

PN-ACB-861

**USAID BIOMEDICAL RESEARCH
WORKSHOP REPORT**

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DECEMBER 15, 1997

This report was prepared under the auspices
of the U.S. Agency for International Development (USAID).

The report was written and revised by the
Health Technical Services (HTS) Project
(Project No. 936.5974.10, Contract No. HRN-5974-C-00-3001-00)
of TvT Associates and The Pragma Corporation.

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Acknowledgments

This workshop resulted from the vision and leadership of Dr. Paul DeLay and Dr. Amy Bloom, of USAID's HIV-AIDS Division. They helped shape the agenda and persuade the leading lights of the most prestigious HIV/AIDS research institutions to devote two days to advising USAID on its biomedical research agenda.

Linda Sanei, Technical and Program Advisor, and Benjamin Fouts, Program Assistant, Health Technical Services Project (HTS), were the major workshop planners and organizers. Dick Wall and John Wooten, HTS consultants, served as workshop facilitators. Cynthia Green, HTS consultant, prepared the workshop report. HTS staff members Callie Curtis, Shirl Smith and Benjamin Fouts served as rapporteurs.

Acronyms

AIDS	Acquired immunodeficiency syndrome
CDC	Centers for Disease Control and Prevention
CIP	Committee of Interested Parties, SDI
FDA	U.S. Food and Drug Administration
HIV	Human immunodeficiency virus
HTS	Health Technical Services Project
IAVI	International AIDS Vaccine Initiative
NCI	National Cancer Institute, NIH
NIAID	National Institute of Allergy and Infectious Diseases, NIH
NIH	National Institutes of Health
SDI	Sexually Transmitted Diseases Diagnostics Initiative (located at UNAIDS)
STD	Sexually transmitted disease
STI	Sexually transmitted infection
UNAIDS	Joint U.N. Programme on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

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Executive Summary

Many innovative ideas for USAID support of HIV/AIDS-related biomedical research emerged during a two and one-half day workshop attended by 32 senior researchers and health experts from the key agencies involved in HIV/AIDS research. Held in Washington, D.C. on November 23-25, 1997, the workshop was organized by the Health Technical Services Project.

Workshop participants recommended that USAID work on the following aspects of HIV/AIDS-related biomedical research over the next 3-5 years:

- **Microbicides.** Participants listed seven priorities for microbicides research: (1) formulation of vaginal products such as a sponge applicator; (2) studies to measure product diffusion in the vagina; (3) a half-time fellow at USAID to monitor microbicides research; (4) technical assistance in operations research to expedite efficacy trials; (5) studies to determine if the cervix is a preferential site of HIV infection; (6) sponsorship of orphan drugs to facilitate their use in clinical trials; and (7) screening promising compounds in animal models. These activities could cost an estimated \$1.6 to \$2.1 million annually plus personnel costs.

- **Vaccines.** USAID could make a valuable contribution in three areas: (1) educating stakeholders in developing countries, including both host country and U.S. officials, to ensure that they understand the importance of vaccine trials and have adequate information about them; (2) developing the methodology for community-level interventions, fostering long-term relations with local communities, measuring indirect effects, and doing impact modeling; and (3) supporting research and development of products useful in developing countries such as DNA vaccines with viral vectors and live-attenuated vaccines.

- **Sexually transmitted diseases diagnostics.** USAID support was recommended in six areas: (1) funding for research on gonorrhea and chlamydia testing, genital inflammation, improved tests for trichomonas, and detection of chemical markers for all major STDs; (2) a study of the potential market for STD diagnostic tests in developing countries; (3) funds to support

the secretariat of Committee of Interested Parties of the STD Diagnostics Initiative (SDI); (4) field testing of products such as syphilis diagnostics; (5) continued support for ongoing research projects; and (6) information dissemination, including a newsletter and the SDI website. These activities would cost about \$1.7 million annually.

- **Vertical transmission.** Recommended inputs from USAID are: (1) studies to determine optimal feeding for infants born to HIV-infected women in developing countries; (2) research on the feasibility of HIV testing on a large scale so that women can make informed choices based on their HIV status; (3) research on "low-tech" interventions such as vaginal and infant washing and nutritional supplements; (4) dissemination of information about vertical transmission, risk assessment and counseling techniques to health workers, decision-makers, researchers and program managers in developing countries; and (6) collection of information on what technologies and assistance women in developing countries need to prevent vertical transmission.

Workshop participants identified four other areas of biomedical research that would benefit from USAID support:

- Development of specialized HIV tests and use of tests to monitor HIV incidence
- Identification of biomedical markers to validate behavior change
- Research on the potential impact of HIV community-level care and therapies on risk reduction behavior change
- Assessment of HIV care strategies, including nutrition and micronutrients.

These additional activities were considered to be long-term initiatives to be undertaken as resources permit.

The major outcome of the meeting is that the key agencies working in HIV/AIDS-related biomedical research believe that USAID's involvement in this sector is essential. Workshop participants stressed that USAID's extensive expertise in advocacy, product design, field support, operations research and product distribution/marketing could make a major contribution to biomedical research. Because USAID's funds for biomedical research are limited to \$1-4 million annually, its investments in specific research projects should be allocated strategically, to fill in gaps or support initiatives specifically tailored to the needs of developing countries. Most of the activities recommended by participants could be categorized as applied research, operations research, or country-level interventions. Many of them could be undertaken under existing USAID contracts or planned procurements.

I. Introduction and Overview

At the request of the HIV-AIDS Division of the U.S. Agency for International Development (USAID), the Health Technical Services Project (HTS) organized a two and one-half day workshop to provide guidance for a strategic plan for future USAID-funded biomedical research related to HIV/AIDS. Held at the State Plaza Hotel in Washington, D.C. on November 23-25, 1997, the workshop had three major objectives:

- To determine the major areas of biomedical research that USAID should be pursuing given its overall mission and funding
- To determine what types of activities USAID should undertake in these research areas
- To develop a process for designing and monitoring these activities.

Workshop participants were asked to suggest research priorities in accordance with USAID's strengths and comparative advantage relative to other agencies working in this area. In their recommendations, they were requested to be as specific as possible regarding research topics, the costs and level of effort needed, and ways to monitor progress and evaluate impact.

Workshop participants were senior research managers and policy-makers from a variety of public and private agencies working in HIV/AIDS. Of the 32 workshop participants, ten were from nongovernmental organizations and USAID contractors, nine were from USAID, six came from the National Institutes of

Health (NIH), six represented universities, and one was from the Joint U.N. Programme on HIV/AIDS (UNAIDS). Annex A provides a list of participants.

The workshop used a mix of brief presentations, small group discussions, and plenary discussions to reach a consensus on USAID's role in biomedical research and research priorities. Following the opening session on Sunday, November 23, the workshop participants heard presentations on USAID's HIV/AIDS research activities and brief summaries on the current status of the four major biomedical research areas related to HIV/AIDS: microbicides, vaccines, STD diagnostics and vertical transmission from mother to child. They then split into four groups to discuss these topics in more detail. On the third day of the workshop, a spokesperson for each group reported its major conclusions back to the plenary. The larger group reviewed these ideas, made further amplifications or revisions, and then discussed common themes and overall priorities. This report reflects the consensus that emerged from this sequence of discussions. Annex B shows the workshop agenda.

II. USAID's Support of HIV/AIDS-related Research

Dr. Paul DeLay, Chief of the HIV-AIDS Division of the USAID Office of Health and Nutrition, provided an overview of USAID's portfolio of current and planned HIV/AIDS projects. USAID's overall objective is to promote increased use of improved, effective and sustainable responses to reduce HIV transmission and to mitigate the impact of the HIV/AIDS pandemic.

Major USAID-supported interventions are: behavior change, access to barrier methods, improved prevention and management of sexually transmitted infections, policy reform, biomedical research, and social science research. USAID also supports operations research on the prevention to care continuum, surveillance, improving community-based responses, improved program impact analysis, improved input and use of research, and improved service to the field.

The major HIV/AIDS projects funded by USAID include:

- "HORIZONS," which supports social science research
- "IMPACT," which provides technical assistance and other country/regional services
- "AIDSMARK," which promotes social marketing of condoms and other products
- UNAIDS, a collaborative program of six U.N. agencies, which promotes best practices.

Additional projects—to provide services for the design, monitoring and evaluation of country programs; to support biomedical research; and to promote NGO/PVO linkages—are not yet operational.

Since FY1993, USAID funding for HIV/AIDS programs has been essentially straight-lined at \$120 million. During this period, the number of new HIV infections worldwide per year has risen from about 2 million in 1993 to 5.8 million in 1997. The developing world spends about \$500 million per year altogether on HIV/AIDS prevention. In contrast, the United States spends \$800 million annually in domestic prevention activities. Given the many demands for USAID funding in the 45 countries in which it works, USAID has only \$1-4 million to spend on biomedical research.

The World Health Organization (WHO) estimates that about 30.6 million people worldwide, or 1 in 100 of the world's inhabitants of reproductive age, are infected with HIV. According to WHO, roughly 7.4 percent of adults aged 15-49 in sub-Saharan Africa are infected, 1 percent of adults in India, 1.9 percent in the Caribbean, and 0.6 percent in North America.

III. Biomedical Research Priorities for USAID

Workshop participants discussed USAID inputs into four major areas of HIV/AIDS-related biomedical research: microbicides, vaccines, STD diagnostics, and vertical transmission.

A. MICROBICIDES

1. Current status

Microbicides are chemicals that can be applied to the woman's vagina to prevent HIV and other sexually transmitted infections. Scientists believe that this goal is technologically feasible. Microbicides that prevent or permit conception are also feasible. Several compounds have been identified and are in various stages of testing. However, even with streamlined testing, a microbicide ready for general use is several years away.

Dr. Zeda Rosenberg, Senior Scientist for Adult Prevention Research, NIH, reported that the U.S. public health agencies (NIH, CDC, FDA) are spending about \$24.5 million annually on microbicides. These funds are for clinical studies, project grants, preclinical trials, therapy development, basic behavioral research, and Phase III clinical trials. Basic research is being done in: identifying the basic steps in HIV transmission, screening prospective agents against HIV/STD pathogens and lactobacillus (changes in vaginal organisms), in vitro

screens, early preclinical studies, review of existing products for microbicidal use, and efficacy trials.

Formulation development is the most critical gap in the research. A "super glue" compound that would adhere to all surfaces would be ideal.

2. USAID's role

Workshop participants agreed that it is important for USAID to maintain its commitment to microbicides research. Areas in which USAID can make a unique contribution are:

- **Advocacy.** USAID took the leadership role in promoting the concept of microbicides and supporting initial biomedical and social science research. Through its high-level contacts with other donors, national leaders, scientists and public and private agencies, USAID can continue to advocate for actions and funding that will accelerate the research process.
- **Product design.** With its in-depth knowledge of field conditions, USAID can provide important inputs into product design features such as cost, ease of use and chemical stability that affect acceptability and usage in developing countries.
- **Field support.** USAID collaboration will be indispensable in conducting clinical trials in developing countries. USAID and its contractors can provide information about the local setting and facilitate linkages with political leaders, scientists, academics and community groups.
- **Product distribution.** USAID has the capability to promote and distribute new health-related technologies to millions of people in the developing world.

3. Priority USAID Activities Within the Next 3-5 Years

Workshop participants recommended that USAID give priority to the following activities within the next 3-5 years; items are listed in descending order of priority.

III. BIOMEDICAL RESEARCH PRIORITIES FOR USAID

a. Formulation. More research is needed on the formulation of vaginal products. In particular, the sponge applicator needs to be evaluated because it may provide better protection than gels or other formulations. NIAID plans to start work on formulation in the year 2000; a gap remains until then. Estimated annual cost: \$500,000.

b. Product diffusion in the vagina. Scientists need to find better ways to measure the distribution and duration of action of compounds placed in the vagina. Both irritation and inflammation are major concerns. Colposcopy (visualization using a metal probe) is currently used, but scientists believe alternative assessment methods are needed. Estimated annual cost: \$500,000 to \$1 million.

c. USAID staffing. A half-time fellow in the HIV-AIDS Division could serve as an advocate for microbicides research and maintain contact with other donor agencies and researchers.

d. Efficacy trials. Technical assistance in operations research could greatly expedite efficacy trials and facilitate collaboration between HIVNET (a network of HIV/AIDS research sites) and USAID. Estimated annual cost: \$300,000, which could be added to existing contracts.

e. Studies of cervical infection. Research is needed to determine whether the cervix is a preferential site of HIV infection and thus would need more protection than the vaginal wall. USAID's collaboration in assessing existing vaginal methods (such as the diaphragm) would be helpful. Estimated annual cost: \$300,000.

f. Sponsoring orphan drugs. The National Cancer Institute (NCI) is examining orphan drugs—those that had preclinical testing but were later abandoned due to inadequate therapeutic effect. Some of these drugs may be effective as microbicides when used externally. If promising compounds are identified, NCI will ask the pharmaceutical company that holds the patent to cede rights to the U.S. government. USAID's role would be to sponsor the drug, which might entail support of some preclinical studies but would mostly be to fund manufacture of small quantities of the drug to be used in clinical trials. Costs will depend upon the drugs identified and the research needed.

g. Screening leads. Scientists are working to develop and validate animal models to test potential microbicides. USAID could assist in screening promising compounds in animal models. This work is expensive but needs more support now. Screening leads in the macaque model costs \$250,000 per compound.

The total cost of items 1-5 is \$1.6 to \$2.1 million annually plus the cost of a half-time fellow.

B. VACCINES

1. Current Status

The need for a vaccine to provide immunity against HIV and reduce HIV transmission has been recognized for more than a decade. Overcoming the scientific challenges to develop such a vaccine has taken longer than initially anticipated, but scientists believe that a vaccine is still attainable. Much progress has been made, and several experimental vaccines are in the pipeline. Three vaccine products are scheduled for clinical trials in the next 3-5 years. Others are in the early stages of Phase I testing and thus will not undergo large-scale clinical trials for at least five years.

Dr. Rodney Hoff, Chief, Vaccine Trials Section, National Institute of Allergy and Infectious Diseases (NIAID), NIH, summarized the scientific problems in developing an HIV/AIDS vaccine: HIV/AIDS is a complicated disease; there are no immunologic correlates for protection; appropriate animal models are lacking; and human trials are critical to vaccine development, despite the ethical and social issues they raise. In the long term, vaccines need to be tested in diverse populations that have different strains of the virus. Vaccine testing is also needed among poorly nourished people and those with micronutrient deficiencies.

NIH is the largest funder of vaccines. The U.S. Army also has a large vaccine program, and the CDC is involved in community preparation for clinical trials. Only about five large pharmaceutical companies and 5-10 smaller ones are interested in HIV vaccine development. The United Kingdom, France, Canada and Russia are also doing vaccine research.

2. USAID's Role

Public investment in HIV/AIDS vaccines is needed because few private companies are willing to invest funds in such a high-risk, low-profit venture. Most of the companies working on vaccines are looking at the clade B (an HIV genetic subtype), which is prevalent in western industrialized countries and Latin America. Clades A, C, D, and E are more common in Africa and parts of Asia.

USAID can make a major contribution to vaccine development by using its in-depth country knowledge to support the planning and implementation of field trials for vaccines. From its work in other health and development sectors, USAID has considerable expertise and extensive field experience that can facilitate community-based research.

3. Priority USAID Activities Within the Next 3-5 Years

a. Educating stakeholders in developing countries. USAID could assist in educating national and local decision-makers in developing countries about vaccines and vaccine trials. This task entails explaining the importance of clinical trials, making accurate information widely available, responding to questions, countering misinformation, and lining up high-level support from both host country and U.S. officials. Plans for vaccine trials can be derailed if local officials are not prepared to respond to allegations of exploitation and fears regarding safety. Stakeholders include: USAID and U.S. embassy officials, host country leaders and officials, scientists, non-governmental organizations, private companies, academics, media representatives, and representatives of other international donor agencies.

b. Methods for community-based research. USAID could play a leading role in: developing the methodology for community-level interventions; fostering long-term, sustained relations with local communities; measuring indirect effects; and doing impact modeling. By working closely with local communities, USAID could ensure that they are ready to participate in clinical trials. USAID has already done some impact modeling that involved calculating the theoretical impact of a partially effective vaccine combined with other interventions.

c. Research and development of products for developing countries. USAID could accelerate the development and testing of products especially useful in developing country settings due to their long-term efficacy, reduction of HIV transmission, cost and delivery systems. Workshop participants suggested two vaccines that show promise for use in developing countries: (1) DNA vaccines with viral vectors; and (2) live-attenuated vaccines. Live-attenuated vaccines are the most likely to succeed but the least likely to be developed due to the fear of infecting people with HIV. To test a DNA vaccine with a viral vector would cost \$1 million per year. USAID could also support product manufacturing and safety studies. These studies would require \$1 to \$1.5 million for 5-10 years.

Workshop participants described these three initiatives as "low-cost but high-impact." Costs for education of stakeholders and community-based research

were not estimated. Many of these activities are already budgeted in other parts of USAID's portfolio and could be added to existing work plans.

C. SEXUALLY TRANSMITTED DISEASES DIAGNOSTICS

1. Current Status

Prevention and control of sexually transmitted diseases is important because of their role in increasing the efficiency of HIV transmission. Furthermore, STDs are second only to maternal causes as a source of death and disability among reproductive-age (ages 15-44) women in developing countries, according to the World Bank. More timely and effective diagnosis of STDs can increase contraceptive adoption, prevent syphilis among newborns, and reduce the incidence of infertility.

Dr. King Holmes, Director, University of Washington Center for AIDS and STDs, stated that effective management of STDs decreases HIV transmission as well. In developing countries, where screening and laboratory support are expensive, syndromic management of STDs works well in cases of urethral discharge, genital ulcer and pelvic inflammatory disease. However, it has limitations in treating vaginal discharge and is not useful in asymptomatic cases.

STD diagnosis requires cheap, simple and rapid screening and diagnostic technology for field use. Improved diagnostic technology would ensure that patients are treated promptly and correctly, thereby controlling the spread of STDs, reducing wastage of drugs due to incorrect diagnosis, and limiting development of antibiotic resistance. Health providers need to be able to detect gonorrhea and chlamydia in low-prevalence populations and to distinguish between trichomonas and chlamydia, which have a similar vaginal discharge.

The major agencies working in STD diagnostics are: USAID, UNAIDS, NIH, CDC and Rockefeller Foundation. The European Economic Community and the World Bank are potential donors. Progress is being made in developing dipsticks and card tests for rapid, low-cost diagnosis. Strip tests for syphilis, chlamydia and gonorrhea are undergoing field trials. Links with industry are being sought.

2. USAID's Role

USAID has played a leading role in initiating work on STD diagnostics and leveraging funds from other donors. Funds and advocacy continue to be needed. USAID can make important contributions to all six stages of STD diagnostics: (1) proof of concept; (2) linking with industry; (3) limited manufacture and evaluation; (4) testing in field sites; (5) manufacturing scale-up; and (6) introduction and marketing. USAID funding is needed in the first five stages, with decreasing amounts as a product is taken up by industry, which typically invests in field testing and marketing. Greater links between the HIV-AIDS Division and the Office of Population would be beneficial.

USAID has been a key member of the Committee of Interested Parties (CIP) of the STD Diagnostics Initiative (SDI) since its inception in 1990. Housed at UNAIDS, the SDI is undergoing reorganization and needs seed money to play a more active catalytic and coordinating role.

3. Priority USAID Activities Within the Next 3-5 Years

a. **Research funding.** Priority areas for further research are:

- Testing for gonorrhea and chlamydia
- Basic research on genital inflammation
- Better tests for trichomonas
- Detection of chemical markers (antigens, antibodies, nucleic acids, enzymes or metabolites) for all major STDs.

USAID should allocate \$400,000 per year to fund four \$100,000 research projects on STD diagnostics. Proposals from small businesses could be referred to the NIH's SBIR program, which provides grants for product discovery, evaluation and production. The Department of Defense may be another funding source.

b. **Market survey.** Information on the size of existing and potential markets is needed to interest pharmaceutical companies in investing in STD diagnostic tests. More thorough and accurate data incorporating current sales information, consumer willingness to pay, and potential donor subsidies are needed. USAID should allocate \$150,000 for a market survey in developing countries.

c. Institutional support. Funds are needed to support the CIP/SDI secretariat, including: (1) secretariat management and staff, costing \$200,000 per year; and (2) meetings with industry and research groups, costing \$75,000 per year.

d. Field testing. Field testing, especially of syphilis diagnostics, is needed before products can be manufactured on a large scale. The development of field testing infrastructure will cost about \$200,000 per year. Conducting field tests of four products is estimated to cost a total of \$500,000 per year.

e. Ongoing research. Funds are needed for continued support of ongoing research projects, at a cost of \$100,000 per year.

f. Information dissemination. The costs of collecting abstracts and publications, producing a newsletter, and maintaining the SDI website are estimated to be \$75,000 per year.

The total cost of these six activities is \$1.7 million annually.

D. VERTICAL TRANSMISSION

1. Current Status

Vertical transmission of HIV from mother to child, either before or during birth or through breastmilk, is a major problem in areas with high HIV seroprevalence. One in three infants born to HIV-infected mothers becomes infected. Of uninfected infants born to HIV-positive mothers, one in seven of those who are breastfed becomes infected.

Dr. Lynne Mofenson, Associate Branch Chief for Clinical Research, Pediatric, Adolescent and Maternal AIDS Branch, Center for Research for Mothers and Children, National Institute of Child Health and Human Development, NIH, reported that the major perinatal interventions being studied are:

- provision of antiretroviral drugs to the mother before delivery and to the newborn infant
- changes in recommended breastfeeding practices such as artificial feeding, where feasible, and weaning at three or six months
- active, passive, and combined active/passive immunization
- provision of micronutrients such as vitamin A

- modification of delivery practices such as performing cesareans and cleansing the birth canal and newborn.

The main agencies doing research on vertical transmission are CDC, NIH, and UNAIDS.

In the U.S. and other developed countries, medical workers have been successful in reducing perinatal transmission of HIV/AIDS by providing antiretroviral drugs to the mother and infant and by encouraging HIV-infected mothers to use artificial feeding rather than breastfeeding. These interventions are difficult to implement in developing countries due to cost, logistics and the difficulty in identifying mothers with HIV. Furthermore, more research is needed to establish the minimum effective dose of antiretroviral drugs and to investigate their long-term effects. Zidovudine, the drug used to block perinatal transmission, has caused cancer in animals, so it is too soon to recommend it for worldwide use.

Similarly, in developing countries breastfeeding is a lifesaving measure for most infants: it provides important nutrients, boosts the infant's immune system, avoids unhygienic feeding conditions, and is affordable. Health policy makers must balance the risk of contracting HIV from breastmilk with those associated with artificial feeding. For example, using one projection modeling analysis, roughly 140 infant deaths per 100,000 live births can be expected due to HIV transmission via breastmilk. On the other hand, 170 infant deaths per 100,000 live births can be expected if women do not breastfeed. More research is needed to determine whether there is an optimal cutoff point for breastfeeding, when the risk of transmission outweighs the benefits of breastfeeding. The role of micronutrients on perinatal transmission is not well understood.

2. USAID's Role

Given the different risk/benefit ratios in developing countries, it is incumbent on USAID to ensure that alternative interventions are studied and that their costs and feasibility in low-resource settings are fully explored. The task of advocating for "low-tech" measures such as vaginal and infant cleansing is also USAID's responsibility.

3. Priority USAID Activities Within the Next 3-5 Years

a. Breastfeeding options. More studies are needed to determine optimal feeding for infants born to HIV-infected women in developing countries. Key research questions are: Is artificial feeding advisable under certain conditions? When is the best time for weaning (at 3 or 6 months)? How is breastmilk affected by HIV infection? How does breastfeeding affect the health of HIV-positive mothers in terms of increased transmission rates or more rapid progression of AIDS? Would food supplements or specific micronutrients benefit HIV-infected mothers and their infants? Should infants be given antiretroviral therapy during the entire time they are breastfeeding?

b. HIV testing. Women's choices regarding pregnancy and infant feeding are clearer if their HIV status is known. Research is needed to determine the feasibility and means of providing HIV testing on a large scale. Currently, HIV testing costs about \$10-16 per person, including the test kit and limited counseling.

c. "Low tech" interventions. USAID needs to maintain research on "low tech" interventions such as vaginal and infant washing and nutritional supplements, since these are more feasible in low-resource settings and thus may have broader impact than interventions that require drugs and medical supervision.

d. Information dissemination. Health workers in developing countries are not well-informed about vertical transmission. They need information on both current scientific evidence as well as risk assessment and counseling techniques for pregnant women. USAID can take a leading role in disseminating information to key decision makers, researchers and program managers in developing countries.

e. Community dialogue. More information is needed on what technologies and assistance women in developing countries need to prevent vertical transmission. USAID can facilitate an exchange of information to develop more effective strategies and research studies to address women's felt needs.

E. OTHER USAID PRIORITIES AND ACTIVITIES

Workshop participants identified other areas of biomedical research that would benefit from USAID support:

III. BIOMEDICAL RESEARCH PRIORITIES FOR USAID

- Development of specialized HIV tests and use of tests to monitor HIV incidence (e.g. detuned HIV, viral burden)
- Identification of biomedical markers to validate behavior change
- Research on the potential impact of HIV community-level care and therapies on risk reduction behavior change
- Assessment of HIV care strategies, including nutrition and micronutrients.

Some of these items are closely linked with other activities recommended under the four major research areas. In general, these additional activities were considered to be long-term initiatives to be undertaken as resources permit.

IV. Major Conclusions

The major outcome of the meeting is that the key agencies working in HIV/AIDS-related biomedical research believe that USAID's involvement in this sector is essential. Researchers recognize that HIV/AIDS research will increasingly need to be done in developing countries because relatively high prevalence rates are needed to obtain an adequate sample size for statistical power and to keep research costs manageable.

HIV/AIDS researchers value USAID's inputs because it brings the perspective of developing countries to the table. USAID offers:

- Knowledgeable technical experts that can provide sound advice on research protocols and can articulate the needs of developing countries
- An extensive network of development and health professionals situated throughout the developing world
- Long-standing contacts with political leaders, health officials and scientists
- Expertise in operations research, community mobilization, communication and advocacy
- The ability to deploy seasoned professionals from diverse disciplines to formulate strategies and apply state-of-the-art practices to new areas such as HIV/AIDS
- Successful advocacy of new approaches
- Influence among the international donor community, enabling it to leverage "seed money" into broader support.

As one workshop participant stated, "USAID provides information from the frontlines on the issues that need to be examined critically."

Workshop participants stressed that USAID's capabilities and resources in areas other than biomedical research are far more important to the overall effort than the small amount of money allocated to specific research projects. Most of the activities recommended under the four major research areas could be categorized as applied research, operations research, or country-level interventions. These are key elements that the agencies currently engaged in biomedical research cannot provide.

Most participants refuted the notion that USAID should fund HIV/AIDS-related biomedical research "in order to buy a seat at the table." They responded that USAID already belongs at the table; it does not need to pay an entry fee. USAID funds for biomedical research should be used strategically and judiciously rather than as *pro forma* supplements to the pot of research funds. Many of the recommended biomedical research activities can be undertaken under existing USAID contracts or planned procurements. Participants were very enthusiastic about working with USAID, its collaborating agencies, and counterparts in developing countries.

In closing the meeting, Dr. Paul DeLay of USAID thanked the participants for their commitment and intensity. He said that they had provided many ideas for new directions in biomedical research that would be reflected in future program planning.

Annexes

Annex A: List of Participants

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Annex B: Workshop Agenda

Sunday Evening, November 23, 1997

7:00 - 9:30 **General Welcome:** Paul DeLay, USAID, HIV-AIDS Division, Office of Health and Nutrition, Center for Population, Health and Nutrition, Bureau for Global Programs, Field Support and Research (G/PHN/HN/HIV-AIDS)

Introduction: Review the goal and objectives for the workshop, the agenda, and USAID and participant expectations

7:30 **Dinner**

Monday, November 24

8:30 - 10:00 **PLENARY SESSION**
USAID and Biomedical Research: Paul DeLay, USAID

Objectives:

- to explain design of USAID's portfolio in HIV/AIDS
- to identify criteria to guide recommendations to USAID
- to clarify which large research questions USAID should address

10:00 - 10:15 **Break**

10:15 - 12:00 **State of the Art in Biomedical Research**
Introduction: Amy Bloom (G/PHN/HN/HIV-AIDS)

Microbicides Update: Dr. Zeda Rosenberg, Senior Scientist for Adult Prevention Research NIH

HIV Vaccine Update: Dr. Rodney Hoff, Chief, Vaccine Trials Section, NIAID/NIH

STD Diagnostics Update: Dr. King Holmes, Director, University of Washington Center for AIDS and STDs

Vertical Transmission Update: Dr. Lynne Mofenson, Associate Chief for Clinical Research, Pediatric, Adolescent and Maternal AIDS Branch, NICHD/NIH

Objectives:

- to briefly update participants on recent technical advances in the four areas
- to discuss their impact on one another and this workshop

12:00 - 1:00 Lunch

1:00 - 2:30 PLENARY
Exploring Potential Roles for AID

Objectives:

- to identify potential roles for USAID in biomedical research
- to identify potential drawbacks for USAID
- to identify how USAID's participation in biomedical research could advance the fight against HIV/AIDS

1:00 - 1:20 Nightline Video (HIV/AIDS in Uganda)
Understanding the context in which USAID works

1:20 - 3:00 SMALL GROUP WORK (Breakout Sessions)

Questions for discussion:

1. What are the critical research questions in these areas of biomedical research for the next three years? For the next 5 - 10 years? Can they be sequenced, or should they be explored in parallel?
2. As effective approaches are designed, how will research evolve into implementation? What will have to be done? What role could/should USAID play?
3. In which areas could USAID participate given its resources, positioning and interests? Who could/should/will cover other areas?
4. What, specifically, should USAID consider doing in each area? Does USAID have adequate resources or will additional resources be required for work in these areas?

5. Who are the likely partner organizations in each activity? How could coordination and collaboration be maximized? What are the best contact points?
6. How can progress be monitored and information disseminated in a way that streamlines the process ("fast-track" approach to development)?

3:00 - 3:15 Break

3:15 - 4:45 Small Groups continue

4:45 - 5:00 PLENARY - Wrap Up

5:00 Adjourn

Tuesday, November 25

8:30 - 8:45 PLENARY SESSION
Review of yesterday's work and link to today's work

8:45 - 10:15 Developing a Consensus for USAID's Role in Biomedical Research
Small groups report out/plenary discussion of findings

Objectives:

Use results of the small group discussions and criteria established on Monday:

- to identify possible role(s) for USAID
- to prioritize those role(s)
- to reach consensus on which role(s) best suit USAID's interests and resources

10:15 - 10:30 Break

10:30 - 12:00 Resource Requirements (Small Group Work)

Objectives:

- to identify the financial, programming, and follow-up requirements for realizing USAID's role

Groups discuss the following issues:

- monitoring and tracking activities
- information dissemination
- potential partners

11:30 - 12:00 PLENARY

Groups report out/plenary discussion

12:00 - 1:00 Lunch

1:00 - 2:45 PLENARY

Next Steps

Objective:

- to identify next steps toward implementation/realization of
USAID's role

2:45 - 3:00 Break

3:00 - 3:30 Wrap up- Paul DeLay, G/PHN/HN/HIV-AIDS

3:30 Closure