

RESPECT PROTECT FULFILL

Best practices guidance
in conducting HIV
research with gay,
bisexual, and other
men who have sex
with men (MSM) in
rights-constrained
environments



*Empowered lives.
Resilient nations.*

Developed in partnership by

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SPECIFIC AIMS

This guidance has been developed for both researchers and community-based organizations in rights-constrained environments. The guidance is intended to help both researchers and community organizations to:

- Better design and conduct meaningful research on HIV among MSM in challenging social, political, and human rights contexts;
- Provide a check list of factors for researchers and community organizations to consider in the design, conduct, and implementation of research studies;
- Offer lessons learned through case studies of research and community partnerships, recent successes, and challenges.

BACKGROUND

The HIV community is increasingly aware of the scale, scope, and severity of the global epidemics of HIV among MSM. Current interventions for HIV prevention, access to treatment, and a range of HIV- and STI-related issues are inadequate. And those interventions that are supported by evidence of efficacy have not been taken to scale for MSM in much of the world. An ambitious research agenda is urgently required to develop new and combined preventive interventions, to markedly improve access to ARV treatment, and to investigate the role of treatment as a prevention tool for MSM. This is a moment of unprecedented scientific opportunity. Yet enormous challenges face all who are engaged in this effort or seeking to become involved. Not least of these is that in much of the world MSM and other sexual and gender minorities still face discrimination, including discrimination in health care, denial of their existence by some states, and criminal sanctions and social exclusion in others. It remains challenging to undertake research with MSM populations in many places, and in some settings the safety of participants and research and clinical staff can be a very real concern. Yet this important work must be done, and done well. How are we to proceed?

This guidance, developed by a collaborative group of investigators, community advocates, and leaders in the field of HIV work with MSM, seeks to address these challenges. It is meant to be a living document, hopefully of use to those working across the spectrum of this research effort.

Terminology and Focus

“Men who have sex with men”—MSM—is a behavioral sciences term that was developed in the 1990s to capture the full range of male-to-male sexual contact. Its use was a deliberate attempt to move away from sexual orientation or identity categories (homosexual, bisexual, heterosexual, or gay, bi, and straight). We will use this term here, since from a research perspective HIV interventions will largely focus on reducing risks and improving services for all MSM, regardless of orientation or identity.

For community groups, the term “MSM” can have limited usefulness. The lesbian, gay, bisexual, and transgender (LGBT) umbrella covers a broadly shared identity that is embraced by many of the groups working for equality, for civil and human rights for sexual and gender minorities, and for health care access and quality. Few community groups identify as “MSM” groups, as few people identify as MSM. In this guidance, we use LGBT when referring to community-based groups that embrace the term and that may be leaders in both the rights struggle and in the HIV response.

Transgender (TG) persons, and particularly TG women who have been assigned the male gender at birth, have often been inappropriately included in the broader category of MSM. We have not addressed the vitally important HIV research agenda for TG persons in this guidance as it is clear to us that many of the unanswered research questions are different, and that a separate TG research guidance is clearly needed.

Finally, “rights-constrained environments” in relation to MSM/HIV services and research are environments where there are major challenges in meeting the needs of MSM based on structural inequalities. These structures may be legal, such as where same-sex behavior is criminalized, or they may be unofficial societal attitudes where same-sex behavior is overtly stigmatized. This document is written from the perspective of low- and middle-income countries, but some of its themes pertain to rights-constrained environments in high-income countries as well.

The Current Context

Recognition of the global nature of MSM epidemics is growing. Advocacy efforts at the local, national, regional, and global levels are seeing results, with increasing recognition—by many national governments, researchers, civil society groups, and

donors—of rising HIV infection rates among MSM, and increasing investment in HIV/MSM-related research studies. The recent iPrEx trial of daily oral chemoprophylaxis was a watershed and the first multi-country phase III preventive intervention for MSM that demonstrated preventive efficacy (44% reduction in HIV acquisition) among MSM. The research was conducted in Peru, Ecuador, South Africa, and Thailand. These opportunities also create challenges in working with MSM in diverse contexts. Power asymmetries can and do exist among research teams, international NGOs, donors, and local community groups who may have unique access to otherwise hidden populations. In countries where same-sex sexual practices are criminalized, research can have unintended adverse outcomes when such research brings increased attention and government awareness to previously low-profile populations. Inadvertent exposure of MSM populations has led to increases in rights abuses in some settings. Even where same-sex practices are not criminalized but are significantly stigmatized, the risk in working with MSM can be just as great. Further, these conditions impact the mobility and migration of MSM populations around the world, contributing to additional challenges in accessing and following particular vulnerable populations over time.

This guidance expands upon existing documents (e.g., *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials* [UNAIDS/AVAC, 2011]¹ and the guidance document, *Ethical Considerations in Biomedical HIV Prevention Trials* [UNAIDS/WHO, 2007]), and informs:

- Researchers of their roles and responsibilities related to best practices in community participation models in these settings; and
- MSM/LGBT community-based organizations and activists of their rights, roles, and responsibilities as partners in conducting this research.

The focus of this guidance is practical, expounding on ways in which all concerned partners can increase the benefits of such research and minimize the potential risks and harms for all concerned. It seeks to increase the capacity of researchers to meet their research obligations, while encouraging gay, bisexual, and other MSM leaders and LGBT organizations to understand and exercise their rights and responsibilities when participating in research. Finally, it provides sample engagement rules for studies and projects that encounter or engender threatening media, political, or social/religious backlash.

INTRODUCTION

Fortunately, the HIV pandemic is gradually slowing. UNAIDS estimates that there were 1.8 million new infections in 2009, compared to 2.2 million in 2001.² Even more significant is the decrease in HIV-related mortality globally.^{3,4} That said, HIV is still a major health concern (especially in Africa) and while the rate of new infections may have slowed, there are still 34 million people living with HIV worldwide.²

While the pandemic appears to be decreasing in magnitude, infections among MSM continue to increase. Several studies have demonstrated increasing rates of new infections among MSM in high-income settings.⁵ And although there is limited prospective data from lower-income settings, HIV incidence reports among MSM from cities such as Bangkok and Mombasa show similar trends.^{6,7} The attributable risk of MSM in concentrated epidemics is relatively uncontroversial, but there is growing evidence of disproportionate HIV risk among MSM within varied HIV epidemics, including those in Africa, Asia, Latin America and the Caribbean, and Eastern Europe/Central Asia.^{8,9}

The current global response, however, is not commensurate with these realities.⁸ Recent assessments of global HIV prevention methods suggest that few HIV/AIDS prevention, treatment, and care programs include targeted programming for MSM. The Global HIV Prevention Working Group has estimated that in areas with concentrated epidemics where prevalence is high among MSM, less than 4% of all HIV-related expenditures address the needs of these populations.¹⁰⁻¹² In generalized epidemics where there is emerging evidence of disproportionate HIV burden among ‘most at-risk populations,’ less than 0.1% of expenditures address the needs of MSM/LGBT populations. There are many causes of this inconsistent implementation of HIV interventions for MSM, including outright homophobia, lack of political motivation to address MSM issues, lack of data describing burden of HIV or risk status, insufficient targeted funding, and lack of a means to define an optimal package of services in resource-constrained settings.^{13,14} Comprehensive responses are needed. It is necessary to improve epidemiologic surveillance of MSM and define appropriate packages of HIV services including biomedical, behavioral, and structural approaches using the highest standard of attainable data. These data can then be used to advocate for

specific HIV prevention interventions for MSM and appropriate scale-up of these programs to address evidence-based needs.

In response to the need for improved epidemiologic data describing patterns of disease burden, as well as implementation science data characterizing effective preventive interventions and treatment access programs, there has been a significant new interest in MSM/HIV research among academic organizations, HIV program implementers, advocacy organizations, and funders. From 2005 to 2010, studies were implemented in countries across Africa, Asia, the Caribbean, Latin America, Eastern Europe/Central Asia, and the Middle East/North Africa, characterizing HIV prevalence rates among MSM for the first time.^{15, 16} In addition, there have been some prospective cohorts in which participants are followed across multiple time points to characterize HIV incidence rates or levels of new HIV infections, including studies in Bangkok and Mombasa. While the majority of research among MSM in low- and middle-income countries has focused on assessing disease burden and associations of prevalent and incident infections, there has been a move towards evaluating preventive interventions. This has included research on new biomedical strategies such as oral and topical chemoprophylaxis and the use of treatment as prevention by lowering community viral loads.^{17,18} There is also a need to increase research on negative social outcomes, such as stigma and

discrimination, and their effects on behavior and HIV disease burden.

Ethical Principles

Working with MSM presents unique challenges given the stigma, discrimination, and danger that are often experienced, plus the lack of community structures offering protection and safe social space. Engaging MSM in research must be done in a manner that is safe and beneficial for both individuals and communities involved across all stages of research.

The Belmont Report highlights the ethical principles and guidelines for the protection of human research subjects. Ethical research should be consistent with the general principles of autonomy, beneficence, non-malevolence, and justice.^{19, 20} This is a given for human research subjects in general, but is particularly important and difficult to achieve in challenging contexts.

Autonomy implies that people have given their free and fully informed consent to partake in the project, and that they have had access to all relevant information about risks and benefits, and are of “sound body and mind.” Beneficence implies that the researcher is aiming to promote the wellbeing of participants either at an individual level or for overall public health. Epidemiologic and clinical research among

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MSM generally provides little direct individual benefit to participants, even though individual risks could be great if sexual practices or orientation are disclosed. The concept of non-malevolence ensures that the researcher will not intentionally do harm, and in the context of research with stigmatized populations this means taking all possible measures to protect participants. Finally, justice implies that decisions are made on the basis of well-recognized principles and rules, in an impartial and verifiable manner, with a view to ensuring the fair and equitable treatment of all study participants. It also suggests that communities that are the subject of research will benefit from that research, rather than taking risks so that another community can benefit.

Additional ethics guidance can be found in the Declaration of Helsinki. While researchers working with MSM must abide by these ethical guidelines to protect their participants as any other human subjects require protection, additional steps may be required for safe and effective engagement of MSM in challenging contexts.

Many MSM remain purposefully secretive about their behaviors due to reasonable fears of social exclusion, stigma, and persecution. Clearly, stigma is pervasive in societies and cultures and is often expressed in laws criminalizing consensual same-sex practices. Research projects in these types of settings are intended to identify and address the needs of the MSM population, but in doing so can highlight their existence and generate both positive and negative attention and social responses. The unintended consequences of research projects intending to help MSM can include heightened stigma and increases in human rights violations, including violence. These realities can shift the ethical balance of costs and benefits, so careful consideration of the potential negative consequences of “minimal risk” scientific research is of special importance in study conception, design, implementation, and dissemination.

The Human Rights Framework and Research on MSM

The World Health Organization (WHO) states that: “Enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”

This research guidance is intended to be a framework to *Respect, Protect, and Fulfill* the fundamental human rights of individuals and populations studied^{21, 22}. Respecting the rights of people means refraining from interfering with the enjoyment of their human rights. In the context of research with various types of MSM, researchers and

communities must not simply limit themselves to the rights to information, non-discrimination, and access to health care.

Protecting the rights of people often means creating mechanisms to prevent violation of human rights and social harm by others. For MSM this will most commonly mean doing the utmost to insure that neither state authorities nor non-state actors violate the rights of participants or staff as a result of participation in research. Researchers and communities working on issues relevant to MSM must not tolerate or be complicit in attempts by others to limit rights for sexual and gender minorities.

Fulfilling human rights means putting in place policies, procedures, and resources to enable people to exercise these rights. This is the most active component of the guiding framework, implying that researchers bear a responsibility to work toward fulfillment of the human rights of their study participants as one of the components of meaningful engagement.

All HIV research should focus on fulfilling the rights of all participants to an adequate standard of health care relevant to the research study. This would include, at a minimum, the rights to privacy, autonomy, confidentiality, dignity in health care, and to nonjudgmental and humane treatment in interactions with all staff, from security guards and intake clerks to investigators and physicians. Realizing these rights in the context of research protocols is the minimum standard we propose for MSM research.



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ROLE OF RESEARCH INSTITUTIONS IN RESPECT, PROTECT, AND FULFILL

Engagement

Effectively engaging LGBT communities is crucial for the development and implementation of comprehensive and effective HIV/AIDS responses. Meaningful engagement with those at risk and with their community can markedly improve the quality of science and its uptake and implementation. The more repressive the environment, and the more unwilling governments and providers are to provide services to MSM and other sexual and gender minority populations, the more critical the role of community engagement. In the most challenging environments, LGBT community organizations may be best suited to take on research, service provision, and advocacy for men at risk, and working without them will simply not be feasible.

Adequate input from the MSM/LGBT community legitimizes the research aims and improves measures of appropriateness, transparency, and social equity across the study spectrum. Given that working with MSM/LGBT community organizations is also a primary means of accessing gay, bisexual, and other MSM for research, there is concern that the engagement of communities is limited to the use of these organizations as a means of recruiting potential study participants. To counteract this, it is crucial that the participation of communities not be limited to any one stage of the design, implementation, analysis, or presentation of research studies; rather, this participation should be a consistent component throughout the research process. Long-term, committed engagement of researchers with communities can result in building of capacity within these community organizations to solve their own problems, such as reducing the spread and impact of HIV, with continually decreasing external involvement and support.

Finding and Working with the MSM/LGBT Community

The conventional model of community advisory boards (CABs) has been for them to provide cultural competence, represent the community in research efforts, “bring back” research issues to constituents, and to facilitate access to potential research

participants. This vital work is necessary but may not be enough to address the many issues involved in MSM research in rights-challenged contexts.

Finding LGBT Leaders: Increasingly, LGBT activists in low- and middle-income countries are gaining the strength to organize and demand their rights. In these countries, health issues (often in the name of increased HIV vulnerabilities) are allowing LGBT leaders to engage with key healthcare stakeholders. At the regional and sub-regional levels, LGBT rights and MSM health networks have formed, such as *the Asia-Pacific Coalition on Male Sexual Health* (APCOM), *the African Men for Sexual Health and Rights Network* (AMShEr), *Asociación para la Salud Integral y la Ciudadanía de América Latina y el Caribe* (ASICAL), *the Purple Sky Network* (Greater Mekong Region/SE Asia), and most recently *the Eurasian Coalition on Male Health* (ECOM). These networks link national, regional, and local MSM/LGBT community organizations, encourage the sharing of intervention and advocacy strategies, and offer legitimacy for research groups interested in engaging with LGBT community groups. Thus researchers interested in finding legitimate LGBT leaders to be collaborators should enquire through these and similar regional, sub-regional, and national networks (see appendix for listing of networks).

Study Design: Study design includes development of instruments, consideration of participant characteristics and accrual, and in many cases biological testing protocols. It is vital that MSM/LGBT community leaders **be fully engaged** in the planning stages of each of these components, given their knowledge about the communities they serve. Their involvement will broaden the reach of the research and also build research literacy, help protect the rights of participants, and potentially build the capacity of community leaders to be engaged in all stages of the research. For example, community leaders should be involved in the development of research instruments (question by question) to ensure that each is culturally and linguistically appropriate, while addressing the needs of the community group’s own strategic plans. Most of these community leaders will not be familiar with research design and may require training on research principles. Also, memorandums of understanding may assist in making roles and responsibilities clear between researchers and community organizations and leaders.

Implementation: Members of the community should be engaged in the implementation of the research, as this can build capacity in the community group itself. For example, if the community group would like to develop programs or a strategic plan, researchers could identify resources to help the organization accomplish these goals. Investing in building the capacity of the community group will also facilitate the implementation of future research studies and ensure

the strength of programming that might be developed as a consequence of research efforts.

Validation/Dissemination: Validation of research findings with MSM/LGBT community leadership is an important component of qualitative, quantitative, and intervention studies. The validation process is made much simpler if MSM/LGBT community voices have been heard at all stages of the research, including

Questions for Researchers to Ask for MSM/HIV Research (see Appendix I)

RESPECT	Status	Notes
Have you included the MSM/LGBT community in:		
Engagement rules		
Situational assessment		
Have you assessed the relevance of the research and potential reactions from greater community structures?		
Have you assessed the interest amongst the MSM/LGBT community, as well as current infrastructure (or lack thereof)?		
Have you assessed the willingness of your research institution to Respect, Protect, and Fulfill rights of participants?		
Have you developed an MOU with community-based organizations—clearly involving them in all aspects of the research?		
Have you clearly defined roles and responsibilities of all stakeholders?		
Have you conducted a comprehensive identification process with stakeholders including:		
Community stakeholders, NGOs, CBOs, community groups, informal networks, etc.		
Government ministries, leaders, etc.		
Local health care facilities and services		
Local religious leaders		
Media		
Have you engaged government, while first discussing effective models of engagement with community representatives?		

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