand in hand with developing policies to implement better health care services directed towards controlling STDs.*

*I'd like to make one final point. There is a continuing need to focus on the use of condoms for the prevention of HIV, as at this moment it is unknown whether a microbicide will ever be more effective than a condom of good quality in preventing the sexual transmission of HIV. The use of condoms is still, and may always be, the best prevention option for women to whom they are accessible and practical.*

## **Reflections and Hopes**

*Christopher Elias, The Population Council  
Adrienne Germain, International Women's Health Coalition*

*We began discussing our plans for a consultation between women's health advocates and Population Council scientists on the topic of microbicides almost a year before our May 1994 meeting. Our thoughts were informed by the various meetings and consultations being held around the world in preparation for the Fourth International Conference on Population and Development in Cairo. We noted with some trepidation the tensions that have developed within the population field -- tensions that have often erupted into complete division and been brought into sharp focus by issues related to technology. Who decides what technology is developed? By whom and for whom? With what motive and with what understanding of the realities of poverty, injustice, and exploitation? We also noted the highly politicized world of AIDS research and wondered about the potential complexity of the process we were contemplating.*

*Within this stormy background, however, we perceived the opportunity to pursue a new model of consultation -- indeed partnership -- around the possibility of developing safe and effective microbicides. Here was a technology that could potentially meet the demands of women for a method of STD protection within their personal control. The scientists involved with microbicides development at the Population Council -- a leading public-sector reproductive health technology*

*development organization -- had achieved enough internal commitment and external resources to begin a small, but promising program of product development. It was still early in the technology development process and these scientists were open to exploring a meaningful dialogue with women's health advocates. If successful, we might not just expedite and improve the relevance and ethical standards of microbicide research, but also identify a model for discussion concerning the development of more contentious technologies.*

*We discussed the need for enough time to overcome the inherent distrust that participants might feel and to review the full range of issues and decided on a two week consultation. At first some wondered how we would fill the time. What if we ran out of things to say on the first day? As is evident from the preceding essays, this did not happen. Indeed, we left feeling some issues had not received the attention they deserved and agreed to meet again in the fall. Through the course of eight long days we exchanged a great amount of information. We also began the process of seeing into each other's worlds, of understanding the shape of our respective discourses. Language revealed itself as an important element of our consultation. What do we mean when we say "acceptability" or "vulnerable population" or "monitoring"? The words we use - whether in advocacy or science - sometimes reveal the divisive assumptions that have polarized the fields of both population and AIDS.*

*And the words represent realities that are even more vastly different. The*

*real world of the product development and registration process, with its scientific uncertainties, regulatory and liability issues, and requirements for demonstration of safety and effectiveness greatly influences what counts as "progress" and "success" in science. Similarly, hearing about the day to day realities of life as a brothel-based sex worker and the problematic implementation of well-designed clinical trials gave a new texture to the challenge of identifying a "vulnerable population" appropriate for microbicide efficacy testing.*

*In summarizing our eight day consultation, it is important to not over-claim our success. We have opened the doors to an effective partnership. In terms of the goals of the meeting, we have made considerable progress in regard to three of the five. As reflected in the earlier essays of this report, we have fostered considerable sensitivity and insight among scientists regarding the realities of women's lives, we have increased the ability of women to serve as effective advocates by increasing access to accurate scientific information, and we have furthered the dialogue between women's health advocates, scientists, and program planners on issues that affect women's sexual and reproductive health. All of these activities need to continue and to form the basis for an on-going exchange and dialogue. Our remaining two goals -- to ensure that the Population Council's current commitment to microbicide development results in the availability of vaginal products that are safe, effective, and meet women's needs and to develop a model for future reproductive health technology*

*development that engages women as active partners in all aspects of the product development process -- are longer term aspirations that will require that we go beyond simply meeting and exchanging information and viewpoints. As Amparo Claro emphasized during our meeting, a true partnership will require a more participatory approach. To this end the group is considering several possible areas of collaboration - as discussed by Lori Heise in the following section.*

*In summary, the outcome of our consultative process is very hopeful. It has documented the benefits of a concentrated exchange of ideas and outlines the possibility of a truly fruitful partnership for the future. In the face of the rapidly expanding global epidemic of sexually transmitted infection and AIDS, the importance and the urgency of this alliance cannot be overstated.*

## ***Furthering the Partnership***

*Lori Heise  
The Pacific Institute for Women's Health*

*In the fall of 1994, the women's health advocates plan to meet again to further consolidate a vision for long term collaboration on microbicide development and testing. The group has decided to seek an identity separate from the Population Council, but remains committed to working with the Population Council scientists and staff to provide input at each step of the microbicide testing and development process. Henceforth, the Pacific Institute for Women's Health in Washington, DC will serve as the secretariat for the group which has renamed itself the "Engendering Microbicide Project."*

*The goal of the Engendering Microbicide Project is to serve as a technical resource and advocacy group to help ensure that women's needs and perspectives are included at every phase of the microbicide development process. A major focus of the group will be interacting with the Population Council's research and development process, although the group hopes to have an impact on the wider research and funding community. Ultimately, the project hopes to forge a new model for reproductive health technology development that engages women as active partners in all phases of the development process.*

*As one of its first activities, the Engendering Microbicide group intends to hold a two-day discussion at its autumn meeting on product "acceptability" from*

*a feminist perspective. Traditionally, there has been very little acceptability research done to inform the development of new contraceptive technologies. What do women want? What criteria are most important to them? What factors will determine whether they will use a product? The research that has been done has generally focused more narrowly on women's formulation preference (e.g.: Do women prefer a cream to a foam?) At the November meeting, women's health advocates will explore the wider set of parameters that affect women's perceptions of "acceptability" including the side effects of new technologies, the preferences of one's partner, and whether a method can be hidden. The group hopes to develop several proposals for research undertaken by and for women, on microbicide acceptability.*

*The group is also planning a major seminar for Spring 1995 to discuss issues surrounding the design and implementation of Phase III trials. The idea is to broaden the current dialogue on trial design and implementation to include voices not normally heard from on this issue: women's health advocates, trial participants, feminist ethicists, human rights workers, and policy makers. By bringing clinical investigators, researchers, and women's health advocates together, the group hopes to forge a new vision of how trials could and should be run. In addition to developing generic principles to guide trial design, implementation, and monitoring, the Engendering Microbicide project hopes to generate concrete suggestions that can be incorporated into the design of Phase*

*II and III testing of possible microbicides.*

*The group will continue to meet twice a year to advance its own and others' thinking on microbicide development and testing. The key will be to stay one step ahead of the technology development process so that the "Engendering Microbicides" network can continue to contribute its expertise and insights into the design and testing of a new vaginal microbicide.*

***Recommendations of the Women's Health Advocates  
Presented to the Senior Officers  
and President of the Population Council***

1. We endorse the process of consultation with women's health advocates in the course of microbicide development. We feel that a sustained commitment to this type of partnership would have a variety of positive benefits for the Population Council and the field of contraceptive technology development in general, including:

- a) building greater understanding and mutual respect among women's health advocates and the Population Council staff and scientists,
- b) helping to ensure that whatever microbicide product is developed truly meets women's needs and will be widely accepted and used, and
- c) helping to mobilize sustained support outside of the Council for greater financial investment in microbicide research.

2. As a leader in the field of reproductive technology and as the best public sector agency positioned to do so, we encourage the Population Council to pursue whatever means necessary to expand current investment in microbicide research. We understand that the Population Council is laboring under staff and space limitations but we feel the urgency of women's need for microbicide products warrants concentrated effort to overcome these barriers. We are greatly encouraged, indeed excited, about the possibilities presented by sulphated polymers, but feel it is essential that the Council (and others) accelerate the search for other potentially microbicide compounds.

3. We urge the International Committee on Contraceptive Research (ICCR) to expand its membership to include a female investigator with special training and expertise in gender issues. Likewise, we encourage the ICCR to invite selected women's health advocates (as it currently invites funders and other outside representatives) to participate in portions of the ICCR meetings. In addition to facilitating a mutual exchange of ideas, such representation would help ensure that women's needs and perspectives are raised early in the technology development process.

4. Beginning now, the Population Council should systemize consultation with this group (and other women's health advocates as appropriate) at each phase of the microbicide development process. This would include periodic updates on the progress of the science, consultation on the selection of research sites and the design of clinical trials, and an opportunity to review and comment on all protocols prior to implementation. The Council should consider expanding this type of consultation process to other reproductive technologies now under development.

5. We strongly believe that the development of topical microbicides for intravaginal use should always be presented in the context of an overall program to reduce women's risk of contracting HIV and other STDs. A new technology is simply one of many complex activities that must be pursued to empower women and reduce their risk. Given the tendency of individuals and institutions to pursue "technological fixes" at the expense of more fundamental social change, it is essential that the Population Council, in both its public statements and internal workplans constantly contextualize microbicide development within a broader program of STD/HIV prevention. We recognize that the Ebert Program represents a firm commitment to this type of multidimensional approach, but we are concerned that the current staffing level may be inadequate to accomplish the objectives laid out in the new mission and mandate regarding STD/HIV prevention and control, especially given Dr. Elias's planned departure from the New York office. We encourage the Council to review its current staffing levels in light of its newly articulated commitment to a broader reproductive health mission.

6. We are encouraged by the Population Council's emerging commitment to institutionalize monitoring of the informed consent process in all of its clinical trials. This represents an important shift toward greater concern with how trials are actually implemented in addition to the research community's long-standing commitment to scientifically and ethically defensible trial designs. Because this is such a pathbreaking area of work, we would suggest strong collaboration between the programs division and CBR in developing the process by which such monitoring can be achieved. We encourage a systematic process of action research and reflection to develop the system and principles upon which to base this monitoring. Important issues remain outstanding: Should the monitors be outside consultants or Council staff? What criteria should be used for picking monitors? Who should such monitors consult

for information in addition to the trial participants themselves? How should such monitors be trained and evaluated? To discover the best methodology for doing such work, the Council should consider sending multidisciplinary teams to several sites to perform monitoring and have them reconvene to share experiences and techniques. Based on these experiences, the Population Council should develop a detailed training manual and list of recommendations for future monitors. The Council should remain open to the possibility that different types of monitors with different scopes of work may be necessary depending on the type of trial and the vulnerability of the trial participants.

7. We are encouraged by the emerging shift in health-related research and care towards including representatives from the communities affected (patients, trial participants, etc.) in the design of research studies and in agenda setting. We recommend that the Population Council explore ways to institutionalize such a commitment in the organization of its work.

8. As a member of the interagency microbicide task force, the Population Council should lobby to add two woman's health advocates as standing members of the committee. This will facilitate the integration of women's perspectives into the research agendas and methodologies of other institutions pursuing microbicide research.

9. We suggest that the Population Council organize activities at the upcoming Cairo ICPD conference to lend prominence to the development of new female-controlled barrier methods within an overall program of STD prevention and control.

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## **AGENDA**

Tuesday, May 3  
The Population Council  
9th Floor  
1 Dag Hammarskjold Plaza

### **Introductions**

- |               |                                                                                                                                                        |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:30          | Coffee and breads available                                                                                                                            |
| 9:00 - 10:30  | Welcome and Background<br>(Christopher Elias, Adrienne Germain, Lori Heise)<br>Brief Introductions                                                     |
| 10:30 - 10:45 | Coffee Break                                                                                                                                           |
| 10:45 - 11:45 | Substantive Overview of the Next 10 Days<br>(Christa Coggins)<br>Review of Draft Objectives for Meeting<br><br>Logistics/Housekeeping (Jennifer Grant) |
| 11:45 - 12:30 | Hopes and Concerns for this Process                                                                                                                    |
| 12:30 - 1:30  | Lunch                                                                                                                                                  |
| 1:30 - 3:30   | Personal Stories (Who are we? What brought us to this work?)                                                                                           |
| 3:30 - 5:00   | Discussion of Additional Meetings/<br>Information Sessions to be Scheduled<br>Group Consensus on Meeting Objectives                                    |

### **Wednesday, May 4**

#### **Meeting With Wider Population Council Community**

Beverly Winikoff, Chairperson

- |             |                            |
|-------------|----------------------------|
| 8:30        | Coffee available           |
| 9:00 - 9:15 | Welcome (Beverly Winikoff) |

|               |                                                                                                                                                                                                                    |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9:15 - 10:15  | <p>Integrating Women's Voices into Technology<br/>Development: A Bit of History<br/>(Adrienne Germain)</p> <p>Practical Realities and Women's Protection Needs in Africa<br/>(Muriel Harris)</p> <p>Discussion</p> |
| 10:15 - 12:15 | <p>The Science of Microbicide Development (David Phillips, Rachael Pearce-Pratt, Vanaja Zacharopoulos, Center for Biomedical Research, The Population Council)</p> <p>Discussion</p>                               |
| 12:15 - 1:15  | Lunch                                                                                                                                                                                                              |
| 1:15 - 2:45   | <p>Clinical Trial Design: Ethics and Science<br/>(Lori Heise)</p> <p>Research Among Vulnerable Populations: A View from the Field (Liz Cameron)</p> <p>Discussion</p>                                              |
| 2:45 - 4:15   | <p>Challenges of Microbicide Development<br/>(Christopher Elias)</p> <p>No Quick Fix: The Role of Technology in an Overall AIDS Prevention Strategy<br/>(Nicolein Wieringa, Women's Health Action Foundation)</p>  |
| 4:15 - 5:00   | <p>Wine and Cheese Reception<br/>Hosted by Beverly Winikoff and the Ebert Program</p>                                                                                                                              |

**Thursday, May 5**

**Meeting with staff from the CBR Laboratories**

|               |                                                                                                                                                                                                                                                                                           |
|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:30          | Coffee available                                                                                                                                                                                                                                                                          |
| 9:30 - 10:45  | Introductions<br><br>Discussion of Outstanding Microbicide Issues<br><br>Issues of Formulation (Esther Adebayo-Olojo)<br><br>Proposed Acceptability Studies (Christa Coggins)<br><br>Prevention of Other STDs (Franca Zaretsky)                                                           |
| 10:45         | Coffee break                                                                                                                                                                                                                                                                              |
| 11:00 - 12:15 | Overview of the Population Council's Contraceptive Development Program (Rosemarie Thau, Director of Contraceptive Development)<br><br>This will be an opportunity for participants to raise questions/issues regarding other technologies such as contraceptive vaccines, NORPLANT®, etc. |
| 12:15 - 2:00  | Discussion of previous presentation over Lunch                                                                                                                                                                                                                                            |
| 2:00 - 5:00   | Continued discussion of PC Contraceptive Development<br>Discussion of acceptability protocol                                                                                                                                                                                              |

## **Friday, May 6**

- 9:00 - 10:30      Review of Research on the Efficacy of Nonoxynol-9  
for STD/HIV Prevention  
(Erica Gollub)
- Discussion
- 10:30 - 10:45      Coffee break
- 10:45 - 12:15      Policymaking in the Face of Uncertainty: New York State's  
Hierarchy of Protection Options for Women (Mike Rampolla)
- Discussion of Nonoxynol-9 Policy Options
- 12:30 - 2:00      Luncheon with local women's health activists  
(Diana Hartel and guests)
- 2:00 - 3:00      Discussion of the Female Condom (Erica Gollub) Findings from  
Recent Acceptability Studies
- 3:00 - 5:00      Further discussion of female condom, N-9 studies

**Monday, May 9th**

Washington, DC

- 8:15 Meet in Hotel Lobby
- 9:00 - 12:00 Briefing on the Activities of Other Actors Involved in HIV/STD Prevention Technologies
- 9:00 - 9:45 The work of the National Institute of Allergy and Infectious Disease (NIAID) (Penelope Hitchcock)
- 9:45 - 10:30 The work of the National Institute of Child Health and Human Development (NICHD)
- 10:30 - 11:15 The work of the Contraceptive Research and Development Program (CONRAD) (Henry Gabelnick)
- 11:15 - 12:00 Lunch and discussion of morning's presentations
- 12:00 - 1:15 Briefing on current and future microbicide research by Family Health International, (Paul Feldblum)
- 1:30 - 3:30 An Open Discussion with USAID staff (Liz McGuire, Jeff Spieler, and colleagues)
- This will be an opportunity for participants to ask questions and exchange views with high-level AID decision makers regarding family planning policy and programs, contraceptive research, HIV prevention policy, etc
- 4:00 - 5:00 The Regulatory Process - An informal discussion with staff from the U.S. Food and Drug Administration (FDA)
- 7:00 Dinner at the home of Lori Heise

**Tuesday, May 10th**

**The Politics of Women and HIV**

- 8:45 Meet in Hotel Lobby
- 9:30 Meeting with Representative Constance Morella (R-MD), sponsor of legislation earmarking money for microbicide research
- 10:30 Strategy Session with staffers of the Congressional Women's Caucus
- 11:30 - 12:45 Lunch/Center for Women's Policy Studies  
  
(Informal discussion with local advocates on the politics of Women and HIV in the U.S.)
- 1:00 - 4:00 Meeting with "The Microbicide Advocacy Project," a coalition of U.S. advocates working to build support for microbicide research
- 5:30 - 6:30 Fly to New York on the Delta Shuttle
- 7:30 - 9:00 Reception at the home of Mrs. Margaret Catley-Carlson, President of the Population Council

**Wednesday, May 11**

**Presentation of Recommendations to Senior Population Council Management**

|               |                                                                                                                                            |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 8:00 - 8:30   | Breakfast - Ninth Floor Conference Room, The Population Council                                                                            |
| 8:30 - 9:45   | Presentation of by Women's Health Advocates to Senior Officers of the Population Council<br><br>(Outside funders and policymakers present) |
| 9:45 - 10:00  | Coffee break                                                                                                                               |
| 10:00 - 11:00 | Continued Discussion                                                                                                                       |
| 11:00         | Senior Officers depart                                                                                                                     |
| 11:00 - 12:30 | Further Discussion and Strategy Session with Remaining Participants                                                                        |
| 12:30 - 1:30  | Break for Lunch                                                                                                                            |
| 2:00 - 5:00   | Discussion of future steps                                                                                                                 |

**Thursday, May 12**

**Strategic Planning for Future of Project  
Evaluation of Process**

|              |                                                                                                                                                                                 |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:30         | Coffee Available                                                                                                                                                                |
| 9:00 - 12:30 | Discussion of Possible Future Activities of Group<br><br>Regional Activities<br><br>Future International Meetings<br><br>Resource Needs<br><br>Developing a Communications Plan |
| 12:30 - 1:30 | Lunch                                                                                                                                                                           |
| 1:30 - 2:30  | Evaluation of Process to Date/Recommendations for Future                                                                                                                        |
| 2:30 - 3:30  | Developing Detailed Plans of Action<br>(for inclusion in a Funding Proposal to the MacArthur Foundation)                                                                        |
| 3:30 - 5:00  | Getting the Word Out: Discussion of ways to mobilize our wider constituencies                                                                                                   |