

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:

Subseries:

OA/ID Number: 19400

FolderID:

Folder Title:

[Issues] - Needle Exchange [2]

Stack:

S

Row:

66

Section:

6

Shelf:

5

Position:

2

National Organizations Supporting Needle Exchange

AIDS Policy Center for Children, Youth & Families
AIDS Action Council
AIDS Legal Referral Panel
AIDS National Interfaith Network
American Public Health Association
American Academy of Pediatrics
American Foundation for AIDS Research
American Bar Association
American Medical Association
American Psychiatric Association
American Nurses Association
American Civil Liberties Union
American Psychological Association
American Society of Addictive Medicine
American Pharmaceutical Association
Association of Schools of Public Health
Association of State and Territorial Health Officials
Association of Nurses in AIDS Care
Center for Women Policy Studies
Cities Advocating Emergency AIDS Relief
Committee for Children
Gay and Lesbian Medical Association
Harm Reduction Coalition
Human Rights Campaign
Legal Action Center
Mother's Voices United to End AIDS
National Native American AIDS Prevention Center
National Association of People with AIDS
National AIDS Treatment Advocacy Project
National Minority AIDS Council
National Latino/a Lesbian and Gay Organization
National Women's Law Center
National Black Caucus of State Legislators
National Alliance of State and Territorial Health Directors
National Association of County and City Health Officials
National Catholic AIDS Network

National Organizations Supporting Needle Exchange (cont.)

National Council for International Health
National AIDS Fund
National Association of Social Workers
National Black Police Association
National Urban League
National Urban Coalition
National Black Nurses Association
New York Academy of Medicine
North American Syringe Exchange Network
People of Color Against AIDS Coalition
Project Inform
The Drug Policy Foundation
The Honorable Xavier Becerra (D-CA), Chair, Congressional Hispanic Caucus
The Honorable Maxine Waters (D-CA), Chair, Congressional Black Caucus
Title II Community AIDS National Network
United States Conference of Mayors
United Church of Christ, AIDS/HIV Network Leadership Team
Women's AIDS Network

EDITORIAL SUPPORT FOR NEEDLE EXCHANGE

The Washington Post, July 14, 1997

"Study after study shows that exchanges do not promote greater use of illegal drugs... The federal government has a clear and important role in the attack on AIDS and drug abuse. Needle exchange is but a part of a broader effort, but it deserves federal support. It must be accompanied by improved drug-abuse prevention and treatment programs."

Detroit Free Press, September 9, 1997

"Studies in cities with needle exchange programs -- including Tacoma, Baltimore, New Haven and New York -- show a decrease of at least 33 percent in HIV and hepatitis transmission... Almost every needle exchange program also provides referrals for drug treatment... Providing for needle exchange does not mean supporting or encouraging intravenous drug use."

Los Angeles Times, July 8, 1997

"Prohibitions cost lives and money. According to the federal Centers for Disease Control, most of the 41,000 new HIV infections each year occur among injected-drug users and their sexual partners and children. The average cost of lifetime care for those infected with HIV or suffering with AIDS runs about \$120,000, while each sterile needle costs about 10 cents."

The Plain Dealer, April 3, 1997

"Just over two years ago, however, this newspaper took a position related to illegal drugs that we have reconsidered... The facts have overtaken our prior conclusion. Those facts demonstrate that needle exchanges do reduce the incidence of HIV transmission among addicts who inject drugs. Just as important, such programs have not increased drug use."

Chicago Tribune, March 10, 1997

"AIDS is spreading faster among intravenous drug users than in any other group. AIDS has become the leading cause of death in the African-American and Hispanic communities, primarily because of drug use and dirty needles. Most tragically, many of the victims are the babies or innocent sex partners of HIV-infected addicts."

The New York Times, February 22, 1997

"The consistency of [scientific] findings justifies Federal support to help pay for needle exchange programs in communities that need and want them. Unfortunately, the debate continues to focus on politics and morality rather than public health needs."

The Seattle Times, July 23, 1997

"Secretary Shalala has the power to lift the ban. Unless misguided lawmakers attempt to interfere with her duties, she can clear the way for use of federal funds for needle exchanges in those communities that seek them. Standing in the way of this proven strategy to reduce HIV infections is folly."

QUESTIONS and ANSWERS: NEEDLE EXCHANGE

At a needle exchange program, injection drug users bring their used equipment to a known exchange site and trade their dirty syringes for clean equipment. Syringes are dispensed on a one-for-one basis only, thus encouraging participants to return all equipment and not increasing the number of needles discarded and available on the streets. Used syringes are disposed of in accordance with established biohazardous waste standards. Needle exchange programs are intended to prevent the spread of the HIV virus and other blood-borne illnesses, such as hepatitis B and C, among injection drug users and, therefore, their sexual partners and children. Equally important as the actual exchange of syringes is the opportunity for outreach workers to provide participants with updated information and referrals regarding medical and social services in the community related to both drug treatment and HIV medical care and support services.

? Does needle exchange reduce the number of HIV infections?

Yes. Scientific study after scientific study has shown that needle exchange reduces the number of new HIV infections. Six federally funded reports, conducted independently by: the National Commission on AIDS in 1991, the General Accounting Office in 1993, the University of California in 1993, the Centers for Disease Control and Prevention (CDC) in 1993, the National Academy of Sciences in 1995 and the Office of Technology Assessment in 1995 are among those scientific studies. Studies show that needle exchange programs can reduce HIV infections by at least one-third and reduce risk behavior by as much as 80%.

? Does needle exchange increase drug use?

No. Scientific study after scientific study has shown that needle exchange does not increase drug use when conducted with referrals to both drug treatment and HIV medical care and support services. The same six federally funded reports (listed above) found that needle exchange programs do not increase drug use and that needle exchange programs do reduce new HIV infections.

? Does needle exchange increase crime?

No. In fact, needle exchange may ultimately result in diminishing drug-related crime. If needle exchange programs are able to link drug users with drug treatment, the number of individuals using drugs may decrease, thereby reducing demand for drugs. Decreased demand for drugs can contribute to decreased drug-related crime, and therefore, increased public safety.

? Does needle exchange increase the number of contaminated syringes on the streets?

No. Needle exchange programs actually encourage individuals to retrieve dirty needles from the streets to trade them in at the needle exchange site. In fact, the discarding of used, infectious needles on the streets was virtually eliminated due to needle exchange in New Haven, according to a US Conference of Mayors report. Eliminating needles on the streets can reduce the risk of accidental needle sticks to children and others. Law enforcement officials report that "pat downs" of those individuals participating in a needle exchange program are less likely to result in needle sticks because syringes are more likely to be capped.

? How can needle exchange help a community?

The CDC reports that more than 33% of all AIDS cases are among injection drug users, their partners and children, and the numbers continue to climb. Over 63% of AIDS cases among women are related to injection drug use and over 50% of AIDS cases among children are attributable to injection drug use by their parents, according to the CDC. Because AIDS cases are growing fastest among these vulnerable populations, needle exchange should be an option for local communities to utilize as part of a comprehensive HIV prevention plan. In San Francisco, needle exchange, coupled with effective prenatal HIV intervention, has been credited with eliminating pediatric AIDS for the past two years. Results like this show that needle exchange can directly reduce HIV infection among drug users, their partners and children.

? Do Americans support needle exchange?

Yes. Two recent national surveys indicate that a majority of voters support needle exchange, and a Kaiser Family Foundation survey in March, 1996 found that 66% of Americans support such programs. At least 100 needle exchange programs, in both fixed and mobile sites, currently operate in the United States. Local communities have developed and implemented needle exchange programs which operate in a manner appropriate to the community standards and norms of the locale.

? What is our current federal policy on needle exchange?

At this time, there are three separate and distinct prohibitions on needle exchange programs at the federal level -- in the Ryan White CARE Act authorization; in the Substance Abuse and Mental Health Services Administration (SAMHSA) authorization; and in the FY 1997 Labor-Health and Human Services (HHS)-Education appropriations legislation. The prohibition in the Labor-HHS appropriations legislation not only applies to the Ryan White and SAMHSA authorizations, but also to HIV prevention funding at the CDC. The Labor-HHS appropriations legislation prohibits needle exchange "unless the Secretary of Health and Human Services determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs."

? What should the federal government do regarding needle exchange?

The Secretary of Health and Human Services, in recognition of the overwhelming scientific evidence that needle exchange is effective in preventing the spread of HIV and does not increase the use of illegal drugs, should exercise the waiver authority provided under the FY 1997 Labor-HHS appropriations legislation. Once the federal prohibition is removed, resources should be made available, if desired, so that state and local public health officials may utilize appropriate federal resources for needle exchange as part of a community's comprehensive HIV prevention plan.

GENERAL INFORMATION: NEEDLE EXCHANGE PROGRAMS

- **Basic explanation of a needle exchange program**
- **Scientific evidence supporting needle exchange**
- **Public health and safety issues related to needle exchange**
- **Broad-based support for needle exchange**
- **How needle exchange can help a community**
- **Current federal policy on needle exchange**

What is a needle exchange program?

Needle exchange programs are intended to prevent the spread of the HIV virus and other blood-borne illnesses, such as hepatitis B and C, among injection drug users and, therefore, their sexual partners and children. Individuals bring their used syringes, anonymously or confidentially, to an exchange site and receive one sterile syringe for each used syringe exchanged. Syringes are dispensed on a one-for-one basis only, thus encouraging participants to return all equipment and not increasing the number of needles discarded and available on the streets. Used syringes then are disposed of in accordance with established biohazardous waste standards.

Equally important as the actual exchange of syringes is the opportunity for outreach workers to provide participants with updated information regarding medical and social services in the community related to both drug treatment and HIV services. Needle exchange allows for individuals, particularly in traditionally hard-to-reach populations, to reduce the harm associated with their addiction until adequate assistance is available. Over 100 needle exchange programs, in both fixed and mobile sites, are currently operating in the United States. Local communities have developed and implemented needle exchange programs which operate in a manner appropriate to the community standards and norms of the locale.

Scientific research supports needle exchange.

Scientific study after scientific study has shown that needle exchange reduces the number of new HIV infections. Six federally funded reports, conducted independently by: the National Commission on AIDS in 1991, the General Accounting Office in 1993, the University of California in 1993, the Centers for Disease Control and Prevention (CDC) in 1993, the National Academy of Sciences in 1995 and the Office of Technology Assessment in 1995 are among those scientific studies. Studies show that needle exchange programs can reduce HIV infections by at least one-third, reduce risk behavior by as much as 80% and do not increase drug use.

In response to a request in the FY 1997 Senate Labor, Health and Human Services (HHS), Education and Related Agencies Appropriations report, HHS Secretary Donna Shalala recently released a report detailing scientific evidence related to the efficacy of needle exchange programs. The report states that, "Needle exchange programs can have an impact on bringing difficult to reach populations into systems of care that offer drug dependency services, mental health, medical and support services. These studies also indicate that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood-borne infectious diseases in communities that choose to include them."

Needle exchange programs support public health and public safety.

Needle exchange programs contribute significantly to public health by reducing HIV infections by at least one-third, by reducing risk behavior by as much as 80%, and by not increasing drug use. Needle exchange programs can serve as a "bridge" to treatment -- a critical component of a comprehensive approach to HIV care and prevention in a community. Needle exchange programs have been found to have a positive impact on bringing drug users, a hard-to-reach population, into systems of care that offer drug treatment, mental health services, medical care and support services. Indeed, needle exchange may have the effect of reducing the number of people who use illicit drugs; although this goal is compromised where there are not enough resources in a community for an individual to access drug treatment immediately, if desired. Because demand for drug treatment currently exceeds available slots, it is all the more necessary to continue to provide needle exchange to slow the spread of HIV until an individual is able to access treatment.

Needle exchange programs can contribute significantly to increased public safety from accidental needle sticks as well as drug-related crime. For example, the discarding of used, infectious needles on the streets was virtually eliminated in New Haven, according to a U.S. Conference of Mayors report. Eliminating needles on the streets can reduce the risk of accidental needle sticks to children and others. Law enforcement officials report that "pat downs" of participants in needle exchange programs are less likely to result in needle sticks because syringes are more likely to be capped. Additionally, if needle exchange programs are able to link drug users with drug treatment, the number of individuals using drugs may decrease, thereby reducing demand for drugs. Decreased demand for drugs can contribute to decreased drug-related crime, therefore increasing public safety.

Broad-based support exists for needle exchange programs.

Two recent national surveys indicate that a majority of voters support needle exchange, and a Kaiser Family Foundation survey in March, 1996 found that 66% of all Americans support such programs. Dr. Harold Varmus, Director of the National Institutes of Health (NIH), as well as a consensus panel convened by NIH, have endorsed needle exchange programs as an effective means of HIV prevention. The American Medical Association, the U.S. Conference of Mayors, the American Nurses Association and the American Public Health Association, among many other national organizations, also support needle exchange as a means to prevent HIV disease. Many newspapers, including: The New York Times; The Washington Post; The Chicago Tribune; The Los Angeles Times; and The Plain Dealer, examined the scientific research on the efficacy of needle exchange and have published editorials endorsing its effectiveness.

In many local communities where needle exchanges operate, effective public-private partnerships have been forged to address the twin epidemics of HIV infection and drug use. Awareness and understanding of the goals of needle exchange among community members can enhance overall public health and public safety. Local communities that have conducted needle exchange programs agree that, ideally, this public-private partnership should be developed among all community leaders, including local elected officials, public health officers, community-based HIV and drug treatment providers, law enforcement agencies, churches and businesses. Education and information-sharing among these groups about the public health and public safety benefits of needle exchange have created broad-based support in local communities across the nation.

Needle exchange programs can help communities.

From a moral perspective, preventing HIV in the communities where it is growing the fastest is a highly laudable goal, both for the protection of drug users as well as their families, partners and children. From a public health perspective, needle exchange is an imperative measure -- the CDC reports that more than 33% of all AIDS cases are among these vulnerable populations. Over 63% of AIDS cases among women are related to injection drug use and over 50% of AIDS cases among children are attributable to injection drug use by their parents, according to the CDC. In San Francisco, needle exchange, coupled with effective prenatal HIV intervention, has been credited with eliminating pediatric AIDS for the past two years. Results like this show that needle exchange is an effective tool in HIV prevention among drug users, their partners and children.

From a fiscal perspective, needle exchange programs also make sense. The average lifetime cost of treating an individual with HIV disease has been estimated to be at least \$119,000. These costs may skyrocket due to new and more effective treatments that are available, including protease inhibitors. In sharp contrast, one sterile needle generally costs less than 10 cents.

What is the current federal policy regarding needle exchange?

At this time, there are three separate and distinct prohibitions on needle exchange programs at the federal level -- in the Ryan White CARE Act authorization; in the Substance Abuse and Mental Health Services Administration (SAMHSA) authorization; and in the FY 1997 Labor-Health and Human Services (HHS)-Education Appropriations legislation. The CARE Act prohibits any funds to be provided to purchase syringes for use with illegal drugs. The SAMHSA authorization prohibits SAMHSA state block grant funding for needle exchange programs unless the Administration determines that they reduce the incidence of HIV and also decrease drug use. The Labor-HHS legislation prohibits the use of federal resources for needle exchange "unless the Secretary of Health and Human Services determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs." The prohibition in the Labor-HHS appropriations legislation not only applies to the Ryan White and SAMHSA funding, but also to HIV prevention funding at the CDC.

s:\shared\document\nep\apr-jun\gentpts.708

Statements/Resolutions/Policies on Increased Access to Clean Needles and Syringes

American Medical Association

H95.958 Syringe and Needle Exchange Programs

The AMA encourages needle exchange programs

American Medical Association A Physician Guide to HIV Prevention

Primary care physicians can help their patients reduce HIV risk from injecting drugs by encouraging their patients to...

- Abstain from using drugs and to seek treatment.
- Use a new needle and syringe each time drugs are injected.
- Have their own personal injection equipment that is never shared.
- Share only needles and syringes that have been correctly cleaned.
- Use condoms with sex partners who share injection equipment.

Resolution 435 - Needle and Syringe Exchange Programs

...That the AMA encourage the extensive application of needle and syringe exchange and distribution programs and the modification of restrictive laws and regulations concerning the sale and possession of needles and syringes to maximize the availability of sterile syringes and needles, while ensuring continued reimbursement for medically necessary needles and syringes. The need for such programs and modification of laws and regulations is urgent, considering the contribution of injection drug use to the epidemic of HIV infection.

That the AMA initiate and support legislation revoking the 1988 federal ban on funding for needle exchange programs for injecting drug users.

That the AMA strongly encourage state medical associations to initiate state legislation modifying drug paraphernalia laws so that injection drug users can purchase and possess needles and syringes without a prescription.

American Academy of Pediatrics

Reducing the Risk of Human Immunodeficiency Virus Infection Associated With Illicit Drug Use, Pediatrics, December 1994, Provisional Committee on Pediatric AIDS

Conclusions and Recommendations:

The adverse consequences of illicit drug use are multiple and are a major factor in the spread of HIV infection to infants, children, and adolescents. The American Academy of Pediatrics believes that initiatives to address these consequences should include:

- 1) preventing illicit drug use, the ready availability of treatment to individuals who are drug users, and reducing the risk associated with continued drug use.
- 2) programs that improve knowledge about decontamination of injection equipment and provide access to sterile injection equipment thereby can reduce the spread of HIV and prevent new cases of AIDS. These programs should be encouraged and expanded; linked to drug treatment; and conducted within the context of continuing research to document effectiveness and clarify those factors that contribute to desired outcomes.
- 3) a reassessment of laws regarding the possession of needles, syringes, and bleach from a public health perspective with attention to both the desire to minimize the potential that such statutes might discourage individuals from engaging in risk-reducing behavior, and the continuing goal of discouraging illicit drug use.

American Foundation for AIDS Research

February 1997 Letter to President Clinton

The ethical imperative to provide sterile injection equipment to intravenous drug users is strongly supported by the nation's foremost bioethicists : Consensus Statement "On the Ethics of Denying Injection Drug Users Access to Sterile Injection Equipment"

...These principles inform our conclusion that the failure to fund needle exchange efforts, with the predictable loss of life that can be traced to HIV infections that might have been averted, is ethically unacceptable.

...We believe that a failure to lift the federal ban on funding of needle exchange programs represents a policy that will consign thousands of men, women and children to early deaths. By every principle of medical ethics this situation calls out for a change.

American Public Health Association

9515: Syringe and Needle Exchange and HIV Disease
therefore

1. Urges both Congress and the executive branch take positive steps to support syringe and needle exchange programs;
2. Urges state and local governments to take steps to improve drug users' access to clean injection equipment (e.g. through decriminalizing possession of injection equipment and institution of needle and syringe exchange programs) and to ensure that such programs complement the drug abuse treatment system; and
3. Urges further evaluation of programs to provide sterile injection equipment.

Association of State and Territorial Health Officials

Policy Statement: Needle Exchange

ASTHO promotes the following policy:

- ... Therefore ASTHO recommends that drug users who continue to inject should be advised of the following guidelines for reducing their risk of infection with injection-related blood-borne infections: Use a new sterile syringe to prepare drugs for injection; Only use clean or never-before-used "cookers and "cotton" in preparing drugs; Use clean water from a reliable source (tap water) and, if possible, sterile water for preparing drugs; Clean the injection site prior to injection with a new alcohol swab; Use a new sterile syringe to inject drugs; Use only syringes obtained from a safe, reliable source (e.g., pharmacy or syringe exchange); Never re-use or share syringes or drug preparation equipment; Safely dispose of syringes after one use.)

- As this nation's lead public health authority, the U.S. Public Health Service should provide in writing clear policy statements regarding the importance of sterile needles and syringes for injection drug users who continue to inject and clear advice to interested states on 1) how to increase access to sterile needles and syringes and 2) to deregulate possession of needles and syringes.

- The federal government should not restrict the use of federal funds for needle exchange services to also interested states and localities the financial flexibility to support successful prevention and treatment initiatives within their jurisdiction.

- As a possible public health strategy to reduce the transmission of injection-related blood-borne infections, states should explore the removal of legal barriers such as drug paraphernalia and prescription laws, which criminalize the distribution and/or possession of needles and syringes.

- States with needle exchange programs should continue development of state and local syringe exchange programs incorporating a strong evaluation component and disseminating the results of the evaluation research to the public health community. Interested states should develop and implement procedures to identify process, outcome and cost-effectiveness evaluation measures to assess the effectiveness of increased needle access.

- State health departments should explore conducting educational programs with pharmacists, police and members of the legal system about the public health importance of sterile syringes for drug users who continue to inject.

- States should provide leadership strategies to increase access to sterile needles and syringes in communities where such strategies are deemed an important component of the public health approach to reducing injection related blood borne infections. Such leadership could include community/provider education and outreach, as well as financial support for successful community based programs.

- Any strategy, whether developed at the federal, state, or local level, should make a good faith effort to include in the planning and implementation processes members of those communities affected/infected by injection related blood borne infections.

National Alliance of State and Territorial AIDS Directors

NASTAD Resolution

Action to Reduce the Transmission of HIV and Other Diseases Through Increased Access to clean Needles and Syringes

Therefore, be it resolved that:

NASTAD calls upon legislative bodies in the US to increase access to sterile needles and syringes and deregulate possession of needles and syringes and other drug paraphernalia as well as increase access to drug treatment for those individuals ready for such treatment.

NASTAD calls upon federal, state and local agencies carrying out HIV prevention programs to encourage injection drug users who continue to inject: to always use sterile needles and syringes obtained from a reliable source (i.e. pharmacy or syringe exchange program) to prepare and inject drugs; to use new cookers, cotton and water each time; and to safely dispose of injection equipment and other materials after one use.

NASTAD encourages each state health department to work with pharmacy boards and police organizations to convince them of the public health importance of sterile injection equipment for injection drug users who continue to inject, and to work together to increase access to sterile injection equipment and for deregulation of possession of needles and syringes.

NASTAD calls on the Department of Health and Human Services to provide in writing clear policy statements regarding the importance of sterile needles and syringes for injection drug users who continue to inject, and clear advice to states to change laws to increase access to sterile needles and syringes and to deregulate possession of needles and syringes. The Department is encouraged to expand resources for drug treatment and to facilitate linkages between syringe exchanges and treatment, health, and social service agencies.

National Black Caucus of State Legislators

Resolution 97-09 Support for Needle Exchange Programs to Limit the Rate of HIV Infection

Be it Further Resolved, that in the face of mounting positive evidence NBCSL calls on Congress to lift the ban on the use of federal funds for needle exchange programs; and

Be it Finally Resolved, that NBCSL calls upon legislative bodies throughout the country to amend drug paraphernalia and prescription requirements in consultation with their state public health authorities to allow greater access to sterile needle and syringes for those addicted to injection drugs.

New York Academy of Medicine

Report of the Academy Committee on Medicine in Society

Legal barriers to obtaining sterile needles and syringes should be removed. We support the enactment of the New York State legislative proposal to permit the sale by pharmacies of hypodermic needles and syringes without a prescription, and to deregulate the distribution and possession of sterile needles and syringes as a cost-effective approach to preventing HIV transmission.

We support increasing the availability of needle exchange programs to all those who seek such services; these programs should incorporate into their outreach services education on the proper disposal of needles. The State Legislature should substantially increase appropriations for state-sponsored needle exchange programs to \$7 million in order to expand capacity at the state's eleven existing programs, develop new programs, and increase the availability of supplies necessary to implement needle exchange. In addition, we advocate rescinding the present ban on utilizing federal funds for needle exchange programs and research.

U.S. Conference of Mayors

Resolution No.26: Rationale for Needle Exchange Programs
65th Annual Conference of Mayors Meeting June, 1997

Now, Therefore, Be It Resolved, that the Secretary of the Department of Health and Human Services, in recognition of the overwhelming scientific evidence that needle exchange is effective in preventing the spread of HIV and does not increase the use of illegal drugs, exercise the waiver authority provided under the FY1997 Labor, Health and Human Services, Education and Related Agencies appropriations legislation; and

Be It Further Resolved, that needle exchange is only one, vital component of a comprehensive HIV prevention program, including information, medical treatment, substance abuse treatment and a broad range of complementary social services necessary to prevent the spread of HIV; and

Be It Further Resolved, that state and local public health officials, consistent with the scientific and public health evidence supporting needle exchange as an effective HIV prevention tool, may utilize appropriate Federal resources for needle exchange programs, as a part of a community's comprehensive HIV prevention plan.

July 1997

AMERICAN BAR ASSOCIATION
SECTION OF INDIVIDUAL RIGHTS AND RESPONSIBILITIES
CRIMINAL JUSTICE SECTION
STANDING COMMITTEE ON SUBSTANCE ABUSE
COMMISSION ON HOMELESSNESS AND POVERTY
COMMISSION ON MENTAL AND PHYSICAL DISABILITY LAW
NATIONAL LESBIAN AND GAY LAW ASSOCIATION

RECOMMENDATION

RESOLVED, That in order to further scientifically based public health objectives to
reduce HIV infection and other blood-borne diseases, and in support of our long-standing
opposition to substance abuse, the American Bar Association supports the removal of
legal barriers to the establishment and operation of approved needle exchange programs
that include a component of drug counseling and drug treatment referrals.

1
2
3
4
5

REVISED DRAFT*

02/14/97 - 1:00 pm



NATIONAL INSTITUTES OF HEALTH
CONSENSUS DEVELOPMENT CONFERENCE 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 panel and is not a policy statement of the NIH or the Federal Government.

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

* The final version of this statement is generally available 6-8 weeks following the date of the conference.

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 1½ 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?

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.

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.

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.

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

1 interventions is the lack of fiscal resources provided to communities to support such
2 interventions once they are proven successful.
3

4 Sufficient training of personnel, monitoring of implementation procedures to ensure
5 fidelity to established methods, and strong evaluation plans are essential components of any
6 implementation strategy. Evaluation results should be reported and widely disseminated in
7 order to advance both science and practice. Newly implemented programs yielding results
8 different from established findings should be compared with original designs, in every aspect
9 level, to explain the variance in outcomes.
10

11 The Next Step

12
13 Just as the FDA conditionally approves experimental drugs in emergency situations, the
14 urgency of the epidemic justifies selective dissemination of programs at this time. A critical
15 issue that must be addressed involves the criteria for choosing interventions most ready for
16 implementation in the community. The most obvious is evidence of strong program effects
17 observed under rigorous, controlled research conditions. Among programs with strong
18 effects, priority should be given to interventions that can be delivered with high reliability and
19 fidelity to the original program model. Usually such programs do not require significant new
20 demands or elaborate training at the delivery site.
21

22 At this next stage there will nevertheless be programs that show promise but still require
23 additional research to ensure their effectiveness. At least two criteria should be considered in
24 choosing promising programs for further research. First, programs that show strong short-term
25 effects but lack long-term results should be studied to estimate their long-term maintenance of
26 effectiveness. Second, programs that have shown promising effects for only a very narrowly
27 defined range of groups or conditions of implementation should be studied to assess the
28 generalizability of their effectiveness with other populations and in other settings.
29

30 Numerous interventions developed by community organizations were not described
31 during the consensus development conference by the researchers, yet were brought to the
32 attention of the panel by community activists and practitioners. As a result, the efficacy of
33 these approaches has not been demonstrated through careful evaluation, which could lead to
34 additional HIV risk interventions. There is a great need for community organizations,
35 practitioners, and program evaluators to work together to further the HIV risk behavior
36 intervention science and practice.
37

38 5. What Research Is Most Urgently Needed?

39
40 The most urgently needed research is that which is essential for containing the HIV/AIDS
41 epidemic. In particular, we need to monitor emerging behavioral risk factors and to aim
42 preventive procedures at these risk factors with as much precision as possible.
43

44 Monitoring Emerging Risk

45
46 A most urgent area for research is in developing improved methods of identifying emerging
47 risks within large populations. For example, in the United States we need to know as early as
48 possible what settings, regions, and subpopulations are likely to show increases in
49 seroconversion to HIV. The best strategy for this identification is to monitor increases in *known*
50 *behavioral risks*, which when combined with sufficiently high HIV prevalence predicts regions
51 of particular vulnerability. Regional strategies are needed for regularly monitoring increases in
52 these behaviors in order to effectively deploy known prevention strategies before seroconversion
53 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?

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.

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
Yale University
Department of Psychology
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
University of Washington
Outpatient Psychiatry Center
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

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

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
 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
 Avondale Estates, 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 Kytle, 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

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.
Administrator

ABOUT THE NIH CONSENSUS DEVELOPMENT PROGRAM

NIH Consensus Development Conferences are convened to evaluate available scientific information and resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public.

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 panel and is not a policy statement of the NIH or the Federal Government.

Statement Availability

Preparation and distribution of this statement is the responsibility of the Office of Medical Applications of Research of the National Institutes of Health. Free copies of this statement and bibliographies prepared by the National Library of Medicine are available from the Office of Medical Applications of Research, National Institutes of Health, or the NIH Consensus Program Information Center by 24-hour voice mail. In addition, free copies of all other available NIH Consensus Statements and NIH Technology Assessment Statements may be obtained from the following resources:

NIH Consensus Program Information Center
P.O. Box 2577
Kensington, MD 20891
Telephone: 1-888-NIH-CONSENSUS (888-644-2667)
Fax: (301) 816-2494

NIH Office of Medical Applications of Research
Federal Building, Room 618
7550 Wisconsin Avenue MSC 9120
Bethesda, MD 20892-9120

Internet
World Wide Web
<http://consensus.nih.gov>

FTP
<ftp://public.nlm.nih.gov/hstat/nihcdcs>

Gopher
<gopher://gopher.nih.gov/Health and Clinical Information>



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FEB 18 1997

The Honorable Arlen Specter
Chairman
Subcommittee on Labor, Health
and Human Services, and Education
Committee on Appropriations
United States Senate
Washington, D.C.

Dear Senator Specter:

In accordance with the request of the Committee included in Senate Report 104-368, I am transmitting the enclosed report reviewing completed and ongoing research on the efficacy of needle exchange programs in reducing HIV transmission and their impact on illegal drug use.

A number of communities have established outreach programs for out-of-treatment drug users to get them into treatment and to get them to reduce high risk sexual and drug using behaviors. Needle exchange programs have also been developed in many communities to reach injecting drug users who are not in treatment and to reduce the transmission of hepatitis and HIV through the reduction of drug use behaviors and unsafe injection practices.

The intravenous use of illegal drugs is wrong and is clearly a major public health problem as well as a law enforcement concern. Among the many secondary health consequences of injection drug use are the transmission of hepatitis, HIV and other bloodborne diseases. The Department supports a range of activities to cope with these public health issues, from basic research supported by the National Institute on Drug Abuse to substance abuse prevention and treatment programs at the community level.

HIV disease is also an urgent public health problem in our Nation as the leading cause of death among adults age 25-44, and the seventh leading cause of death for all Americans. Injecting drugs with nonsterile equipment is one of three key risk factors for HIV infection, along with unprotected sexual intercourse and untreated sexually transmitted diseases. Unsafe drug injection is the second most frequently reported risk behavior for HIV infection, accounting for a growing proportion of new HIV infections among users, their sexual partners and their children. To realize our goal of effective HIV prevention, it is vital that we identify and evaluate sound public health strategies to address the twin epidemics of HIV and substance abuse.

Page 2 - The Honorable Arlen Specter

The Department has played an important role in supporting evaluations of needle exchange programs as they impact HIV transmission and patterns of drug use. As requested, this report provides the Committee with the findings of published studies conducted in our country, and a description of current research and interim findings where these are available.

Sincerely,

A handwritten signature in cursive script, appearing to read "Donna E. Shalala".

Donna E. Shalala



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FEB 18 1997

The Honorable Tom Harkin
Ranking Minority Member
Subcommittee on Labor, Health
and Human Services, and Education
Committee on Appropriations
United States Senate
Washington, D.C.

Dear Senator Harkin:

In accordance with the request of the Committee included in Senate Report 104-368, I am transmitting the enclosed report reviewing completed and ongoing research on the efficacy of needle exchange programs in reducing HIV transmission and their impact on illegal drug use.

A number of communities have established outreach programs for out-of-treatment drug users to get them into treatment and to get them to reduce high risk sexual and drug using behaviors. Needle exchange programs have also been developed in many communities to reach injecting drug users who are not in treatment and to reduce the transmission of hepatitis and HIV through the reduction of drug use behaviors and unsafe injection practices.

The intravenous use of illegal drugs is wrong and is clearly a major public health problem as well as a law enforcement concern. Among the many secondary health consequences of injection drug use are the transmission of hepatitis, HIV and other bloodborne diseases. The Department supports a range of activities to cope with these public health issues, from basic research supported by the National Institute on Drug Abuse to substance abuse prevention and treatment programs at the community level.

HIV disease is also an urgent public health problem in our Nation as the leading cause of death among adults age 25-44, and the seventh leading cause of death for all Americans. Injecting drugs with nonsterile equipment is one of three key risk factors for HIV infection, along with unprotected sexual intercourse and untreated sexually transmitted diseases. Unsafe drug injection is the second most frequently reported risk behavior for HIV infection, accounting for a growing proportion of new HIV infections among users, their sexual partners and their children. To realize our goal of effective HIV prevention, it is vital that we identify and evaluate sound public health strategies to address the twin epidemics of HIV and substance abuse.

Page 2 - The Honorable Tom Harkin

The Department has played an important role in supporting evaluations of needle exchange programs as they impact HIV transmission and patterns of drug use. As requested, this report provides the Committee with the findings of published studies conducted in our country, and a description of current research and interim findings where these are available.

Sincerely,

A handwritten signature in cursive script, appearing to read "Donna E. Shalala".

Donna E. Shalala

REPORT TO THE COMMITTEE ON APPROPRIATIONS
FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION AND RELATED AGENCIES

NEEDLE EXCHANGE PROGRAMS IN AMERICA:
REVIEW OF PUBLISHED STUDIES AND ONGOING RESEARCH

DONNA E. SHALALA
SECRETARY OF HEALTH AND HUMAN SERVICES
FEBRUARY 18, 1997

REPORT TO THE COMMITTEE ON APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES

NEEDLE EXCHANGE PROGRAMS IN AMERICA: REVIEW OF PUBLISHED STUDIES AND ONGOING RESEARCH

Introduction

On September 12, 1996, the Committee on Appropriations for the Departments of Labor, Health and Human Services, Education and Related Agencies made the following request of the Department of Health and Human Services:

"The Committee understands the Department is continuing to support research, reviewing the effect of clean needle exchange programs on reducing HIV transmission, and on whether such programs encourage illegal drug use. The Committee requests that the Secretary provide a report by February 15, 1997 on the status of current research projects, an itemization of previously supported research, and the findings to date regarding the efficacy of needle exchange programs for reducing HIV transmission, and not encouraging illegal drug use." Senate Report 104-368, p.68

In response to the Committee's request, this report provides an overview of the current status of knowledge regarding needle exchange programs (NEPs) with a compilation of relevant reviews and abstracts pertinent to the issues of efficacy of NEPs in reducing HIV transmission and their effect on utilization of illegal drugs. In reviewing the body of literature gathered, it is important to note the wide range of methodologic approaches utilized and the impact of these study design choices on the conclusions drawn. For example, studies varied significantly in terms of study populations, survey instruments, and assumptions made in the design of mathematical models used to predict seroincidence and seroprevalence. Given the significantly different design elements, making comparisons or drawing conclusions across studies requires an understanding of these complexities.

In the Department's assessment, providing the findings and conclusions from specific studies without benefit of the context of their specific methodologies would not facilitate a sound understanding of this issue, as the nature of the findings is not consistent. For these reasons, the original reviews and source documents with their discussions of methodological issues are being provided to the Committee for consideration along with the findings and conclusions. The data presented are limited to published studies conducted in the United States, consistent with the approach taken by the National Academy of Sciences, as the legal and cultural

environments of other countries differ sufficiently enough to raise questions about whether the conclusions are applicable to the United States.

The report is presented in four parts. Part One provides a review of completed studies and published abstracts addressing the efficacy of needle exchange programs for reducing HIV transmission and their effect on illegal drug use. Several major reviews, including a report by the National Research Council/Institute of Medicine (NRC/IOM) analyzes those studies published prior to 1995; subsequent studies are identified individually. Part Two describes the status of federally supported evaluation studies of needle exchange programs, with preliminary findings noted where these are available. Part Three provides the results of a national survey of State and local regulation of syringes and needles. Part Four is a set of Appendices which include the reviews of needle exchange programs described in Part One, two studies published since the NRC/IOM review, and relevant abstracts presented at the XI International AIDS Conference in Vancouver, BC in July, 1996.

I. Review of Published Studies

Three reviews of the literature on needle exchange programs have been commissioned by the federal government: (1) Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy, United States General Accounting Office, March 1993; (2) The Public Health Impact of Needle Exchange Programs in the United States and Abroad, prepared by the faculty and research staffs of the San Francisco and Berkeley campuses of the University of California for the Centers for Disease Control and Prevention, U.S. Public Health Service, in September 1993; and (3) Preventing HIV Transmission: The Role of Sterile Needles and Bleach, National Research Council and Institute of Medicine, September 1995.

Report of the U.S. General Accounting Office

The U.S. General Accounting Office (GAO) was requested by the Chairman of the House Select Committee on Narcotics Abuse and Control to: (1) review the results of studies addressing the effectiveness of needle exchange programs in the United States and abroad, (2) assess the credibility of a forecasting model developed at Yale University that estimates the impact of a needle exchange program on the rate of new HIV infections, and (3) determine whether federal funds can be used in support of studies and demonstrations of needle exchange programs.

The GAO conducted a literature review and site visits to two needle exchange programs. While the GAO noted that there were 32 known needle exchange programs in operation in 27 different U.S. cities or counties, their staff visited only those programs located in Tacoma, Washington and New Haven, Connecticut. Needle exchange programs studied by GAO were located in Australia (1), Canada (1), Netherlands (2), Sweden (1), United Kingdom (3), and the United States (1).

The full report with data from nine needle exchange programs and GAO findings are provided at Appendix A. The Results in Brief are abstracted below:

"Measuring changes in needle sharing behaviors is an indicator often used to assess the impact of needle exchange programs on HIV transmission. We identified nine needle exchange projects that had published results. Only three of these reported findings that were based on strong evidence. Two of these three reported a reduction in needle sharing while a third reported an increase.

One concern surrounding needle exchange programs is whether they lead to increased injection drug use. Seven of the nine projects looked at this issue, and five had strong evidence for us to report on outcomes. All five found that drug use did not increase among users; four reported no increase in frequency of injection and one found no increase in the prevalence of use. None of the studies that addressed the question of whether or not the needle exchange programs contributed to injection drug use by those not previously injecting drugs had findings that met our criteria of strong evidence. Our review of the projects also found that seven reported success in reaching out to injection drug users and referring them to drug treatment and other health services.

We also found the forecasting model developed at Yale University to be credible. This model estimated a 33 percent reduction in new HIV infections among New Haven, Connecticut, needle exchange program participants over 1 year. Based on our expert consultant review, we found the model to be technically sound, its assumptions and data values reasonable and the estimated 33 percent reduction in new HIV infections defensible. This reduction stems from the program's ability to lessen the opportunity for needles to become infected, to be shared, and to infect an uninfected drug user. To gather data in assessing program impact for use in the New Haven model, the researcher developed a new system for tracking and testing for HIV in returned needles.

While these findings suggest that needle exchange programs may hold some promise as an AIDS prevention strategy, HHS is currently restricted from using certain funds to directly support the funding of needle exchange programs. Under the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, block grant funds authorized by title XIX of the PHS Act may not be used to carry out any needle exchange program unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. However, HHS does have the authority to conduct demonstration and research projects that could involve the provision of needles." Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy, GAO/HRD-93-60, pages 3-4.

Report of the University of California

Under a contract with the Centers for Disease Control and Prevention (CDC), faculty of the University of California, at Berkeley and San Francisco, undertook a review and analysis of the literature on needle exchange programs to answer a set of 14 research questions, including the effect of needle exchange programs on HIV infection rates and prevention of HIV infection and effect on drug using behavior. At the time this study, 37 active needle programs were known to exist in the U.S.; the 33 programs which were up and running for sufficient time to be included in this review operated a total of 102 sites. Over 1900 data sources were analyzed and ranked according to the quality of study design and evidence reported; study results report only on those judged to be of acceptable quality, or better. A complete summary of findings and data sources utilized is provided in the final report at Appendix B.

The Executive Summary of the report is provided below:

***How and Why did Needle Exchange Programs Develop?**

Needle exchange programs have continued to increase in number in the US and by September 1, 1993 at least 37 active programs existed. The evolution of needle exchange programs in the US has been characterized by growing efforts to accomodate the concerns of local communities, increasing likelihood of being legal, growing institutionalization, and increasing federal funding of research, although a ban on federal funding for program services remains in effect.

How do Needle Exchange Programs Operate?

About one-half of US needle exchange programs are legal, but funding is often unstable and most programs rely on volunteer services to operate. All but six US needle exchange programs require one-for-one exchanges and rules governing the exchange of syringes are generally well enforced. In addition to having distributed over 5.4 million syringes, US needle exchange programs provide a variety of services ranging from condom and bleach distribution to drug treatment referrals.

Do Needle Exchange Programs Act as Bridges to Public Health Services?

Some needle exchange programs have made significant numbers of referrals to drug abuse treatment and other public health services, but referrals are limited by the paucity of drug treatment slots. Integrating needle exchange programs into the existing public health system is a likely future direction for these programs.

How Much Does it Cost to Operate Needle Exchange Programs?

The median annual budget of US and Canadian needle exchange programs visited is relatively low at \$169,000, with government-run programs tending to be more expensive. Some needle exchange programs are more expensive because they also

provide substantial non-exchange services such as drug treatment referrals. The annual cost of funding an average needle exchange program would support about 60 methadone maintenance slots for one year.

Who Are the IDUs Who Use Needle Exchange Programs?

Although needle exchange program clients vary from location to location, the programs generally reach a group of injecting drug users with long histories of drug injection who remain at significant risk for human immunodeficiency virus (HIV) infection. Needle exchange program clients in the US have had less exposure to drug abuse treatment than IDUs not using the program.

What Proportion of All Injecting Drug Users in a Community Uses the Needle Exchange Program?

Studies of adequately funded needle exchange programs suggest that the programs do have the potential to serve significant proportions of the local injecting drug user population. While some needle exchange programs appear to have reached large proportions of local drug injectors at least once, others are reaching only a small fraction of them. Consequently, other methods of increasing sterile needle availability must be explored.

What Are the Community Responses to Needle Exchange Programs?

Unlike in many foreign countries, including Canada, proposals to establish needle exchange programs in the US have often encountered strong opposition from a variety of different communities. Consultation with affected communities can address many of the concerns raised.

Do Needle Exchange Programs Result in Changes in Community Levels of Drug Use?

Although quantitative data are difficult to obtain, those available provide no evidence that needle exchange programs increase the amount of drug use by needle exchange program clients or change overall community levels of non-injection and injection drug use. This conclusion is supported by interviews with needle exchange program clients and by injecting drug users not using the programs, who did not believe that increased needle availability would increase drug use.

Do Needle Exchange Programs Affect the Number of Discarded Syringes?

Needle exchange programs in the US have not been shown to increase the total number of discarded syringes and can be expected to result in fewer discarded syringes.

Do Needle Exchange Programs Affect Rates of HIV Drug and/or Sex Risk Behaviors?

The majority of studies of needle exchange program clients demonstrate decreased rates of HIV drug risk behavior but not decreased rates of HIV sex risk behavior.

What is the Role of Studies of Syringes in Injection Drug Use Research?

The limitations of using the testing of syringes as a measure of injecting drug users' behavior or behavior change can be minimized by following syringe characteristics over time, or by comparing characteristics of syringes returned by needle exchange program clients with those obtained from non-clients of the program.

Do Needle Exchange Programs Affect Rates of Diseases Related to Injection Drug Use Other than HIV?

Studies of the effect of needle exchange programs on injection-related infectious diseases other than HIV provide limited evidence that needle exchange programs are associated with reductions in subcutaneous abscesses and hepatitis B among injecting drug users.

Do Needle Exchange Programs Affect HIV Infection Rates?

Studies of the effect of needle exchange programs on HIV infection rates do not and, in part due to the need for large sample sizes and the multiple impediments to randomization, probably cannot provide clear evidence that needle exchange programs decrease HIV infection rates. However, needle exchange programs do not appear to be associated with increased rates of HIV infection.

Are Needle Exchange Programs Cost-effective in Preventing HIV Infection?

Multiple mathematical models of needle exchange programs impact support the findings of the New Haven model. These models suggest that needle exchange programs can prevent significant numbers of infections among clients of the programs, their drug and sex partners, and their offspring. In almost all cases, the cost per HIV infection averted is far below the \$119,000 lifetime cost of treating an HIV-infected person." The Public Health Impact of Needle Exchange Programs in the United States and Abroad, Volume 1, pp.iii-v.

Report of the National Academy of Sciences

In 1992, Congress included a provision in the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act directing the Secretary of DHHS to request the National Academy of Sciences (NAS) to conduct a study of the impact of needle exchange and bleach distribution programs on drug use behavior and the spread of infection with the human immunodeficiency virus (HIV). The National Research Council and the Institute of Medicine (NRC/IOM) of the NAS convened an expert panel in 1993, conducted a thorough review of the scientific literature on these issues, and published the report Preventing HIV Transmission: The Role of Sterile Needles and Bleach, in September, 1995.

Approximately 75 needle exchange programs had been initiated in 55 US cities at the time of this report. Data was also newly available assessing the effects of a 1992 Connecticut law decriminalizing the possession of syringes without a prescription.

The scope of the NRC/IOM study extended well beyond the information requested for this report. A review of the scientific data on the effects of needle exchange programs on reduction in HIV transmission rates and impact on drug utilization is presented in Chapter Seven of the report. The text of the full report is provided at Appendix C. The study reviewed and expanded on the previous studies of the GAO and University of California as well as analyzing subsequently published studies through 1994. The NRC/IOM study panel included a discussion of experimental study design and data quality issues in weighing the contribution of published studies. The conclusions and recommendations of the report were based in part on an assessment of the patterns of evidence, and not solely on the quality of evidence in individual studies.

Provided here is a summary of the conclusions of the NRC/IOM panel on the scientific assessment of needle exchange program effectiveness:

Scientific Assessment of Program Effectiveness

- On the basis of its review of the scientific evidence, the panel concludes:
- o Needle exchange programs increase the availability of sterile injection equipment. For the participants in a needle exchange program, the fraction of needles in circulation that are contaminated is lowered by this increased availability. This amounts to a reduction in an important risk factor for HIV transmission.
- o The lower the fraction of needles in circulation that are contaminated, the lower the risk of new HIV infections.
- o There is no credible evidence to date that drug use is increased among participants as a result of programs that provide legal access to sterile equipment.
- o The available scientific literature provides evidence based on self-reports that needle exchange programs do not increase the frequency of injection among program participants and do not increase the number of new initiates to injection use.
- o The available scientific literature provides evidence that needle exchange programs have public support, depending on locality, and that public support tends to increase over time." Preventing HIV Transmission: The Role of Sterile Needles and Bleach, Executive Summary, page 4.

Other Recent Studies

Other studies and abstracts published since the NRC/IOM report which address the effects of needle exchange programs on HIV transmission and drug-using behavior are provided at Appendix D. These include: (1) a study published by Des Jarlais et al in Lancet, October 1996 researching the question if NEPs have an individual-level protective effect against HIV transmission, (2) an evaluation commissioned by the Massachusetts Department of Public Health on the effects of a pilot needle exchange program, presenting Year One and Year Two data, and (3) abstracts accepted at the XI International Conference on AIDS held in Vancouver, BC July 1996. Although many abstracts included findings relevant to NEPs, only those designed to specifically study the research questions raised by the Appropriations Committee are included in this report.

- (1) Des Jarlais DC, et al. HIV incidence among injecting drug users in New York City syringe-exchange programmes. Lancet 1996; 348: 987-991.

This study employed meta-analytic techniques to compare HIV incidence among injecting drug users participating in syringe-exchange programs in New York City with that among non-participants. Data from three cohorts (total n=1630) was pooled to assess HIV incidence rates.

- Findings HIV incidence among continuing exchange users in the Syringe Exchange Evaluation was 1.58 per 100 person-years at risk (95% CI 0.54, 4.65) and among continuing exchange users in the Vaccine Preparedness Initiative it was 1.38 per 100 person-years at risk (0.23, 4.57). Incidence among non-users of the exchange in the Vaccine Preparedness Initiative was 5.26 per 100 person-years at risk (2.41, 11.49), and in the National AIDS Demonstration Research cities (non-exchange users) 6.23 per 100 person-years at risk (4.4, 8.6). In a pooled-data multivariate proportional-hazards analysis, not using the exchanges was associated with a hazard ratio of 3.35 (95% CI 1.29, 8.65) for incident HIV infection compared with using the exchanges.

Interpretation We observed an individual-level protective effect against HIV infection associated with participation in a syringe-exchange programme. Sterile injection equipment should be legally provided to reduce the risk of HIV infection in persons who inject drugs." p. 987.

- (2) The Medical Foundation, Final Report: First Year of the Pilot Needle Exchange Program in Massachusetts, October 1995; and Second Year Update: Program Characteristics of Massachusetts Needle Exchange Programs, 1994-95, August 1996.

These two reports were prepared by The Medical Foundation under contract to the Massachusetts Department of Public Health, to evaluate the effects of a pilot needle exchange program (AHOPE) authorized by State law in 1993. Two needle exchange programs served 1,315 and 1,999 unduplicated clients in 1994 and 1995, respectively. The Executive Summary of the 1995 report and the Second Year Update of 1996 summarize study results to the following questions:

- o What were the demographic characteristics of people who enrolled in the program and did the program reach those at risk for HIV infection in Metro Boston and Cambridge
- o What were the reported injection behaviors and risks of program clients
- o How many client-contacts did the program have and what supplies were distributed
- o Did the program act effectively as a "bridge to treatment" for needle exchange clients
- o Did crime increase in areas with needle exchange sites compared to areas without needle exchange sites
- o Did needle stick injuries to public service workers increase as a result of the program

"Conclusion: Upon completion of its first full year of operation, AHOPE has been successful in enrolling 1,315 clients, exchanging 37,575 syringes, and linking 16.6% of the eligible clients to drug treatment. Many of the major concerns regarding the establishment of the program -- namely the danger of increased crime, the initiation of young people into drug use and injection, the attraction of addicts from wide geographic areas into Boston, and the possibility of needle stick injuries to public workers -- did not come to pass. AHOPE appears to have significantly contributed to the reduction of HIV risk among a diverse population at high risk for HIV infection and transmission with little negative community impact." Final Report: First Year of the Pilot Needle Exchange Program in Massachusetts, October 1995, p.7.

"Conclusion: The program is expanding into areas of the state where there is much need for prevention services while maintaining continuity of care in areas where the program is already established. There is no evidence that the program is attracting young or new injectors, there have been no other negative community impacts. The programs have had significantly positive impacts, both in preventing HIV through the provision of sterile syringes and prevention supplies and education and in the form of enhanced drug treatment linkage for the older, impoverished long-term addicts who utilize the program." Second Year Update: Program Characteristics of Massachusetts Needle Exchange Programs, 1994-1995, August 1996, p.3.

- (3) Abstracts from the XI International Conference on AIDS, Vancouver, BC, July 1996. The following two abstracts reported on US needle exchange programs in Baltimore, MD and New York City.

Vlahov, D et al. Evaluation of the Baltimore Needle Exchange Program: Preliminary Results. [Abstract Mo.D.361] The following key variables were addressed in the abstract: frequency of drug injection, frequency of needle exchanges, needle sharing patterns, use of shooting galleries, number of injections on the street, and disposal of used needles on the street.

"Conclusion This NEP has recruited a large number of IDUs and preliminary data suggest that the NEP attracts high risk IDUs, and that a reduction in HIV risk drug use is observed."

Schoenbaum, EE et al. Needle Exchange Use Among a Cohort of Drug Users. [Abstract Tu.C.2523] The abstract reports on a prospective study of injection behaviors among IDUs enrolled in a methadone maintenance program who did and did not utilize a local needle exchange program in the Bronx, New York City between 1985-1993. The following key variables were addressed in the abstract: the percent of clients injecting over time, percent of clients using the needle exchange program, needle sharing behavior, and HIV seropositivity status.

"Conclusion Methadone treated IDUs with access to a needle exchange decreased injection and needle sharing. This pattern of harm reduction, which began years before the needle exchange program opened, occurred in those who did and did not utilize the needle exchange. Needle exchange, as a strategy to decrease injection-related harm, should not be viewed as discordant with methadone treatment."

II. Current Federally Supported Research on Needle Exchange Programs

The Department has taken an active interest in evaluating the public health impact of needle exchange programs since 1992, in light of the opportunity to reduce bloodborne transmissible diseases among IDUs and to serve as a gateway to substance abuse treatment. These research activities have been centered at the National Institute on Drug Abuse (NIDA). A description of NIDA's needle exchange research portfolio which includes 15 funded studies is described in Appendix E. All federally sponsored research is limited by statute to evaluations of existing NEPs and does not support the purchase or distribution of needles.

Of the 15 studies funded by NIDA, only two have been completed. A summary of findings to date follows here. Of 4 studies reporting data on frequency of injection, three report no evidence of increased injection frequency, and one shows a decreased rate of injections. All four of the 15 studies reporting data on multi-person reuse, or sharing, of syringes show a decrease in the reuse of syringes. Data on the prevalence or incidence of hepatitis and HIV is available for 2 of the 15 projects. In one study between 51% - 55% of syringes returned were seropositive; of note, multiple syringes may have been returned by a single

individual affecting interpretation of these results. In the other study, a 33 percent relative reduction in HIV incidence in needle exchange program users was predicted based on a mathematical model. This model was reviewed and assessed to be methodologically sound in the GAO report found at Appendix A.

III. National Survey on the Regulation of Syringes and Needles

A recent national survey of laws and regulations governing the sale and possession of needles and syringes in the United States and its territories is included at Appendix F, to provide the Committee with additional background on the variety of state and local drug paraphernalia laws, syringe prescription statutes, and pharmacy regulations in effect. A number of states and local ordinances have created exceptions to laws and regulations for operators of syringe exchange programs and their participants. An overview of the legislative history and the specifics of exemptions are included along with the results of the national survey.

Summary

This review provides the Committee with an overview of the current status of knowledge regarding the impact needle exchange programs may have on the seroincidence of HIV and their impact on drug using behavior of needle exchange participants. Overall these studies indicate that needle exchange programs can have an impact on bringing difficult to reach populations into systems of care that offer drug dependency services, mental health, medical and support services. These studies also indicate that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood borne infectious diseases in communities that choose to include them.

IV. Appendices

- Appendix A. Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy. U.S. General Accounting Office. 1993
- Appendix B. The Public Health Impact of Needle Exchange Programs in the United States and Abroad, Volume 1. San Francisco, CA: University of California. 1993
- Appendix C. Preventing HIV Transmission: The Role of Sterile Needles and Bleach. National Research Council and Institute of Medicine. 1995.
- Appendix D. Des Jarlais DC, Marmor M, Paone D et al. HIV Incidence Among Injecting Drug Users in New York City Syringe-Exchange Programmes. Lancet. 1996;348:987-991.

First year report (October 1995) and Second Year Update (August 1996) of the Pilot Needle Exchange Program in Massachusetts. The Medical Foundation, for the Massachusetts Department of Public Health.

Abstracts from the XI International Conference on AIDS, Vancouver, BC July 1996:

- 1) Vlahov D. et al. Evaluation of the Baltimore Needle Exchange Program: Preliminary Results. Abstract Mo.D.361
- 2) Schoenbaum, E. et al. Needle Exchange Use Among a Cohort of Drug Users. Abstract Tu.C.2523

Appendix E. NIDA's Needle Hygiene and Needle Exchange Evaluation Research Program Portfolio, 1992 - Present.

Appendix F. Gostin LO, Lazzarini JD, Jones TS, Flaherty K. Prevention of HIV/AIDS and Other Blood-Borne Diseases Among Injection Drug Users. JAMA. 1997;277:53-62.



Report to the Chairman, Select
Committee on Narcotics Abuse and
Control, House of Representatives

March 1993

NEEDLE EXCHANGE PROGRAMS

Research Suggests Promise as an AIDS Prevention Strategy





Prepared by the
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service



APPENDIX B

THE PUBLIC HEALTH IMPACT OF NEEDLE EXCHANGE PROGRAMS IN THE UNITED STATES AND ABROAD

Volume 1

**SCHOOL OF PUBLIC HEALTH,
UNIVERSITY OF CALIFORNIA, BERKELEY**

**INSTITUTE FOR HEALTH POLICY STUDIES
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**

PREPARED FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

October 1993

AIDS-D. C.

PREVENTING HIV

Transmission

The Role of
Sterile Needles
and Bleach

NATIONAL RESEARCH COUNCIL • INSTITUTE OF MEDICINE

- thromboembolic disease. *Lancet* 1993; 346: 1582-85.
- 23 Jick J, Jick SS, Gurwitz V, Myers MW, Vasilakis C. Risk of idiopathic cardiovascular death and non-fatal venous thromboembolism in women using oral contraceptives with differing progestagen components. *Lancet* 1995; 346: 1589-93.
- 24 Bloemenkamp KWM, Rosendaal FR, Helmerhorst FAL, Muller HR, Vandenbroucke JP. Enhancement by factor V Leiden mutation of risk of deep-vein thrombosis associated with oral contraceptives containing a third-generation progestagen. *Lancet* 1994; 346: 1543-46.
- 25 Nachigall LE, Nachigall RH, Nachigall RD, Beckman EM. Estrogen replacement therapy II: a prospective study on the relationship to carcinoma and cardiovascular and metabolic problems. *Obstet Gynecol* 1979; 54: 74-79.
- 26 Stampfer MJ, Goldhaber SZ, Manson JE, et al. A prospective study of exogenous hormones and risk of pulmonary embolism in women. *Circulation* 1992; 86 (suppl 1): 1-676 (abstr).
- 27 Peller L, Thomson JM, Coope J. Conjugated equine estrogens and blood clotting: a follow-up report. *BMJ* 1977; i: 935-36.
- 28 Stangel JJ, Innerfield I, Rejniak J, Stone ML. The effect of conjugated estrogens on coagulability in menopausal women. *Obstet Gynecol* 1977; 49: 314-16.
- 29 Nadelovitz M, Kitchens CS, Ware MD. Coagulation and fibrinolysis in estrogen-treated surgically menopausal women. *Obstet Gynecol* 1984; 63: 621-25.
- 30 Nadelovitz M, Kitchens C, Ware MD, Hirschberg K, Coone L. Combination estrogen and progestin replacement therapy does not adversely affect coagulation. *Obstet Gynecol* 1983; 62: 596-600.
- 31 Postmenopausal Estrogen/Progestin Interventions Trial Writing Group. Effects of estrogen/progestin regimens on heart disease risk factors in postmenopausal women. *JAMA* 1995; 273: 199-208.
- 32 Grady D, Rubin SM, Petitti DB, et al. Hormone therapy to prevent disease and prolong life in postmenopausal women. *Ann Intern Med* 1992; 117: 1016-37.

HIV Incidence among Injecting drug users in New York City syringe-exchange programmes

Don C Des Jarlais, Michael Marmor, Denise F. Jone, Stephen Titus, Qihu Shi, Theresa Perlis, Benny Jose, Samuel R Friedman

Summary

Background There have been no studies showing that participation in programmes which provide legal access to drug-injection equipment leads to individual-level protection against incident HIV infection. We have compared HIV incidence among injecting drug users participating in syringe-exchange programmes in New York City with that among non-participants.

Methods We used meta-analytic techniques to combine HIV incidence data from injecting drug users in three studies: the Syringe Exchange Evaluation (n=280), in which multiple interviews and saliva samples were collected from participants at exchange sites; the Vaccine Preparedness Initiative cohort (n=133 continuing exchangers and 188 non-exchangers, in which participants were interviewed and tested for HIV every 3 months; and very-high-seroprevalence cities in the National AIDS Demonstration Research (NADR) programme (n=1029), in which street-recruited individuals were interviewed and tested for HIV every 6 months. In practice, participants in the NADR study had not used syringe exchanges.

Findings HIV incidence among continuing exchange-users in the Syringe Exchange Evaluation was 1.58 per 100 person-years at risk (95% CI 0.54, 4.65) and among continuing exchange-users in the Vaccine Preparedness Initiative it was 1.38 per 100 person-years at risk (0.23, 4.57). Incidence among non-users of the exchange in the Vaccine Preparedness Initiative was 5.26 per 100 person-years at risk (2.41, 11.49), and in the NADR cities, 6.23 per 100

person-years at risk (4.4, 8.6). In a pooled-data, multivariate proportional-hazards analysis, not using the exchanges was associated with a hazard ratio of 3.35 (95% CI 1.29, 8.65) for incident HIV infection compared with using the exchanges.

Interpretation We observed an individual-level protective effect against HIV infection associated with participation in a syringe-exchange programme. Sterile injection equipment should be legally provided to reduce the risk of HIV infection in persons who inject illicit drugs.

Introduction

The provision of sterile injection equipment (syringe exchanges or pharmacy sales) has been the main method for reducing HIV infection among injecting drug users (IDUs) in most industrialised countries.¹ After nearly a decade of research on legal injection equipment for preventing HIV infection, there is no evidence that such programmes are associated with increased illicit drug injection, whereas that participation is associated with lower rates of drug-injection HIV-risk behaviour.²⁻⁷ To date, however, there has been no direct evidence that participation is associated with a lower risk of incident HIV infection for the individual IDU.⁸

New York City had rapid transmission of HIV among drug injectors between 1978 and 1984, with seroprevalence reaching about 50%.⁹ A small-scale pilot syringe-exchange programme was started by the City Department of Health in 1988, although this programme was discontinued by a new mayor in 1990.¹⁰ Community activists then opened a number of "underground" exchanges. In 1992, the New York State Health Department permitted legal operation of five community exchanges. These exchanges expanded rapidly, providing services to about 36 000 IDUs by September, 1995, and exchanging 1.75 million syringes in 1994.

We report on incident HIV infections among IDUs in community-based syringe-exchange programmes in New York City from 1992 to 1995. We have reported on reductions in HIV risk behaviour among participants.¹¹⁻¹³

Lancet 1996; 348: 987-91

Beth Israel Medical Center (Prof D C Des Jarlais MD, D F. Jone MD, Q Shi MS), New York University Medical Center (Prof M Marmor MD, S Titus MD), and National Development and Research Institutes, Inc (D C Des Jarlais, T Perlis MS, B Jose MD, S R Friedman MD), New York, New York, USA

Correspondence to: Prof Don C Des Jarlais, Beth Israel Medical Center, Chemical Dependency Institute, 1st Avenue and 16th Street, New York, NY 10003, USA

[Mo.D.361] EVALUATION OF THE BALTIMORE NEEDLE EXCHANGE PROGRAM:
PRELIMINARY RESULTS

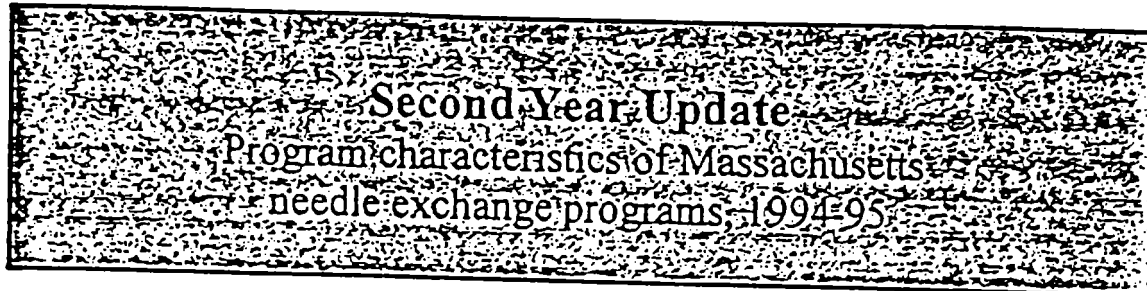
Vlahov D, Junge, Benjamin, Beilenson P*, Brookmeyer RS, Cohn S, Armenian H. The Johns Hopkins School of Public Health; *Baltimore City Health Department.

Objective: To evaluate the first year of the Needle Exchange Program (NEP) for injection drug users (IDUs).

Methods: All participants between 8/12/94 and 8/11/95 who underwent enrollment interviews on sociodemographic and drug use practices. A systematic sample was interviewed at initial, two week and six month follow-up visits about needle acquisition, use and disposal practices during the 2 weeks before each interview. Data were analyzed using paired T-tests. In a community cohort (the ALIVE Study) demographics and HIV seroconversion rates were compared between participants who used vs. did not use the NEP.

Results: During the first year, 2965 IDUs enrolled in the NEP of whom 87% were African-American, 72% were male, 56% had < 12 years of education, 92% were unemployed and 90% injected | 1/day; the median age was 38 years old. Within the ALIVE cohort, NEP users were more likely to inject | 1/day, otherwise IDUs not enrolled in NEP were statistically similar. Of the 2965, 55% returned at least once to exchange, and 7% were high volume exchangers (> 50/visit); among high volume exchangers injection frequency and needles exchanged were similar. In the interviewed subset, there was a significant decrease ($p < .05$) of injections on the street, frequency of injection, needle sharing, use of galleries, and discarding needles on the street in the 2 weeks prior and subsequent to enrollment. These changes were sustained at the six month visit. **Conclusion:** This NEP has recruited a large number of IDUs and preliminary data suggest that the NEP attracts high risk IDUs, and that a reduction in HIV risk drug use is observed.

Benjamin Junge, Johns Hopkins SHPH, 627 N. Washington Street, Baltimore, MD 21205, USA
Phone: 410-614-3632 Fax: 410-614-9910



August 1996

THE MEDICAL FOUNDATION

Final Report

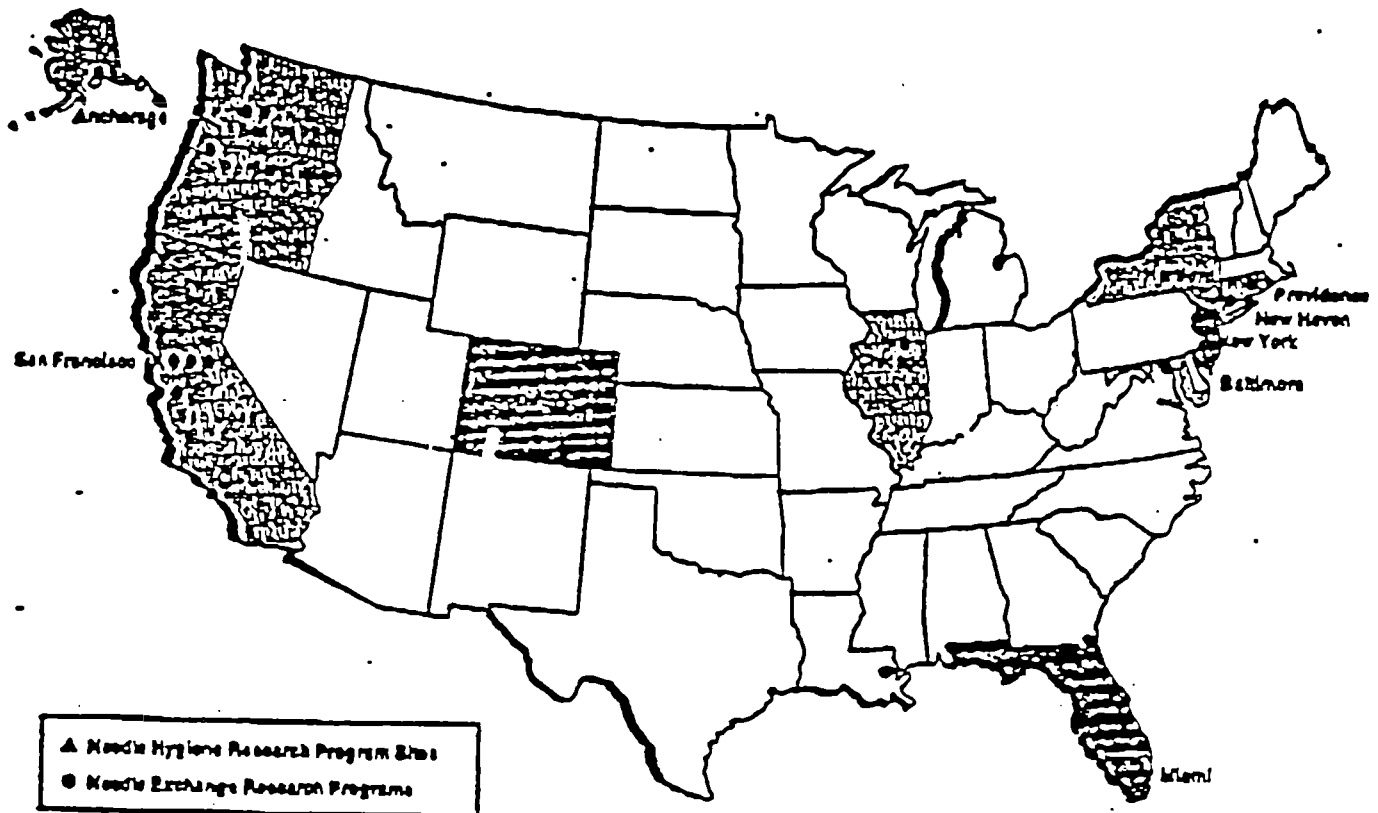
First Year of the Pilot Needle Exchange Program in Massachusetts

October 1995

The Medical Foundation
95 Berkeley Street
Boston MA 02116

NIDA'S NEEDLE HYGIENE AND NEEDLE EXCHANGE EVALUATION RESEARCH PROGRAM PORTFOLIO 1992-PRESENT

NEEDLE HYGIENE AND NEEDLE EXCHANGE EVALUATION RESEARCH PROGRAM SITES:



Needle Exchange Research Program Grantees

Russell E. Alexander, Ph.D., Seattle, WA; Frederick Altice, M.D., New Haven, CT; Don Des Jarlais, Ph.D., New York, NY; Dennis G. Fisher, Ph.D., Anchorage, AK; David R. Gibson, Ph.D., San Jose, CA; Holly Hagan, Ph.D., Seattle-King County, WA; Edward H. Kaplan, Ph.D., New Haven, CT; Peter G. Lurie, Ph.D., San Francisco, CA; Sheila B. Murphy, Ph.D., San Francisco, CA; Lawrence J. Ouellet, Ph.D., Chicago, IL; Josiah Rich, M.D., Providence, RI; Merrill C. Singer, Ph.D., Hartford, CT; Thomas W. Valente, Ph.D., Baltimore, MD; David Vlahov, Ph.D., Baltimore, MD; Ricky Bluthenthal, M.A., San Francisco, CA.

Needle Hygiene Research Program Grantees

Michael Clatts, Ph.D., New York, NY; Steve Koester, Ph.D., Denver, CO; Clyde B. McCoy, Ph.D., Miami, FL.

Prevention of HIV/AIDS and Other Blood-Borne Diseases Among Injection Drug Users

A National Survey on the Regulation of Syringes and Needles

Lawrence O. Gostin, JD; Zita Lazzarini, JD, MPH; T. Stephen Jones, MD, MPH; Kathleen Flaherty, JD

We report the results of a survey of laws and regulations governing the sale and possession of needles and syringes in the United States and its territories and discuss legal and public health proposals to increase the availability of sterile syringes, as a human immunodeficiency virus (HIV) transmission prevention measure, for persons who continue to inject drugs. Every state, the District of Columbia (DC), and the Virgin Islands (VI) have enacted state or local laws or regulations that restrict the sale, distribution, or possession of syringes. Drug paraphernalia laws prohibiting the sale, distribution, and/or possession of syringes known to be used to introduce illicit drugs into the body exist in 47 states, DC, and VI. Syringe prescription laws prohibiting the sale, distribution, and possession of syringes without a valid medical prescription exist in 8 states and VI. Pharmacy regulations or practice guidelines restrict access to syringes in 23 states. We discuss the following legal and public health approaches to improve the availability of sterile syringes to prevent blood-borne disease among injection drug users: (1) clarify the legitimate medical purpose of sterile syringes for the prevention of HIV and other blood-borne infections; (2) modify drug paraphernalia laws to exclude syringes; (3) repeal syringe prescription laws; (4) repeal pharmacy regulations and practice guidelines restricting the sale of sterile syringes; (5) promote professional training of pharmacists, other health professionals, and law enforcement officers about the prevention of blood-borne infections; (6) permit local discretion in establishing syringe exchange programs; and (7) design community programs for safe syringe disposal.

JAMA. 1997;277:53-62

THE MAGNITUDE OF THE EPIDEMICS OF DRUG USE AND BLOOD-BORNE DISEASES

The dual epidemics of drug use and the human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) are highly destructive of public health and social life in

America.¹ The drug-related health problems of the estimated 1.5 million injection drug users (IDUs) in the United States^{2,3} range from blood-borne infections such as hepatitis B and C, HIV/AIDS, endocarditis, and malaria^{4,5} to physical deterioration and death. Illegal drug use and the drug industry that fuels it are associated with a multitude of crimes against persons and property. Drug use induces family disintegration, child neglect, economic ruin, and social decay. Drug use exacts an estimated annual cost to society of \$58.3 billion—in lost productivity, motor vehicle crashes, crime, stolen property, and drug treatment.⁶

Injection drug use is the second most frequently reported risk for AIDS, accounting for 184 359 cases through December 1995.⁸ In 1995, 36% of all AIDS cases occurred among IDUs, their heterosexual sex partners, and children whose mothers were IDUs or sex partners of IDUs.¹⁰ In contrast, in 1981, only 12% of all reported AIDS cases were associated with injection drug use.¹¹ In some areas, seroprevalence among IDUs is as high as 65%; in other areas, the rates are significantly lower.¹²⁻¹⁴ Minorities, moreover, bear a disproportionately high burden. The rate of IDU-associated AIDS per 100 000 population is 8.1 for whites, 21.9 for Hispanics, and 50.9 for African Americans.¹⁵

Transmission of HIV infection through injection drug use has a cascading effect; infections spread from IDUs to their sexual and needle-sharing partners and from HIV-infected mothers to their children. Of the 71 818 AIDS cases among women reported through December 1995, nearly 65% were IDUs or were sexual partners of an IDU. Further, of the 6256 perinatally acquired AIDS cases reported through December 1995, 60% had mothers who were IDUs or had sex with an IDU.¹⁶ These data suggest that drug use and related behaviors¹⁷ are potent catalysts for spreading HIV throughout the population.¹⁸ It has been estimated that approximately half of all new HIV infections in the United States occur among IDUs.¹⁹

THE ROLE OF SYRINGES IN THE TRANSMISSION OF BLOOD-BORNE DISEASE

Injection drug users transmit HIV infection and other blood-borne diseases to other users primarily through multiperson use (often called "sharing") of syringes.²⁰ (For the purpose of this article, "syringe" includes both syringes and needles.) Each time an IDU injects drugs, the syringe

From the Georgetown/Johns Hopkins Program in Law and Public Health, Washington, DC, and Baltimore, Md (Mr Gostin and Ms Flaherty); Harvard School of Public Health, Boston, Mass (Ms Lazzarini); and the Centers for Disease Control and Prevention, Atlanta, Ga (Dr Jones).

The views expressed herein are those of the authors and do not necessarily reflect the official policy of the US Department of Health and Human Services, the Center for Disease Control, the Centers for Disease Control and Prevention, or the cosponsors of the consultation held at the Center for Disease Control.

Corresponding author: Lawrence Gostin, JD, Georgetown University Law Center, 600 Massachusetts Ave NW, Washington, DC 20001 (e-mail: gostin@law.georgetown.edu).

Health Law and Ethics section editors: Lawrence O. Gostin, JD, Georgetown University Program on Law and Public Health, Washington, DC, and Baltimore, Md; Helene M. Cole, MD, Contributing Editor, JAMA.

The Washington Post

MONDAY, JULY 14, 1997

K

... Offering Clean Needles

ONE TERRIBLE side effect of drug abuse is the spread of AIDS among intravenous drug users. Those who share contaminated needles and other drug paraphernalia endanger not only their own lives but also those of their sexual partners and their children. What is less known and more difficult for some people to accept is the mounting evidence that needle-exchange programs do save lives, markedly lowering rates of HIV infection, but do not increase drug use. This is why state and local officials—and most recently, the U.S. Conference of Mayors—are urging Secretary of Health and Human Services Donna Shalala to eliminate the ban on the use of federal funds for needle-exchange programs.

The federal government has a clear and important role in the attack on AIDS and drug abuse. Needle exchange is but a part of a broader effort, but it deserves federal support. It must be accompanied by improved drug-abuse prevention and treatment programs. This is the chief concern of those who resist the clean-needle approach: They fear that by distributing the tools of drug use, governments are surrendering to drug abuse and even abetting it.

Yet study after study shows that the exchanges do not promote greater use of illegal drugs. The best programs do refer—not order—their par-

ticipants to treatment centers, although facilities are few. It is established that drug users who are not under treatment will not or cannot stop their drug use just because clean needles aren't available. They will go to infected needles for that fix.

If administration officials need an example of a program that offers clean needles and also instruction and equipment for cleansing syringes and other paraphernalia, they may look in their own backyard. The D.C. Needle Exchange, run by the Whitman-Walker Clinic with limited city funds, refers users to treatment programs, offers free HIV tests and has become a useful communications link to more than 1,600 addicts. Staffers make no great claims of reducing addiction; they note that treatment services are critical—and in this city, seriously limited.

The National Institutes of Health reports that needle exchange has brought about an estimated 30 percent or greater reduction of HIV in injection users of illegal drugs. In terms of expense, a sterile needle costs about a dime, while officials of AIDS organizations estimate the average lifetime cost of treating an individual with HIV/AIDS is at least \$119,000. Needle exchange programs alone certainly will not stop substance abuse, but they are helping to stop HIV—and that needs to be a priority of the federal government.

LOS ANGELES TIMES EDITORIALS



Needle Programs Are Needed

Evidence is in: They can reduce AIDS without fostering drug use

Understandably uneasy with government agencies giving drug addicts needles and other paraphernalia, Congress prohibited federally funded needle exchange programs in 1988. The ban could be lifted, Congress said, when there was proof that such programs reduced transmission of the AIDS virus without increasing illegal drug use. Now, that time has come.

Since 1993, several major studies have shown that the programs that give addicts clean needles in exchange for used ones decrease HIV infection in injected-drug users by 30%, increase the likelihood that addicts will enter drug treatment programs and do nothing to lead nonusers into drug habits. But, unlike in most developed nations, many U.S. state laws and federal law prohibit government from supplying clean needles. (California does not prohibit private programs, but Gov. Pete Wilson has thrice vetoed bills that would have explicitly legalized such programs.)

Prohibitions cost lives and money. According to the federal Centers for Disease Control, most of the 41,000 new HIV infections each year occur among injected-drug users and their sexual partners and children. The average cost of lifetime care for those infected with HIV or

suffering from AIDS runs about \$120,000, while each sterile needle costs 10 cents.

Citing "an urgent public health need," the American Medical Assn. and the U.S. Conference of Mayors have called for revocation of the 1988 law and of similar state laws prohibiting needle exchange programs. In a resolution sponsored by Los Angeles Mayor Richard Riordan and San Francisco Mayor Willie Brown, the Conference of Mayors went a step further, urging Health and Human Services Secretary Donna Shalala to use her authority to permit federal funding.

Reflecting the conventional wisdom in Washington, conservative public policy analyst Gary L. Bauer says the idea of lifting the ban on needle exchange is unthinkable because it "strikes the average voter in the gut as being against common sense." But recent polls suggest otherwise: A Kaiser Family Foundation survey last year found that 66% of Americans support needle exchange programs.

Washington should listen to the civic leaders and public health experts who have seen close up how the programs can be an effective and inexpensive way of curbing the spread of a deadly disease.

ALEX MACHASKEE
President and Publisher

DAVID HALL
Editor

BRENT W. LARKIN
Editorial Page Director

ROBERT M. LONG
Executive Vice President

THOMAS H. GREER
Vice President, Senior Editor

Point taken

Studies of needle-exchange programs show a practicality that must be recognized

The use of illegal drugs is wrong and physically devastating both to individuals and communities. The consumption of cocaine, heroin and widely available barbiturates not only plays havoc in society, but contributes directly to predatory crime, human misery, loss of life and enormous public expense.

Just over two years ago, however, this newspaper took a position related to illegal drugs that we have now reconsidered. That opinion, born out of a sense of moral outrage and frustration in the failing effort on the war on drugs, declared that an experimental needle-exchange program the city of Cleveland had sanctioned amounted to morally untenable surrender.

Given the dearth of hard data on the effectiveness of needle exchanges and our conclusion that any effort that provided syringes to addicts would only encourage consumption, we judged the needle-exchange program misguided. Although we agreed that better efforts were needed to slow the spread of HIV among intravenous drug users, we could not quite conceive of how providing needles to addicts could retard the spread of AIDS.

The facts have overtaken our prior conclusion. Those facts demonstrate that needle exchanges do reduce the incidence of HIV transmission among addicts who inject drugs. Just as important, such programs have not increased drug use.

Health and Human Services Secretary Donna Shalala recently briefed a Senate committee evaluating the effectiveness of needle exchanges. Her conclusion: "Needle-exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood-borne infectious diseases in communities that choose to include them."

No less authorities than the National Academy of Sciences, the General Accounting Office and the Centers for Disease Control have concluded that such programs work. These research-based organizations say programs they monitor have radically reduced the numbers of HIV-tainted needles in circu-

lation and have slowed the rate of infection. That means such endeavors have prevented the infection of some babies who might otherwise have been born HIV-positive and spared others who would have been at risk from a drug-addicted spouse.

Indeed, the GAO, after evaluating a forecast model developed at Yale University, estimated that an exchange program operating in New Haven, Conn., had reduced the rate of new HIV infections by 33 percent. That much-circulated program also has proved an effective route into drug treatment for users. Furthermore, the National Academy of Sciences concluded that 75 needle-exchange programs it examined offered no credible evidence that such efforts encourage drug use.

Needle exchange is not a panacea. Heroin addicts, by their nature, are destructive to themselves and those around them. But AIDS is now the leading cause of death for Americans between the ages of 25 and 44. Although the number of deaths experienced in some high-risk groups has declined recently, the rate of new infection among IV drug users has skyrocketed. This group, fueling an epidemic that is decimating some urban neighborhoods, desperately needs to be reached.

Finally, it costs nearly \$120,000 for the care of someone stricken with AIDS. A clean needle costs 6 cents. When we wrote our original needle-exchange editorial in February 1995, Cleveland had not joined the ranks of cities with more than 2,000 documented cases of HIV infection. Today, that has changed. Cleveland now ranks among the top 15 cities in documented cases.

Heroin users now compose the fastest-growing group of people with AIDS. They pass this illness off to unborn children, lovers and, ultimately, to wider society. Making clean needles accessible to them has been shown not only to save some of their lives, but to save our money.

That in itself makes needle exchange a worthy endeavor.

Chicago Tribune

FOUNDED JUNE 10, 1847

JACK FULLER, *Publisher* HOWARD A. TYNER, *Editor*

N. DON WYCLIFF, *Editorial Page Editor* ANN MARIE LIPINSKI, *Managing Editor*

JAMES O'SHEA, *Deputy Managing Editor/News* GEROULD KERN, *Deputy Managing Editor/Features*

R. BRUCE DOLD, *Deputy Editorial Page Editor* F. RICHARD CICCONE, *Associate Editor*

14 Section 1

Monday, March 10, 1997

Editorials

Shalala punts on a crucial call

The Feb. 18 memo by Health and Human Services Secretary Donna E. Shalala, forwarding to Congress a report on the latest research on the effectiveness of needle-exchange programs in reducing HIV infections among drug users, is a triumph of pusillanimous politics and double talk over facts and sound public policy.

All the research cited in the report corroborates what already has been known for years: Needle-exchange programs reduce HIV infections and save money. They even encourage a significant percentage of addicts to seek treatment.

Yet Shalala couldn't bring herself to ask Congress to lift its 1992 ban on HHS funding of needle-exchange programs. The ban stands until the surgeon general—who reports to Shalala—vouches to Congress that such programs are safe and effective.

AIDS is spreading faster among intravenous drug users than in any other group. According to a study by the National Academy of Sciences, between 1981 and 1993 the percentage of new HIV infections due to unsafe homosexual sex dropped to 47 percent from 74 percent, while those attributable to the use of dirty needles by intravenous drug users doubled, to 24 percent.

Indeed, despite the recently reported annual decline in AIDS deaths overall, AIDS has become the leading cause of death in the African-American and Hispanic communities, primarily because of drug use and dirty

needles. Most tragically, many of the victims are the babies or innocent sex partners of HIV-infected addicts.

Needle-exchange programs work. In a 1993 study by Yale University, they were shown to reduce HIV infections by a third. Another study, funded by the Centers for Disease Control and Prevention, indicated that needle exchanges even worked as a bridge for getting significant numbers of users into rehabilitation.

One of the most persuasive arguments is financial. Some 70 needle-exchange research projects, of varying sizes and uncertain funding, operate mostly in large cities, including Chicago. Their average annual budget comes to approximately \$169,000—about what it costs to treat just one HIV-infected addict during the course of the disease.

None of the six studies cited in the HHS report found any basis for the fear that needle exchanges encourage drug use.

Yet the argument—largely symbolic—against these programs is that it looks incongruous for one branch of the government to "subsidize" drug use, however indirectly, while other agencies wage a multibillion-dollar war against it.

It is Shalala's responsibility to sort out facts from symbols—and fears from reality—and argue for sound, effective federal policies. By simply tossing the needle-exchange hot potato back to Congress without comment, she has failed in that role.

The New York Times

Founded in 1851

ADOLPH S. OCHS, *Publisher 1896-1935*
ARTHUR HAYS SULZBERGER, *Publisher 1935-1961*
ORVIL E. DRYFOOS, *Publisher 1961-1963*
ARTHUR OCHS SULZBERGER, *Publisher 1963-1992*

ARTHUR OCHS SULZBERGER JR., *Publisher*

JOSEPH LELYVELD, *Executive Editor*
GENE ROBERTS, *Managing Editor*

Assistant Managing Editors

SOMA GOLDEN BEHR CAROLYN LEE
GERALD M. BOYD JACK ROSENTHAL
DAVID R. JONES ALLAN M. SIEGAL

HOWELL RAINES, *Editorial Page Editor*
PHILIP M. BOFFEY, *Deputy Editorial Page Editor*

JANET L. ROBINSON, *President, General Manager*
WILLIAM L. POLLAK, *Executive VP, Circulation*
PENELOPE MUSE ABERNATHY, *Senior VP, Planning*
DANIEL H. COHEN, *Senior VP, Advertising*
RICHARD H. GILMAN, *Senior VP, Operations*
RAYMOND E. DOUGLAS, *VP, Systems and Technology*
CHARLES E. SHELTON, *VP, Distribution*
DENNIS L. STERN, *VP, Human Resources*
DAVID A. THURM, *VP, Production*

Federal Funds for Clean Needles

Health and Human Services Secretary Donna Shalala says in a new report to the Senate that needle-exchange programs are an effective way to combat the spread of H.I.V., the virus that causes AIDS. But the Secretary does not go far enough. It is time the Clinton Administration lifted the ban on Federal funding for needle-exchange programs.

Such programs now exist in more than 50 American cities, including New York. They provide intravenous-drug users with sterile needles, thus reducing the likelihood that addicts will share needles contaminated with H.I.V. The programs typically have very small budgets, often are run by volunteers and are plagued with unstable funding from year to year. Yet even these modest programs have been effective.

Secretary Shalala's report reviews the research on the issue. Earlier studies done by the National Academy of Sciences, the General Accounting Office, the Centers for Disease Control and the University of California at Berkeley found that providing addicts with sterile needles could help slow the spread of the virus. Equally important, those studies found no evidence that needle-exchange programs increased the amount of drug use by addicts or attracted new users.

More recent studies done for the Massachusetts Department of Public Health and in Baltimore by the Johns Hopkins School of Public Health con-

firmed those observations. Federally funded studies conducted by the National Institute on Drug Abuse also report no increase in the frequency of drug injection associated with needle-exchange programs. A conference of scientists convened by the National Institutes of Health on AIDS prevention stated unequivocally last week that there is no doubt that needle-exchange programs work.

The consistency of these findings justifies Federal support to help pay for needle-exchange programs in communities that need and want them. Unfortunately, the debate continues to focus on politics and morality rather than public health needs. Opponents argue that providing addicts with needles implies approval of drug abuse. They forget that addicts can infect their spouses and offspring who do not abuse drugs and yet must live with the consequences of dirty needles.

Congress imposed the ban on Federal funding for needle exchanges in 1992. But the Administration can lift the ban if the Surgeon General declares that the programs can reduce H.I.V. spread and do not increase drug use. Secretary Shalala's report offers ample evidence that both requirements have been met. The Administration no doubt wants to avoid giving its opponents any reason to bash President Clinton for being soft on drugs. But lives can be saved with needle-exchange programs. The President should show some courage on this issue.

The Washington Post

AN INDEPENDENT NEWSPAPER

Needles and Classroom Candor

THE AIDS EPIDEMIC has been a politically charged subject since the discovery of the virus more than 15 years ago. Patients have demanded and won public attention, a well-financed research effort, privacy and civil rights protections and a streamlined FDA approval system to get drugs for the disease on the market faster. None of this has been easy. Now a panel of 12 nongovernment public health experts has highlighted more obstacles in the path of those working to stem the epidemic and charged that political considerations have brought about a "dangerous chasm" between science and public policy. Two problems in particular were cited.

Sex education is the first. While political leaders give lip service to prevention programs in the classroom, the panel found that the curricula with the most public support are far too timid. They focus on—and in some cases are limited to—encouraging abstinence by teenagers. This is an unexceptionable position that just about everyone can support. But it simply isn't enough. This is not an easy problem to correct, since parental attitudes and moral convictions about sexual practices vary widely and are strongly held. But young lives are at stake and, in the case of AIDS, ignorance kills. Realistic programs designed to modify behavior, both in the teenage years and beyond, are necessary and—according to the panel's scientists—effective.

So are needle-exchange programs aimed at preventing the spread of infection among intra-

venous drug users who share paraphernalia. There are about 100 such programs in operation around the country, and there are now data, cited by the panel, demonstrating that they greatly reduce the sharing of needles and slow the spread of infection without increasing drug use. In this city, an exchange program started small four years ago. Local law initially required that users be in a drug treatment program before being eligible for needle exchange. But it quickly became clear that the shortage of drug treatment slots made this requirement extremely difficult to meet. Now a privately funded effort by the Whitman-Walker Clinic and others exchanges 4,000 needles a week. The city is about to take over the funding of the program, and while this will cost \$200,000 a year, it is far less expensive than caring for AIDS patients in this vulnerable group.

It is tempting to be lulled by recent progress in the development of drugs to treat AIDS. But that is premature and wrong. The rate of new infection continues to be high, and emphasis must remain on prevention. Young people and drug users are at the greatest risk. Scientists have demonstrated that better sex education and needle exchanges are effective ways to limit the spread of the disease without encouraging either sexual promiscuity or drug addiction. Government policies that reject these findings and ignore these preventive steps should be changed.

Needle-Exchange Studies: Summary of Major Findings

Needle Exchange Programs Reduce the Spread of HIV/AIDS & Other Diseases

- In New Haven, CT, HIV infections were estimated to be reduced by 33% among participants in a needle exchange program

Kaplan, E.H. & O'Keefe, E. (1993). "Let the needles do the talking! Evaluating the New Haven needle exchange." *Interfaces*, 23: 7-26.

- A study of injecting drug users in New York City found that the HIV incidence rate for participants in a needle exchange program was 1.58 (per 100 person-years at risk) versus a rate of 5.26 for non-participants. Thus, persons participating in needle exchange were *less likely to have HIV*.

Des Jarlais, D.C. et al. (1996). "HIV incidence among injecting drug users in New York City syringe-exchange programmes." *Lancet*, 348: 987-991.

- Needle exchange programs decrease by 7-8 times the number of Hepatitis B & C infections

Lurie, P., Reingold, A.L., Bowser, B, et al (1993). "The public health impact of needle-exchange programs in the United States and abroad." Prepared for the *Centers for Disease Control and Prevention*.

- An analysis of six (6) government studies showed that needle exchange programs *reduce* the incidence of HIV infection among injecting drug users.

National Research Council/Institute of Medicine. (1995). "Preventing HIV Transmission: The Role of Sterile Needles and Bleach."

- Participants in needle exchange programs reduce the amount and frequency of needle sharing and drug injections, thus reducing the risk for contracting and transmitting HIV.

Vlahov, D., et al. (1996). "Evaluation of the Baltimore Needle Exchange Program: Preliminary Results " [Abstract Mo.D.361] *XI International Conference on AIDS*, Vancouver, BC, July 1996.

Schoenbaum, E.E. et al (1996). "Needle Exchange Use Among a Cohort of Drug Users." [Abstract Tu.C.2523] *XI International Conference on AIDS*, Vancouver, BC, July 1996.

Frischer, M. & Elliott, L. (1993). "Discriminating needle exchange attenders from non-attenders." *Addiction*, 88(5): 681-687.

Needle Exchange Programs Do Not Encourage or Increase Drug Use

- A study of injecting drug users in San Francisco, CA, reported injections *decreased* from 1.9 injections per day to 0.7 injections per day following the establishment of a needle exchange program. Also, the percentage of new initiates into injection drug use *decreased* from 3% to 1%.

Watters, J.K. et al. (1994). "Syringe and needle exchange as HIV/AIDS prevention for injection drug users " *Journal of the American Medical Association (JAMA)*, 271(2): 115-120.

- Regular users of needle exchange programs are more likely to be older and have used drugs for several years, indicating that programs do NOT attract or encourage new drug users.

Khoshnood, K., Kaplan, E.H. & Heimer, R. (1995). "'Dropouts' or 'drop-ins'? Client retention and participation in New Haven's needle exchange program." *Public Health Report*, 110(4): 462-466.

Lurie, P., Reingold, A.L., Bowser, B., et al. (1993). "The public health impact of needle exchange programs in the United States and abroad." Prepared for the *Centers for Disease Control and Prevention*.

Elnitsky, S.L. & Abernathy, T.J. (1993). "Calgary's needle exchange program: Profile of injection drug users." *Canadian Journal of Public Health*, 84(3): 177-180.

- There is no evidence that needle exchange programs increase the amount of drug use by needle exchange clients or in the wider community.

Lurie, P., Reingold, A.L., Bowser, B., et al. (1993). "The public health impact of needle exchange programs in the United States and abroad." Prepared for the *Centers for Disease Control and Prevention*.

National Research Council/Institute of Medicine. (1995). "Preventing HIV Transmission: The Role of Sterile Needles and Bleach."

Guydish, J., Bucardo, et al. (1993). "Evaluating needle exchange: Are there negative effects?" *AIDS*, 7(6): 871-876.

The Medical Foundation. (1996). "Second Year Update Program Characteristics of Massachusetts Needle Exchange Programs, 1994-95."

Needle Exchange Programs Can Help Drug Users Receive Drug Treatment

- A study of an urban needle exchange program showed that 510 referrals for services for program participants were made in little over a year, 60% of which were for *drug treatment services*.

Carvell, A.M. & Hart, G.J. (1990). "Help-seeking and referrals in a needle exchange: A comprehensive service to injecting drug users." *British Journal of Addiction*, 85(2): 235-240.

- Researchers found that the primary value of a needle exchange program in New York City was *drug counseling* and referrals for *drug treatment*.

Joseph, S.C. (1989). "A bridge to treatment. The needle exchange pilot program in New York City." *AIDS Education and Prevention*, 1(4): 340-345.

Needle Exchange Programs Save Lives and Help Reduce the Costs of HIV/AIDS Treatment

- Conservative estimates of the number of HIV infections that could have been prevented with a national needle exchange program in the U.S. range from 4,394 to 9,666. The costs of treating these preventable cases of HIV range from \$244 million to \$538 million.

Lurie, P. & Drucker, E. (1997) "An opportunity lost: HIV infections associated with lack of a national needle-exchange programme in the USA." *Lancet*, 349: 604-608

FY98 Needle Exchange Prohibition - LHTS Approps

Statute :

SEC. 505 Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

SEC. 506. Section 505 is subject to the condition that after March 31, 1998, a program for exchanging such needles and syringes for used hypodermic needles and syringes (referred to in this section as an "exchange project") may be carried out in a community if—

(1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and

(2) the project is operated in accordance with criteria established by such Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

Report Language:

TITLE V.—GENERAL PROVISIONS

DISTRIBUTION OF STERILE NEEDLES

Both the House and Senate bills contained restrictions on the use of federal funds for the distribution of sterile needles for the injection of any illegal drug (section 505). The Senate bill repeated language from previous appropriations bills allowing the Secretary to waive the prohibition if she determined that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs. The House bill removed the Secretary's authority over this issue.

The conference agreement includes the House bill language prohibiting the use of federal funds for carrying out any program for the distribution of sterile needles or syringes for the injection of any illegal drug. This provision is consistent with the goal of discouraging illegal drug use and not increasing the number of needles and syringes in communities.

The conference agreement also includes bill language limiting the use of federal funds for sterile needle and syringe exchange projects until March 31, 1998. After that date such projects may proceed if 1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and 2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs. This provision is consistent with the goal of allowing the Secretary maximum authority to protect public health while not increasing the overall number of needles and syringes in communities.

With respect to the first criteria, the conferees expect the Secretary to make a determination based on a review of the relevant science. If the Secretary makes the necessary determination, then the conferees expect the Secretary to require the chief public health officer of the State or political subdivision proposing to use federal funds for exchange projects to notify the Secretary that, at a minimum, all of the following conditions are met: 1) a program for preventing HIV transmission is operating in the community; 2) the State or local health officer has determined that an exchange project is likely to be an effective component of such a prevention program; 3) the exchange project provides referrals for treatment of drug abuse and for other appropriate health and social services; 4) such project provides information on reducing the risk of transmission of HIV; 5) the project complies with established standards for the disposal of hazardous medical waste; and 6) the State or local health officer agrees that, as needs are identified by the Secretary, the officer will collaborate with federally supported programs of research and evaluation that relate to exchange projects.

It is hoped that the delay in implementation of the provision with regard to exchange projects will allow the authorizing committees sufficient time to conduct a complete review and evaluation of the scientific evidence, as well as any conditions proposed by the Secretary, and consider the need for legislation with regard to these programs. It is the intent of the conferees that the Appropriations Committees refrain from further restrictions on the Secretary's authority over exchange projects after March 31, 1998.