



Proceedings of the
New York HIV Research Centers Consortium
Scientific Conference
May 16, 2005



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Introduction to the Proceedings of the New York HIV Research Centers Consortium 2005 Scientific Conference on “Identifying Future Directions in International HIV Research”

The New York HIV Research Centers Consortium held its second scientific conference in May 2005. Co-sponsored by the Fogarty International Center, the conference theme was “Identifying Future Directions in International HIV Research”.

The conference provided an overview of HIV-related international research on behavioral/prevention interventions, treatment and basic science based at New York/tri-state area institutions in partnership with researchers around the world. The goal of the meeting was to enhance multidisciplinary collaborative research efforts among participating institutions in the tri-state New York metropolitan area, to identify emerging international HIV research needs, and to exchange information about international training opportunities.

Over 170 investigators attended, from Consortium Centers and from the local AIDS International Training and Research Programs (AITRPs) funded by the Fogarty International Center. The conference included a plenary session which provided an overview of HIV prevention research, AITRP HIV research and training opportunities, and summaries of biomedical and social science perspectives on HIV research. Two sets of workgroups were held: the first consisted of Topical issues covering cutting-edge topics in international HIV research; the second set focused on Regional issues in conducting HIV/AIDS research in various geographical areas of the world. A prime purpose of both sets of workgroups was to identify the future international research agenda for HIV/AIDS.

Brief History of the Consortium

The New York HIV Research Centers Consortium was founded in 2002, by Dr. Sherry Deren (Director, Center for Drug Use and HIV Research at NDRI) and Dr. Anke A. Ehrhardt (Director, HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute and Columbia University), with the goal of bringing together the directors of major HIV/AIDS research programs in the New York area to share information and expertise regarding the HIV/AIDS research undertaken across New York centers, and to facilitate inter-institutional multi-disciplinary collaborations between Centers. Dr. Jack DeHovitz (Director, HIV Center for Women and Children, SUNY Downstate Medical Center) became a third member of the steering committee in 2004. The Consortium currently consists of 21 Centers in the tri-state area of New York, New Jersey and Connecticut (see Appendix for membership).

Mission and Activities of the Consortium

Despite the substantial progress that has been made in understanding the risk factors and epidemiology of HIV/AIDS and in developing treatments which have significantly affected AIDS incidence, prevalence and mortality, many important issues remain to be addressed, both domestically and internationally; multi-disciplinary efforts are essential to successfully address them. The mission of the Consortium is to enhance scientific knowledge of the HIV/AIDS epidemic and related issues by facilitating inter-institutional, multi-disciplinary collaborations by scientists affiliated with HIV research centers in the New York region.

The first scientific conference of the Consortium was held in December 2003 with approximately

130 HIV/AIDS investigators attending, and was funded in part by the Office of AIDS Research, NIH. The conference entailed plenary panel discussions stressing a multidisciplinary approach to two focused themes: “Integration of Prevention and Care for HIV-Infected Populations on both the Domestic and International Fronts” and “Factors that Mediate the Relationship between Risk and HIV Incidence or Prevalence.” These were followed by workgroups charged with developing recommendations for urgent and emergent research needs in the epidemic. Six multi-disciplinary scientific papers were prepared based on this conference, and have recently been published (Journal of Urban Health, January/February 2006).

For the second conference, Consortium members selected the topic of “Identifying Future Directions in International HIV Research”, in light of the increasing devastation brought by the global HIV/AIDS epidemic, and the fact that increasingly, U.S.-based scientists (including many Consortium members), were lending their expertise to research and training efforts throughout the world.

The Proceedings of the conference provide a summary of the plenary presentations, an executive summary of the workgroups’ recommendations, and the individual workgroup reports. In addition, the Appendices include information regarding the Consortium and AITRP members at the time the conference was held.

These Proceedings were prepared to share the recommendations developed during the Conference, and to encourage communication and collaboration across HIV/AIDS investigators domestically and internationally.

Jack A. DeHovitz, M.D., M.P.H.

Sherry Deren, Ph.D.

Anke A. Ehrhardt, Ph.D.

Steering Committee, New York HIV Research Centers Consortium

Acknowledgments

The Steering Committee would like to acknowledge Dr. Kenneth Bridbord, Director of the Division of International Training and Research of the Fogarty International Center, for his encouragement and support for the conduct of this conference. Thanks are also extended to the members of the Planning Committee of the 2005 Conference. In addition, these proceedings were developed with the assistance of David Odegaard, Kathy Tanner, and Dorline Yee, and especial thanks are extended to Patricia Warne for her contribution in preparing these materials. Acknowledgment is also extended to the grants which provided the resources of the Steering Committee (FIC, Grant # D43 TW000233, J. DeHovitz, PI; NIDA Grant # P30 DA11041, S. Deren, PI; NIMH Grant # P30 MH43520, A. Ehrhardt, PI). It should also be noted that throughout this document, names of participants (e.g., steering committee members, workgroup chairs, etc.) are provided in alphabetical order and do not necessarily reflect their order of contributions.

The views expressed in these Proceedings do not necessarily reflect the views of the funding sources, the Consortium member Centers, or the AITRPs.

February 2006

Plenary Presentations

Biographical Sketches of Plenary Presenters

Plenary Presentation Abstracts

Biographical Sketches of Plenary Presenters

Quarraisha Abdool Karim, Ph.D. is an Executive Committee member of the Centre for the AIDS Program of Research (CAPRISA) in South Africa and Executive Director of the International Partnerships for Microbicides, a not-for-profit organization to fast-track microbicide development. In addition, Dr. Abdool Karim coordinates the Columbia University Southern African Fogarty International Training and Research Program in Durban, South Africa. Her current research interests include understanding the evolving HIV epidemic in South Africa, factors influencing HIV infection in adolescent girls and sustainable strategies to introduce antiretroviral therapies in resource limited settings.

Judith D. Auerbach, Ph.D., is Vice President of Public Policy and Program Development at the American Foundation for AIDS Research (amfAR). Dr. Auerbach served as the HIV Prevention Science Coordinator in the Office of AIDS Research at the National Institutes of Health. In this capacity, she provided oversight to activities related to the development of scientific and budgetary priorities for AIDS research in the social, behavioral and prevention sciences. Her current research interests include developing basic and intervention approaches to health promotion and disease prevention taking into account the interaction of biological, behavioral and social factors.

Kenneth Bridbord, M.D., is Director of the Division of International Training and Research of the Fogarty International Center (FIC). Dr. Bridbord has been with the FIC since 1983. He has been instrumental in helping develop a wide range of international and training research capacity building programs. Under his direction, the AIDS International Training and Research Program has supported the training of over 2000 scientists in over 100 developing countries to address the AIDS epidemic. In 2001, Dr. Bridbord was the recipient of the American Association for the Advancement of Science Award for International Scientific Cooperation.

Gerald H. Friedland, M.D., is Director of the AIDS Program at Yale-New Haven Hospital and Professor of Medicine and Epidemiology and Public Health at Yale University School of Medicine. Dr. Friedland has been involved in the development of comprehensive HIV care programs and engaged in HIV epidemiologic and clinical research since the beginning of the epidemic. His current research includes clinical trials of antiretroviral therapies, operations research aimed at providing access to antiretroviral therapy in resource limited settings and interventions to improve adherence to HIV therapies and reduce HIV transmission risk among HIV-positives in clinical care.

Presentation Abstract

Global Overview of HIV Prevention Research: Opportunities and Challenges in Reducing Heterosexual HIV Transmission

Quarraisha Abdoool Karim, PhD, MS

Associate Professor, Department of Epidemiology

Columbia University, Mailman School of Public Health

Head: CAPRISA Women and AIDS Programme

Director: Columbia University-Southern African Fogarty AITRP

The magnitude and continued spread of HIV globally presents us with a moral and ethical imperative for prevention research. Of the estimated 39.4 million prevalent infections at the end of 2004, 87% were acquired through heterosexual transmission. Of the 4.9 million new infections and 3.1 million AIDS deaths in that year, almost 90% were among persons who acquired HIV infection heterosexually. Data reflecting the geographic distribution of HIV around the world further highlight the urgency of reducing sexual transmission of HIV in nearly every continent if we are to achieve control of this epidemic. The fact that 25% of new infections in 2003 occurred in South and Southeast Asia and Eastern Europe points to the importance of the emerging HIV epidemic in these regions. The epidemics in China and Eastern Europe are driven principally by injected drug use, which extends inevitably to sexual transmission, and successful prevention efforts focused on sexual transmission could reduce the possibility of devastating generalized epidemics in these countries.

HIV transmission is centrally dependent on the infectiousness of the host and the susceptibility of a partner. Classical sexually transmitted infections (STIs) are probably the most important co-factors for HIV transmission. STIs that cause mucosal ulceration and/or inflammation substantially increase shedding of HIV in the genital tract of both women and men 4-8 fold. The stage of HIV infection may also help define the probability of transmission, and the probability of transmission associated with early/acute infection may be about 20 times higher than during later, established infection. Generally, HIV prevention in persons already infected has received little attention; but as access to HAART increases globally, there will be a growing number of persons who become aware of their HIV status, creating opportunities for prevention in positives.

Current proven strategies for prevention of heterosexual HIV transmission can control HIV in developing countries. Promotion of male condoms to reduce HIV does work, and promotion of female condoms in addition to male condoms can increase overall condom use. Preliminary data suggest that ARV prophylaxis, HSV-2 control, and male circumcision may also reduce HIV transmission, and clinical trials of these strategies are underway.

Presentation Abstract

Update on International HIV Research and Research Training Opportunities at AITRP

Kenneth Bridbord, MD, MPH

Director, Division of International Training and Research

Fogarty International Center

National Institutes of Health

Department of Health and Human Services

The Fogarty International Center (FIC), the international component of the National Institutes of Health, addresses global health challenges through innovative and collaborative research and training programs and international partnerships. FIC fulfills its mission through 14 training programs for foreign health scientists, two training programs for U.S. health scientists, and eight research programs that prepare current and future health scientists to meet global health challenges.

FIC-supported programs are characterized by stability and long-term commitment and mentoring, responsiveness to local needs and priorities, individual and institutional partnerships, advanced in-country research with re-entry support, flexibility, networking, and empowerment and mutual respect. Several focus on HIV/AIDS. The AIDS International Training and Research Program (AITRP) supports HIV/AIDS-related research training to strengthen the capacity of institutions in low and middle-income countries to conduct multi-disciplinary biomedical and behavioral research capacity to address the AIDS epidemic in the collaborating country. Grants are awarded to U.S. and developed country institutions with strong HIV-related research training experience and HIV-related research collaborations with institutions in low and middle-income countries. The International Clinical, Operational, and Health Services Research Training Award for HIV/AIDS and Tuberculosis (ICOHRTA-AIDS/TB) supports research to strengthen the capacity of institutions in low and middle income countries where AIDS, TB, or both are significant problems to conduct training integrated clinical, operational and health services. The program emphasizes integration of therapy and care with prevention efforts, builds capacity to support the integration of clinical, operational, and health services research, and builds upon leadership and skills developed through FIC's AITRP.

Among the other programs included in this presentation are three relatively new efforts: the Fogarty/Ellison Program, which provides mentored clinical research training opportunities for U.S. medical and other graduate students in NIH-funded research centers in developing countries; the Global Health Research Initiative Program, which promotes productive re-entry of NIH-trained foreign investigators into their home countries to enhance the scientific research infrastructure in developing countries, stimulate research on high priority health-related issues in these countries, and advance NIH efforts to address health issues of global import; and the Framework Programs for Global Health, which provides support to educational institutions to develop trans-institutional programs in Global Health.

Presentation Abstract

International HIV Research: Integrating HIV Care and Prevention

Gerald Friedland, MD

*Professor, Medicine and Epidemiology and Public Health
Director, Yale AIDS Program*

Prevention efforts have until recently largely focused on HIV negative individuals or those whose HIV serostatus is unknown. Prevention among those already infected with HIV has been largely ignored. The number of people living with HIV in both developed and resource-limited countries is increasing as is the proportion who are aware of their HIV status. Further, the number having access to HIV clinical care and antiretroviral therapies is increasing dramatically. Of concern, however, is the emergence of data from community and clinic settings indicating continued, and in some cases increased, risk behaviors among all groups of already HIV-infected individuals (e.g., MSM, IDUs, and heterosexuals). Further, an estimated 10-40% of patients on ART for more than six months have a detectable viral load, and approximately half of these carry resistant viruses. Increasing rates of antiretroviral resistance among new HIV infections and evidence for super-infection with resistant strains suggests that HIV transmission occurs from those receiving antiretroviral therapy, with resulting loss of treatment benefit and adverse public health consequences.

This scenario, now well known in developed countries, is likely to be repeated in resource-limited countries embarking on treatment programs. Strategies that integrate prevention and care offer opportunities to avoid or lessen these adverse consequences. However, policy, culture, and practice differences between the prevention and care enterprises have impeded such integration in the past. Common ground for prevention and care integration is essential to move both forward. One approach is to develop, integrate, and evaluate prevention programs in the expanding clinical care setting. Although it presents unique medical and behavioral prevention opportunities, the clinical setting has been underutilized for prevention purposes.

Several projects have addressed this issue in a rigorous manner. Among these, The Options Project, a theoretically based clinician centered behavioral intervention has been shown to be feasible and to significantly reduce transmission risk behaviors compared to a control population. Determining the generalizability of this and other strategies in routine clinical settings and extension to resource-limited settings where future need may be greatest is necessary. Available information suggests that although many barriers remain, with substantial effort, behavioral as well as traditional medical prevention interventions can be successfully incorporated into clinical care settings. This strategy is one important model of integration of prevention and care at a practical "on-the-ground" level, with potential widespread utility in both developed and resource-limited international settings.

Presentation Abstract

Social Science Perspectives on International HIV/AIDS Research

Judith D. Auerbach, PhD

*Vice President, Public Policy and Program Development
American Foundation for AIDS Research*

For most of the life of the global HIV epidemic, the field of behavioral and social research has been dominated by a limited number of models that focus chiefly on the concept of individual behavioral risk and behavioral change. Over time, there has been a greater recognition of the social factors, forces, and contexts that contribute to HIV/AIDS vulnerability and impact, not just for the individual but for populations, communities and societies.

HIV prevention strategies must take into account access to and delivery of prevention services (including financing of these services and challenges involved in scaling up effective model programs); issues of stigma, discrimination, and social support; issues of social equity and inequality on the levels of race and ethnicity, sex and gender, age, immigration status and citizenship, class, and income and wealth; and the balance of social stability and instability presented by war, violence, migration, and famine. The social impact of HIV/AIDS manifests itself in the demographics of the individuals and households affected, among women and gender relations, in educational and economic opportunity, and in governance and security.

Social interventions that can respond to HIV/AIDS include program evaluation, community and network interventions, and structural interventions. Clearly, the future must bring greater involvement of social scientists, better integration of theory and method from social sciences, better integration of biological, social and political analysis, greater focus on social institutions, and rethinking of "outcomes."

This presentation will highlight these social factors, forces and contexts as they relate to the development and implementation of effective HIV prevention and care strategies. It will include a discussion of some of the challenges in incorporating social-level analysis and interventions into HIV/AIDS research, program, and policy agendas.

Workgroup Summaries

Workgroup Executive Summary

Topic Workgroups

How Coinfections Affect HIV Transmission/Disease Progression

Integrating Treatment and Prevention: Models that Work

Microbicides Research

Impact of Clade Distribution on Pathogenesis and Public Health

Youth Sexual Transmission Prevention: ABC Approach

Impact of Drug and Alcohol Use on HIV Prevention and Treatment

HIV Impact on Orphans and Children

(No summary received for: Building Local Partnerships: Overcoming Barriers to International Collaboration)

Regional Workgroups

Sub-Saharan Africa

Latin America

Central/Eastern Europe

South Asia (India and nearby countries)

East Asia (China and nearby countries)

(No summary received for: Caribbean)

Workgroup Executive Summary

Workgroups were designed to elicit recommendations for future directions in international research as well as stimulate inter-institutional research collaborations. The first workgroup session focused on eight topic areas, the second session focused on six geographic regions. While detailed summaries are available for most workgroups, some important common themes emerged across workgroups in each of the two sessions (and, indeed, between the two sets of workgroups) and are summarized below.

Topic Workgroups

During the first session, the workgroups addressed eight topics of import in international HIV/AIDS research: impact of co-infections on HIV transmission and disease progression; integration of treatment and prevention; microbicides; impact of clade distribution on public health; building local partnerships; prevention of sexual transmission in youth; impact of drug and alcohol use on HIV prevention and transmission; and impact of HIV on orphans and children. While recommendations having specific relevance for each topic area emerged, some overarching issues also became apparent, in particular the recognition that international research is critical in order to avoid inappropriate and possibly misleading extrapolation from clinical, behavioral, and epidemiologic data gathered in developed countries.

The impact of culture and ethnicity on risk behaviors and ability to access services must be examined, as well as the particular role of stigma in societies that may be characterized by political and social oppression or repression of certain groups (e.g., drug users, MSM).

Integration of prevention and care is of paramount importance in order to reach people living with HIV as well as those at risk for infection and should be based on an understanding of specific local structural issues (e.g., venues for care, political will).

Prevention and medical management programs must be developed that are sustainable in international settings, which are often resource-poor and have particular cultural and social norms.

Individuals must be understood in the context of their family and community, building upon community expectations, norms, taboos, and resources. Similarly, differing conceptualizations of children, adolescents, and families must be taken into consideration in HIV primary or secondary prevention programs.

Research must take into account variations in the prevalence of pathogens and HIV clades, and the epidemiology of HIV/AIDS in different countries.

Regional Workgroups

The six regional workgroups focused on Sub-Saharan Africa, Latin America, Central/Eastern Europe, South Asia, East Asia, and the Caribbean. While specific obstacles exist in each of these regions, common challenges in conducting international research were identified. These centered on coping with political apathy or outright oppression, difficulties in obtaining or administering research funding (particularly delays in obtaining international administrative approvals), dissonance between the priorities of researchers based in the U.S. and of those in the

developing country, lack of infrastructure, and language barriers. Recommendations for training and implementing research emerged across the six regions.

Considerations of local political will and social change must be incorporated into HIV prevention and provision of care.

Investigators (and funding sources) from developed countries, which often sponsor and financially underwrite international research, must be committed to adapting to local models of research and incorporating non-traditional measures of success into their programs.

Research must address the needs of populations that may be especially hidden in developing countries (e.g., drug users, MSM) relative to, for instance the U.S. or western European countries.

Integration of prevention into care is again a priority in all regions and new models of care delivery appropriate to and sustainable in specific countries are needed.



Topic Workgroup Summaries

1. How Coinfections Affect HIV Transmission/Disease Progression

*Chairs: Holly Hagan, PhD, CDUHR, National Development and Research Institutes, Inc. (NDRI)
David Perlman, MD, Beth Israel Medical Center*

OVERARCHING THEMES

International considerations are particularly relevant in the case of coinfections, and a number of research questions related to specific management of coinfections may best – or only – be addressed abroad, where agents of coinfection (e.g., malaria, tuberculosis) are more prevalent. Public health planning to allocate resources for managing coinfection needs to be based on epidemiologic studies and surveillance of trends in coinfections in international settings. While extrapolation of clinical and epidemiologic data in developed settings may be important, it cannot replace international data. Strategies for prevention and medical management that can be implemented in international settings must be developed and evaluated.

SPECIFIC RECOMMENDATIONS

Specific Coinfections

- Tuberculosis: Among the specific coinfections discussed, TB was deemed the most critical because of its high prevalence and morbidity.
 - Since recent data suggest that the risk of TB disease may increase markedly early in the course of HIV infection, research is needed on the effect of treating latent TB infection during early HIV infection.
 - Although the anticipated roll-out of HAART in areas of high TB/HIV co-endemicity is expected to be only gradual in the near future, we have the opportunity now to start to understand the inter-relationship of treatments for HIV and TB and their effect on the courses of these diseases. What is the impact of HAART on incidence of TB disease? What is the impact on treatment for TB of the initiation of HAART and the timing of this initiation?
 - Research is needed to improve our ability to detect or rule out (subclinical or clinical) active TB diseases in HIV-infected persons in international clinical settings.
 - Treatment of latent TB infection (with INH and/or other agents) in international settings that have not historically relied on anti-mycobacterial agents must be re-examined. Studies of new candidate TB vaccines are also needed.
- Blood-borne coinfections: International settings may vary in the manner and extent to which blood products are screened for HIV or other blood-borne coinfections. Better data is needed on the proportion of HIV cases (and associated sequelae) in international settings that are due to blood product contamination.
- Malaria: Little is known about the relationship between HIV and malaria, including the potential impact of malaria coinfection on perinatal HIV transmission and the feasibility and value of co-locating TB and malaria screening and clinical services.
- HBV and HCV: Further research on the prevalence of HBV and HCV co-infection in international settings is needed and the resulting data (for instance on drug tolerance) may influence choice of HAART agents as their international roll-out proceed.

- Opportunistic infections: Research on prophylaxis against opportunistic infections, either as an adjunct or a bridge to the institution of HAART, is needed and should include studies of isoniazid (or isoniazid-rifampin), sulfamethoxazole-trimethoprim, and fluconazole (as simple or combination prophylactic agents).

Prevention and Care

- Practical and implementable models must be evaluated for screening and treating multiple coinfections and should include programs that link large-scale screening of patients to specific risk reduction interventions such as pharmacologic opportunistic infection prophylaxis (e.g., sulfa-trimethoprim, fluconazole, isoniazid).

Ethical Considerations

- The issue of standards of care and ethical guidelines for international research was noted throughout the discussion as a factor affecting all international clinical research. Questions remain of what constitutes best practices and what constitutes appropriate standard of care for control groups.

2. Integrating Treatment and Prevention: Models that Work

Chairs: Gerald Friedland, MD, CIRA, Yale University

Robert Remien, PhD, HIV Center, Columbia University

OVERARCHING THEMES

Prevention entails creation of a "safety net" to help reduce risk behaviors and their adverse outcomes. It is not a discrete outcome or one time static event, but an ongoing process. Prevention also must be seen realistically in terms of significant risk and transmission reduction rather than complete elimination of disease. Sustained prevention is required for people who are both chronically and episodically at risk for HIV infection and transmission, and prevention strategies should focus on risk reduction both in populations at risk and those already infected. For the latter, strategies that integrate prevention and care need further development and rigorous testing. Likewise, a broader support infrastructure must be implemented for the sustained integration of prevention into ongoing care.

SPECIFIC RECOMMENDATIONS

Operations Research

- Assessment of readiness: Research is needed to understand the impediments (barriers) and opportunities for bridging the gap between prevention and care. Part of this assessment would include an assessment of readiness. How "ready, willing, and able" are specific settings to integrate prevention and care? What might this look like in different settings? Such assessments may have to take place at the community level. More formative research is needed to assess the feasibility of integrating the two.
- Rapid Assessment model: Given the urgent need for interventions that integrate prevention and care, formative research should make use of a "Rapid Assessment" model.
- Standard of care and integration of diverse providers: Little is known about interactions among different types of practitioners. How can these interactions be measured? How might they be encouraged? What are the routine standard of care practices in clinical settings? How can we integrate prevention messages into daily routines? How can we better understand the relationship of clinical care sites with NGOs/CBOs?
- Other structural barriers: Barriers to integrating prevention and care include the dichotomization and separation of HIV prevention from other STI prevention work, perhaps as a result of separate categorical funding structures and bureaucratic vertical program histories and traditions. In some health care contexts, including our own, focusing on prevention may be logistically difficult for clinicians, given that it is not a service that is reimbursed. Additional clinic-level issues must be identified, and some may be specific to international contexts.

Research on Voluntary Counseling and Testing (VCT)

- How do patients get from VCT settings to care settings? Who facilitates and ensures these transitions, and how are such transitions made?

- What effect does VCT vs. "opt-out" testing have on HIV-related social stigma or on testing rates?
- Can "routine" testing in clinical care sites be effectively accomplished by clinical staff?

Research on Family-Centered Care

- HIV affects families not just individuals. How can family centered care that aggressively deals with the full range of issues faced by couples/families be encouraged/facilitated? For example, in resource-limited settings, treating an HIV-infected woman without treating her partner may result in medication-sharing within the family. Women may be more likely to present for care, either because they are often first identified during pregnancy or for other reasons. New strategies for ensuring family-centered care will be critical for treatment roll-out efforts.
- How can partners/husbands be more involved in PMTCT service delivery without placing women at increased risk for violence or abuse?

Training

One of the barriers to integrating prevention and care has been that prevention has not often been seen as an "appropriate" role for providers. This perception of the medical provider's role in prevention may vary across contexts. One of the key issues appears to be training.

- Clinicians in training: Medical education is currently oriented toward diagnosis and treatment, and not prevention. Comprehensive prevention and care programs should be part of clinical training early on in the training process.
- Established providers: Currently practicing clinicians need to be "de-trained" from the idea that prevention is not part of their role, and necessary skills to enable them to deliver prevention services must be identified and be part of remedial training.

Incentives

Incentives must be identified and created to encourage the interdisciplinary efforts of clinicians and researchers to integrate prevention and care.

- Funding requirements: Connecting such integration to funding is a logical strategy. For example, the Global Fund now requires that potential grantees include a plan for integration of HIV and TB services in new proposals.
- Practical benefits: Incentive might be provided if integration resulted in demonstrated cost effectiveness at both the programmatic and research levels. For example, partnerships between basic and behavioral scientists in microbicide work – with the former developing new products and the latter testing acceptability – are logical and more efficient than separate, parallel programs.

Identification of Venues for Integrating Prevention and Care

We should be thinking beyond traditional care settings to identify new venues in which prevention and care can be integrated.

- What kinds of venues might provide support to HIV+ patients who will not be started on treatment because they do not yet meet eligibility criteria? How might models of health maintenance and chronic illness management be used to broaden the idea of prevention to include wellness?
- How might community-based organizations that meet people on the continuum of risk behavior prevention, diagnosis of infection, and entry into care be enlisted to promote integration of prevention and care?
- If prevention and care take place in different physical locations, how might they be linked together? How might we gain a better understanding of how different organizations can participate in partnerships and establish networks?
- How can traditional healers be incorporated into prevention/care efforts?
- In what kinds of venues might acute seroconverters be identified, and how can providers in different venues be educated to recognize this syndrome? How might people at risk be educated about the symptoms of acute HIV infection and be encouraged to present for testing and appropriate treatment? Given that acute seroconverters have high potential for infecting others, how might the identification and treatment of seroconverters change the dynamics of the epidemic?
- Are there venues other than care settings in which individuals will disclose their positive HIV status and that might, thus, be an entry point for prevention-for-positives as well as a link to care? Given that HIV-infected individuals are highly marginalized and stigmatized in many parts of the world, what can we do to better "meet people where they are?"

Intervention Models

New, context-specific interventions are needed in order to integrate prevention and care. The range of possible interventions include the following:

- Interventions to reduce stigma
- Biomedical interventions for treatment of STIs (including HSV) that might lead to reduction in HIV transmission. These would include STI diagnosis and treatment for HIV-infected patients as well as those at high risk for infection. Protocols should optimize treatment of STIs in order to reduce HIV transmission.
- Culturally appropriate models for prevention-for-positives are needed for non-Western countries.
- Interventions should target people en route from VCT to entry into care to prevent "delayed entry into care"?
- Interventions should be developed for seronegative partners of HIV-infected individuals.

3. Microbicides Research

Chairs: Joanne Mantell, PhD, HIV Center, Columbia University

Ken Mayer, MD, Brown University

OVERARCHING THEMES

Given the legacy of nonoxynol-9 and the variety of mechanisms by which microbicides prevent HIV infection, challenges faced by the field include: (1) current lack of an effective microbicide; (2) inadequacy of clinical exams (e.g., colposcopy) and laboratory tests to detect side effects (e.g., irritation) and lack of validated surrogate markers to assess toxicity or protection; (3) the need for large, multi-armed trials to determine microbicide efficacy; (4) limited acceptability data; and (5) limited generalizability to “real world” (i.e., non-clinical trial) settings. Also, the need for educational materials about microbicides for media, and policy maker tool kits, and timelines for anticipated product availability was noted.

SPECIFIC RECOMMENDATIONS

The Workgroup's research recommendations centered on: (1) measurement and study design; and (2) acceptability research.

Measurement and Study Design

- Surrogate markers: More clinical research is necessary to establish reliable surrogate markers of safety and efficacy. Currently, the only marker available for efficacy is HIV incidence and, for safety, genital inflammation. Additional markers of safety might eliminate the need for costly colposcopies.
- Standardized measures: A core set of acceptability measures should be developed to facilitate comparison of findings across microbicide trials. The interrelationship between perceptions of safety and acceptability should be examined.
- Participation bias in clinical trials: Assessment of reasons for non-participation should be incorporated into Phase II and III trials to address self-selection bias. This would mean conducting interviews with people to whom microbicides may not be acceptable.
- Reproductive preferences: The range of women's reproductive intentions need to be considered in the design of clinical trials of microbicides. Studies need to factor in different methods of contraception and the desire for pregnancy.

Acceptability Research

A stepped-up approach to assessment of acceptability should be used in Phase I to Phase IV trials. There is a need to layer in acceptability studies in all phases of clinical trials, but the role and value of the acceptability assessment should be considered carefully.

- Women's male partners: Studies that assess acceptability of microbicides among male partners of female users are needed and should include HIV+ men. These studies should explore men's and the couple's perceptions of the different dimensions of acceptability. And include a focus on the meaning and implications of microbicide use in long-term sexual partnerships.

- Health care providers: Studies of knowledge of microbicides and recommendation and prescription practices among a broad range of health care providers (e.g., lay counselors, nurses, doctors, and pharmacists) are needed, as is effective training of providers in harm-reduction approaches.
- Community perceptions and expectations: Microbicide trials require long-term partnerships with communities; therefore, it is important to understand community members' expectations of what microbicides will offer and their acceptability and efficacy.
- Culture: Studies must address cross-cultural assessment of perceptions of safety and acceptability of potential users and their partners, as well as adherence to effective microbicide use.
- Cost: Cost considerations are likely to affect acceptability and must be documented along with cost-benefit analyses.
- Operations research: We must identify efficient and acceptable ways in which various microbicial products can be made available and accessible in “real-world” settings. How will microbicides be used vis-a-vis other prevention technologies? Would users prefer pre-exposure prophylaxis, such as a pill? Other considerations will be: side effects associated with delivering a microbicide in the form of a pill versus a gel; differences in acceptability and uptake of prescription versus over-the-counter product distribution; and identification of the most successful venues for microbicide availability and uptake.

4. Impact of Clade Distribution on Pathogenesis and Public Health

Chairs: Harold Burger, MD, Wadsworth Center, NYSDOH

Vinayaka Prasad, PhD, Albert Einstein College of Medicine

OVERARCHING THEMES

Two main themes were: (1) key differences in the genetic (LTRs, Tat, envelope sequences) and biological (replication fitness, pathogenesis, fitness) characteristics between the clades; and (2) differences in the clinical presentation of the disease including opportunistic infections, diagnostic criteria and disease progression. The biological basis for the fact that HIV-1 clade-C is responsible for more than 60% of global infections was of much interest to the workgroup participants and prompted discussion about the fitness of the different clades. Various explanations for this discussed included: (i) the increased survival benefit due to the fact that clade-C HIV-1 being less fit, (ii) viral loads in seminal fluid vs. susceptibilities of mucosal tissues, and (iii) the ratios of R5 to X4 viruses.

SPECIFIC RECOMMENDATIONS

The recommendations of the workgroup are as follows:

- Natural history studies: Well-conceived longitudinal cohort studies are required to document disease progression and should focus on a consolidated picture ranging from clinical features, immunology, epidemiology and viral characteristics.
- Methods: Clade-specific methodologies must be developed, including genotypic drug resistance assays, HTA assays to detect interclade recombinant viruses, single molecule PCR, etc. Molecular clones of full-length HIV genomes and their sequencing for molecular virology studies are also needed.
- Geographic specificity: Country- and region-specific drug susceptibility studies for different clades of HIV-1 are a pre-requisite to implementing or recommending expensive, HAART protocols based solely on clade-B experience.
- Biological compartmentalization: More must be understood about the distribution of virus of different HIV clades in different physiological compartments, such as blood, cerebrospinal fluid, semen, and vaginal secretions.

5. Youth Sexual Transmission Prevention: ABC Approach

Chair: Anke Ehrhardt, PhD, HIV Center, Columbia University

Noelle Leonard, PhD, CDUHR, NDRI

OVERARCHING THEMES

Prevention of sexual transmission among youth as embodied by the ABC (Abstinence, Be faithful, use Condoms) approach has several significant deficiencies. The approach focuses on individual behavior and ignores social, cultural, and other factors that affect youth's sexual behavior; furthermore, the emphasis on abstinence and being faithful is unrealistic.

The Uganda case is often heralded as a success story of ABC, but its true success is unclear. While a generation may have been saved by being "fed on fear," there is evidence that research fatigue and disinhibition is now setting in. Conflicts exist between the ABC mandate and local factors, and the fact that ABC worked in one place does not mean it will work everywhere. Furthermore, the perception exists that ABC is a political ploy to take attention away from more pressing (structural) issues that should be addressed.

Programs for prevention of sexual transmission among adolescents are challenged by opposing attitudes about adolescent sexuality. On the one hand there are tensions over how much sexuality education youth should receive and when in their development they should receive it. There is a concern that candid policies and educational programs will accelerate sexual behavior among youth although no evidence exists supporting that assumption. Access to information/education on sex is a human right for young people and we need to move away from ABC-type approaches towards comprehensive sexuality education for youth.

Two issues have great urgency for international research:

1. We urgently need to overcome structural barriers for implementation of evidence-based and effective programs to promote sexual health and affect behavior change among adolescents in countries around the world. Research must systematically investigate these barriers (including working with gatekeepers such as parents, school officials, healthcare providers and also policy makers and political leaders).
2. Research is needed to identify effective ways of including adolescents in planning, execution, and dissemination of programs for youth. Adolescents do not have enough of a voice in research, programs, and policies that deal with them and affect them.

SPECIFIC RECOMMENDATIONS

Specific research recommendations clustered around several domains:

Key Concepts

- There is a dearth of information on youth in general, and more research is needed in countries where little is known about the needs of youth and parents.
- How do we define adolescence? Is it limited to the second decade of life? Need to incorporate younger people - include the 1st decade of life?

Determinants of Risk

- Adolescents are not homogeneous, and programs need to be tailored for different populations of youth (for instance drug-using youth, sexual minorities) and their diverse needs. There is a particular lack of information about and programs for homosexual and bisexual youth.
- What are the environmental factors that affect adolescent sexual behaviors, attitudes, beliefs? How do economic issues (including mobility and immigration) affect risk among adolescents?

Overcoming Structural Barriers to Prevention

We already know a lot about what works for HIV prevention with youth, so the challenge is in implementing that knowledge and overcoming political and ideological barriers. Research is needed on how to intervene with processes of advocacy and policy-making and must incorporate historical and cultural perspectives.

- In many societies, taboos exist that discourage talking to youth about sex. How do we get key "gatekeepers" (parents, government, etc.) to endorse adolescent sex education? Outreach to parents must be a priority.
- What is the most appropriate forum in which to provide sex education? In particular, political and often parental barriers exist to instituting sex education for younger (i.e., primary school-age) children.
- More programs are needed that empower communities to advocate for themselves (e.g., skills building, information, etc.).
- Economic interventions must be developed and implemented.
- Educational reforms that address inequalities must be promoted.

Methodology

- Issues of fidelity in different settings must be addressed to ensure that programs will be implemented in standard ways while allowing for adaptation.
- More qualitative studies are needed.

Types of Programs

- Providing youth with information and education about sex is important but not sufficient. We must identify ways of promoting adolescent health that go beyond comprehensive sex information-based education, for instance by incorporating motivational components.
- Interventions must be developed that address sex given in exchange for material things (i.e., money, drugs, food, housing), especially in resource-poor settings.
- Programs should stress avoidance of concurrency of partners.
- Research and programs must address issues of gender inequality and power, including examining these issues from a developmental perspective.

Adolescent Perspective

Research must prioritize understanding the norms, attitudes, behaviors of adolescents from their perspective.

- Interventions must be based on fundamental concepts of human rights for adolescents.
- Programs should aim to change the context in which youth live – making youth safer regardless of what they do or don't do.
- Research, interventions, and access to information must address the needs of the most marginalized (especially the economically marginalized) populations, which are often also the most affected by HIV/AIDS.
- Youth conferences should be held to empower adolescents.

6. Impact of Drug and Alcohol Use on HIV Prevention and Treatment

Chairs: Kim Blankenship, PhD, CIRA, Yale University

Don Des Jarlais, PhD, CDUHR, NDRI & CDI, BIMC

OVERARCHING THEMES

Two general types of research questions must be considered to understand the relationship between drug/alcohol use and HIV prevention and treatment. First is the question of what factors are associated with induction into substance use. To the extent that it is possible to address these factors and thereby prevent substance use altogether, HIV-prevention goals are well-served. Second is the question of how to reduce the harm associated with substance use, which requires both research relating to HIV prevention among HIV-negative substance users and research relating to treatment and prevention among HIV-positive substance users.

SPECIFIC RECOMMENDATIONS

- Relationships among different forms of substance use and groups of substance users: While common issues unite all groups of substance users, the differences among them have important implications for HIV-risk. In the U.S., for example, African American substance users report less risky behaviors, yet are more likely to be HIV-infected. The factors associated with this disproportionate risk remain the subject of study. In international contexts, minority status – whether based on race, ethnicity, culture, or religion – likely influences the form that substance use takes, its associated harms, and the availability of HIV treatment for the infected. Research is needed to better understand how these differences operate and with what impact. Similarly, while all forms of substance use have negative impacts on health, different substances involve different routes to risk, and it is not always appropriate to group them. In separating them, however, drug use may receive greater attention than alcohol at the expense of understanding the relation between them, the ways in which substance users move from one form of substance use to another, and the reasons for these transitions. Thus, the relationships among different types of substance use and their impact on HIV risk is a critical subject for research. Particularly important is the impact of alcohol use on HIV-related risk and treatment.
- Family, community, and social support related to drug use: While issues of family and community are often addressed in relation to causes, consequences, and interventions for alcohol use, these issues are not well understood in drug use, which is often treated as an individual-level problem. In the context of international research, we need to know more about how family and community factors shape induction into drug use, success or failure of drug treatment, and formulation of harm reduction strategies. Also important are questions of social support and networks in prevention and treatment of drug users.
- Ethical and policy issues: International substance use research presents numerous critical ethical and policy issues. Though drug users are marginalized in the U.S., the risks to their lives are far greater in countries where they are systematically targeted for repression. This has implications for the conduct of research as well as the development of interventions, both of which invariably bring a degree of visibility to drug users that can put their lives at risk. International drug use researchers must be aware of these issues and develop and share strategies for conducting their research that are safe for both users and researchers yet

maintain scientific integrity. Another critical research issue with ethical implications is how best to undertake HIV prevention and treatment when drug treatment is not available. Since drug treatment is itself an effective form of HIV prevention, understanding the policy and other barriers to the implementation of drug treatment are critical to HIV prevention research. Also important are case studies from countries or locations where drug treatment has been successfully introduced that describe the approaches and circumstances under which they were successful and policy studies that identify how policy barriers were eliminated. While anti-retroviral therapy is increasingly available in resource-poor countries, it is not clear whether substance users will be a priority for receiving treatment and how these priorities are determined.

- Challenges to scaling up interventions: What are effective approaches to moving beyond small, targeted interventions and transposing what is learned in tightly controlled trials to a broader scale? How applicable are lessons in both impact and scale-up from one context or culture to another?
- Interrelationships between substance use risk and other health-related risks: Substance use and HIV risk both are strongly interconnected with mental health, and it is important to understand these links, particularly in resource-poor settings where there may be little infrastructure for addressing mental health issues. Furthermore, mental health has important cultural dimensions that must be understood in relation to substance use and HIV risk. More research is also needed on the links between substance use and sexual transmission of HIV. In the general context of the global pandemic, countries are often identified as facing HIV primarily through drug use or primarily through sexual transmission (often commercial sex). When drug use is viewed as a primary risk factor, not enough attention is given to understanding the sexual behaviors of drug users, and vice versa.
- Methodological issues: Effectively conducting international research requires adoption of a multi-disciplinary array of methods. At minimum, an understanding of the cultural dimensions of risk and the many different meanings of behavior is critical to successful international substance use research and the interpretation and generalizability of the resulting findings. Furthermore, international substance use research provides an important opportunity to develop and implement new types of comparative methodologies.

7. HIV Impact on Orphans and Children

Chairs: Brian Forsythe, PhD, CIRA, Yale University

Claude Mellins, PhD, HIV Center, Columbia University

OVERARCHING THEMES

With increasing rates of HIV infection and increasing mortality, the effects of HIV/AIDS on children who experience parental illness and death are substantial. UNAIDS estimates that there are 15 million children orphaned by AIDS, with 80% of these living in sub-Saharan Africa where 12.3% of children are orphans. The rate in Botswana is the highest: 20%. Although prevalence of HIV infection is lower in countries in Asia and a smaller proportion of children are orphans, the absolute number of orphans in Asian countries is high because their general populations are so large. Finally, AIDS is more likely than other causes of death to create double orphans, i.e., children who lose both parents.

Most research on the psychological effects of parental HIV disease on children has been conducted in the U.S.. These studies have demonstrated high rates of mental health problems among children of HIV-infected parents but have also emphasized the contribution of other factors such as parental drug use and disadvantaged family living circumstances. Severity of a parent's illness and issues of disclosure are also important factors that may affect outcomes. Little research has documented the effectiveness of interventions.

Reports from resource-poor countries have largely focused on changes of caretakers (e.g., reliance on grandmothers and child-headed households), diminished economic security, school absenteeism, and changes in health and nutrition. Responses must be multi-level and include developing government policies, organizing communities, and supporting families and individuals.

SPECIFIC RECOMMENDATIONS

Research is needed in many different areas, e.g., epidemiology, policy, ethnography, sociology, and mental and physical health. Given the course of the epidemic, especially in developing countries, there is urgency, and pressure exists to act quickly.

General Issues Pertaining to Research

- There is a need for building capacity of researchers in resource-poor countries.
- The appropriateness and validity of instruments used in the U.S. need to be examined in other cultural settings and other instruments may need to be developed.
- Alternative forms of research (e.g., ethnography) may be more helpful than traditional program evaluation in understanding "what works" in an intervention.

Research Related to Definitions

The word "orphan" has a number of different qualifiers that may have important implications.

- Do "AIDS orphans" have different needs from other orphans or other vulnerable children?
- How do maternal, paternal, and double orphans differ?

- What is the meaning and cultural conception of childhood and how does it relate to orphans?

Effects of Parental HIV Disease on Children

- What are the mental health and psychosocial needs of children affected by and orphaned by HIV? What factors contribute to outcomes?
- What is the impact of stigma and of disclosure of diagnosis to children? How does one work with youth who may not know about their parents or their own HIV? When studying the impact of disclosure on children's well-being, the relationship of disclosure and severity of illness should be taken into consideration (i.e., parents may be more likely to disclose their illness only when they are ill).
- Does permanency planning (such as that implemented in the U.S.) affect future adjustment of children?
- What is the impact on children of the roll-out of antiretroviral treatment, i.e., how does the impact of growing up with a parent's long-term chronic illness compare to that of coping with a parent's death?

Educational Needs of Children

- What are the educational needs of orphans?
- What kinds of interventions can promote ongoing education for orphans? Who stays in and who drops out? What are the barriers to these children staying in school?
- Is staying in school associated with better outcomes (including reduced risk behavior and HIV infection)?
- What is the impact of initiatives taken by different countries (e.g., abolition of school fees in Kenya) on child outcomes?

Interventions

- We must learn from existing programs and evaluate the many interventions already in place. What lessons can be learned from these programs without clinical trials (the "gold standard" of evaluation research), which are costly and time-consuming?
- What is the role of religion and faith-based institutions in meeting the needs of orphans?
- What kinds of community-based support systems are needed for children? How do these differ by the age and gender of the child? What kinds of programs are needed to support children in child-headed households, and in grandparent/elderly headed households? What should the role of the community be in supporting different household configurations?
- What is the effect of different residential settings? Are there times when group settings are appropriate and does this differ by age of child and cultural setting? For example, a 14 year old may have a difficult time being incorporated into an overcrowded family, whereas a small group home may be more supportive of the adolescent. How are group homes regulated and how might this type of care for children be improved?

- How do caretaking needs differ based on whether children live in rural, peri-urban or urban settings?
- How can interventions focused on the child, parent, or other caregivers promote resilience among children?



Regional Workgroup Summaries

1. Sub-Saharan Africa

Chairs: Alan Berkman, MD, AITRP, Columbia University

Phillipe Nyambi, PhD, NYU School of Medicine

MAJOR CHALLENGES

Conflicting Funding Priorities

- There is a lack of trust, and conflicts exist with the short/intermediate-term goals required by funders.
- There is a huge discrepancy between compensation of in-country and U.S. researchers.

Conflicting Research Priorities

- The relevance and ethics of conducting research are not evident when the on-the-ground situation is so dire.
- The U.S.-centric concept of research ethics and IRB procedures often are in conflict with those of the host country.
- When conducting behavioral research, differing community norms may make it difficult to ask about sexual risk behaviors. For instance, in some societies, it is considered inappropriate for young people to voice their own opinions at all.

Infrastructure Challenges

- The scientific infrastructure required for longitudinal studies, whether cohort or clinical trials, is not well developed in most countries.
- Difficulties in communication arise from language differences and lack of resources (e.g., access to computers).
- Other technological shortcomings include issues relating to specimen repositories.

Methodological Challenges

- Rural-urban migratory patterns of some communities may lead to high rates of attrition, posing challenges for study design and data analytic approaches.
- Inconsistent or inadequate clinical, laboratory and radiological diagnosis can make it difficult to conduct trials with certain clinical outcomes.
- Variations across the continent, and even within countries, in HIV clades may make it difficult to conduct cross-country research.

RECOMMENDATIONS

- Operations research that focuses on scale-up of prevention and treatment should be a priority.
- Certain areas of cross-cutting collaborative research should be stressed; combining prevention with treatment, working with adults and children together.
- Discrepancies between compensation of in-country and U.S. researchers must be resolved and agreement must be reached on how funds are channeled and who benefits.

- Conflicts between the short/intermediate-term goals required by funders and in-country priorities must be addressed and resolved.
- Discussion of and agreement on the handling of specimens should be decided before starting the study.

2. Latin America

Chairs: Alejandra Gurtman, MD, Mt. Sinai Hospital

Jennifer Hirsch, PhD, HIV Center, Columbia University

MAJOR CHALLENGES

Political Challenges

- Latin America is not seen as a priority region for HIV prevention or research by U.S. policymakers; Latin America deserves a reassessment of its place in the funding scale for several reasons:
 - Currently available surveillance data may underestimate breadth and development of the epidemic.
 - Latin America plays a critical role in the U.S. economy as a source of primary products, a location for mid-level manufacturing, a consumer of U.S.-produced goods and services, and a vital source of labor.
 - Infectious diseases do not respect borders, which, given the amount of population mobility throughout the Americas – including to the U.S., should generate shared concern and a collective response.
- U.S.-initiated research efforts are often perceived of as being – or actually are – colonialist in approach. Since most funding comes from the U.S., U.S. researchers and policymakers tend to set the agenda, rather than research being truly responsive to local needs.
- Inequalities between the U.S. and Latin America complicate all aspects of the collaborative research relationship; enormous economic inequalities make it even more critical to be vigilant about building respectful and equitable research collaborations.
- U.S. politics around sexuality and HIV present an enormous barrier that make some prevention approaches impossible regardless of their scientific merit.
- Political instability in Latin American countries can mean that those responsible for key institutions or programs change overnight or that appointees are political choices rather than scientific ones.
- Throughout Latin America, high levels of transnational mobility mean that many people engage in risk behaviors when they are outside their own countries; thus, to effectively protect their own populations, countries must work collaboratively throughout the region to acknowledge major population flows.
- There is a deliberate unwillingness on the part of Central American governments to recognize the developing HIV-IDU nexus, a result both of a shift from being countries through which drugs are trafficked to, increasingly, countries in which drugs are also consumed and of the drug consumption habits brought home by deportees from the U.S.

Infrastructural and Financial Challenges

- Challenges relate to actually transferring research and training funds to Latin America, especially given currency fluctuations and institutional corruption. Some have dealt with these challenges by sending money via NGOs rather than state-funded universities, or even by sending it directly to responsible investigators, but it is important to try to work through

institutions to empower them to leverage even limited research and training funds for their own development.

- Communications present a significant challenge both because of lack of infrastructure and resources and because of over-commitment of collaborators working in developing countries at publicly-funded institutions under considerably less than ideal conditions.
- U.S.-mandated human research participant processes are often difficult to implement. For instance NGOs frequently lack IRBs, and it is inappropriate for U.S. mandatory Human Subjects Certification testing to be available only in English.

Research Agendas

- There is an uneasy fit between the research-dominated culture of U.S. funding streams and the more programmatic or activist orientation of colleagues in Latin America. CBOs want to provide services, not conduct randomized controlled trials. How can we develop a common agenda between U.S. scientists and programmatic people on the front lines in Latin America?
- There are both strengths and limitations to training people in the biomedical model. Focusing solely on biomedical aspects of HIV/AIDS may obscure social, cultural and structural factors that have been critical to both the spread of and effective responses to the pandemic. However, it is also vital to develop the human resources necessary to ensure that developing countries can make full use of available effective prevention strategies (e.g., MTCT).

RECOMMENDATIONS

Political Will and Social Change

- We need to better understand how political will is generated and the role of social movements. Where does policy change come from? How are social movements generated and sustained?
- Demonstration of epidemiological and social connections of concentrated epidemics to the broader population may be used to generate political will. Building surveillance infrastructures appropriate to resource-poor settings is a priority, since surveillance data currently available in Latin America are not sufficiently reliable to be a basis for policy formation.
- The impact of the recent political, economic, and social changes on the epidemic (e.g, currency shocks in Argentina, political upheaval in Venezuela, etc.) must be understood and incorporated into prevention and care.
- Research and training on clinical or behavioral approaches to HIV prevention must address the way that politics at the community level (via CBOs) or at the national level (via development of political will) can be key to effective response to HIV/AIDS (e.g., Thailand, Brazil, the gay community in the U.S.).

Models of Research

- Latin American countries would prefer our funding the replication of proven strategies; they perceive research that prioritizes theoretical and methodological sophistication at the expense of translation into practice as unrelated to their local situations.
- Bi-directional learning must be a priority. What can we (the U.S.) learn from them (Latin America) in terms of effective prevention? Given the growing number of Latin Americans who are living in the U.S., collaborations should be organized in such a way as to promote bi-directional learning. There is a certain amount of intellectual imperialism implicit in the whole organization of north-south training and funding; the fact that we have more money than they do should not distract us from all we could learn from them.

Specific Research Areas

- There is a need to study indigenous populations, both in Latin America and those who have come here, looking especially at the role of drugs and migration.
- If current surveillance information does indeed present a reasonably correct portrait, why has the epidemic developed so differently in Latin American than in Africa and Asia? Macro-level cross-regional comparisons can be used to learn more about the relationships among structural factors, policy responses, social organization, and transmission patterns.
- In places like Brazil (and, increasingly, Honduras, the Dominican Republic) where there is a substantial burden of infection, how is availability of treatment a force for social change? How does access to treatment affect stigma and risk behaviors?
- How do new technologies like the internet shape the epidemic?
- What role has sex tourism played in the epidemic? How have economic development policies deliberately or inadvertently contributed to the dissemination of HIV?
- What is the role of the Catholic Church and other religious organizations in terms of HIV prevention? Of addressing stigma?
- How might it be possible to work with providers around sexuality and HIV prevention (via medical training, etc)?
- How would it be possible to integrate prevention messages into everyday life now in low prevalence countries? The classic public health point is that the time for primary prevention is now, but precisely because prevalence is low it is hard to get people excited about HIV prevention on a massive scale.
- We should examine experiences across Latin American countries to identify lessons learned about the region, to help countries learn from their neighbors, and to develop regional networks and policies.
- Little is known about HIV orphans in Latin America. For example in Honduras this is increasingly an issue.
- There is a need to work more on mental health, which is very stigmatized in Latin America, and to explore the intersections of mental health, stigma, and HIV.

- Given the mismatch between the U.S. culture of research and local needs in Latin America, we must identify ways to leverage existing research opportunities to support the CBOs that want to work on the broad social factors (e.g., human rights for sexual minorities, the strengthening of civil society, health sector reform) that have been important elsewhere in effective social responses to HIV/AIDS.
- More research is needed on the social organization of sexuality, which includes secret bisexuality, the intersection between labor migration and consumption of sexual services, sex tourism, and masculine privilege expressed through the double standard, which are major factors shaping regional patterns of transmission.

Research Issues in Specific Countries

- In Nicaragua, more attention is needed to how the very concentrated epidemic with MSM is related to risk at the broader population level.
- In Argentina, prevention efforts should focus on working with NGOs on community mobilization, as well as more needs assessments.
- More work is needed looking at the extent to which Brazilian successes can be extrapolated and transferred to other countries.
- Key vulnerable populations exist in Brazil, who are still underserved.
- In both Brazil and Argentina, there is a critical need for operations research to eradicate mother to child transmission – a reasonable objective in those countries, given prevalence and available resources.
- In El Salvador and Mexico, marital transmission was flagged as an important and still understudied issue.

3. Central/Eastern Europe

Chairs: Robert Heimer, PhD, CIRA, Yale University

Dale Morse, MD, MS, NYSDOH & Albany School of Public Health

MAJOR CHALLENGES

Two classes of issues were discussed, which can be divided into those related to the structures of care and prevention services in the countries of Central Europe and the former Soviet Union and those related to the nature of the financing by the U.S. government of training and research.

Infrastructure and Political Forces

- In many countries, there has been a general decline in service provision since Soviet days. This is often manifested as a concentration of scarce resources in specialty hospitals, which, in turn, limits the integrated approach to clinical care and prevention that marks the most successful responses to the HIV epidemic.
- Health officials at the local and ministerial level are not supportive. This takes three forms:
 - Lack of willingness to coordinate with NGOs that have taken the lead in responding to the epidemic, high turnover and reduced authority of officials, and corruption.
 - The availability of ARVs is limited by multiple factors including delayed roll-out despite the availability of resources through the Global Fund (e.g., Kazakhstan, Ukraine), unwillingness to use generic drugs, and unwillingness to treat active drug users (e.g., Georgia, Russian Federation).
 - There is neither a tradition of training in modern epidemiology nor a trained public health workforce.

Funding Issues

- U.S. funders prescribe low salaries for clinical, basic, and prevention researchers, which results in competent young researchers seeking gainful employment elsewhere.
- New funding mechanisms, instituted to increase accountability, delay the engagement of trainees in productive research upon their return home.
- There is a paucity of funds earmarked for infrastructure and capacity development to assist research institutions.

RECOMMENDATIONS

- Although the HIV epidemics emerged throughout the region in populations of injection drug users, the possibility of a generalized heterosexual epidemic has been neither ruled out nor demonstrated. Has it already occurred? If it has not, can we establish research programs that will allow us to know that it is happening in time to effectively intervene?
- Operations research on harm reduction and HIV prevention is needed. There are different models of program implementation that can be divided into three major categories - run by NGOs, run by government agencies, run by NGO/government agency collaborations. The question is: Does a particular model work better?

- What is the status of the epidemic among MSM, how high are the risks for spread in this population, and will targeted prevention programs be effective in reducing risk and transmission?
- Why has prevalence remained low in some locations (e.g., Georgia, Kazakhstan, Romania, Poland, Lithuania) despite high levels of injection drug use and high prevalences of hepatitis virus infections?
- What can be done to improve occupational safety and prevent nosocomial infections?

4. South Asia (India and nearby countries)

Chairs: Ellie Schoenbaum, MD, Albert Einstein College of Medicine

Susan Zolla-Pazner, PhD, NYU School of Medicine

MAJOR CHALLENGES

Major challenges included the following

- Obtaining international approvals can take up to two years. For instance, to conduct research in India, approvals are required from (1) the local Institutional Ethics Committee; (2) the International Health Division of the Indian Council for Medical Research (ICMR); (3) the Health Minister's Screening Committee (HMSC); and finally (4) the ICMR. Once ICMR approval is obtained, documentation must be submitted to the U.S. Embassy in New Delhi, and U.S. approvals must be obtained from (1) the State Department, (2) FIC, and (3) the funding institute at NIH. Additional problems may be encountered on projects conducted with NGOs.
- Support and research "seed" money must be available for trainees returning from the US.
- Challenges exist in sharing specimens, both in terms of sharing of technologies, bi-directional exchange, and ownership of the data.
- "Non-traditional" measurements of success, i.e., other than U.S.-led publications and grants, are needed.

RECOMMENDATIONS

Obtaining International Approvals

- Researchers must have the active involvement of Indian collaborators in order to move the paperwork forward. To ensure that approval applications conform to requirements, unofficial review should be obtained before formal submission.
- The process of obtaining approvals can and should begin before funding is finalized; in fact approvals can be obtained without funding if the project is submitted as a collaborative project without funding.
- Funders (i.e., FIC) should identify a point person in ICMR who will work with training programs.
- For research undertaken by trainees and their U.S. mentors, someone could be identified at the in-country Embassy and at FIC/AITRP to facilitate/expedite approvals. Given the special issues involved in working in India, someone at FIC involved with AITRP/ICOHRTA should be assigned to work with investigators, the U.S. Embassy, and ICMR to expedite this process.

Support and Research "Seed" Money for Returning Trainees

- AITRPs allow support of "developmental projects" but they must be reviewed by both internal and external reviewers. This transitional, short-term support is mentored and peer-reviewed.
- AITRP can support a "mini-sabbatical" for trainees to return to the U.S. to write up data after they have done their project, and/or to write up a grant proposal. It helps if the manuscript

or grant application is at least partially written before returning to the U.S.. Bringing the trainees back the U.S. was viewed as a productive way to complete their papers.

- Other support for trainees could be:
 - R03s: small developmental award. \$50,000/yr. Linked to various RFAs or RFPs.
 - CFARs can support international work through their Developmental Cores.
 - GRIP
 - Fogarty/Ellison awards
 - K01s: These require that the recipient spend 50% of time overseas during a funding period of up to 4 years.

Sharing Specimens

- It may be useful for trainees to bring specimens and reagents with them to work on during their training in the U.S. as part of the learning process.
- Indian specimens may be part of a long-term process to transfer technology or to establish a quality control program. Specimens are then analyzed in U.S. and India.
- When specimens are supplied by an investigator/trainee in India, all parties involved at the Indian institution should co-author any papers that result.
- It is helpful if part of the work on the specimens is done in India. For example: clone here, sequence there. Also sera and urine were easier to transport out than cells.
- It is extremely helpful if there is an exchange of specimens in both directions and it is very important that the products emanating from the specimens (such as monoclonal antibodies or pseudoviruses) are made available to the investigators and institution in India where the specimens originated.

"Non-Traditional" Measurements of Success

- Design and/or establishment of clinics in India based on clinics in U.S. where trainees worked.
- Design of new facilities inspired by or based on those observed in U.S..
- Manuals produced in U.S. for use in India, in English and in local languages (Hindi, Punjabi).
- Trainees sent by former trainees.
- Acquisition of funding to support collaboration with a U.S. mentor.
- Practical public health benefits.
- Leadership taken in the country
 - Papers published without U.S. authors by trainees after their return to India.
 - In-country workshops.
 - Internal training as a resource for other in-country clinicians, etc.
 - Participation in establishing national and international guidelines, working with national AIDS Control Organization, development of national clinical standards.
 - Participation in local, regional and national in-country advisory committees.
 - Establishment of new areas of research.

5. East Asia (China and nearby countries)

Chairs: Roger Detels, MD, University of California, Los Angeles

Kaveh Khoshnood, PhD, CIRA, Yale University

MAJOR CHALLENGES

Two categories of challenges were addressed: (1) challenges encountered in providing/obtaining training, and (2) challenges in conducting research.

Training

- Trainees want to learn community-based models of HIV/AIDS care provision and (especially nurses) expressed interest in getting more patient care experience. However, U.S. faculty feel that the focus of training is to learn research not public health practice.
- Language is a significant obstacle to trainees' fully benefitting from courses taken in the U.S.
- In China, there are not sufficient public health courses.
- While there was a consensus that training should include involvement in research projects in the U.S. and not just taking courses, involving trainees in research projects in the U.S. is very labor intensive.

Research

The main challenge in conducting research related to the changing context in the HIV/AIDS epidemic.

- Increase in availability of ART
- Less focus on VCT and more on routine or mandatory testing

RECOMMENDATIONS

Training

- Methods-based courses are very useful and should be taken by trainees before engagement in research projects in the U.S..
- After completing training in the U.S., trainees returning to, e.g., China should be supported in developing new courses on HIV/AIDS and using new (i.e., more interactive) teaching methods.
- Duration of training should be longer (at least 6 months).
- Trainees might be involved in research projects in the U.S. through summer research internships that are customized for each trainee. These should be applicable to work in the home country.

Research

The following research topics were considered of high priority:

- Evaluation research, including evaluation of both HIV prevention and treatment programs such as methadone programs in China, needle exchange programs, and China-Care program.

- Intervention research with high priority groups: MSM, migrant workers, sex workers and IDUs.
- Formal and rigorous assessment of health care workers' (especially in rural areas) knowledge and readiness for provision of HIV care.
- Integration of HIV prevention into care settings.
- Adherence.
- Identification of optimal models of HIV/AIDS care delivery, especially in rural areas, including health system related factors and financing of HIV care.
- Epidemiological studies to document overlap in high risk groups or extent of "bridge" populations; interventions based on these data.

Appendices

Member Lists (May 2005)

New York HIV Research Centers Consortium

New York-Area AIDS International Training and Research Programs (AITRPs)

New York HIV Research Centers Consortium (May 2005)

Aaron Diamond AIDS Research Center (ADARC)

AIDS Policy Research Group, Rutgers the State University of New Jersey

AIDS Research Program, Montefiore Medical Center

Baron Edmond de Rothschild Chemical Dependency Institute (CDI), Beth Israel Medical Center

Center for AIDS Research (CFAR), New York University School of Medicine

Center for Drug Use and HIV Research (CDUHR), National Development and Research Institutes, Inc.

Center for Health/HIV Intervention & Prevention (CHIP), University of Connecticut

Center for Health, Identity, Behavior & Prevention Studies (CHIBPS), Department of Applied Psychology, New York University

Center for HIV/AIDS Educational Studies and Training (CHEST), Hunter College

Center for Infectious Disease Epidemiologic Research (CIDER), Columbia University Mailman School of Public Health

Center for Interdisciplinary Research on AIDS (CIRA), Yale University School of Medicine

Center for Urban Epidemiologic Studies (CUES), New York Academy of Medicine

Columbia-Rockefeller Center for AIDS Research (CR-CFAR)

Division of Public Health and Policy Research, Montefiore Medical Center

Harlem Health Promotion Center, Columbia University Mailman School of Public Health

HIV Center for Clinical and Behavioral Studies, NYS Psychiatric Institute & Columbia University

HIV Center for Women and Children, SUNY Downstate Medical Center

Hunter College Center for Community and Urban Health

Mount Sinai Center for AIDS Research

New York City Department of Health and Mental Hygiene, HIV Epidemiology Program

New York State Department of Health, Office of Program Evaluation and Research, AIDS Institute

Social Intervention Group (SIG), School of Social Work, Columbia University

**New York-Area AIDS International Training and Research Programs (AITRPs)
(May 2005)**

Albert Einstein College of Medicine of Yeshiva University AITRP

Columbia University Mailman School of Public Health AITRP

Mount Sinai School of Medicine AITRP

New York University School of Medicine AITRP

SUNY Downstate Medical Center AITRP

Weill Medical College of Cornell University AITRP

Yale University School of Medicine AITRP