

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records
Subgroup/Office of Origin: National AIDS Policy Office
Series/Staff Member: Todd Summers
Subseries:

OA/ID Number: 21080
FolderID:

Folder Title:
Issues - Needle Exchange - Studies - NIH [National Institutes of Health]

Stack:	Row:	Section:	Shelf:	Position:
S	66	6	3	3

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

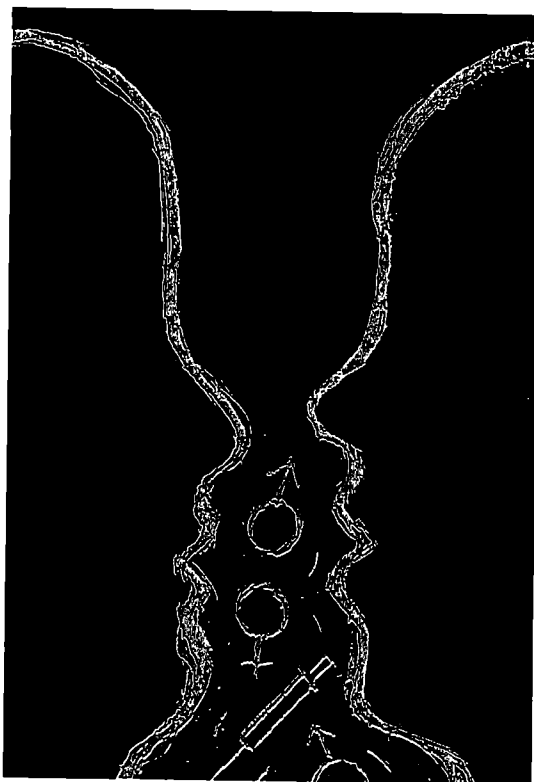
NIH Consensus Statement

Vol. 15, Number 2

February 11-13, 1997

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

SCIENTIFIC STUDIES SINCE FEBRUARY 1997 - Published or Accepted to be Published

Annotated Bibliography

Centers for Disease Control and Prevention. Update: Syringe-Exchange Programs - United States, 1997. Morbidity and Mortality Weekly Report, June 20, 1997 Vol 46. No. 24 p.565-568.

Provided data from national survey of 101 needle exchange programs that are members of the North American Syringe Exchange Network. Among the 87 reporting programs, 97% referred participants to treatment; 81% provided STD prevention education; 40% provided HIV testing and counseling on site; 17% provided primary health care.

Vlahov D, Junge B, Brookmeyer R et al. Reductions in High-Risk Drug Use Behaviors Among Participants in the Baltimore Needle Exchange Program. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology 1997; 16:400-406.

221 participants in the Baltimore NEP were studied at baseline, 2- week and 6-month follow-up visits. Reductions were reported in the mean number of injections per syringe and the mean number of injections per day. Significant reductions were reported in using a previously used syringe (21.6%, 11%, 7.8% respectively) , and lending one's syringe to a friend (26.7%, 18.4%, 12% respectively). These results are consistent with other studies that show an association between behavioral risk reduction and participation in an NEP. Treatment enrollment was also positively associated with NEP participation. At baseline, 6% of NEP users were in drug treatment; at 2 weeks, 9.6% were in drug treatment; at 6 months, 16% were in drug treatment.

Hurley SF, Jolley DJ, Kaldor JM Effectiveness of Needle-Exchange Programmes for Prevention of HIV Infection. Lancet 1997; 349:1797-1800.

Examined 81 cities around the world which had HIV seroprevalence data and information on the presence or absence of needle exchange programs. Those 52 cities that did not have NEPs showed a 5.9% increase in HIV seroprevalence per year during the time period of 1988 to 1993. The 29 cities that had NEPs showed a 5.8% decrease in HIV seroprevalence per year. These figures are based on average increases and decreases in seroprevalence across the cities. The nature of the study does not rule out the possibility of a number of confounding variables, yet the authors put forward "as a plausible explanation that NEPs led to a reduction in HIV incidence among injecting drug users."

Two Canadian studies in which an increase in HIV seroincidence was observed are described on the next two pages with talking points



DRAFT--DRAFT--DRAFT

National Institutes of Health Consensus Development Statement

INTERVENTIONS TO PREVENT HIV RISK BEHAVIORS

February 11-13, 1997

NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the consensus panel and is not a policy statement of the NIH or the Federal Government.

Contents

- ☐ Introduction
- ☐ 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?
- ☐ Conclusions and Recommendations
- ☐ Consensus Development Panel
- ☐ Speakers
- ☐ Planning Committee
- ☐ Conference Sponsors and Cosponsors

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 use of unsafe 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 toward understanding 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 began 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 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 substance abuse treatment programs; community-based organizations; sexually transmitted disease clinics; inner-city health programs reaching disenfranchised high-risk women, men, and adolescents; 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, people, 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?

[Back to Contents](#)

1. 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 transmission of HIV to be unprotected anal and vaginal intercourse, multiple sexual partners, untreated sexually transmitted diseases (STDs), and 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 than anal or vaginal sex for contracting HIV.

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 in the local population, which greatly enhances 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, and use of alcohol and stimulants; 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, minorities, sex workers, and injection drug users; and political and economic policy factors such as laws and regulations, employment opportunities, poverty, 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 a threat mainly for older men. Negotiation about safe sex practices is much more difficult for women where there are cultural barriers to doing so. Programs targeting sex workers have been among the most efficacious in other countries, but in this country are culturally and politically unacceptable. The impact of poverty on seeking treatment for STDs is much greater in countries without universal medical care access. 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 with 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, 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 in order to design tailored interventions that are responsive to the needs and preferences of people in particular communities. In addition, this information can help explain why a particular intervention is not effective for some participants in ways that 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 continuing 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, although a trend for decreased condom use as they get older. Among gay men, the infection rate is

increasing among African-American men and younger men. Injecting drug users (IDUs) are at increased risk because of conditions in their communities, including unavailability of sterile injecting equipment, dealer provision of infected needles, and group situations that encourage needle sharing. Women, particularly women of color, have increased dramatically as a risk group in the United States recently 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 them at risk. Vertical transmission from infected mothers to their infants continues to be a source of high risk for the infant even with treatment available. In addition, a variety of other special settings and groups at increased risk deserve increased attention, including incarcerated youth and adults and the mentally ill.

[Back to Contents](#)

2. 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 entire body of literature, available knowledge converges on a clear conclusion: prevention programs have substantial effects on 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 imposed different criteria for evaluating studies. The most rigorous design used in some areas of research, the randomized controlled trial (RCT), has been used in HIV prevention 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 effects, as do randomized studies. The studies with random assignment to groups have 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, problemsolving, 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 doubling of condom use from 26 percent to 56 percent for all intercourse occasions; no such change occurred for women in the comparison group. Another randomized trial, targeted at pregnant women,

shows similar results at a 6-month followup. Results from another randomized study yet to be published show reductions in unprotected sex and STDs. A study in rural Tanzania involving STD treatment, 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.

Couples. There is evidence that consistent 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 the most rigorous studies. Five RCTs 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 brief, but results were consistently positive.

Injection Drug Users

Prevention for IDUs has involved drug abuse treatment in some cases, and outreach focused on both drug use and on 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 tip the balance away from 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 measures such 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, there were no increases in new drug users after introduction of a needle exchange program.
3. Do programs increase 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, with estimates of a 30 percent or greater reduction of HIV in IDUs. The cost of such programs is relatively low. Such 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 risk behavior. Regulations on the use of condoms by sex workers in Thailand also led to fewer unprotected sex acts. The results produced thus far have been impressive. Given the potential benefit of policy change, these should be implemented as local circumstances allow and should be evaluated as 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 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 infection. Native American and Asian Pacific Islanders have elevated infection rates where population clusters exist. The application of culturally appropriate strategies demands ethnographic research to understand values, attitudes, and behaviors in different communities. Cultural differences 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 hearing-impaired individuals.

Prenatal care and STD clinics have 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 hospitals require special attention.

Maintenance, Generalizability, and Theory

To understand and evaluate the maintenance of behavior change, multivariate, longitudinal studies are necessary. In this way, patterns of behavior change and causal associations can be tested. 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 reliance on self-report, nonequivalence of interventions within a study, absence of attention to personal values, lack of information on nonresponders, and lack of attention to change over time in important aspects of living.

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?

Impact and Cost-Effectiveness

Reviews on HIV prevention conclude that programs produce significant effects, but a statistical advantage may not equate to meaningful change. An example is a study on condom use in more than 13,000 IDUs. An intervention nearly doubled consistent condom use, from a baseline level of 10 percent to 19 percent. Although 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 impact as well as 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, and 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. 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. 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 individuals and communities will react with respect to 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.

Plans to conduct a study of biochemical preventive treatment after sexual exposure to HIV raises questions about risk reduction counseling (e.g., will individuals feel free to engage in risky sex if post-exposure treatment becomes an option?).

Methods now exist to prevent transmission of HIV from mother to newborn child. This accepted prevention approach offers new opportunities to study behavioral issues in a new and important context.

Policy

Current evidence suggests that some of the most powerful 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 a single legislative action permitting the purchase of sterile injection equipment had an immediate and profound 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 and legal change and community mobilization are powerful means of intervention and must be a legitimate area of inquiry at the NIH and CDC.

Several examples beyond the Connecticut experience show the power of policy changes. Australia, for

instance, despite similar population profiles in some areas to areas in the United States with high HIV seroconversion rates, has a low rate of HIV. Cities such as Tacoma, Toronto, Sydney, Glasgow, and Lund have kept the HIV infection rate low, coincident with policies making sterile needles available for IDUs, boosting education aimed at risk reduction, making condoms more available, and enhancing programs for the treatment of STDs. 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. Millions 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 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 approach places policy in direct conflict with science and ignores overwhelming evidence that other programs would be effective. Such 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). At the same time that this knowledge has reached a critical mass, Federal funding of drug treatment programs has been slashed. 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 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 leadership has taken this issue seriously and has prevented even more tragedy from occurring from AIDS.

[Back to Contents](#)

3. 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 IDUs 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.

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 outcome variable for some programs. When practical, ethical, and fiscal barriers make reliance on measured seroconversion undesirable, proxy indices—including other biological markers or modeled estimates of seroincidence based on behavioral outcomes—can be used.

Study Designs That Lend Themselves to Using Seroconversions 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 lend themselves to prevention efforts of this scale.

Many of these studies were conducted in developing countries where incidence is high and policy interventions or community-level programs were 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 IDUs.

Constraints on Using Seroconversion Outcomes

Although seroconversion may be seen as a preferred standard for interventions, other difficulties in using HIV infection as an outcome include the need for consent to draw blood and the high cost of repeat testing. The ethical requirement for pre- and post-test counseling for all participants and treatment for HIV-positive participants greatly increases the complexity and cost of studies. In some cases, newer tests of HIV infection using saliva samples may make HIV tests more acceptable.

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

When HIV seroconversion outcomes are not feasible, well-designed behavioral outcomes have been shown to be 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 functional relationships, a reasonable range of estimates about the probable impact of the intervention on HIV can thus be generated. In theory, estimates of HIV conversion during the study may be extended into the future under varying estimates of the maintenance of the behavioral outcome. The models may also be extended to estimate the potential impact that would ensue if the program were more widely implemented in similar contexts. Finally, potential effects on seroconversion in field settings may be modeled using behavioral outcomes from studies done in research settings, under alternative models of lower effectiveness.

Such 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 population prevalence. We recommend that such estimates be employed as a secondary outcome 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 on 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.

Using Other Biological Markers as Surrogates for HIV Seroconversion

Incidence of certain STDs has been used as a plausible surrogate for HIV seroconversion. The same sexual behaviors are risks for HIV and some STDs. STDs are a powerful potentiator of HIV seroconversion in exposed persons. The higher incidence of STDs also makes detection of program effects more sensitive. In addition to international studies such as the study in Tanzania, two ongoing multicenter RCTs for heterosexual populations have chosen STD incidence as a biologic marker to study the efficacy of HIV prevention interventions. Unpublished results of a CDC project show a decrease in STD rate to be correlated with change in HIV-related risk behavior. Hepatitis B and C have been used effectively as biological markers in studies involving IDU populations, because of overlapping transmission routes. STD incidence, hepatitis incidence, and other infectious disease incidence are reasonable markers for expected HIV exposure.

[Back to Contents](#)

4. How Can Risk-Reduction Procedures Be Implemented Effectively?

Studies Ready for Implementation

Based on current research, a number of interventions have been evaluated and are ready to be implemented within communities. Interventions at the *individual level* include the following:

- ☐ Community outreach, needle exchange activities, and treatment programs for substance-abusing populations
- ☐ Cognitive-behavioral small group, face-to-face counseling, and skills-building (proper condom use) programs for men who have sex with men
- ☐ Cognitive-behavioral small group, face-to-face counseling, and skills building (i.e., negotiation, refusal) programs for women that pay special attention to gender-specific concerns (e.g., child care, transportation, and relationships with significant others)
- ☐ Condom distribution and testing and treatment for STDs for sex workers
- ☐ Cognitive-behavioral psychoeducational skills-building groups for youth and adolescents in various settings.

At the *family or dyad level*, interventions include counseling for couples (including HIV-sero-discordant 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.

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
- ☐ Support for sex education interventions that focus on areas other than abstinence-only programs
- ☐ Lifting constraints on condom availability, for example, in schools and correctional facilities.

Implementation Considerations

Several factors may influence implementation of HIV risk behavior interventions within the United States. Compliance with interventions is improved when targeted individuals are involved at every phase of the process including conceptualization. Input of these individuals is needed to help solve this health crisis. Similarly, programs need to be culturally sensitive, which requires attention not only to ethnicity, race, and language but also to social class, age, developmental stage, and so on.

Another consideration is the selection of the appropriate intervention dose for the population, which 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 (fewer than 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.

When HIV risk behavior interventions are being introduced, it is important to address community myths. 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. Neither 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, these programs address community concerns. IDUs inject less frequently and the number of users decreases; young people tend to delay initiation of intercourse, or, if they are sexually active have fewer partners; and adults engage in fewer incidences of risky sexual behavior. Armed with this knowledge, those who implement programs should consider soliciting the support and involvement of local leaders (e.g., from government, education, religious community).

It must be noted that very little cost analysis information has been provided to guide those in community-based organizations and other practitioners to assist in determining the most cost-effective interventions for implementation. Another barrier to implementation of such interventions is the lack of fiscal resources provided to communities to support such interventions once they are proven successful.

Sufficient training of personnel, monitoring of implementation procedures to ensure fidelity to established methods, and strong evaluation plans are essential components of any implementation strategy. Evaluation results should be reported and widely disseminated in order to advance both science and practice. Newly implemented programs yielding results different from established findings should be compared with original designs, in every aspect level, to explain the variance in outcomes.

The Next Step

Just as the FDA conditionally approves experimental drugs in emergency situations, the urgency of the epidemic justifies selective dissemination of programs at this time. 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 research. First, programs that show strong short-term effects but lack long-term results should be studied to estimate their long-term maintenance of effectiveness. Second, programs that have shown promising effects for only a very narrowly defined range of groups or conditions of implementation should be studied to assess the generalizability of their effectiveness with other populations and in other settings.

Numerous interventions developed by community organizations were not described during the consensus development conference by the researchers, yet were brought to the attention of the panel by community activists and practitioners. As a result, the efficacy of these approaches has not been demonstrated through careful evaluation, which could lead to additional HIV risk interventions. There is a great need for community organizations, practitioners, and program evaluators to work together to further the HIV risk behavior intervention science and practice.

[Back to Contents](#)

5. 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 monitor emerging behavioral risk factors and to aim preventive procedures at these risk factors with as much precision as possible.

Monitoring 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 monitor increases in known behavioral risks, which when combined with sufficiently high HIV prevalence predicts regions of particular vulnerability. Regional strategies are needed for regularly monitoring increases in these behaviors in order to effectively deploy known prevention strategies before seroconversion occurs. Research is needed on how to operate these regional monitoring centers. How can they draw representative samples from the regional populations in ways that are fully acceptable to local communities involved? This regional strategy of risk monitoring can draw on two areas of established research. First, there are clearly established risky behaviors that reliably serve as harbingers of seroconversion. These include behaviors that directly increase the likelihood of HIV transmission such as rates of unprotected sex and needle sharing and the prevalence of conditions 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. What is needed is careful evaluation of the most cost-efficient approaches to regional monitoring, approaches to modifying these strategies to ensure that they are compatible with community values, and resources to maintain these regional monitoring centers at full levels of effectiveness.

Intervention With Young People

The epidemic is currently shifting in the United States to young people, particularly those who are gay and in racial and ethnic minorities. Thus, the U.S. program of research must give highest priority to

providing effective prevention programs to these groups. Programs already shown to be effective for these groups 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 assure fidelity of delivery, continuous evaluation of effectiveness, and modification where required by community needs and circumstances.

HIV-Positive Individuals

Effective interventions with people who are HIV positive can enable them to practice safe sex and safe needle use and thus help to contain the HIV epidemic. There is a startling paucity of well-developed interventions specifically designed for this group. Moreover, as biological treatment for people 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 developments should focus on the effect of community expectations of women and power differentials in their relationships with men. Moreover, additional research on 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 report 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. As evidence is rapidly accumulating on success with these programs, however, legislation has been passed to make provision of these interventions extremely difficult. There is no more urgent need than to understand and 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?

[Back to Contents](#)

Conclusions and Recommendations

1. Interventions are effective for reducing behavioral risk for HIV/AIDS. These interventions should 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; where effectiveness in field settings is reduced, program modifications must be undertaken immediately.

The panel concluded that three approaches are particularly effective for risk in drug abuse behavior: needle exchange programs, drug abuse treatment, and outreach programs for drug abusers not enrolled in treatment. Several programs were deemed to be 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 safe sex. Safe 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 monitoring of changes in behavioral risk is necessary to identify groups and geographical regions with special risk for seroconversion to HIV-positive status. The panel believes that this is a critical part of national strategy to contain the spread of HIV.
4. Preventive programs are essential for individuals already infected with HIV. Programs must be developed to help these individuals eliminate risky sexual and substance abuse behavior. This national priority will become more pressing as new biological treatments prolong life.
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. Such programs are discouraged by welfare reform provisions, which provide support only for programs using abstinence as the only goal.
7. The erosion of funding for drug abuse treatment programs must be halted. Research data are clear that the programs reduce risky drug abuse behavior and often eliminate drug abuse itself. Drug abuse treatment is a central bulwark in the nation's defense against HIV/AIDS.
8. The catastrophic breach between the behavioral science of 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.

[Back to Contents](#)

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 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

[Back to Contents](#)

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 Intervention Research Branch
Division of HIV/AIDS Prevention
Associate Director for Behavioral Science
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
Avondale Estates, 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"
Assistant Professor
Director of Opiate and AIDS Research
Centers 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 Preventing HIV: Rigor or Reality in Study Design"
Sergievsky Professor of Epidemiology
Emeritus and Special Lecturer
Gertrude H. Sergievsky Center
PH-19-112
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

Back to Contents

Planning Committee

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

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

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
Rockville, 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
Avondale Estates, Georgia

Steven W. Gust, Ph.D.
Acting Director
Office on AIDS
National Institute on Drug Abuse
National Institutes of Health
Rockville, 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

Willo Pequegnat, Ph.D.
Associate Director for Behavioral and Neuroscience Research
Office on AIDS
National Institute of Mental Health
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

[Back to Contents](#)

Conference Sponsors

National Institute of Mental Health
Steven E. Hyman, M.D.
Director

Office of Medical Applications of Research, NIH
John H. Ferguson, M.D.
Director

Conference Cosponsors

National Institute of Child Health and Human Development
Duane F. Alexander, M.D.
Director

National Institute of Allergy and Infectious Diseases
Anthony S. Fauci, M.D.
Director

National Institute on Alcohol Abuse and Alcoholism
Enoch Gordis, M.D.

Director

National Institute on Aging

Richard J. Hodes, M.D.

Director

National Institute on Drug Abuse

Alan I. Leshner, Ph.D.

Director

National Institute of Nursing Research

Patricia A. Grady, R.N., Ph.D.

Director

Office of AIDS Research, NIH

William E. Paul, Ph.D.

Director

Office of Research on Women's Health, NIH

Vivian W. Pinn, M.D.

Director

Centers for Disease Control and Prevention

David Satcher, M.D., Ph.D.

Director

Health Resources and Services

Administration

Ciro V. Sumaya, M.D., M.P.H.T.M.

[Back to Contents](#)