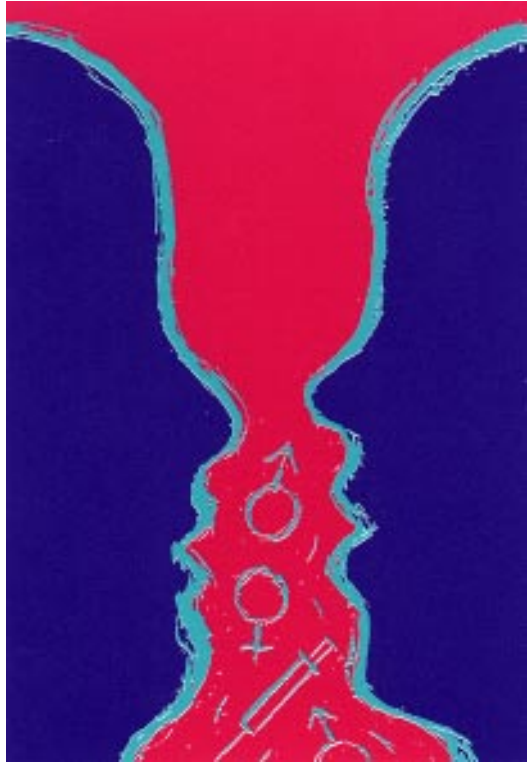


NIH Consensus Statement

Volume 15, Number 2
February 11-13, 1997



Interventions to Prevent HIV Risk Behaviors

NATIONAL INSTITUTES OF HEALTH
Office of the Director

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This statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.



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Abstract

Objective

To provide health care providers, patients, and the general public with a responsible assessment of behavioral intervention methods that may reduce the risk of HIV infection.

Participants

A non-Federal, nonadvocate, 12-member panel representing the fields of psychiatry, psychology, behavioral and social science, social work, and epidemiology. In addition, 15 experts in psychiatry, psychology, behavioral and social science, social work, and epidemiology presented data to the panel and a conference audience of 1,000.

Evidence

The literature was searched through Medline and an extensive bibliography of references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience.

Consensus Process

The panel, answering predefined questions, developed its open forum and the scientific literature. The panel composed a draft statement that was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference.

Conclusions

Behavioral interventions to reduce risk for HIV/AIDS are effective and should be disseminated widely. Legislative restriction on needle exchange programs must be lifted because such legislation constitutes a major barrier to realizing the potential of a powerful approach and exposes millions of people to unnecessary risk. Legislative barriers that discourage effective programs aimed at youth must be eliminated. Although sexual abstinence is a desirable objective, programs must include instruction on safer sex behaviors. The erosion of funding for drug abuse treatment programs must be halted because research data clearly show that such programs reduce risky drug abuse behavior and often eliminate drug abuse itself. Finally, new research must focus on emerging risk groups such as young people, particularly those who are gay and who are members of ethnic minority groups, and women, in whom transmission of the HIV virus to their children remains a major public health problem.

Introduction

One in 250 people in the United States is infected with the human immunodeficiency virus (HIV), which causes AIDS; AIDS is the leading cause of death among men and women between the ages of 25 and 44. Every year, an additional 40,000–80,000 Americans become infected with HIV, mostly through behaviors that are preventable. In the United States, unsafe sexual behavior among men who have sex with men and unsafe injection practices among drug users still account for the largest number of cases. However, the rate of increase is greater for women than men, and there have been larger annual increases from heterosexual HIV transmission than among men who have sex with men.

The purpose of this conference was to examine what is known about behavioral interventions that are effective with different populations in different settings for the two primary modes of transmission: unsafe sexual behavior and nonsterile injection practices. Experts also provided the international and national epidemiology of HIV and a review of AIDS prevention efforts.

An extensive body of research has led to significant information on how to help individuals change their HIV-related risk behaviors. The interventions studied were based on a variety of models of behavior change, including social learning theory and related health and substance abuse models. The interventions begin with HIV and substance abuse education, but also include skill acquisition, assertiveness training, and behavioral reinforcement components. Recent research leads to the conclusion that aggressive promotion of safer sexual behavior and prevention and treatment of substance abuse could avert tens of thousands of new HIV infections and potentially save millions of dollars in health care costs. To date, however, there has not been widespread agreement among health professionals as to which interventions are most effective, in which settings, and among which populations.

Because behavioral interventions are currently the only effective way of slowing the spread of HIV infection, recommendations coming from this conference have immediate implications

for service delivery in health care and educational settings, including schools; substance abuse treatment programs; community-based organizations; sexually transmitted disease clinics; inner-city health programs reaching disenfranchised high-risk women, men, and adolescents; rural health programs; and mental health programs that serve high-risk people with chronic mental illness. Knowing which behavior change interventions are most effective will assist public health personnel in allocating resources.

The conference brought together behavioral and social scientists, prevention researchers, statisticians and research methodologists, clinicians, physicians, nurses, social workers, mental health professionals, other health care professionals, and members of the public.

Following 1-1/2 days of presentations and audience discussion, an independent, non-Federal consensus panel weighed the scientific evidence and developed a draft consensus statement that addressed the following five questions:

- How can we identify the behaviors and contexts that place individuals/communities at risk for HIV?
- What individual-, group-, or community-based methods of intervention reduce behavioral risks? What are the benefits and risks of these procedures?
- Does a reduction in these behavioral risks lead to a reduction in HIV?
- How can risk-reduction procedures be implemented effectively?
- What research is most urgently needed?

How Can We Identify the Behaviors and Contexts That Place Individuals/Communities at Risk for HIV?

Major Behavioral Risks

Research to date has identified the key risk behaviors for HIV transmission to be unprotected anal and vaginal intercourse, having multiple sex partners, and using nonsterile drug injection equipment. Although there are some documented cases of transmission through oral-genital sexual contact, methodological issues make it difficult to precisely determine risk. At the present time, oral-genital sexual contact is considered to be a somewhat less risky behavior for contracting HIV than anal or vaginal intercourse.

Contexts That Influence Risk

Important social and biological contexts and cofactors increase or decrease the likelihood of risk behaviors. A major contextual influence is the prevalence of HIV itself in the local population, which greatly influences the impact of any risk behavior. Other contextual influences include: individual factors such as age and developmental stage, early initiation of sexual behavior, sexual identity, self-esteem, untreated sexually transmitted diseases, use of alcohol, and use of other drugs; interpersonal factors such as sex with a partner of unknown HIV status, partner commitment, and negotiation of safe sex; social norms and values such as cultural and religious beliefs, gender role norms, and social inclusion versus marginalization of gay men, ethnic minorities, people of color, sex workers, women, and drug users; and political, economic, and health policy factors such as laws and regulations, employment opportunities, poverty, sexism, racism, homophobia, and availability of basic public health tools for protective behavior, such as condoms and sterile injection equipment.

Although many of the behavioral risk factors are quite well known, the contextual risk factors are only beginning to be understood. For example, intervention programs with younger

gay men need to address the fact that some of them consider HIV to be a threat mainly to older men. Negotiation about safe sex practices is much more difficult for women in populations where there are cultural barriers to doing so. Programs targeting sex workers have been highly efficacious in other countries, but in this country would encounter cultural and political barriers. The impact of poverty on seeking treatment for sexually transmitted diseases is much greater in countries without access to universal medical care. These contextual factors combine in dynamic ways to increase behavioral risk.

Means of Identifying Behaviors and Contexts

Behavioral risks have been identified by combining data from epidemiological studies and data from studies of homosexual and heterosexual couples with only one HIV-positive partner. Ongoing measurement of biomedical transmission factors will continue to be important as the epidemic changes. Because contextual factors are more numerous and more difficult to measure than biomedical factors, a wide variety of methods have been used to identify and measure them, including qualitative, ethnographic, and observational techniques. This work is multidisciplinary and requires ongoing consultation with local community groups. Contextual information is essential for designing tailored interventions that respond to the needs and preferences of people in particular communities. In addition, if a particular intervention is not effective for some participants, this information could guide development of the next generation of interventions.

Changing Trends in Specific Behaviors and Community Contexts That Produce Elevated Risk for HIV Infection

A number of established and several new and emerging behaviors and community contexts increase risk for HIV infection. In general, youth in school are showing an increase in condom use at last contact, but a trend for decreased condom use as they get older. Among gay men, the infection rate is increasing among African-American, Latino, and

younger men. Injecting drug users are at increased risk because of conditions in their communities, including unavailability of sterile injecting equipment, dealer provision of infected needles, and social situations that encourage multiperson reuse of needles and other drug paraphernalia. Women, particularly women of color, recently increased dramatically as a risk group in the United States and constitute 50 percent of those infected worldwide. Much of the growth in their risk is caused by sexual contact with partners whose sexual or drug use behavior put the women at risk. Vertical transmission from infected mother to infant continues to be a source of high risk for the infant, even with the treatment for mothers and infants that is now available. In addition, a variety of other special settings and subpopulations at increased risk, including incarcerated youth and adults and individuals with chronic mental illnesses, deserve greater attention.

What Individual-, Group-, or Community-Based Methods of Intervention Reduce Behavioral Risks? What Are the Benefits and Risks of These Procedures?

When we consider the available knowledge from the entire body of literature, we can reach a clear conclusion: Prevention programs significantly reduce HIV risk behaviors. This is true across a variety of risk behaviors and in a variety of populations at risk.

Do Prevention Programs Reduce Behavioral Risk?

Experts in the field have used different designs for evaluating prevention programs. The most rigorous design used in some areas of research, the randomized controlled trial, has been used in HIV prevention research but is more appropriate for testing some questions than others. For example, evaluating the effects of legislative changes would rarely be possible with randomized research. To draw its conclusions, the panel examined the body of literature in a given area by considering all existing approaches to research, the strength of a given design for addressing a specific question, the number and strength of existing studies, and the convergence of effects.

Men Who Have Sex With Men

Considerable research has focused on risk reduction in men who have sex with men. Descriptive studies and nonrandomized studies with control groups show positive behavioral effects, as do randomized studies. The studies with random assignment to groups are clustered in two areas: individual interventions delivered in small group settings and programs aimed at changing community norms (e.g., using peer leaders in community settings to deliver programs). These intervention programs focus on information, skills building, self-management, problem solving, and psychological factors such as self-efficacy and intentions. Studies with clearly defined interventions, retention of samples to allow followup periods as long as 18 months, and reasonable sample sizes show

substantial effects for intervention over minimal intervention or control conditions. More intensive interventions (e.g., more sessions) boost efficacy.

Heterosexual Transmission

Adult Women at Risk From Sexual Transmission. Data from a variety of settings demonstrate the ability to prevent HIV risk behaviors in women. A randomized trial involving a cognitive behavioral intervention aimed at inner-city women with high risk of acquiring HIV through heterosexual contact provides some of the strongest evidence of impact. Three months after intervention, women in the intervention reported a slightly greater than doubling of condom use from 26 percent to 56 percent for all intercourse occasions; no such change occurred for women in the comparison group. A second randomized trial, targeted at pregnant women, shows similar results at a 6-month followup. Results from a third randomized study yet to be published show reductions in unprotected sex and sexually transmitted diseases. A study in rural Tanzania involving treatment for sexually transmitted diseases, condom distribution, and health education found more than a 50 percent reduction in HIV seroconversion incidence over a 2-year period in women ages 15–24. Seroconversion also diminished in counseling programs for women attending a clinic in Kigali, Rwanda, and for sex workers in Bombay, India.

Couples. There is evidence that consistent and correct condom use reduces HIV seroconversion to nearly zero in both male and female heterosexual partners. Counseling of couples in a European study was associated with large increases in protected sexual behavior.

Adolescents. The strongest support for reductions in a broad array of risky sexual behaviors comes from rigorous studies. Five randomized controlled trials used cognitive and behavioral skills training and targeted male and female, African-American, Latino, and European-American adolescents in health clinics and inner-city schools. Studies varied in sample size, and followups were limited to 1 year or less, but results were consistently positive, with outcomes such as condom acquisition, condom use, and reduced number of partners.

Injecting Drug Users

Prevention for injecting drug users has involved drug abuse treatment in some cases, and outreach focused on both drug use and HIV risk behavior in others. Both approaches have been effective. Programs aimed specifically at treating drug abuse show positive effects on risk behavior and have the additional benefit of affecting drug use. These have shown minimal effects on high-risk sex. Community studies training outreach workers or using an educational media campaign to reduce the use of nonsterile needles show increased protected sexual behavior and slowing of seroconversion rates, along with impressive reductions in drug use.

Needle Exchange Programs

An impressive body of evidence suggests powerful effects from needle exchange programs. The number of studies showing beneficial effects on behaviors such as needle sharing greatly outnumber those showing no effects. There is no longer doubt that these programs work, yet there is a striking disjunction between what science dictates and what policy delivers. Data are available to address three central concerns:

1. Does needle exchange promote drug use? A preponderance of evidence shows either no change or decreased drug use. The scattered cases showing increased drug use should be investigated to discover the conditions under which negative effects might occur, but these can in no way detract from the importance of needle exchange programs. Additionally, individuals in areas with needle exchange programs have increased likelihood of entering drug treatment programs.
2. Do programs encourage non-drug users, particularly youth, to use drugs? On the basis of such measures as hospitalizations for drug overdoses, there is no evidence that community norms change in favor of drug use or that more people begin using drugs. In Amsterdam and New Haven, for example, no increases in new drug users were reported after introduction of a needle exchange program.

3. Do programs increase the number of discarded needles in the community? In the majority of studies, there was no increase in used needles discarded in public places.

There are just over 100 needle exchange programs in the United States, compared with more than 2,000 in Australia, a country with less than 10 percent of the U.S. population. Can the opposition to needle exchange programs in the United States be justified on scientific grounds? Our answer is simple and emphatic—no. Studies show reduction in risk behavior as high as 80 percent in injecting drug users, with estimates of a 30 percent or greater reduction of HIV. The cost of such programs is relatively low. Needle exchange programs should be implemented at once.

Policy and Large-Scale Interventions

As in other areas (e.g., smoking, injury control), policy interventions can remove barriers to protective behavior. In the United States and other countries, such interventions have resulted in dramatic reductions in risk behavior. In Connecticut, for example, a single legislative action legalizing over-the-counter purchase of sterile injection equipment led to an immediate and profound reduction in the sharing of nonsterile needles. A national campaign in Switzerland to promote the use of condoms dramatically reduced risky sexual behavior. Regulations on the use of condoms by sex workers in Thailand also led to fewer unprotected sex acts. The results thus far have been impressive. Given the potential benefit of policy changes, these should be implemented as local circumstances allow and, once implemented, should be evaluated as often and thoroughly as possible.

Issues in Need of Further Work

Populations and Settings

A promising start has been made to reduce risk in persons often marginalized. Homeless, chronically mentally ill, runaway, incarcerated, HIV-positive, and physically and developmentally challenged persons face obstacles that affect their ability to initiate and maintain behavior change. In addition, little is

known about the risk behaviors of lesbians and bisexual women, heterosexual men, persons over 50 years old, and sexually active youth.

African-American and Latino communities experience disproportionate rates of infection. The application of culturally appropriate strategies demands ethnographic research to understand values, attitudes, behaviors, and factors such as socioeconomic status in different communities. Cultural factors may affect the ability of individuals to change behavior. Researchers from different ethnic or cultural backgrounds may help address this issue. Language and cultural barriers to delivery of interventions must be addressed, with special consideration for individuals whose physical or other impairments limit access to most programs.

Prenatal care and sexually transmitted disease clinics are proven to be effective settings for delivery of HIV intervention. Further research is needed in these and other medical settings. In addition, individuals in institutions such as prisons and mental health facilities, and those in remote areas, require special attention.

Maintenance, Generalizability, and Theory

Understanding and evaluating the maintenance of behavior change requires multivariate, longitudinal studies. In this way, changes in patterns of behavior and causal associations can be estimated. Long-term followup of subjects is necessary. Similarly, more attention to generalizability is needed. An intervention proven effective in one city may not be applicable in another city with a similar population but with different community norms. Methodological issues in need of additional attention include research strategies that measure and enhance validity of self-report, standardization of risk behavior questions and questioning techniques, comparability of intervention conditions across different studies, examining participants and nonresponders to an intervention, and measuring changes in multiple risk profiles over time.

A developmental framework may be helpful for considering the origins of HIV risk behavior. Efforts are needed to incorporate knowledge of childhood antecedents of HIV risk behaviors

in adolescents. Can early intervention that alters these antecedents reduce or delay HIV risk behaviors? The body of research now being done to reduce already existing risk behaviors such as unprotected sex and drug use needs to be linked with other research traditions that target antecedents of HIV risk behaviors.

Impact and Cost-Effectiveness

Reviews on HIV prevention conclude that programs produce significant effects, but a statistical advantage may not necessarily equate to meaningful change. An example comes from a study on condom use in more than 13,000 injecting drug users. An intervention nearly doubled consistent condom use, from a baseline level of 10 percent to 19 percent. Although the change was significant from a public health perspective, 81 percent of this high-risk population still engaged in high-risk sexual behavior. This highlights the importance of examining and improving impact as well as assessing statistical significance. Impact is assessed by understanding the efficacy of an intervention, the magnitude of behavior change, and the influence of this change on seroconversion.

A key issue is the degree to which the field has confronted the issue of efficacy (impact of interventions in controlled circumstances) versus effectiveness (effects in real-world setting). Little effectiveness research has been done. This limits the ability to estimate the impact likely to occur if the current generation of risk-reduction strategies, proven useful in efficacy trials, were applied on a large scale outside the research setting. The panel concluded that HIV prevention research is mature enough that some, but not all interventions, are ready for tests of effectiveness. This will require different research strategies and the involvement of professionals from additional disciplines beyond those used for efficacy trials.

The cost-effectiveness of interventions is an important issue in decisions about resource allocation. Research thus far has been positive, but more research is needed to examine the costs and benefits of HIV risk prevention programs.

Behavioral Issues Arising From Biomedical Advances

Important advances in medicine have created new and pressing behavioral issues. Pharmacologic treatment of HIV-positive individuals may increase longevity, but it is not known how such successfully treated individuals will alter their recreational drug use or sexual behavior. Complicated medical regimens raise issues of adherence, with the possibility that incomplete adherence will lead to resistant strains of the virus. Studies of biochemical preventive treatment after sexual exposure to HIV raise questions about risk-reduction counseling. For example, will individuals feel free to engage in risky sex as post-exposure treatment becomes more an option?

Pharmacologic treatment profiles now exist to reduce transmission of HIV from mother to newborn child. This demonstrated preventive intervention offers new opportunities to study behavioral issues and barriers to access in a new and important context.

Policy

Current evidence suggests that some of the most powerful positive effects on HIV risk behavior have been produced by legislative and regulatory changes. One need look no further than to the experience in Connecticut, where one legislative action permitting the purchase of sterile injection equipment had an immediate and pronounced effect on behavior. Here we see the potentially low cost and high effectiveness of intervention at the policy level. Policymaking can be conceptualized as behavior, and as such can and should be studied. Social policy, legal change, and community mobilization are powerful means of intervention and must be a legitimate area of inquiry at the National Institutes of Health and the Centers for Disease Control and Prevention.

Several examples beyond the Connecticut experience show the power of policy changes. Australia, for instance, has a low rate of HIV despite population profiles in some areas similar to profiles in areas in the United States that have high HIV seroconversion rates. Cities such as Tacoma, Toronto, Sydney, Glasgow, and Lund have kept the HIV infection rate low,

coincident with policies making sterile needles available for injecting drug users, boosting education aimed at risk reduction, making condoms more available, and enhancing programs for the treatment of sexually transmitted diseases. Impressive results have been reported from around the world on government action to reduce risk and infection in many populations at risk.

Little qualitative and quantitative research has been done in HIV prevention policy, and no body of evidence exists to inform the field about the factors that influence policy, where policy intervention is most likely to be effective, and how best to encourage policy and legislative changes. We believe that funding should be devoted to the study of policy and legislative changes and that National, State, and local levels be considered.

Of utmost importance is that HIV prevention policy be based, whenever possible, on scientific information. This occurs too little—the behavior placing the public health at greatest risk may be occurring in legislative and other decisionmaking bodies. The Federal ban on funding for needle exchange programs as well as restrictions on selling injection equipment are absolutely contraindicated and erect formidable barriers to implementing what is known to be effective. Many thousands of unnecessary deaths will occur as a result.

The single greatest increase in HIV prevention funding occurred with 1996 Federal legislation in the United States providing \$50 million within block grant entitlements for programs teaching adolescents abstinence from sexual behavior. Among the criteria for programs funded through the block grant program are the following two requirements: (1) “has as its exclusive purpose, teaching the social, psychological, and health gains to be realized by abstaining from sexual activity” and (2) “teaches that a mutually faithful monogamous relationship in the context of marriage is the expected standard of human sexual activity” (Public Health Service Act, Public Law 104-193, Sec. 912). Some programs based on an abstinence model propose that approaches such as the use of condoms are ineffective. This model places policy in direct conflict with science because it ignores overwhelming evidence

that other programs are effective. Abstinence-only programs cannot be justified in the face of effective programs and given the fact that we face an international emergency in the AIDS epidemic.

Another instance of policy conflicting with knowledge is in providing treatment for drug abuse. Research shows that treatment of drug abusers with methadone maintenance, outpatient drug-free treatments, residential treatment, or detoxification not only decreases drug use but has a substantial effect on risk behaviors (use of shared needles and unprotected sex). At the same time that this knowledge has reached a critical mass, funding of drug treatment programs has been reduced in many localities. This tragic trend must be reversed.

Policy and legislative change can have rapid, powerful, and positive results. This key area of the field has been given little attention, a problem that needs remedy. A coordinated effort is needed, and the Government must take strong and immediate steps to protect its citizens. Drawing together legal and policy changes and program implementation occurring at international, National, and local levels offers great promise. Strong political leadership is necessary to direct this effort. The United States has much to learn from other countries where political leaders have taken this issue seriously and, by supporting vigorous prevention strategies, have prevented even more tragedy from occurring from AIDS.

Does a Reduction in These Behavioral Risks Lead to a Reduction in HIV?

The evidence is unequivocal that consistent and effective use of condoms and of sterile injecting equipment on the part of injection drug users is nearly 100 percent effective in protecting against HIV. Reduction in risky behavior leads to reduction in HIV to a degree that depends on context, particularly the local prevalence of HIV infection.

It is important to keep HIV seroincidence in mind as the ultimate outcome of interest for HIV prevention efforts. Seroincidence estimates also allow us to compare effectiveness and cost of different programs. Direct measurement of HIV infection is a feasible and desirable outcome variable for some programs. However, practical, ethical, and fiscal barriers often make reliance on measured seroconversion undesirable. In these instances, proxy indices—including other biological markers or modeled estimates of seroincidence based on behavioral outcomes—can be used to estimate the effects of prevention programs on seroincidence.

Study Designs That Lend Themselves to Using Seroconversion as an Outcome

To find reliable differences between intervention and control or comparison samples, one must expect a minimum number of seroconversions in the control sample within the timeframe of the study. These are found in populations where seroconversion rates are high, in large samples, or in studies with long followup. Only a limited number of situations have lent themselves to clinical trials and other studies on this scale.

Many studies using seroincidence as a measure of outcome were conducted in developing countries where HIV incidence is high and policy interventions or community-level programs have been implemented. Among these are studies from Tanzania and Bombay with comparison populations and from Thailand, where an historical comparison was employed. Few studies in the United States have used HIV or any biological measure as an endpoint for the reasons cited above. In the United States and elsewhere, seroconversion has been used

to measure the effect of sterile injection equipment availability, bleach cleaning interventions, and methadone treatment with injecting drug users.

Constraints on Using Seroconversion Outcomes

Although seroconversion is a preferred standard for intervention efficacy, there are practical and ethical obstacles to its use. For example, there is a potential selective dropout of research participants who will not agree to repeated HIV testing. Furthermore, research costs can be greatly increased by pre- and post-test counseling and followup or referral for research subjects who are identified as HIV-positive in the study. Counseling and referral are, of course, required by ethical research practice. Nevertheless, where possible and feasible, it is important that behavioral and policy interventions be validated using seroconversion as an outcome.

Transmission Models To Estimate Effects of Behavioral Outcomes on HIV Infection Rates

When HIV seroconversion outcomes are not feasible, well-designed self-report behavioral outcomes have shown indications of being valid and reliable. These behavioral outcomes can be employed in transmission models to estimate the number of averted cases. The models have been developed from studies of HIV-discordant couples and epidemiological studies. Although use of these models requires assumptions about future prevalence and about relationships among variables being studied, a reasonable range of estimates about the probable impact of the intervention on HIV can thus be generated. In theory, estimates of HIV seroconversion during the study may be extended into the future under varying estimates of the maintenance of positive behavioral outcome. The models may also be extended to estimate the potential impact were the program more widely implemented in similar contexts. Finally, potential effects on seroconversion in field settings may be estimated, using these models, from data on behavioral outcomes from studies done in research settings. These models can estimate the impact on seroconversion using reasonable assumptions that the interventions will have less effectiveness in field settings.

Estimates of the effects of behavioral outcomes on HIV seroconversion are still relatively few and mostly retrospective. It should be possible to produce such estimates in advance of prevention trials, contingent on the targeted magnitude of behavioral outcomes and the expected prevalence of HIV infection in the local population. We recommend that such estimates be employed as an additional outcome measure for trials with behavioral endpoints whenever possible. Ongoing work on these models is needed to update and improve the database used to produce and validate them. Furthermore, there is a need to validate, by use of empirical data, the assumption that transmission rates based on naturally occurring behaviors are equivalent to transmission rates based on behavioral changes in response to prevention efforts. These models can also be used to estimate the validity of self-reports.

Other Biological Markers as Surrogates for HIV Seroconversion

Incidence of certain sexually transmitted diseases has been used as a plausible surrogate for HIV seroconversion. The same sexual behaviors are risks for HIV and some sexually transmitted diseases. Sexually transmitted diseases are a powerful potentiator of HIV seroconversion in exposed persons. The higher incidence of sexually transmitted diseases also makes detection of program effects more sensitive. Two ongoing multicenter randomized controlled trials for heterosexual populations have chosen incidence of sexually transmitted diseases as a biologic marker to study the efficacy of HIV prevention interventions, as have international studies such as the study in Tanzania. Unpublished results of a Centers for Disease Control and Prevention project show a decrease in the rate of sexually transmitted diseases to be correlated with a decrease in HIV-related risk behavior. Hepatitis C has been used effectively as a biological marker in studies involving injecting drug user populations, because of overlapping transmission routes. Sexually transmitted disease incidence, hepatitis C incidence, and other infectious disease incidence are reasonable markers for expected HIV exposure.

How Can Risk-Reduction Procedures Be Implemented Effectively?

Studies Ready for Implementation

A number of interventions have been evaluated in current research and are ready to be implemented within communities. Indeed, some are already being implemented by health departments and community-based organizations. Interventions at the individual level include the following:

- Outreach, needle exchange activities, treatment programs, and face-to-face counseling programs for substance-abusing populations
- Cognitive-behavioral small group, face-to-face counseling, and skills-building (i.e., proper condom use, negotiation, refusal) programs for men who have sex with men
- Cognitive-behavioral small group, face-to-face counseling, and skills building (i.e., proper condom use, negotiation, refusal) programs for women that pay special attention to their concerns (e.g., child care, transportation, and relationships with significant others)
- Condom distribution and testing and treatment for sexually transmitted diseases for sex workers and other sexually active individuals at high risk for sexually transmitted diseases
- Cognitive-behavioral educational and skills-building groups for youth and adolescents in various settings.

At the family or dyad level, interventions include counseling for couples (including HIV-serodiscordant couples) in both the United States and other countries. Within the community, interventions include changing community norms through community outreach and opinion leaders for men who have sex with men as well as injection drug-using networks.

At the policy level there are a number of strategies:

- Lifting government restrictions on needle exchange programs
- Providing increased government funding for drug and alcohol treatment programs, including methadone maintenance
- Support for sex education interventions that focus beyond abstinence
- Lifting constraints on condom availability (e.g., in correctional facilities).

Implementation Considerations

Several factors may influence implementation of HIV risk behavior interventions within the United States.

First, compliance with interventions is improved when targeted individuals are involved at every phase of the process of conceptualization, development, and implementation of the programs. Input of these individuals is needed to help solve this health crisis.

Second, programs need to be culturally sensitive. This requires attention not only to ethnicity and language but also to other factors including social class, age, developmental stage, and sexual orientation.

Third, an appropriate intervention dosage must be selected for the population; this includes the number, length, and intensity of the intervention. Studies demonstrate that numerous intervention points over extended periods of time are more efficacious than once-only approaches for most populations. Almost all reported studies have short followup (3–18 months), which suggests that attention must be paid to maintenance efforts. It may be necessary to include additional, periodic intervention points for subsets of the population; longer term followup would assist in determining this fact.

Fourth, when HIV risk behavior interventions are being introduced, it is important to address community myths. For example, scientifically derived results do not support

assertions that needle exchange programs will lead to increased needle-injecting behavior among current users or an increase in the number of users. Nor do the data indicate that sex education programs result in earlier onset of sexual behavior or more sexual partners, or that condom distribution fosters more risky behavior. To the contrary, outcomes of these programs are quite consistent with the values of most communities. For example, behavioral interventions lead injecting drug users to inject less frequently, and the number of users in a community may decrease; after interventions, young people tend to delay initiation of intercourse or, if they are sexually active, have fewer partners; and adults, following intervention, engage in fewer incidents of risky sexual behavior. Armed with this knowledge, those who implement programs should confidently solicit the support and involvement of local government, educational, and religious leaders.

Despite notable gains relevant to implementation of prevention programs, very little cost analysis information has been available to guide community-based organizations, State and local health departments, and other practitioners. These analyses are important in determining the most cost-effective interventions for implementation. In addition, communities lack fiscal resources to support such interventions once they are proven successful. Finally, there are social and cultural barriers to implementation of programs; these include homophobia, gender inequality, and racism.

Sufficient training of personnel, monitoring of procedures to ensure fidelity to key components and established methods, and strong evaluation plans are essential components of any implementation strategy. When training and local capacity-building are necessary for implementation, training and technical assistance should be available to facilitate prevention programs at State and local levels. Evaluation results should be reported and widely disseminated so as to advance both science and practice. Newly implemented programs yielding results different from established findings should be carefully compared with original designs in order to explain the variance in outcomes.

The Next Step

Just as the Food and Drug Administration conditionally approves experimental drugs in emergency situations, so should policymakers support active dissemination of the most promising programs at this time based on the urgency of the AIDS epidemic. A critical issue that must be addressed involves the criteria for choosing interventions most ready for implementation in the community. The most obvious is evidence of strong program effects observed under rigorous, controlled research conditions. Among programs with strong effects, priority should be given to interventions that can be delivered with high reliability and fidelity to the original program model. Usually such programs do not require significant new demands or elaborate training at the delivery site.

At this next stage there will nevertheless be programs that show promise but still require additional research to ensure their effectiveness. At least two criteria should be considered in choosing promising programs for further evaluation. First, programs that show strong short-term effects but lack long-term results should be studied to estimate their long-term effectiveness. Second, programs that have shown promising effects for only a very narrowly defined range of settings or conditions of implementation should be studied to assess the generalizability of their effectiveness in other settings and contexts.

Numerous other interventions developed solely by community organizations were not described during the consensus development conference by the researchers, yet were brought to the attention of the panel by the public statements at the conference by community activists and practitioners. The efficacy of these approaches has not been demonstrated through careful evaluation. However, because community workers have developed a number of innovative and promising programs, there is a great need for them to work together with researchers to further HIV risk behavior intervention science and practice.

What Research Is Most Urgently Needed?

The most urgently needed research is that which is essential for containing the HIV/AIDS epidemic. In particular, we need to track emerging behavioral risk factors and to aim preventive procedures at these risk factors with as much precision as possible.

Tracking Emerging Risk

A most urgent area for research is in developing improved methods of identifying emerging risks within large populations. For example, in the United States we need to know as early as possible what settings, regions, and subpopulations are likely to show increases in seroconversion to HIV. The best strategy for this identification is to track increases in known behavioral risks, which when combined with sufficiently high HIV prevalence predicts regions of particular vulnerability. Regional strategies are needed for regularly tracking increases in these behaviors in order to effectively offer known prevention strategies before seroconversion occurs. These regional strategies must be coordinated with the National HIV tracking system. Research is needed on how to collect this information regionally. How can studies collect representative data/behavioral information from regional populations in ways that are fully acceptable to the local communities involved? This regional strategy of risk tracking can draw on two areas of established research. First, clearly established risky behaviors serve as reliable harbingers of seroconversion. These include behaviors that directly increase the likelihood of HIV transmission, such as unprotected sex and needle sharing and practices that make these behaviors more likely, such as alcohol abuse in adolescents. Second, methods for inquiring about these risky behaviors have been established and validated. Careful evaluation of the most cost-efficient approaches to regional tracking is needed, as well as approaches to ensure that strategies used are compatible with community values and maximum effectiveness.

Young People

The epidemic in the United States is currently shifting to young people, particularly those who are gay, members of racial and ethnic minorities, and out-of-school adolescents. Because adolescents may be at risk for HIV infection in their early to mid teens, it is important to establish interventions for youth at an earlier age before the onset of risk behavior (sexual activity and drug use). Thus, the U.S. program of research must give highest priority to providing effective prevention programs for these subpopulations. Programs already shown to be effective for these subpopulations must be improved to ensure long-term maintenance of the reduction in risky behavior. Current interventions should be widely disseminated, and improved interventions, as they become available, should quickly replace those that have been less effective. Dissemination should include careful training of providers, monitoring to ensure fidelity of delivery, continuous evaluation of effectiveness, and modification where required by community and cultural needs and circumstances.

HIV-Positive Individuals

Effective interventions with people who are HIV-positive can enable them to practice safer sex and safer needle use and thus help to contain the HIV epidemic. There is a startling paucity of well-developed interventions specifically designed for HIV-positive persons. Moreover, as biological treatment for those who are HIV-positive improves, the need for these preventive services will become even more pressing.

Women

It is essential to continue development of interventions to reduce heterosexual transmission of HIV to women as well as their risk of drug abuse behavior. These interventions should focus on the effect of community expectations of women and power differentials in their relationships with men. Moreover, additional research with female condoms and microbicides may facilitate preventive interventions that enhance women's control of exposure to HIV risk.

Linking Scientific Findings to Law and Policy

Most urgent is the need to rapidly bridge the serious gap that is widening between clear scientific results and the law and policies of the United States. As this statement has noted forcefully, there is clear scientific evidence supporting needle exchange programs, drug abuse treatment, and interventions with adolescents as essential components of our National program to contain the AIDS epidemic. Even as evidence rapidly accumulates on the success of these programs, however, legislation has been passed to make provision of these interventions extremely difficult. There is no more urgent need than to remedy this dangerous chasm. National leaders, legislators, scientists, and service providers must unite to understand fully this growing catastrophe. Why are voters unaware of these issues? What pressures and circumstances of government make it unresponsive to these compelling public health needs and effective programs? What are the limits in scientific communication that may obscure the legislative import of these scientific findings?

Conclusions and Recommendations

1. Preventive interventions are effective for reducing behavioral risk for HIV/AIDS and must be widely disseminated. Their application in practice settings may require careful training of personnel, close monitoring of the fidelity of procedures, and ongoing monitoring of effectiveness. Results of this evaluation must be reported, and where effectiveness in field settings is reduced, program modifications must be undertaken immediately.

Three approaches are particularly effective for risk reduction in drug abuse behavior: needle exchange programs, drug abuse treatment, and outreach programs for drug abusers not enrolled in treatment. Several programs were deemed effective for risky sexual behavior. These programs include (1) information about HIV/AIDS and (2) building skills to use condoms and to negotiate the interpersonal challenges of safer sex. Effective safer sex programs have been developed for men who have sex with men, for women, and for adolescents.

2. The epidemic in the United States is shifting to young people, particularly those who are gay and who are members of ethnic minority groups. New research must focus on these emerging risk groups. Interventions must be developed and perfected, and special attention must be given to long-term maintenance of effects. In addition, AIDS is steadily increasing in women, and transmission of HIV virus to their children remains a major public health problem. Interventions focused on their special needs are essential.
3. Regional tracking of changes in behavioral risk will be necessary to identify settings, subpopulations, and geographical regions with special risk for seroconversion to HIV-positive status as the epidemic continues to change. This effort, if properly coordinated with National tracking strategies, could play a critical part in a U.S. strategy to contain the spread of HIV.

4. Programs must be developed to help individuals already infected with HIV to avoid risky sexual and substance abuse behavior. This National priority will become more pressing as new biological treatments prolong life. Thus, prevention programs for HIV-positive people must have outcomes that can be maintained over long periods of time, in order to slow the spread of infection.
5. Legislative restriction on needle exchange programs must be lifted. Such legislation constitutes a major barrier to realizing the potential of a powerful approach and exposes millions of people to unnecessary risk.
6. Legislative barriers that discourage effective programs aimed at youth must be eliminated. Although sexual abstinence is a desirable objective, programs must include instruction in safe sex behavior, including condom use. The effectiveness of these programs is supported by strong scientific evidence. However, they are discouraged by welfare reform provisions, which support only programs using abstinence as the only goal.
7. The erosion of funding for drug and alcohol abuse treatment programs must be halted. Research data are clear that the programs reduce risky drug and alcohol abuse behavior and often eliminate drug abuse itself. Drug and alcohol abuse treatment is a central bulwark in the Nation's defense against HIV/AIDS.
8. The catastrophic breach between HIV/AIDS prevention science and the legislative process must be healed. Citizens, legislators, political leaders, service providers, and scientists must unite so that scientific data may properly inform legislative process. The study of policy development, the impact of policy, and policy change must be supported by Federal agencies.

Consensus Development Panel

David Reiss, M.D.

*Panel and Conference
Chairperson
Professor and Director
Division of Research
Department of Psychiatry
and Behavioral Science
George Washington University
Medical Center
Washington, DC*

C. Hendricks Brown, Ph.D.

*Professor
Department of Epidemiology
and Biostatistics
College of Public Health
University of South Florida
Tampa, Florida*

Kelly D. Brownell, Ph.D.

*Professor of Psychology,
Epidemiology, and
Public Health
Director of the Yale Center for
Eating and Weight Disorders
Master of Silliman College
Department of Psychology
Yale University
New Haven, Connecticut*

Patricia Cohen, Ph.D.

*Professor
Division of Epidemiology
Department of Psychiatry
Columbia University
New York, New York*

Julia R. Heiman, Ph.D.

*Professor
Department of Psychiatry and
Behavioral Sciences
Outpatient Psychiatry Center
University of Washington
Seattle, Washington*

Richard H. Price, Ph.D.

*Professor of Psychology
and Research Scientist
Department of Psychology
Institute for Social Research
University of Michigan
Ann Arbor, Michigan*

Sohail Rana, M.D.

*Associate Professor
Director, Pediatric HIV Service
Department of Pediatrics
Howard University Hospital
Washington, DC*

Edward Seidman, Ph.D.

*Professor
Department of Psychology
Center for Community Research
and Action
New York University
New York, New York*

Mickey W. Smith, B.A.S.W.

*Manager, Scott-Harper
Recovery House
Mental Health and Addictions
Treatment Services
Whitman-Walker Clinic, Inc.
Washington, DC*

William Snow

*AIDS Vaccine Advocacy
Coalition and ACT
UP/Golden Gate
San Francisco, California*

Steven F. Wakefield

*The Night Ministry
National Task Force on
AIDS Prevention
Chicago, Illinois*

Robert A. Washington, Ph.D.

*Director of Education
St. Francis Center
Washington, DC*

Speakers

Thomas J. Coates, Ph.D.

“Reducing High-Risk HIV Behaviors: An Overview of Effective Approaches”
Professor of Medicine and Epidemiology
Director, Center for AIDS Prevention Studies
Interim Director, UCSF AIDS Research Institute
University of California, San Francisco
San Francisco, California

Don C. Des Jarlais, Ph.D.

“International Epidemiology of HIV Among Injecting Drug Users”
Director of Research
Chemical Dependency Institute
Beth Israel Medical Center
Professor of Epidemiology
Department of Epidemiology and Social Medicine
Albert Einstein College of Medicine
c/o Beth Israel Medical Center
New York, New York

Lynda S. Doll, Ph.D.

“Epidemiology of HIV-Related Behaviors in Risk Populations”
Chief, Behavioral Interventions Research Branch
Division of HIV/AIDS Prevention
Associate Director for Behavioral Science
Centers for Disease Control and Prevention
Atlanta, Georgia

Presented by Ellen D. Sogolow, Ph.D.
Behavioral Scientist
Behavioral Interventions Research Branch
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention
Atlanta, Georgia

Anke A. Ehrhardt, Ph.D.

“Behavioral Interventions With Women”
Professor of Medical Psychology
Director, HIV Center for Clinical and Behavioral Studies
Department of Psychiatry
Columbia University College of Physicians and Surgeons
New York State Psychiatric Institute
New York, New York

Martin Fishbein, Ph.D.

“Theoretical Models of HIV Prevention”
Professor
Department of Psychology
University of Illinois, Champaign–Urbana
c/o Centers for Disease Control and Prevention
Atlanta, Georgia

Helene D. Gayle, M.D., M.P.H.

“Epidemiology of HIV Infection and AIDS: National and International Perspective”
Director, National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention
Atlanta, Georgia

David R. Holtgrave, Ph.D.

“Consequences of HIV Prevention Interventions and Programs: Spectrum, Selection, and Quality of Outcome Measures”
Associate Professor and Director of Cost-Effectiveness Studies Core
Center for AIDS Intervention Research
Department of Psychiatry and Behavioral Medicine
Medical College of Wisconsin
Milwaukee, Wisconsin

Steven E. Hyman, M.D.

“Welcome and Introduction”
*Director, National Institute
of Mental Health*
National Institutes of Health
Bethesda, Maryland

John B. Jemmott III, Ph.D.

“Behavioral Interventions With
Heterosexual Adolescents”
Professor
Department of Psychology
Princeton University
Princeton, New Jersey

Jeffrey A. Kelly, Ph.D.

“Behavioral Interventions
With Gay and Bisexual
Men and Youth”
*Professor of Psychiatry and
Behavioral Medicine*
*Director, Center for AIDS
Intervention Research*
Medical College of Wisconsin
Milwaukee, Wisconsin

Michael H. Merson, M.D.

“International Perspective on
AIDS Prevention Research”
Dean of Public Health
*Chairman, Department of
Epidemiology and
Public Health*
Yale University School
of Medicine
New Haven, Connecticut

David Metzger, Ph.D.

“Drug Abuse Treatment
as AIDS Prevention”
Associate Professor
*Director of Opiate and
AIDS Research*
Center for Studies of Addiction
University of Pennsylvania
Philadelphia, Pennsylvania

Richard H. Needle, Ph.D., M.P.H.

“Community-Based Outreach
Risk-Reduction Strategy To
Prevent HIV Risk Behaviors
in Out-of-Treatment Injection
Drug Users”
*Chief, Community Research
Branch*
Division of Epidemiological
and Prevention Research
National Institute on Drug Abuse
National Institutes of Health
Bethesda, Maryland

Mary Jane Rotheram, Ph.D.

“Interventions To Reduce
Heterosexual Transmission
of HIV”
*Professor, Division of Social
and Community Psychiatry*
Department of Psychiatry
*Director, Clinical Research
Center*
University of California,
Los Angeles
Los Angeles, California

Ellen Stover, Ph.D.

“Contextual Overview of
Presentations at Consensus
Development Conference”
Director, Office on AIDS
National Institute of Mental
Health
National Institutes of Health
Bethesda, Maryland

**Mervyn Susser, M.B., B.Ch.,
F.R.C.P.(E.), D.P.H.**

“Some Principles for Prevent-
ing HIV: Rigor or Reality in
Study Design”
*Sergievsky Professor of
Epidemiology*
Emeritus and Special Lecturer
Gertrude H. Sergievsky Center
Columbia University
New York, New York

David Vlahov, Ph.D.

“The Role of Needle Exchange Programs in HIV Prevention”
Professor
Infectious Diseases Program
Department of Epidemiology
School of Hygiene and Public Health
Johns Hopkins University
Baltimore, Maryland

Elsa A. Bray

Program Analyst
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Kendall J. Bryant, Ph.D.

Coordinator, AIDS Behavioral Research
National Institute on Alcohol Abuse and Alcoholism
National Institutes of Health
Bethesda, Maryland

Planning Committee

Willo Pequegnat, Ph.D.

Planning Committee Chairperson
Associate Director for Behavioral and Neuroscience Research
Office on AIDS
National Institute of Mental Health
National Institutes of Health
Bethesda, Maryland

Judith D. Auerbach, Ph.D.

Behavioral and Social Science Coordinator
Office of AIDS Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Elaine Baldwin

Chief, Public Affairs and Scientific Reports Branch
Office of Scientific Information
National Institute of Mental Health
National Institutes of Health
Bethesda, Maryland

Andrea Baruchin, Ph.D.

National Institute of Mental Health
National Institutes of Health
Bethesda, Maryland

David D. Celentano, Sc.D., M.H.S.

Professor
Division of Infectious Diseases
Department of Epidemiology
Johns Hopkins University
Baltimore, Maryland

Thomas J. Coates, Ph.D.

Professor of Medicine and Epidemiology
Director, Center for AIDS Prevention Studies
Interim Director, UCSF AIDS Research Institute
University of California, San Francisco
San Francisco, California

James W. Curran, M.D., M.P.H.

Dean, Rollins School of Public Health of Emory University
The Robert W. Woodruff Health Sciences Center
Atlanta, Georgia

Lynda S. Doll, Ph.D.

Chief, Behavioral Intervention Research Branch
Division of HIV/AIDS Prevention
Associate Director for Behavioral Science
Centers for Disease Control and Prevention
Atlanta, Georgia

Anita Eichler, M.P.H.

*Director, Division of HIV
Services*
Health Resources and Services
Administration
Bethesda, Maryland

John H. Ferguson, M.D.

*Director, Office of Medical
Applications of Research*
Office of the Director
National Institutes of Health
Bethesda, Maryland

Martin Fishbein, Ph.D.

Professor
Department of Psychology
University of Illinois,
Champaign–Urbana
c/o Centers for Disease
Control and Prevention
Atlanta, Georgia

Steven W. Gust, Ph.D.

Acting Director
Office on AIDS
National Institute on Drug Abuse
National Institutes of Health
Bethesda, Maryland

William H. Hall

Director of Communications
Office of Medical Applications
of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Rayford Kyle, M.A.

Public Affairs Specialist
Public Affairs and Scientific
Reports Branch
Office of Scientific Information
National Institutes of Health
Bethesda, Maryland

June R. Lunney, Ph.D., R.N.

Scientific Program Administrator
Division of Extramural Activities
National Institute of Nursing
Research
National Institutes of Health
Bethesda, Maryland

Susan F. Newcomer, Ph.D.

Statistician
Demographic and Behavioral
Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
National Institutes of Health
Bethesda, Maryland

Kevin R. O'Reilly, Ph.D.

*Chief, Reproductive Tract
Infections*
Division of Reproductive Health
Global Programme on AIDS
World Health Organization
Geneva, Switzerland

Marcia G. Ory, Ph.D., M.P.H.

*Chief, Social Science Research
on Aging*
Behavioral Social Research
Program
National Institute on Aging
National Institutes of Health
Bethesda, Maryland

David Reiss, M.D.

*Panel and Conference
Chairperson*
Professor and Director
Division of Research
Department of Psychiatry
George Washington University
Medical Center
Washington, DC

Amy R. Sheon, Ph.D., M.P.H.

*Former Senior Prevention
Scientist*
Division of AIDS, NIAID
*Program Director for Social
and Behavioral Studies
in Cancer Genetics*
Division of Cancer Epidemiology
and Genetics
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Charles Sherman, Ph.D.
Deputy Director
Office of Medical Applications
of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Ellen Stover, Ph.D.
Director, Office on AIDS
National Institute of Mental
Health
National Institutes of Health
Bethesda, Maryland

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**Health Resources and Services
Administration**
Ciro V. Sumaya, M.D., M.P.H.T.M.
Administrator

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Interventions to Prevent HIV Risk Behaviors

A Continuing Medical Education Activity Sponsored by the National Institutes of Health

OBJECTIVE

The objective of this NIH Consensus Statement is to inform the biomedical research and clinical practice communities of the results of the NIH Consensus Development Conference on Interventions to Prevent HIV Risk Behaviors. The statement provides state-of-the-art information regarding effective behavioral interventions to prevent HIV risk behaviors and presents the conclusions and recommendations of the consensus panel regarding these issues. In addition, the statement identifies those areas of study that deserve further investigation. Upon completing this educational activity, the reader should possess a clear working clinical knowledge of the state-of-the-art regarding this topic.

ACCREDITATION

The NIH/FAES is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

The NIH/FAES designates this continuing medical education activity for 1 credit hour in Category I of the Physician's Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

EXPIRATION

This form must be completed and **postmarked by October 31, 1998**, for eligibility to receive continuing medical education credit for this continuing medical education activity. The expiration date for this test may be extended beyond October 31, 1998. Beginning November 1, 1998, please check the NIH Consensus Development Program web site (<http://consensus.nih.gov>) or call the NIH Office of Medical Applications of Research at 301-496-1144 for information regarding an extended expiration date for this continuing medical education activity.

INSTRUCTIONS

The consensus statement contains the correct answers to the following 16 questions. Select your answer(s) to each question and write the corresponding letter(s) in the answer space provided. Mail the completed test by the expiration date shown above to the address at the end of this test. You will receive notification of your test results within 2 to 3 weeks. If you have successfully completed the test (11 or more correct answers), you will receive a certificate for 1 hour of credit along with your test results. Photocopies of this form are acceptable. There is no fee for participating in this continuing education activity.



National Institutes Of Health
Continuing Medical Education

1. AIDS is the leading cause of death for: (*You must indicate all that are true.*)

- a. children under 12 months of age
- b. men and women between 25 and 44 years of age
- c. young men between 18 and 21 years of age
- d. men over 45 years of age

ANSWER(S) _____

2. The AIDS epidemic is shifting to: (*You must indicate all that are true.*)

- a. youth
- b. older people
- c. alcoholics
- d. commercial sex workers

ANSWER(S) _____

3. Key risk behaviors for HIV infection are: (*You must indicate all that are true.*)

- a. multiple sexual partners
- b. unprotected anal and vaginal intercourse
- c. use of nonsterile drug injection equipment
- d. none of the above

ANSWER(S) _____

4. Biomedical factors are more difficult to measure than psychosocial contextual factors:

- a. true
- b. false

ANSWER _____

5. Which of the following behavioral trends is false:

- a. injection drug users are at an increased risk for HIV infection because of community conditions
- b. among gay men, African American men are at increasing risk for HIV infection
- c. youth show an increase in condom use as they get older
- d. the risk of HIV infection in women has increased because of sexual contact with injection drug users

ANSWER _____

6. The randomized controlled trial is the most appropriate design for testing all HIV prevention research:

- a. true
- b. false

ANSWER _____

7. Several successful cognitive behavioral interventions in women demonstrated an increase in condom use:

- a. from 15 to 26 percent
- b. from 26 to 56 percent
- c. by 50 percent
- d. by 62 percent

ANSWER _____

8. Needle exchange programs: (*You must indicate all that are true.*)

- a. do not promote drug use among current drug users
- b. promote drug use among non-drug users
- c. lead to an increase in discarded needles
- d. lead to a decrease in discarded needles
- e. none of the above

ANSWER(S) _____

9. The panel identified which of the following as the most urgently needed research:

- a. school-based interventions for sexually-active youth
- b. developing better condoms
- c. interventions that can be delivered in community settings
- d. developing methods of identifying emerging risks within large populations

ANSWER _____

10. Which of the following cities has kept the seroconversion rate among injection drug users low because of aggressive HIV prevention policies:

- a. Montreal
- b. Sydney
- c. Miami
- d. Amsterdam

ANSWER _____

11. The evidence is unequivocal that consistent and effective use of condoms and sterile injection equipment reduces the risk of HIV infection by nearly:

- a. 100 percent
- b. 98 percent
- c. 93 percent
- d. 90 percent

ANSWER _____

12. Social and cultural barriers to implementation of effective AIDS prevention programs include: (*You must indicate all that are true.*)

- a. racism
- b. religious discrimination
- c. gender inequality
- d. homophobia
- e. none of the above

ANSWER(S) _____

13. Because of the importance to AIDS prevention, there must be a stop to the “erosion of funding” for: (*You must indicate all that are true.*)

- a. drug and alcohol abuse treatment programs
- b. mental health treatment programs
- c. school-based prevention programs for adolescents
- d. abstinence-only education programs
- e. none of the above

ANSWER(S) _____

14. Policy interventions are effective because they: (*You must indicate all that are true.*)

- a. make risky behavior illegal
- b. remove barriers to self-protective behaviors
- c. make AIDS prevention programs uniform
- d. none of the above

ANSWER(S) _____

15. There is a significant lack of research on interventions to prevent HIV transmission in which of the following groups: (*You must indicate all that are true.*)

- a. infants
- b. seropositive persons
- c. older Hispanic couples
- d. older gay men

ANSWER(S) _____

16. The consensus panel stated that science was in conflict with policy on which of the following issues: (*You must indicate all that are true.*)

- a. providing treatment for drug abuse
- b. legalization of sterile needle exchange
- c. abstinence-only programs for youth
- d. none of the above

ANSWER(S) _____

Your response to the following two questions is optional and will have no effect on the grading results of this test.

Was the objective of this continuing education activity clearly stated?

- a. not at all
- b. very little
- c. somewhat
- d. considerably
- e. completely

ANSWER _____

Did the activity planners provide the necessary information to meet the stated goals and objectives?

- a. not at all
- b. very little
- c. somewhat
- d. considerably
- e. completely

ANSWER _____

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