

# GLOBAL CONSULTATION ON MSM AND HIV/AIDS RESEARCH



September 28-29, 2008  
Washington, D.C.

**amfAR**<sup>™</sup>  
AIDS RESEARCH

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# PREFACE

The Global Consultation on MSM and HIV/AIDS Research and this report of proceedings represent only the first steps in a collaborative and ongoing process that will continue to unfold in the months and years ahead. In planning for the event, amfAR neither intended nor expected that the meeting and report would provide definitive answers to the myriad pressing questions surrounding MSM and HIV/AIDS research. Rather, both the meeting and this report should be viewed as the start of an inclusive dialogue whose objectives are to:

- Engage interested members of the research community, as well as key stakeholders in the broader “community” of individuals and organizations working on MSM and HIV/AIDS;
- Foster communication and collaboration among researchers;
- Promote the undertaking of relevant research activities;
- Advance our collective understanding of the specific needs of MSM for HIV/AIDS prevention, treatment, care and support; and
- Optimally inform interventions and programs to effectively address those needs in a timely way.

amfAR remains committed to working with interested stakeholders to secure the resources needed to achieve these objectives.

# BACKGROUND

## A Range of Pressing Needs

Numerous studies have demonstrated that men who have sex with men (MSM)<sup>1</sup> around the world are particularly vulnerable to—and disproportionately affected by—HIV/AIDS. Yet despite their vulnerability, little attention has been focused on these men in resource-limited settings.

Denial of male-male sexual activity is high, yet male-male sex is widespread and often hidden from view. Stigma and discrimination have marginalized MSM and rendered them invisible, with the unique prevention and treatment needs of these populations largely ignored. Ignorance about the extent of male-male sexual activity results in a lack of MSM programming, which in turn leads to high levels of risk behaviors.

The barriers to this work are many. As stated by UNAIDS, HIV prevention programs for MSM are hindered by several factors:<sup>2</sup>

- Denial that sexual behavior between men takes place.
- Stigmatization or criminalization of men who engage in sex with other men.
- Inadequate or unreliable epidemiological information on HIV transmission through male-male sex.

- Difficulty reaching many MSM because large numbers of these men do not identify themselves as such and are consequently hidden from MSM-specific programming.<sup>3</sup>
- Inadequate or inappropriate health facilities, including sexually transmitted infection (STI) clinics, and lack of awareness or sensitivity among STI clinic staff about the existence of anal, rectal, and oral STIs.
- Lack of interest among donor agencies in supporting and sustaining prevention programs among men who engage in same-sex behavior, and a lack of programs addressing male sex workers in particular.
- Lack of attention within national AIDS programs to the issue of MSM.

MSM-specific studies have been conducted in many settings but, considering the vast size and diversity of these populations, the coverage falls far short of what is necessary. Many countries appear not to have conducted any epidemiological research among MSM groups at all. Even where there is evidence of concentrated reservoirs of HIV and a high prevalence of risk behaviors among MSM populations, countries generally expend few resources on either monitoring these populations or establishing prevention and education programs. Indeed, a 2008 amfAR review of 128 country reports submitted to the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) revealed that almost half of the countries in Africa, Asia, Latin America, Eastern Europe, and the Middle East did not report on any of the five UNGASS indicators relevant to MSM,<sup>4</sup> further evidence of the wide knowledge gap regarding MSM and HIV/AIDS in developing countries.

Far more research is needed on all aspects of male-male sex and HIV/AIDS, and research is needed at multiple levels:

- Surveillance is needed to assess needs, plan responses, and evaluate outcomes. In particular, male-male sex should be included as a risk category in national HIV surveillance surveys and in behavioral surveillance surveys. Surveillance that validates successful programs will encourage the continuation of such efforts.
- More research with MSM is needed to evaluate knowledge, attitudes, beliefs, and practices.
- Contextual (social and epidemiological) research is needed to determine the size, structures, and behavior patterns of MSM populations, how and where each MSM sub-group meets, and how different MSM sub-groups interact with each other.

<sup>1</sup>Sexual identity among MSM is a complex issue that calls for a nuanced understanding of these populations. For this consultation, MSM were defined as biological males engaging in sexual activities with other biological males.

<sup>2</sup>AIDS and men who have sex with men. UNAIDS, 2000.

<sup>3</sup>This hidden group includes: masculine-acting MSM in many cultures who often view sexual encounters with transgenders as heterosexual; married men who engage in male-male sex but keep it hidden from their families and friends; and male sex workers who fail to identify as MSM because of the stigma associated with male-male sex.

<sup>4</sup>The five UNGASS indicators relevant to MSM include (1) What percentage of MSM are living with HIV? (2) What percentage of MSM have taken an HIV test in the last year? (3) What percentage of MSM know how to prevent HIV? (4) What percentage of MSM used a condom the last time they had sex? (5) What percentage of MSM are being reached by HIV prevention programs?

Much about the intersection of the epidemic and MSM populations still remains unclear or misunderstood and, where understood, often simply neglected. In addition, much of the information that is known about MSM and HIV/AIDS has not reached policy and decision makers. This systemic neglect of MSM must also be addressed as a matter of human rights.

Increased attention to MSM and HIV/AIDS is essential if the current epidemics are to be contained. A number of researchers and non-governmental organizations (NGOs) have been sounding the alarm on MSM and HIV. With grateful acknowledgment of this work, amfAR seeks to further raise the profile of HIV/AIDS and MSM needs so that existing country epidemics can be halted and future ones avoided. Political support and commitment of resources will be needed for these actions—both from national governments and from bilateral and multilateral agencies.

## GLOBAL CONSULTATION ON MSM AND HIV/AIDS RESEARCH

In an effort to examine current understanding of MSM and HIV/AIDS, identify gaps in knowledge, and develop a roadmap for future research, amfAR brought together more than 40 experts from around the world to Washington, D.C., on September 28 and 29, 2008, for a global research consultation on HIV/AIDS and MSM. (For details about the planning process, see Appendix A.) Participants represented a range of disciplines, including epidemiology, biomedicine, social and behavioral science, and human rights. This report provides an overview of those discussions as well as recommended steps for moving forward to gain a better understanding of how best to address the needs of MSM around the world.

The consultation began with welcoming remarks by Kevin Robert Frost, amfAR's chief executive officer. Dr. Kenneth Mayer (Fenway Community Health and The Miriam Hospital/Brown University) then presented a brief report on the key findings of a 2003 consultation on HIV/AIDS and MSM sponsored by the Office of AIDS Research at the National Institutes of Health. Dr. Judith D. Auerbach (San Francisco AIDS Foundation) also provided a short introduction to MSM orientations and nomenclature.

## Plenary Presentations

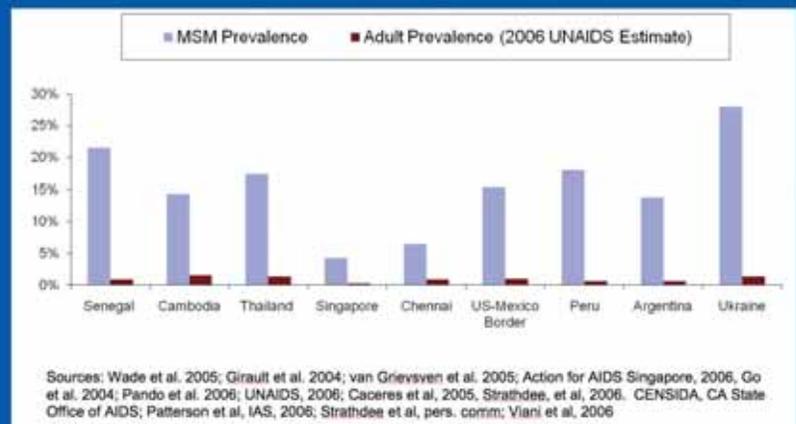
Following the opening remarks, distinguished researchers acknowledged as experts in their respective fields gave 15-minute plenary presentations providing an overview of state-of-the-art knowledge in five areas. The presentations are summarized briefly below. Copies of the PowerPoint presentations that accompanied each plenary are available on amfAR's website at [www.amfar.org/msmresearch](http://www.amfar.org/msmresearch).

### HIV/AIDS Among MSM: The Epidemiology and Surveillance Research Agenda

Chris Beyrer, MD, MPH, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland

- Epidemics of HIV among MSM are underway in high, middle and low income countries.

### HIV prevalence among MSM in Selected settings



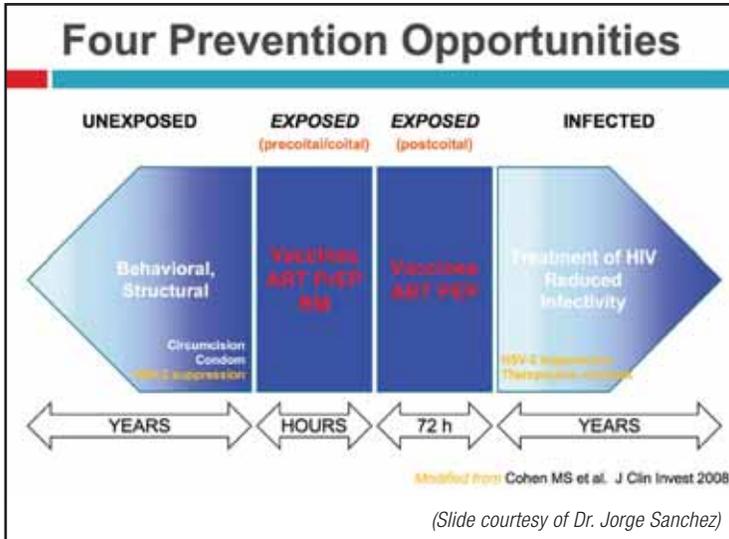
(Slide courtesy of Dr. Chris Beyrer)

- Many MSM epidemics occur in “hidden” contexts due to discrimination, stigma, criminalization, rights abrogations and limited HIV surveillance.
- MSM are a group of distinct populations, with varying socio-demographic characteristics, sexual practices, and differential risk for HIV.
- As a group of distinct populations, MSM are markedly under-studied; much of the world is still unmapped for MSM in 2008.
- HIV epidemiology and surveillance are the bases of informed and evidence-based responses to local epidemics and, more broadly, the HIV pandemic.
- There are new epidemiologic tools including respondent-driven sampling (RDS), molecular epidemiology, and social network analysis that can be utilized to better inform prevention, treatment, and care for MSM.

## Biomedical Interventions Among Men Who Have Sex With Men

Jorge Sanchez, MD, MPH, INMENSA, Lima, Peru

- Options/strategies for biomedical intervention vary according to HIV exposure/sero-status and timeframe.



- Unexposed:** For those at risk of exposure, intervention options are both behavioral and structural. Such interventions include encouraging access to treatment services for sexually transmitted infections or drug abuse, delaying the onset of sexual intercourse, increasing consistent condom use, and reducing the number of sexual partners. These interventions should be employed over a long timeframe of years. Voluntary HIV counseling and testing remains a cornerstone among prevention intervention options and should be widely available, encouraged and utilized at all levels (individual physicians, clinics, and other community healthcare settings).
- Exposed:** Beyond the mechanical barriers, strategies to prevent HIV infection at the time of exposure, or soon thereafter, may include development of protective HIV vaccines and antiviral therapies (including rectal microbicides), options with a very short (hours to days) window for deployment.
- Infected:** For those already infected, options include HIV treatment to reduce infectivity, HSV-2 suppression, and the possibility of future therapeutic vaccines—strategies with a very long timeframe of many years or a lifetime.
- Data suggests that herpes simplex-2 (HSV-2) and HIV-1 infections have synergistic interactions. HIV-1 alters the clinical presentation of HSV-2 and may increase HSV-2 transmission. Conversely, HSV-2 may increase the likelihood of acquiring HIV-1. Some observational studies have also

suggested that HSV-2 may increase HIV-1 transmission. However, two recent clinical trials have shown that HSV-2 suppressive therapy offers no protection against acquisition of HIV.

- More data is needed in order to evaluate the effectiveness of male circumcision as a biomedical intervention among MSM. Research needs to include: acceptability in high-incidence populations; efficacy in U.S. versus non-U.S. sites; formative and uptake studies; better understanding of sexual practices; interaction with other factors (e.g., HSV-2, vaccines, etc.); and relation to condom use.
- Dr. Sanchez reported on the current state of research on pre- and post-exposure prophylaxis (PrEP and PEP)—what is known and unknown, as well as the perceived advantages and disadvantages of these intervention strategies.
- A recent Phase 1 trial for a current rectal microbicide candidate (UC-781) revealed that the product appears safe. But much remains to be learned, including:
  - Distribution and concentration studies (where the drug goes in the colon and how long it stays there).
  - Does the drug inhibit HIV?
  - How long before and after sex is coverage effective?
  - What drug(s) can be used and which would be least likely to provoke resistance?
- Likely future directions for biomedical interventions against HIV include:
  - The greatest impact on reducing HIV infections among MSM will involve a combined package of biomedical and behavioral prevention approaches to improve adherence and minimize risk.
  - It will be necessary to collect and review epidemiological and intervention data and conduct mathematical modeling as a guide to selecting individuals and appropriate prevention interventions for MSM target populations.
  - Components of a menu-driven HIV prevention package must be developed and individual randomized clinical trials designed to evaluate the package's effect on HIV incidence.
  - Feasibility and acceptability must be determined for individual and combined components of proposed prevention interventions.

## Legal Frameworks and Human Rights in Relation to Sexual Diversity: Implications for Research

Carlos F. Cáceres, MD, PhD, Universidad Cayetano Heredia, Lima, Peru

- Fundamental human rights of people in sexual minority groups include, but are not limited to, the rights to respect and dignity, non discrimination, equality, participation, life, identity, self determination, and access to health.



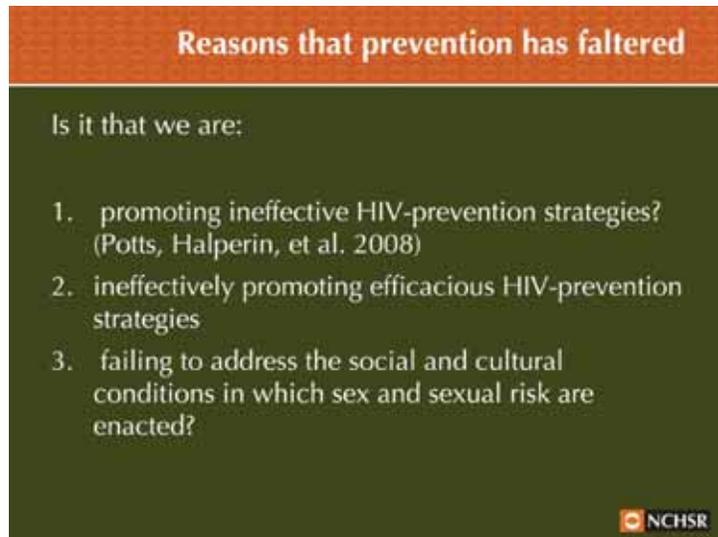
(Slide courtesy of Dr. Carlos Cáceres)

- The respect, protection and fulfillment of human rights (and recognition of human rights violations) are key determinants of the HIV epidemic.
- Social exclusion means that many people in sexual minority groups are among the most marginalized, overlooked, and discriminated against in many parts of the world. This, in turn, leads to an increased vulnerability to many social and health problems—including an increased risk of HIV transmission.
- Sexual minorities suffer high levels of violence in many parts of the world.
- A review in 2007 found that 85 member states of the United Nations criminalized consensual same-sex acts among adults. Penalties ranged from fines and imprisonment, to physical and capital punishment.
- However, the absence of laws criminalizing sexual minorities does not guarantee a life free of discrimination. Cultural norms at a societal level may result in self-segregation of sexual minorities, and more specifically, in health services not offering a welcoming environment or with limited capacity to resolve health issues.
- A focus on improving the legal environments and the human rights of sexually diverse populations is needed as part of a comprehensive response to the HIV epidemic in all countries.

## HIV Prevention in MSM: The Role of Social Science

Susan Kippax, PhD, National Centre in HIV Social Research, University of New South Wales, Sydney, Australia

- Effective HIV prevention is not only dependent on efficacious HIV prevention tools/technologies, but also on effective promotion of those strategies.



(Slide courtesy of Dr. Susan Kippax)

- Effective promotion relies on:
  - Ethnographic and “insider know-how” about the forms that homosexual activity takes and how its expression is regulated;
  - Understanding the local macro-level political, socio-cultural and economic ‘drivers’ that give rise to:
    - Sexual identities
    - Sexual practice
    - HIV risk practice
    - HIV risk reduction strategies;
  - Addressing social and cultural norms that regulate sexual practice and its expression; and
  - Acknowledging, for example, that anal intercourse (a behaviour) is different depending on whether it is enacted in a regular/committed relationship (a practice) or in a casual encounter (another practice) and changing the practice.
- In order to ensure the effective promotion of efficacious HIV prevention strategies:
  - Researchers need to work in partnership with communities and social networks to develop HIV prevention strategies – and these are likely to come from communities and networks; and
  - Governments need to fund communities and networks so that they can (with input from researchers) develop and run their own HIV-prevention campaigns, and thus sustain the response.

## Behavioral Practices Research Priorities

Thomas Coates, PhD, University of California, Los Angeles

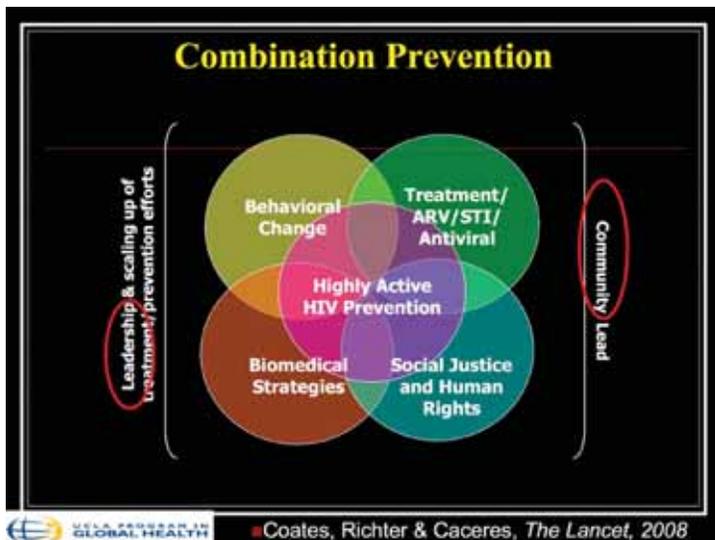
### Research Priorities

- What do we need to know; about whom; and for what purposes?
- Who gets the data and how soon is it available?
- Need to be cognizant of disparities between and within countries.

### Time to Change the Framework

- HIV prevention is even more difficult now: HIV is no longer a highly lethal disease; treatment is accessible and continuous; monitoring is adequate.
- Prevention cannot be subtle or short-term; it needs to be multi-level, sustained, and constantly evolving in response to community needs.
- The best prevention solutions are not imposed from outside.
- Testing and treatment are integral to prevention, and prevention needs to be a central part of treatment.
- HIV prevention is not always the priority of leadership in established or emerging advocacy movements.

- Combination prevention efforts, or “Highly Active HIV Prevention,” must be community-led and involve the intersecting elements of: behavioral change, biomedical strategies, treatment/ARV/STI/antiviral, and social justice and human rights (see diagram).



(Slide courtesy of Dr. Thomas Coates)

### Behaviors of Interest

- Behavioral Epidemiology – Determine the prevalence and incidence of male-male sexual and health-seeking practices.
  - Identify characteristics of individuals and groups engaging in male-male sex and how they access health care.

- Identify venues and circumstances of male-male sex and perceptions and practices related to health care.
- Identify actions undertaken to avoid acquiring HIV, for example: decrease in number of partners, serosorting, seropositioning, avoiding certain behaviors, using protective devices, using antivirals (orally or anally), male circumcision, testing and re-testing, care-seeking and barriers to care, adherence to medications, and disclosure.

- Other Important Experiences to Consider: Behavioral responses to legal and social discrimination; violence and climates that condone violence; discriminatory or stigmatizing health care systems; disparities in access to new technologies, devices, and medications.

- Advocacy and Community Development — What leads to: Community development? Formation of advocacy groups? Effective policy change?

- Focus on those parts of the world for which we have the least data or focus on those populations in developed countries about which there is the least data. Incorporate data on male-male sex within demographic health surveys and include transgenders.

### Changing the Framework

- Behavioral practice studies need to be linked to epidemiology, but not constrained by it.
- Behavioral practice studies also need to be linked to social and clinical science as well as to legal and human-rights studies.
- We must recognize that people may have higher priorities than avoiding HIV, and research on prevention and care must acknowledge and accommodate this reality.
- We must develop a comprehensive perspective on behaviors/practices based on a combination prevention/treatment framework. This comprehensive perspective needs to include the full spectrum of behaviors/practices that protect against HIV at the individual and community level.
- New models and more powerful or explanatory studies of determinants/correlates are needed.
- Improved evaluation models are needed.

### Challenges

- Goal should be to change the research framework.
- Behavior/practice research needs are highly contextual.
- How do we collect usable data and get it into the right hands in a timely way?
- How can we prioritize?

## Charge to Working Groups

Each of the plenary presentations was followed by a short discussion. Drawing on their varied areas of expertise, the participants then divided into five parallel working groups, each focusing on one of the five research areas covered in the plenary presentations. The groups were charged with identifying and prioritizing key research needs in their respective disciplines and reporting back to the full assembly.

Each of the working groups was charged with answering the following four questions:

1. What are the key things that we know (i.e., that are supported by data and/or front-line experience) that may not require additional research?
2. What are key things that we do not yet know or fully understand (i.e., some future directions for research)?
3. What are creative, innovative ways to address some of the research gaps?
4. What recommendations for future research would you make from your particular area that would cut across various research disciplines?

At the end of the two-day consultation, participants gathered as a group to present their conclusions and to consider the next steps toward creation of an overall research agenda.

## Summary Findings of the Working Groups

Several common themes and clear priorities emerged from the five working groups, many of which are also reflected in the top research priorities that appear on page 11. These included:

- Information about MSM and HIV/AIDS is generally better and more widely available in high-income settings. In low- and middle-income settings there are major data gaps in a variety of areas, such as prevalence rates, attributable risk, etc.
- There is need for the formation of multi-disciplinary research groups—e.g., social/behavioral, anthropological, biomedical—combined with iterative processes.
- There is an urgent need to better understand the health disparities among races and across different segments of the MSM population.
- More research is needed on local expressions of identity and sexuality, sexual relationship dynamics, risk, and risk reduction in different social contexts.
- Much more research is needed on potentially promising biomedical prevention strategies such as pre-exposure prophylaxis (PrEP); circumcision; rectal microbicides; and keratinization, especially with regard to population attributable risk and identifying and addressing levels of risk compensation among MSM.

- Resources are needed regarding best practices in research among MSM populations.
- A constructive relationship between researchers and communities is needed in order to achieve the best outcomes.
- Questions remain about how HIV/AIDS research among MSM can contribute to and inform human rights advocacy and policy change.

These themes are reflected in greater detail in the notes of the five working groups that follow. It should be noted that these summaries are necessarily abbreviated representations of much more nuanced and complex conversations of the various topics covered.

## Epidemiology and Surveillance Group

### What Is Known?

- Epidemiological information about MSM and HIV/AIDS is generally strong in high-income settings. But HIV infection rates have either remained high or are resurgent with average incidence of about 2.5%.
- Huge disparities exist among MSM even within each high-income country, chiefly due to socioeconomics and race.

### What Is Unknown?

- In low- and middle-income settings the knowledge base about HIV/AIDS among MSM is generally weaker. There are major data gaps in areas such as prevalence rates and attributable risk.
- Research data and methods need to be better defined, including the defining characteristics of sample groups, sampling strategies, MSM subcategories in each setting, and risk data for each subcategory.
- There is a paucity of data regarding male sex workers and transgenders, categories that have been largely excluded from the research agenda.

### Creative Strategies and Recommendations for Future Research

- Attempts need to be made to fast-track biological measures of HIV testing to generate incidence data from cross-sectional studies.
- There is an urgent need to ramp up molecular epidemiology and learn more about epidemiological dynamics in order to better understand the disparities between races and among different segments of the MSM population.
- A global epidemiology working group dedicated to MSM should be created involving:
  - Collaboration with existing organizations such as the Global Forum on MSM & HIV and the subgroups of other organizations dedicated to MSM including UNDP, UNAIDS, etc.

- Developing strategies for prevention, research, and surveillance.
- Creating resources for best practices in research in areas such as:
  - Questionnaires
  - Surveillance
  - Human rights contexts
  - Development of a broader health agenda
  - Methodology around sampling, denominators, refining RDS, disparities, etc.
- Attempting to better characterize prevalence “tipping points” in situations where incidence rises quickly, and to obtain process data on a regional level on how best to do this work.
- Creating standardized reviews of prevalence and incidence.
- Ways should be identified to creatively use the Internet, which has been massively under-utilized, to move forward on some of the research gaps.

### Cross-Cutting Issues

The Epidemiology and Surveillance Group also identified what they regarded as some “cross-cutting issues”:

- *Fung muk*—penile implants<sup>5</sup>.
- A greater knowledge of country-specific sexual practices is needed. There is a lack of work-based learning.
- There is a need to better characterize disparities using clinic settings to collect data from HIV-positive MSM about prevalence of same-sex behavior, an approach which has been used successfully in Mexico.
- A better understanding is needed of incarcerated populations and the risks they face. How do various syndemics drive HIV and other epidemics (including the roles of poverty, STIs, intravenous drug use, and sex work)?

## Biomedical Interventions Group

### What Is Known and Unknown?

The biomedical prevention strategies about which we know the most are: pre-exposure prophylaxis (PrEP)<sup>6</sup>; circumcision; STI control; treatment-as-prevention; rectal microbicides; and keratinization<sup>7</sup>. (Note: The Biomedical Working Group included STI control and treatment-as-prevention as biomedical prevention strategies, but time constraints did not permit in-depth discussion of these topics.)

### Pre-Exposure Prophylaxis (PrEP)

Known:

- PrEP is partially effective in non-human primates.
- The combined use of two drugs is better than one.

- Some limited data suggest that PrEP is tolerable and safe in women.
- MSM are not yet utilizing PrEP to any great degree (<0.5%), and most do not yet know about it.

Unknown:

- Is PrEP effective and, if so, to what extent? If PrEP is only partially effective, could it do more harm than good?
- How safe is PrEP and what lab monitoring is needed to ensure safety?
- What level of adherence would be required for efficacy?
- How would PrEP be scheduled (daily, intermittent, or “disco dosing”)?
- Will men be prepared to adopt PrEP?
- What impact might PrEP have on patterns of risk-taking? Will it lead to increased unprotected anal intercourse?
- In exploring PrEP, are there better drugs than tenofovir and emtricitabine? Should we be putting “all the eggs in one basket”?

### Circumcision

Known:

- Studies have shown that circumcision has resulted in a 50% reduced risk among some heterosexual men.
- There is some recent evidence that shows reduced insertive risk for circumcised men, but relatively low population attributable risk in populations where circumcision is widely practiced.
- Some recent evidence from Peru shows that circumcision as a strategy for risk reduction would be acceptable among men there.

<sup>5</sup>A practice reported in Asia, the Pacific and parts of Europe, *fung muk* is a form of penile modification involving the insertion of one or more “muks” (plastic or glass balls, ball bearings, marbles or pearls) into the shaft of the penis. Reasons for the practice include perceived enhanced female sexual pleasure, peer influence and penile enlargement. Post-modification complications include infection and dysfunction, difficulties using condoms and trauma during sex, and the spread of blood borne pathogens. See Thomson N, Sutcliffe CG, Sirojrn B, et al. “Penile modification in young Thai men: risk environments, procedures and widespread implications for HIV and sexually transmitted infections.” *Sex Transm Infect* 2008; Vol 84:195-197.

<sup>6</sup>The administration of antiretroviral drugs just before a potentially risky sexual encounter. The efficacy of this strategy is unclear, despite large-scale clinical trials, and complete protection in animal models has been shown to require high daily doses of at least two antiretrovirals, typically tenofovir and emtricitabine. In addition, PrEP accelerated transmitted drug resistance among monkeys with breakthrough infections.

<sup>7</sup>Organic process by which keratin is deposited in cells and the cells become horny (as in nails and hair). Keratinization has been proposed as a potential chemical means of mimicking the efficacy of male circumcision. The external foreskin and shaft of the penis are keratinized and not susceptible to HIV infection. In contrast, the inner foreskin and frenulum have a keratin layer about half the thickness of the layer on the penile shaft. Their surfaces contain cells—Langerhans cells, dendritic cells, CD4+ T cells, and macrophages—that are highly susceptible to HIV infection and more abundant in men with a history of STIs. This has raised the question: could the keratinization of these susceptible tissues be enhanced as a form of chemical circumcision that might be equally protective against HIV and not prone to the procedure-based risks of surgical circumcision?

Unknown:

- The population attributable risk in countries with low circumcision rates is not known, although it is assumed that it would be higher.
- The level of risk compensation among MSM is unknown.
- The acceptability of circumcision is unknown for many geographical settings and societies.
- The sexual abstinence required during the higher-risk period of wound healing may pose a significant problem in some settings.
- Currently, there is no evidence from randomized clinical trials of the effectiveness of circumcision in MSM.

### Rectal Microbicides

Known:

- Research up to this point has indicated that vaginal microbicides do not work.
- Use of Nonoxinol-9 as a rectal lubricant has been shown to be toxic.
- Some use of lubricants is acceptable to gay men.

Unknown:

- Very little else is known about rectal microbicides and their potential efficacy. Is this an approach that is likely to work? If vaginal microbicides don't work, how can rectal?
- Very little is known about overall acceptability among MSM, particularly if a large volume of lubricant is required for effectiveness.
- Would an effective rectal microbicide be safe for frequent use?

### Keratinization

Known:

- Application of estrogen creams to the uncircumcised penis leads to increased keratinization and protection against SIV in macaques.
- To increase the keratin layer in humans, estrogen creams need to be applied regularly.

Unknown:

- Acceptability is not known. Given that circumcision is unacceptable in many settings (e.g., India, Indonesia, and other locales), it is not known if keratinization would prove acceptable in such contexts.
- The potential side effects of keratinization are unknown.
- The potential for systemic uptake of creams that might be used in keratinization is unknown.
- It is not known to what degree keratinization might reduce sexual sensation.

## Creative Strategies and Recommendations for Future Research

### Pre-Exposure Prophylaxis (PrEP)

- If in current PrEP trials, poorly adherent participants are also protected, that might suggest the effectiveness of intermittent dosing. In the next generation of trials, other schedules versus daily dosing should be explored.
- Should we be doing a superiority trial of intermittent dosing versus placebo now?
- Studies with other drugs (e.g., maraviroc, lamivudine (3TC), emtricitabine (FTC) used alone, or raltegravir) should be undertaken.
- How can the issue of risk compensation be addressed? This must be confronted immediately after efficacy results become available, and implementation studies must begin immediately after any results suggesting efficacy. Scenario planning is needed now.

### Circumcision

- Initial randomized clinical trials of circumcision as a prevention strategy for MSM should involve enrolling MSM who are regularly the insertive partner in anal intercourse ("tops") in countries with high incidence of HIV and low prevalence of circumcision. Future research should be designed to cut across various MSM subgroups.
- Future research should be undertaken to explore the socio-cultural issues surrounding circumcision among MSM.
- Wide advocacy and use of circumcision as a prevention strategy would need to be coupled with a very strong educational message.

### Rectal Microbicides

- There is debate about how much investment should occur in connection with microbicides.
- Research could be undertaken using agents with higher concentrations of antiretrovirals.
- Future research should be designed to cut across various MSM subgroups.
- Research should be conducted to better understand how MSM currently use lubricants. Could future research in microbicide use among MSM be built upon this?

### Keratinization

- Early-phase research in humans should be undertaken.

## Behavioral Sciences Group

### What Is Known?

- Reproducing surveys and measures from high income countries often does not translate well in responding to needs in resource-limited settings; “bottom up” research is needed in these contexts.
- There is a need for greater regional and local knowledge, e.g., around such questions as fluidity of sexual identity.
- Research can spur community processes.

### What Is Unknown?

- There are some key unknowns regarding sexuality, community, and sexual behavior, as well as risk behaviors and their correlates that arise from under-researched local contexts.
- We lack an overall picture of sexual health in various social contexts.
- Research would profit from a greater understanding of the roles of resilience and self-regulation in various social settings.
- Longitudinal data is needed utilizing life histories and other qualitative methods.
- Research that is focused on social, sexual, and affinity networks would be useful.
- MSM need to be included on demographic and health surveys, but caution must be exercised with results in stigmatized contexts.
- We lack a strong understanding of how technology may be used for the spread of information and for HIV interventions.

### Creative Strategies and Recommendations for Future Research

- More research is needed on:
  - Local expressions of identity and sexuality, risk, and risk reduction in different social contexts (e.g., in terms of condom use, seeking voluntary counseling and testing, etc.);
  - The dynamics of risk taking, self-regulation, etc., in various social settings;
  - Cultural limitations of proven intervention strategies;
  - Effective strategies to access MSM in hidden contexts;
  - How to foster leadership, community-building, empowerment of communities, etc.;
  - Where (in what contexts) MSM connect to the general population;
  - The connection between HIV prevention and human rights.
- There is need for the formation of multi-disciplinary research groups—e.g., social/behavioral, anthropological, biomedical—combined with iterative processes.

- We should explore the use of random dynamical systems as a tool, while being conscious of its limitations.
- We need to explore the use of triangulation with venue-based, popular opinion leader methods.
- Interventions should be designed that place emphasis on the quality, not quantity, of sexual partnerships. How can we foster more meaningful social/sexual interactions?
- We must be aware of the challenges of multidisciplinary social science approaches and how to research “meaning” in a relevant way.
- Mechanisms must be developed for moving from social structural theory to individual/group behavior change. What are the models (epidemiology? social network theory? molecular epidemiology?) and what is the meaning of these approaches for prevention programs?
- How does one work with all this information to move from a “neutral” research framework to active intervention?

## Social Sciences Group

### What Is Known?

- Context – social, cultural and political – really matters. Quantitative and qualitative studies can reveal underlying contextual factors.
- Personal and social history have consequences for the present. Lived experience is a major resource for prevention.
- Behavior is socially produced. A focus on practices is likely to be more profitable than a focus on individual behaviors.
- High-quality ethnographic studies are important, not as formative research but in and of themselves for explaining the “why” of behaviors.
- There is a need to link this work, where relevant, to larger-scale investigations in order to generate good understanding, providing both the “what” and the “why.”
- Social and sexual “connectedness” is important in promoting both safer sex and understanding sexual risk.
- In some countries, many men are, in fact, practicing safer sex. We should focus our attention more on groups and settings where the risk is higher.
- There are dangers in seeking to transport so-called “best practices” across contexts and times.
- A constructive but critical working relationship between researchers and community is needed in order to achieve the best outcomes.
- Achieving sustained long-term changes in sexual risk-taking takes time. We must recognize this and develop good new measures to keep track of what is achieved and assemble a mix of monitoring and research practices to get at local particularities.
- Communities do not wait for well-developed programs and interventions, so a challenge lies in keeping one step ahead of both the epidemic and community responses.

## What Is Unknown?

- Little is known about the variability and changes over time in sexual cultures in various settings.
- Forms of knowledge beyond local understanding regarding the “when and with whom” of sexual behavior are most useful, but the best approaches for gaining this kind of knowledge are unclear.
- There is a need to determine how best to frame HIV prevention programs so as to be both effective and reduce the risk of stigmatization, discrimination and denial.
- There is a related need to determine how best to engage HIV-positive men in prevention in ways that are in their interest and non-stigmatizing.
- There is a need to better understand the role of gender as a factor influencing men’s relationships with other men (i.e., different masculinities and the expectations associated with them, together with implications these expectations hold for sexual practices and risk).
- A better understanding is needed of sexual relationship dynamics, including their contextual specificity.
- Studies should be undertaken to determine how structural factors affect diversity of male-male sexual expression and how this relates to access to treatment, care and prevention.
- Studies should be undertaken of variations in specific cultural groups (e.g., Latino MSM) to determine if such variations matter.
- Studies where context is the focus also could be undertaken:
  - What happens when there is legal and policy change?
  - What is role of faith organizations and of spirituality?
  - What is the influence of institutional factors on sexual practices?

## Creative and Innovative Ways to Address Gaps

- Funding mechanisms are needed for work requiring interdisciplinary teams in which social scientists have a key role in setting the agenda.
- Research activities should be undertaken to promote parity of respect between the ‘social’ and the ‘biomedical’ in HIV research.
- There is a need to support meetings involving different groups of social scientists to hash out problems and share ideas. (Not all social scientists are the same.)
- Research should be undertaken to study the ways in which biomedical ‘understandings’ and practices frame HIV and MSM and the implications of these for HIV prevention.
- It would be useful to have a venue/channel in which some of the disciplinary issues could be worked through, perhaps in partnership with a community group such as the Global Forum on MSM and HIV.

## Recommendations for Future Research

- Studies that bring together advances in molecular epidemiology and social/sexual networking focused on (1) acute HIV infection and (2) concurrency among other factors (and to include different groups of MSM and the relationships between them).
- Studies of men’s same-sex relations in heterosexual populations (with a focus on how best to ‘characterize’ men who regularly or occasionally have sex with other men) with a view to examining the adequacy of (1) existing social and epidemiological categories for MSM and (2) adequacy of advocacy and rights-based approaches which use sexual minority categories).
- Studies of the effect of institutional cultures and practices (e.g., jail, law enforcement practices, bath houses, churches, media, the Internet) on HIV risk, vulnerability, and resilience among different groups of MSM, with the focus on how particular institutions produce their effects.
- Studies that ensure proper integration/partnership between social, behavioral and biomedical research at every phase of trial development and implementation (e.g., with respect to male circumcision, pre-trial studies of what male circumcision means to MSM; and with respect to PrEP, follow-up studies of changes in sexual practice including risk compensation). The ultimate goal of these studies would be to achieve a proper assessment of effectiveness.
- Studies of how different groups of MSM develop and understand their rights and ‘citizenship’ in the context of HIV and other health issues.

## Human Rights/Policy Group

### What Is Known?

- Police abuse and violence contribute to HIV risk, vulnerability, and poor health.
- Stigma and discrimination limit access to prevention, treatment, care, and support.
- We know how to get marginalized populations into health services.
- It is possible to bring politicians and leaders to a point where they support MSM initiatives.
- Travel bans and other laws that force people to hide their identity increase risk.
- It is possible to bring about shifts in policy and resources for particular groups, for example, in the case of injection drug users (IDUs).
- Some human rights interventions have worked to bring about change.
- Identities are not trans-historical and trans-cultural, but we do not know the impact of funding on the creation and expression of identities (see: HIV funding in India).

- We know the new paradigm: working together with the community (community must be consulted as an official requirement), but we do not know what kind of negotiation is needed for real partnership (i.e., tokenism vs. participation).
- There are too many AIDS groups and agendas and too much time is spent arguing; they need to be brought together in one coalition.
- Project monitoring is useful and can provide the numbers/figures that people can readily understand and that decision makers can use. It can accurately explain what constitutes success and facilitate learning from both success and failure.

### What Is Unknown?

- The policy process – what drives change?
- In legal terms, what other laws are having an impact on HIV prevention?
- How does one measure criminalization in terms of:
  - Sodomy law reforms?
  - Law enforcement?
  - Social discrimination after decriminalization?
- How can public health arguments be refashioned to make sense in a human rights advocacy context? Evidence is needed but it must be very carefully selected.
- Where are the government programs that translate legal change into social change?
- What are the specific government policies that can enhance HIV prevention?
- What constitutes an adequate amount of funding? (For example, if x% of the epidemic is among MSM, then shouldn't x% of the funding be assigned to MSM?) However, there is no policy guidance. On the other hand, how can the proportion of funding that should be assigned to a particular group be determined given that intervention needs can vary?
- To what extent should funding be directed to institutions? Funding is important, but money can also create problems – a benefit to the individual institution is not necessarily a benefit for the broader community. Funding can have undermining effects.
- What type of coverage is needed to have epidemic impact?
- How do we get to the tipping point? What appeals most to political decision makers? In the United States, individual stories have been proven to make an impact. What works in other parts of the world? Is this question researchable at all?
- “Operationalization” is needed. We have a lot of available information—on policy, advocacy, and at the grassroots level—but we do not recognize it and we do not utilize it.
- The role of activism in creating social change must be understood in a broader context. Every social movement is producing knowledge; activism produces new knowledge and that should be recognized.

### Addressing Gaps and Recommendations for Future Research

- Summary: There is need for:
  - Case studies, contextualization;
  - Comparative studies;
  - Small grants for specific policy interventions;
  - Budget monitoring;
  - Donor mapping;
  - Adapting IDU research.

## CONCLUSIONS

### Top Research Priorities (Unranked)

In order to arrive at a consensus regarding which research questions should be prioritized, each working group was asked to identify its top research priorities. These were then placed on charts around the room and each participant was asked to identify his/her top three priorities. The following are the unranked top research priorities identified by the participants:

1. Optimize Surveillance Methodologies
  - Develop sampling methods that are useable by developing world community-based organization (CBOs).
  - Use the methods developed to inform preventive practice.
  - Conduct sampling and measuring experiments.
  - Determine denominator estimation methods.
  - Disseminate surveillance methods to NGOs within a best practices framework.
2. Filling in the Gaps on the Map
  - Plan and initiate community-based-and-led research for low- or no-data countries in order to strengthen the evidence base for prevention, treatment and care.
  - Map current status and developments in epidemiology, behavioral, psychosocial, and human rights.
3. Undertake studies of institutional cultures and practices (e.g., law enforcement practices, bathhouses, etc.) and implications for risk, vulnerability, and resilience.
4. Address questions of effectiveness: Biomedical research should involve other research disciplines in every phase of clinical trial development including pre-trial and post-trial (Phase 4) research. Examples:
  - MSM Circumcision Trial.
  - Preparing for PrEP:

- Because results are expected in two years, there is a need for readiness.
  - Access: social research/human rights.
  - Community engagement (with people living with HIV/AIDS).
  - Audience: departments of health, donor agencies, CBOs.
  - Scenario planning for 30-90% efficacy:
    - Measuring behavioral compensation
    - Measuring resistance in practice
5. Develop theoretical models and innovative research methods to support operations research studies to be conducted in partnership with MSM and transgender populations on the impact of interventions targeting human rights issues and frameworks on HIV vulnerability.
  6. Investigate the use of molecular epidemiological methods to inform HIV transmission, prevention, and treatment research among MSM and develop tools to:
    - Study how sexual networks function to drive HIV transmission;
    - Understand how viremia and social network interaction fuel rapid bursts of HIV transmission.
  7. Reconceptualize the idea of “community” in terms of affinity networks: study community formation, leadership processes, etc.
  8. Increase support for research on the relationship between human rights and HIV vulnerability including: case studies; knowledge management with LGBT organizations; epidemiology; and biomedical studies.

## Recommendation for a Future Research Network on MSM and HIV/AIDS

Following the Consultation’s two days of productive dialogue and the identification of key research priorities, the participants felt that additional opportunities to meet, share information and strategize about future priorities of HIV/AIDS and MSM research would be invaluable. It was proposed and agreed that a MSM and HIV research network be created to help follow up on the recommendations. Participants identified the following activities that such a research network could address:

- Conducting and illuminating trans-disciplinary research (beginning with establishing levels of risk among MSM, followed by understanding what leads to that risk).
- Disseminating key research findings and lessons learned on MSM and HIV/AIDS.
- Consulting among various research disciplines and with other key stakeholders.

- Developing research tools.
- Mentoring, with a specific focus on young investigators.
- Engaging with communities about MSM and HIV/AIDS, and HIV/AIDS research.
- Engaging with other networks about MSM and HIV/AIDS, and HIV/AIDS research.
- Engaging with donor institutions to discuss how MSM research priorities can be addressed and funded.
- Advocacy: engaging with a wide array of entities to help promote this agenda on MSM and HIV/AIDS and HIV/AIDS research.
- Providing technical assistance to grassroots organizations on MSM and HIV/AIDS.

The participants charged amfAR with disseminating the findings of the Consultation and undertaking the necessary follow-up activities to create a research network on MSM and HIV/AIDS.

# APPENDIX A

## Planning Process

To assist with planning the Global Consultation, amfAR enlisted the support of a distinguished planning committee of internationally recognized experts in MSM work. Members of the committee included: Maxim Anmeghichean (International Gay and Lesbian Alliance-Europe, Brussels); Dr. Judith Auerbach (San Francisco AIDS Foundation); Dr. Chris Beyrer (Johns Hopkins University, Baltimore); Dr. Thomas J. Coates (University of California, Los Angeles); Prof. John De Wit (University of New South Wales, Sydney, Australia); Dr. Kenneth Mayer (Fenway Community Health, Boston & Brown University, Providence); Dr. Greg Millett (Centers for Disease Control & Prevention, Atlanta); Dr. Jorge Sanchez (INMENZA, Lima, Peru); and Dr. Ron Stall (University of Pittsburgh). The planning committee held six weekly teleconferences during August and September during which the consultation goals were discussed and refined, invitation lists assembled, plenary speakers recruited, and an agenda formulated.

# APPENDIX B

## Participants

Dr. Barry Adam  
Ontario HIV Treatment Network  
Toronto, ON  
Canada

Prof. Peter Aggleton  
Thomas Coram Research Unit  
Institute of Education  
London  
United Kingdom

Dr. Joseph Amon  
Human Rights Watch  
Health & Human Rights Division  
New York, NY  
United States

Maxim Anmeghichean  
ILGA-Europe  
Brussels  
Belgium

Dr. Judith D. Auerbach  
San Francisco AIDS Foundation  
San Francisco, CA  
United States

Dr. Stefan Baral  
Johns Hopkins University  
Baltimore, MD  
United States

Dr. Linda-Gail Bekker  
Desmond Tutu HIV Centre  
University of Cape Town  
Cape Town  
South Africa

Dr. Linus Bengtsson  
Division of International Public Health  
Karolinska Institutet  
Stockholm  
Sweden

Dr. Chris Beyrer  
Bloomberg School of Public Health  
Johns Hopkins University  
Baltimore, MD  
United States

Dr. Pierre Brouard  
Centre for the Study of AIDS  
University of Pretoria  
Pretoria  
South Africa

Dr. Carlos Cáceres Palacios  
Universidad Peruana Cayetano Heredia  
Lima  
Peru

Dr. Alex Carballo Dieguez  
Columbia University  
New York, NY  
United States

Dr. Héctor Carrillo  
Department of Sexuality Studies  
San Francisco State University  
San Francisco, CA  
United States

Dr. Suwat Chariyalertsak  
Research Institute for Health Sciences  
Chiang Mai University  
Chiang Mai  
Thailand

Dr. Tom Coates  
University of California, Los Angeles  
Los Angeles, CA  
United States

Jonathan Cohen  
Open Society Institute  
New York, NY  
United States

Prof. John De Wit  
National Centre in HIV Social Research  
University of New South Wales  
Sydney, NSW  
Australia

Pedro Goicochea  
INMENSA/Gladstone Institute  
San Francisco, CA  
United States

Dr. Robert Grant  
University of California, San Francisco  
San Francisco, CA  
United States

Prof. Andrew Grulich  
HIV Epidemiology & Prevention Program  
University of New South Wales  
Sydney, NSW  
Australia

Prof. Graham Hart  
Centre for Sexual Health & HIV Research  
University College London  
London  
United Kingdom

John D. Hassell  
UNAIDS-USA  
Washington, DC  
United States

Dr. Jeffrey H. Herbst  
Centers for Disease Control & Prevention  
Atlanta, GA  
United States

Dr. Jeffrey Jin  
National Center In HIV Epidemiology and  
Clinical Research  
University of New South Wales  
Sydney, NSW  
Australia

Dr. Susan Kippax  
National Centre in HIV Social Research  
University of New South Wales  
Sydney, NSW  
Australia

Dr. Tim Lane  
Center for AIDS Prevention Studies  
University of California, San Francisco  
San Francisco, CA  
United States

Scott Long  
Lesbian, Gay, Bisexual & Transgender  
Rights Program  
Human Rights Watch  
New York, NY  
United States

Dr. Kenneth H. Mayer  
The Miram Hospital  
Brown University  
Providence, RI  
United States

Lou McCallum  
AIDS Projects Management Group  
Newtown, NSW  
Australia

Dr. Gregorio Millett  
Centers for Disease Control & Prevention  
Atlanta, GA  
United States

Dr. Matthew Mimiaga  
The Fenway Institute & Harvard Medical  
School  
Boston, MA  
United States

Mr. Orlando Montoya  
Fundacion Equatoriana Equidad  
Ecuador

Dr. Bera U. Moseng  
Gay & Lesbian Health Norway  
Oslo  
Norway

Dr. Kane Race  
Department of Gender & Cultural Studies  
University of Sydney  
Sydney, NSW  
Australia

Dr. Jorge A. Saavedra  
SIDA CENSIDA  
Mexico City, DF  
Mexico

Dr. Jorge Sánchez Fernández  
INMENSA  
Lima  
Peru

Dr. Theo Sandfort  
HIV Center  
Columbia University  
New York, NY  
United States

Richard Seifman  
AIDS Campaign Team for Africa  
The World Bank  
Washington, DC  
United States

Dr. Ron Stall  
Department of Behavioral & Community  
Health Services  
Graduate School of Public Health  
University of Pittsburgh  
Pittsburgh, PA  
United States

Dr. Judith Takács  
IS HAS & Hättér Support Society  
Budapest  
Hungary

Christopher Thomas  
Education & Human Development  
Department,  
East Asia & Pacific  
The World Bank  
Washington, DC  
United States

Dr. Frank Wong  
Georgetown University  
Washington, DC  
United States



**amfAR, The Foundation for AIDS Research**

120 Wall Street, 13th Floor  
New York, NY 10005-3908, USA  
t: +1 212.806.1600  
f: +1 212.806.1601

1150 17th Street, NW, Suite 406  
Washington, DC 20036-4622, USA  
t: +1 202.331.8600  
f: +1 202.331.8606

amfAR/TREAT Asia  
Exchange Tower, 388 Sukhumvit Road, Suite 2104  
Klongtoey, Bangkok 10110, Thailand  
t: +66 (0)2 663.7561  
f: +66 (0)2 663.7562

**[www.amfar.org](http://www.amfar.org)**