

HIV

evidence-based prevention

San Francisco AIDS Foundation

Confronting the “Evidence” in Evidence-Based HIV Prevention: Summary Report

The San Francisco AIDS Foundation (SFAF), in partnership with a number of other HIV/AIDS organizations, recently organized a series of discussions around issues of what constitutes “evidence” in HIV prevention. These discussions took place in late 2007 and early 2008 in conjunction with the U.S. Conference on AIDS, the National HIV Prevention Conference, the Microbicides 2008 Conference, and the California HIV/AIDS Research Program Meeting. (See Appendix for a list of meetings and participating agencies). A central goal of these discussions was to broaden the understanding and definition of “evidence” to encompass both science and community experience.

The meetings focused on salient issues in gathering and interpreting evidence of efficacy and effectiveness in HIV prevention interventions and programs, and in guiding what to implement and scale up at the local, state, federal, and global levels. While participants expressed divergent perspectives and priorities, there was general consensus around most of the issues that must be addressed in order to move prevention efforts forward. This report represents a synthesis of these discussions.

Ways of Knowing

The tension between the multiple “ways of knowing” employed by the community and in academic research is evident in the credence given to both the means of generating data and the data themselves, with greater value placed on rigorous research and program evaluation techniques that are beyond the means of most community-based organizations (CBOs). This tension is most apparent in the hierarchy of evidence used by the Centers for Disease Control and Prevention (CDC) to evaluate and fund HIV prevention programs. This hierarchy “privileges” the randomized controlled trial (RCT) at the expense of other methodologies and ways of knowing.

This focus on rigorous scientific research is perhaps understandable given the history and context of the epidemic: early AIDS activism for therapeutic clinical trials, the emergence of rational antiretroviral drug development, and opposition from social conservatives to “morally questionable” prevention interventions have occurred within the context of an ongoing attack on the scientific method in research arenas ranging from tobacco use to climate change.

Yet strict adherence to methodologies drawn from evidence-based medicine overlooks an equally significant facet of the epidemic’s history:

the success of established prevention interventions that are not supported by the highest tiers of evidence. The extensive behavior changes in sexual and other practices effected in the gay community and in some African countries were not suggested by RCT methodology but nonetheless had a tremendous impact on the course of the epidemic. Counseling to reduce risk behavior, the provision of condoms, and the treatment of sexually transmitted infections have been adopted as cornerstones of HIV prevention based on levels of evidence “lower” than the RCT. At the same time, RCTs have been instrumental in establishing the efficacy of targeted, short-term behavior-change interventions, male circumcision, and using antiretroviral therapy to reduce mother-to-child transmission.

Establishing Efficacy and Effectiveness: Limitations of the RCT

While the RCT can be quite relevant to a situation consisting of a limited number of variables and an intervention with a potentially immediate effect, such as a drug trial, it often fails to capture the “messiness” of real-world situations, particularly where the impact of the intervention may be incremental rather than dramatic. Indeed, a frequent criticism of therapeutic RCTs is that complexity within the patient population is controlled

to such an extent—such as through excluding from a drug trial any participants with comorbid conditions—that the *efficacy* outcomes often are significantly higher than the *effectiveness* seen when the intervention enters typical use in a population.

In addition, the assessment of an intervention's efficacy may be hampered by elements of the research design. For example, all participants in studies of biomedical interventions—such as trials of vaccines, microbicides, and latex diaphragms—must be offered condoms, education and counseling on safer sex, and treatment for sexually transmitted infections. Although an ethical imperative, providing this “standard of prevention” makes it difficult to tease out the effect of the intervention under study from the contributions of established HIV prevention tools.

Moreover, people lead real lives while participating in controlled trials, and the conditions of those lives enter the study and affect the outcomes in ways that can confuse the assessment of an intervention's efficacy. For example, non-adherence to study protocol, loss of study participants due to pregnancy, and non-truthful self-reports of sexual activity contributed to null findings in recent trials of microbicides, latex diaphragms, and herpes suppression therapy for HIV prevention. A null or negative finding may therefore say more about the behaviors and lives of study participants than about the efficacy of a given intervention.

In any HIV prevention study, the qualities of sound evidence include relevance, coherence, verisimilitude, justifiability, and contextuality. The latter is particularly important in two senses: the milieu in which the intervention and its evaluation occur, and the values of the investigators making the observations and assessments. While the highly valued RCT is un-

doubtedly capable of generating solid evidence characterized by these qualities, the unique contributions of other research methods and technologies should not be ignored.

Case studies, for example, have the power to “humanize” a data point, giving it far richer meaning than a simple number can convey. They also can yield unanticipated insights: participants in one such study revealed that the most valued benefit of participation was receiving a photo ID, which opened access to facilities that had previously been closed to them for lack of identification. Insights derived from case studies reveal much about the contexts in which study participants remain HIV negative or acquire or transmit the virus, and can therefore point to improvements in study design or even additional opportunities for intervention.

Also illuminating are technologies such as Gapminder, which can be used to visually display trends in large sets of complex data. Such presentation can generate insights into relationships that might otherwise remain hidden in static columns of numbers on paper (statistical findings) and be missed as potential intervention targets.

One driver of recent discussions of “evidence” in HIV prevention is the idea that, rather than ever more tightly defining the conditions under which an intervention might work, prevention research would be better served by a methodology designed to identify those interventions that are robust enough to withstand local variation and implementation. A novel goal of HIV prevention research should be to move beyond the ideal of “best practices” indicated by RCTs and toward a range of good practices, applicable under broader circumstances, and gleaned from multiple ways of knowing.

Structural and Institutional Issues

Can the number of new HIV infections be significantly reduced without addressing the context of mental health issues, depression, substance abuse, poverty, stigma, racism, homophobia, and violence? Many discussion participants thought not. Instead, the consensus was that truly sustainable prevention activities are likely to be those that address the larger context of social justice and that meet people's basic needs.

Chief among these needs, participants agreed, are comprehensive health care and a sense of connection to a community. Arising out of the discussions was a critique of the compartmentalization of medical and public health services, which tend to treat the disease rather than the person. Discussion participants expressed the desire for a holistic approach that addresses all aspects of the individual's health and wellness and simultaneously provides a sense of community.

Some also suggested that a paradigm shift in communities is the key to significant behavior change. Useful lessons might be drawn from the experience of community-driven change regarding such unhealthy behaviors as tobacco use and drunk driving.

Just as HIV transmission occurs in a social context, HIV prevention interventions—biomedical and social—are developed, evaluated, and implemented (or not) in the context of politics, governmental and academic standards and priorities, and community needs and demands. Examination of each of these structural and institutional issues surrounding HIV prevention suggests future directions for HIV prevention research.

Politics and Policy Makers

Ideologically driven politics have often overridden scientific evidence in the HIV prevention research arena, and government agencies that ostensibly make decisions based on scientific facts have not been immune to these pressures. While a given political climate may fluctuate, there is little reason to expect that politics will disappear entirely from a field of research that focuses on a virus spread primarily through sex and drug use.

For this reason, discussion participants agreed, one primary use of evidence must be to establish credibility with political players whose support is necessary for funding and implementing ongoing research and prevention activities. Evidence must therefore be translatable into terms that have validity and credibility with funders, agencies, and politicians, as well as with the organizations and individuals who will implement and use the prevention programs.

In the experience of the meeting participants, policy makers think about research with implementation in mind. Criteria for assessing evidence in this regard include the feasibility of implementation, the costs involved, any health systems constraints, the potential for adverse outcomes, and other health and social benefits that might occur as a result of implementing particular interventions. Prevention researchers would do well to remember these criteria when developing—and seeking support for—intervention programs.

Government Agencies

Two subsets of values and institutional dynamics are embedded in governmental funding decisions. The National Institutes of Health (NIH) is dominated by a basic and clinical science orientation that values evidence generated through RCTs. Thanks to this RCT bias, male circumcision was recently added to the HIV prevention armamentarium. A downside of this focus, however, is the over-valuation of evidence gathered through this methodology and the resulting difficulty in securing support for research that employs alternative study designs.

CDC has its own battlefields of interests and ideologies, not the least of which are the competing needs for data to drive national policy, and smaller studies that fine-tune implementation at a local level and under local conditions. The agency maintains that researchers can enter projects into its tiered evaluation process at any level, yet meeting participants expressed frustration at first having to establish the efficacy of an intervention before testing its effectiveness under real-world conditions—a research path that requires extended time and extra funding.

The existing funding cycles and peer review structure of these agencies also make it difficult to secure support for non-traditional research, and funding often is “siloes” or compartmentalized. Participants also observed that NIH and CDC are ill-equipped to consider cross-disciplinary approaches, particularly those addressing broader contributing societal factors, such as racism, stigma, poverty, and community development. Filling this gap will require a shift in the “culture” of peer review and how it operates, and possibly revisiting the mission statements and legislative authorities of federal agencies that limit their scope.

A further issue is harmonizing HIV prevention policy goals with those of other governmental domains, which often impede successful implementation of prevention activities. The ban on condoms and sterile syringes by most U.S. prison systems is a prime example, in which criminal justice concerns are seen to conflict with public health concerns.

Academia

In academic settings, funding streams and cycles and the pressure of tenure tend to discourage junior faculty from investigating long-term interventions that require close relationships with the communities in which they

would be implemented. This distance between prevention researchers and prevention implementers hinders the development of novel interventions.

Structuring the university/community interface along the lines of the agricultural extension model—in which multidisciplinary academic resources and community knowledge and experience are exchanged—was proposed by discussion participants as a way to foster valuable relationships and the development of innovative and community-appropriate HIV prevention interventions.

The structure of HIV prevention research in Australia was noted as a model in which community organizations are funded to implement programs, and university researchers are funded to observe and provide feedback—an implementation and evaluation structure that takes advantage of the unique strengths of CBOs and academia.

Community-Based Organizations

An ongoing tension exists between the demands of program evaluation and the mandate of a CBO to respond to the client who walks through the door in need of immediate services.

As mentioned previously, many smaller CBOs depend on government funding for their prevention programs but are unable to perform the rigorous program evaluation demanded by funders. In the discussion sessions, the dissemination of a set of simple, standardized data collection tools was proposed as a way to enhance practice-based research, simplify CBOs’ grant reporting requirements, and help organizations secure continued funding for HIV prevention programs.

The largest CBOs, by contrast, often argue that they have the capacity and experience to create interventions that better fit their communities’ needs than do CDC-approved Diffusion of Effective Behavioral Interventions (DEBI) programs. For example, programs developed by larger CBOs have achieved success in building a sense of identity and community among African-American and Latino men who have sex with men (MSM), thereby supporting behavior change and reducing HIV risk.

Representatives from CBOs of all sizes reported a sense of paternalism from CDC and university- and state government-affiliated researchers. Changing that paradigm will require recognition of community knowledge and experience and a partnership of equals.

Methodology: Toward a More Comprehensive Approach

Common among discussion participants was the sense that HIV prevention research has allowed itself to become constrained by the biomedical model, and that the research question should drive the method, and not the reverse. HIV prevention research must shift from a focus on measuring efficacy in controlled settings toward a more comprehensive approach that addresses effectiveness in the real world.

To this end, it is essential that, both methodologically and conceptually, prevention research move beyond focusing on the individual, the couple, or the social network, and instead consider the broader social context. There was a consensus at the meetings in acknowledging the importance of the social context of poverty and disenfranchisement as factors

affecting the success of HIV prevention activities, and frustration that most of the theoretical models of health are based on individual behavior, not social constructs. In addition, many programs and interventions have been created “in the street,” and methodologies are needed to evaluate them in this environment rather than forcing diverse programs into a single methodological construct.

Also crucial is that the time frame for measuring behavior change and the duration of its effects must expand from a period of months to one of years. This extension will require confronting structural factors of funding and publication cycles that currently encourage shorter-term research projects and intervention programs.

General Principles

Several general principles that should characterize this more comprehensive approach to prevention research were articulated at the meetings, including the following:

- No one discipline or methodology is superior; all should be valued and institutionalized for use as appropriate.
- The question should determine the method, and the method should encompass multiple disciplines.
- Value judgments should be explicitly acknowledged at every stage of study activity.
- No single tool can supply all the answers; multiple tools should be employed.
- A null or negative finding should not necessarily condemn the individual components of an intervention; such findings derive from a particular combination of interventions and contextual factors.
- Unintended and unanticipated outcomes and implementations are as important as those that were intended and should be fully evaluated.
- Research should be conducted *with* the affected community, not *on* it.
- The research and evaluation processes should:
 - include every stage of design, implementation, and evaluation;
 - be iterative;
 - be continuously interactive with participants and community stakeholders;
 - distinguish between and separately evaluate individual, community, and systems levels of change; and
 - generate practice-based evidence derived from implementation characteristics, not client characteristics.
- Measurement of acceptance and adherence to an intervention should be an integral part of every study.
- A better understanding and presentation of background trends should be included in program evaluation. (For example, a stable rate of infection within the study population may be seen as a success rather than failure if the background rate of infection is increasing.)
- Evaluations should seek to identify both root causes and immediate triggers that may play roles in risky behavior and that may be amenable to interventions.

Operational Lessons

In addition to following the principles outlined above, researchers must be careful to ascertain that study protocol is actually being implemented, and that study participants are truly experiencing and internalizing the intervention rather than merely being exposed to it.

To this end, investigators must possess sufficient community literacy to be able to understand what is really going on within communities and maintain an ongoing dialog. It is also essential that independent evaluators understand the goals of the prevention program, accept them, and use them as the basis for their evaluation.

The meetings included an extended discussion of modeling, with a consensus that while theoretical or mathematical models stimulate

thought, most have not been validated in real-world situations and are seldom used to implement programs. Similar skepticism was expressed about the value of meta-analyses of prevention interventions for making decisions about what to implement.

Priorities for Research and Evaluation

A consensus emerged about the need for methodological tools capable of answering key questions in the conduct of HIV prevention research and program evaluation. Many of these tools are applicable to a range of interventions that extend far beyond HIV prevention. They seek to address the following questions:

- How does any behavioral intervention relate to the social, cultural, legal, and community context in which individual behavioral decisions are made, and how can that relationship be characterized?
- How can causality be ascribed in social/structural interventions, in particular?
- What is the intervention's effectiveness and how can it be measured when multiple interventions are combined?
- How can evidence gathered from one setting and population be applied to others?
- How can the greater effect of an intervention on a community be measured when the intervention is delivered to an individual?
- How can structural and social interventions be meaningfully evaluated, particularly when their effects may not be observed for years?
- How can opportunity costs be measured and included in evaluations?

In order to determine what kinds of interventions to prioritize for investigation, a number of basic social and behavioral science questions need to be addressed, including:

- How can behavioral and social interventions that constrain health and pleasure be conducted and studied in a way that is open to and promotes public health and social change?
- How do we better understand the vulnerabilities that make individuals more susceptible HIV infection? Are some vulnerabilities specific to marginalized populations, e.g., MSM of color?
- How can we better understand non-gay-identified MSM, their patterns of sexual activity, interactions with transgendered persons, and the importance of the availability of "freely available sex" as a factor in shaping risky behavior?
- Where is increased routine testing for HIV taking place, among which populations, and with what linkage to prevention and care?
- What is the effect of and potential for HIV prevention interventions as part of integrated health care systems?

Answering questions such as these is the first step toward a more comprehensive methodology for HIV prevention research—one that recognizes not only the social drivers of HIV transmission, but also the social context which any prevention intervention must address for successful implementation and effectiveness.

Conclusion

HIV prevention remains a complex undertaking, and there is agreement in the prevention field that we must move toward more comprehensive and multidisciplinary approaches in both science and program implementation in order to have the greatest impact on reducing new HIV infections. And although some resistance remains, there is an emerging consensus that a broader but still rigorous view of what constitutes evidence of efficacy and effectiveness in HIV prevention must be adopted in order to move forward.

A rigid, RCT-focused concept of evidence stymies the development, testing, evaluation, and implementation of programs that may have a

meaningful (if not immediately observable) effect on the HIV epidemic. Scientists, program implementers, policy makers, and advocates must continue to begin research with the appropriate questions—about the nature of local epidemics, the dynamics of transmission between people in relational and social contexts, and the structural barriers to implementing prevention strategies—before determining the best methods for designing biomedical, behavioral, and social interventions to address them.

Appendix

This report synthesizes presentations and panel and audience discussions from the following conferences and meetings:

U.S. Conference on AIDS

Palm Springs, California; November 8, 2007.

National HIV Prevention Conference

Atlanta, Georgia; December 3, 2007.

Microbicides 2008

New Delhi, India; February 27, 2008.

California HIV/AIDS Research Program Meeting

San Francisco, California; March 6–7, 2008.

Sponsoring and participating organizations included:

San Francisco AIDS Foundation (SFAF)

Caucus for Evidence-Based Prevention

The AIDS Institute

AIDS Vaccine Advocacy Coalition (AVAC)

Alliance for Microbicide Development

amfAR, The Foundation for AIDS Research

California HIV/AIDS Research Program (CHRP)

Community HIV/AIDS Mobilization Project (CHAMP)

National Minority AIDS Council (NMAC)

Sexuality Information and Education Council of the U.S. (SIECUS)

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