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Folder Title:

Issues - Needle Exchange - Announcement/Rollout

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CRITERIA	ESTIMATE OF ELIGIBLE PROGRAMS
Currently Operating Needle Exchange Programs	110-120 programs
Articulated by Congress 1. A program for preventing HIV transmission is operating in the community; 2. The State or local health office has determined that an exchange project is likely to be an effective component of such a prevention program; 3. The exchange project provides for 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.	90-100 programs <i>NB: Only six cities receive HIV prevention funding directly; the remainder would have to go through State authorities for approval</i>
7. Programs must comply with State and local legal requirements and waivers	50-60 programs
8. States or localities requesting use or redirection of funds must: -- have a high incidence of substance abuse; or -- have a high incidence of injection drug-related HIV/AIDS; or -- have a high proportion of new HIV/AIDS cases among women of childbearing age.	8-12 programs <i>(estimated number of States or localities that are able to meet this criterion and are likely to complete a funding redirection process during the next year)</i>

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Scientific Certification of the Effectiveness of Needle Exchange Programs Roll-Out Strategy

Overall Roll-Out Goals

- To maximize positive exposure for the Secretary as the guardian of public health and sound science; and
- To minimize the risk of negative exposure through appropriate planning and management of the roll-out, and through the inclusion of a broad array of mainstream supporters.

Summary of Basic Components

- Press Event/s
 - Press briefing on the science
 - Press conference on the Secretary's certification
- Supplemental Press Strategy/ Community Coordination
 - Major National Media -- print and electronic
 - Major Local/Regional Media Markets
 - Specialty Press (medicine/health, gay, black constituencies)
 - Editorial Boards
- Congressional Outreach
- Timing

Press Events

Scientific Press Briefing:

This 30-45 minute briefing would be designed to present and highlight the scientific evidence that has accumulated demonstrating that needle exchange programs reduce HIV transmission and do not encourage drug use. In addition, data demonstrating that needle exchange can be an effective bridge to treatment would also be presented.

Drs. Varmus, Leshner, Fauci, Gayle, Goosby (and perhaps Satcher and Chavez) could be present to show an impressive and united scientific front from HHS and to answer any scientific questions the press may have, including those related to the General's spin on the Montreal and Vancouver data. We might also include the authors of those studies.

The press would receive two handouts:

1. document summarizing the science and signed by all of the above described HHS docs.
2. an epidemiological profile showing the more than 50% and growing number of men, women, and children directly or indirectly HIV infected through IV drug use.

Press Conference:

This 30-45 minute press conference would be designed to highlight the broad based mainstream support for the Secretary in her certification of the scientific data on the effectiveness of needle

exchange. The photo is a “we are the world” shot of an “army behind her” with two or three recognizable individuals or organizations standing with her and speaking in support of her action. Following her statement and two or three other thematic statements, questions would be in order. Given that the scientific briefing would have preceded the press conference, questions would likely be limited to political realities (i.e. timing, White House, General McCaffrey, Congress, etc).

Other possible speakers include:

American Medical Association -- AMA could speak on behalf of the vast army of other medical and health organizations in support of needle exchange. Nancy Dickie is their new Board Chair and is an articulate Texas Republican with strong ties to Gov. Bush. In the alternative, Lonnie Bristow, their past Chair and emeritus, is African-American, and is now working closely with a new group called “Physician Leadership on Substance Abuse.” Finally, Reed Tuckson, also African-American, is the AMA Vice President and former President of the March of Dimes. He is a pediatrician and could also talk about the relationship of IV drug use to pediatric AIDS (80% of cases).

Association of State and Territorial Health Officers -- ASHTO could speak on behalf of state and local health officials who are charged with the development and implementation of HIV prevention programs. It may be useful to have the Connecticut Health Officer represent ASHTO as a state with a Republican governor who funds a needle exchange program which is showing very promising results (New Haven). She could talk about the importance of states rights, local control, and needle exchange as part of a broadly supported comprehensive strategy that has saved lives in her state.

NAACP -- Kuwasi Mfume could speak for a range of organizations representing the African-American community including the NAACP, National Medical Association, National Urban League, National Black Police Association, and others to dispel the myth that the black community opposes this strategy. He could highlight the disproportionate impact of HIV on communities of color and explain why this action is consistent with, and an integral part of, the Administration's race initiative. Finally, as a former Member of the Congressional Black Caucus and the representative from Baltimore (which has a great needle exchange program), he has a few extras he can bring as well.

Former Administration Health Official -- It may be worth checking on an appearance by Lou Sullivan or Bill Roper. Throughout the Bush Administration, HHS often articulated the policy that when it came to HIV prevention, the federal government should neither force communities to take action they were not comfortable with or prevent them from taking action they thought was necessary to slow the spread of HIV. An appearance by either of these officials would provide significant cover with the Congress. Roper, former director of the CDC, is now Dean of the School of Public Health at the University of North Carolina. Collectively, the Schools of Public Health have passed a resolution in support of needle exchange. He could represent the group.

Other representatives could be present to show broad support for the Secretary's action. They would not be asked to speak but could be available as a resource to the Secretary (at her option) during the Q and A. These individuals and organizations might include:

- National Black Mayors' Conference
- US Conference of Mayors
- American Bar Association
- National Black Police Association: a member, Melvin Wearing, the Chief of Police for New Haven, is an extremely strong supporter of the needle exchange, and would probably be willing to attend. He has written to the Secretary asking her to move forward with this important action. He attended the White House Conference on 0-3 and sat on the panel with the President.
- AIDS organizations: AIDS Action, HRC, NAPWA, AMFAR, NORA
- Dr. Varmus (to show support on the science)
- Sandy Thurman (to show support from the White House)

Note: If there was a desire to streamline this press event, the press briefing-conference could be consolidated by adding Dr. Varmus to the speaking line-up at the press conference. He could present the science and then be available for the Q & A. Further, if the desire was to simply make this announcement on paper, without an event, the Department could release the scientific summary (signed by Varmus, Fauci, Leshner, et.al.) and a statement by the Secretary making the official certification. This could be supplemented by a written statement from each of the organizations applauding the Secretary for her leadership.

Supplemental Press Strategy/Community Coordination

Major National Media: Beyond those in attendance at the press event, we would want to reach out to the national media to ensure that they have science and the Secretary's statement. In addition, our "friends" among the weekend "talking heads" should receive our information so that they can push the science during political round-table discussions. Finally, the Department will have to decide if spokespeople (i.e. Secretary, Varmus, et. al.) would be made available following the formal announcement.

Major Local/Regional Markets: To ensure positive stories in each of the major media markets, we would put together a list of health and AIDS point people on the ground in each of the markets who would be available to applaud the Administration's leadership and to help manage the story locally.

Specialty Press: Materials would be made available to the specialty press with a constituency interest in this issue including the gay press, the black community press, and the medical-health journals and newsletters. In each case, we would work with the

appropriate constituency to ensure that materials from the Department were supplemented by press releases from the most relevant and influential organizations.

Editorial Boards: The Department should consider an editorial board mailing to the major papers. Again, we would talk with health and AIDS point people on the ground to follow up and to provide city specific epidemiological data and any information from needle exchange programs that are currently operating. It would certainly not hurt to have papers like the Philadelphia Inquirer and the Chicago Tribune do editorials in support of the Secretary's leadership and the soundness of this policy.

Congressional Outreach: To maximize positive relations with the Congress, the document summarizing the science and the Secretary's certification should be delivered the press event to Capitol Hill leaders with special attention given to Labor-HHS Appropriators and authorizers. A call to Porter and Specter from the Secretary or Rich Tarplin would also help. In addition, caucus chairs (Black, Hispanic, and Women's) and friendly Republicans who may be inclined to support the Secretary's action (Johnson, Foley, Gansky) should be brought into the loop before they hear it through the media. Briefings by Dr. Varmus, et. al. should be offered to all of the above.

**General, McCaffrey's
Positive Influence on the Administration's
Needle Exchange Policy**

- A joint statement has been issued by the ONDCP and ONAP affirming the entire Administration's strong **support for a needle exchange policy based on “sound science”** and determined by Secretary of HHS Shalala and the world class scientists at the NIH (Varmus, Fauci, Leshner) [see attached]
- To affirm the Administration's strong **support for the primary importance of drug treatment**, the Administration's needle exchange policy will ensure that:
 - no money is diverted from drug treatment to needle exchange [Note: to accomplish this goal, the Administration is willing to support inclusion of a flat ban on needle exchange funding in the SAMHSA reauthorization, thereby eliminating access to 90% of the potential funding for needle exchange]; and
 - no needle exchange program is authorized to use federal funds unless it is linked to referral to drug treatment services.
- To affirm the Administration's **strong support for law enforcement**, the Administration's needle exchange policy will ensure that no needle exchange program is authorized to use federal funds unless its operation is consistent with state and local legal requirements (i.e. paraphernalia laws).

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
April 20, 1998

Contact: HHS Press Office
(202) 690-6343

RESEARCH SHOWS NEEDLE EXCHANGE PROGRAMS REDUCE HIV INFECTIONS WITHOUT INCREASING DRUG USE

Health and Human Services Secretary Donna E. Shalala announced today that based on the findings of extensive scientific research, she has determined that needle exchange programs can be an effective part of a comprehensive strategy to reduce the incidence of HIV transmission and do not encourage the use of illegal drugs.

Under the terms of Public Law 105-78, the Secretary of HHS is authorized to determine that such programs reduce the transmission of the human immunodeficiency virus (HIV) and do not encourage the use of illegal drugs. The act's restriction on federal funding, however, has not been lifted.

"This nation is fighting two deadly epidemics -- AIDS and drug abuse. They are robbing us of far too many of our citizens and weakening our future," said Secretary Shalala. "A meticulous scientific review has now proven that needle exchange programs can reduce the transmission of HIV and save lives without losing ground in the battle against illegal drugs. It offers communities that decide to pursue needle exchange programs yet another weapon in their fight against AIDS."

While the use of federal funds continues to be restricted, and criteria for their use have not been established, Secretary Shalala emphasized that needle exchange programs that have been successful have had the strong support of their communities, including appropriate State and local public health officials. The science reveals that successful needle exchange programs refer participants to drug counseling and treatment as well as necessary medical services, and make needles available on a replacement basis only.

The Administration has decided that the best course at this time is to have local communities which choose to implement their own programs use their own dollars to fund needle exchange programs, and to communicate what has been learned from the science so that communities can construct the most successful programs possible to reduce the transmission of HIV, while not encouraging illegal drug use.

Since the AIDS epidemic began in 1981, injection drug use has played an increasing role in the spread of HIV and AIDS, accounting for more than 60% of AIDS cases in certain areas in 1995. To date, nearly 40% of the 652,000 cases of AIDS reported in the U.S. have been linked to injection drug use. More than 70% of HIV infections among women of childbearing age are related either directly or indirectly to injection drug use. And more than 75% of babies diagnosed with HIV/AIDS were infected as a direct or indirect result of injection drug use by a parent.

Communities' use of needle exchange programs has increased throughout the epidemic. According to data reported to the Centers for Disease Control and Prevention, communities in 28 states and one U.S. territory currently operate needle exchange programs, supported by State, local, or private funds. Many of these programs provide a direct linkage to drug treatment and counseling as well as needed medical services.

Since 1989, the use of federal funds for needle exchange programs has been restricted by the Congress. Funding has, however, been authorized by the Congress to conduct research into the efficacy of such programs as a public health intervention to reduce transmission of HIV and to examine the impact of such programs on drug use. The federal government has supported numerous studies of the effectiveness of needle exchange programs in reducing the transmission of HIV among injection drug users, their spouses or sexual partners, and their children. Many of these studies also examined whether or not needle exchange programs encourage the use of illegal drugs.

In February 1997, Secretary Shalala reported to Congress that a review of scientific studies indicated 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." She also directed the Department's scientific agencies to continue to review research findings regarding the effect of needle exchange programs on illegal drug use. The scientific evidence indicates that needle exchange programs do not encourage illegal drug use and can, in fact, be part of a comprehensive public health strategy to reduce drug use through effective referrals to drug treatment and counseling.

"An exhaustive review of the science in this area indicates that needle exchange programs can be an effective component of the global effort to end the epidemic of HIV disease," said Harold Varmus, MD, Director of the National Institutes of Health. NIH has funded much of the research into the effectiveness of needle exchange programs and their impact on drug use. "Recent findings have strengthened the scientific evidence that needle exchange programs do not encourage the use of illegal drugs," Dr. Varmus said. Specifically, he cited:

- In March 1997, the National Institutes of Health published the Consensus Development Statement on Interventions to Prevent HIV Risk Behaviors. That report concluded that needle exchange programs "show a reduction in risk behaviors as high as 80% in injecting drug users, with estimates of a 30% or greater reduction of HIV." The panel also concluded that the preponderance of evidence shows either a decrease in injection drug use among participants or no changes in their current levels of drug use.
- An October 1997, study of needle exchange programs in Baltimore, Maryland, indicated that needle exchange programs that are closely linked to or integrated with drug treatment programs have high levels of retention in drug treatment. A 1998 NIH Consensus Conference report on the effectiveness of treatment for heroin addiction found that drug treatment programs can assist heroin users in halting their drug use.

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

April 20, 1998

Contact:

HHS Press Office
(202) 690-6343

NEEDLE EXCHANGE PROGRAMS: PART OF A COMPREHENSIVE HIV PREVENTION STRATEGY

Overview: Since 1981, injection drug use has played an increasing role in the spread of HIV and AIDS, accounting for more than 60% of AIDS cases in certain areas in 1995. To date, nearly 40% of the 652,000 cases of AIDS reported in the U.S. have been linked to injection drug use. More than 70% of HIV infections among women of childbearing age are related either directly or indirectly to injection drug use. And more than 75 percent of babies diagnosed with HIV/AIDS were infected as a direct or indirect result of injection drug use by a parent.

To protect individuals from infection with HIV and other blood-borne infections, several communities have established needle or syringe exchange programs. In communities that choose to use them, needle exchange programs are a form of public health intervention to reduce the transmission of the human immunodeficiency virus (HIV) among drug users, their sex partners, and their children. They provide new, sterile syringes in exchange for used, contaminated syringes. Many needle exchange programs also provide drug users with a referral to drug counseling and treatment, medical services, and provide risk reduction information.

Under the terms of Public Law 105-78, federal funds to support needle exchange programs were conditioned on a determination by the Secretary of Health and Human Services that such programs reduce the transmission of the human immunodeficiency virus (HIV) and do not encourage the use of illegal drugs. The Secretary has made that determination. The Act's restriction on federal funding, however, has not been lifted.

The Administration has decided that the best course at this time is to have local communities which choose to implement their own programs use their own dollars to fund needle exchange programs, and to communicate what has been learned from the science so that communities can construct the most successful programs possible to reduce the transmission of HIV, while not encouraging illegal drug use.

In a February 1997 report to Congress, Health and Human Services Secretary Donna E. Shalala reported that a review of the findings of scientific research indicated 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."

On April 20, 1998, Secretary Shalala announced that a review of research findings indicated that needle exchange programs also "do not encourage the use of illegal drugs."

FEDERAL RESEARCH ON NEEDLE EXCHANGE

While Congress has restricted the use of federal funds for needle exchange programs since 1989, lawmakers have authorized funding for research into the efficacy of needle exchange programs as a public health intervention to reduce the transmission of HIV and to examine the impact of such programs on drug use. The federal government has supported and will continue to support research into the effectiveness of needle exchange programs.

Effect of Needle Exchange Programs on HIV Transmission

Three major expert reviews of the scientific literature on needle exchange programs conclude that such programs can be an effective component of a comprehensive community-based HIV prevention effort. Additionally, needle exchange programs can provide a pathway for linking injection drug users to other important services such as risk reduction counseling, drug treatment, and support services. The reviews include:

- *Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy*, United States General Accounting Office, March 1993, is an extensive review of U.S. and international data looking at the effects of needle exchange programs. It estimated that a needle exchange program in New Haven, Connecticut, had led to a 33% reduction in HIV infection rates among drug users in that city.
- *The Public-Health Impact of Needle Exchange Programs in the United States and Abroad*, prepared by the University of California, San Francisco, September 1993, reported that needle exchange programs served as an important bridge to other health services, particularly drug counseling and treatment. It also found that needle exchange programs reached a group of injecting drug users with long histories of drug use and limited exposure to drug treatment.
- *Preventing HIV Transmission: The Role of Sterile Needles and Bleach*, National Research Council and Institute of Medicine, September 1995, concluded that needle exchange programs have beneficial effects on reducing behaviors such as multi-person reuse of syringes. It estimated a reduction in risk behaviors of 80% and reductions in HIV transmission of 30% or greater.

Based on that scientific evidence, in February 1997, Secretary Shalala reported to Congress that a review of scientific findings indicated 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.” She also directed the Department’s scientific agencies to continue to review research findings regarding the effect of needle exchange programs on illegal drug use.

Impact of Needle Exchange Programs on Drug Use

Extensive research indicates that needle exchange programs do not encourage illegal drug use and can, in fact, reduce drug use through effective referrals to drug treatment and counseling. Several recent studies strengthen the conclusion that needle exchange programs do not encourage the use of illegal drugs. They include:

- In March, 1997, the National Institutes of Health published the Consensus Development Statement on Interventions to Prevent HIV Risk Behaviors. That report concluded that needle exchange programs “show a reduction in risk behaviors as high as 80% in injecting drug users, with estimates of a 30% or greater reduction of HIV.” The panel also concluded that the preponderance of evidence shows either a decrease in injection drug use among participants or no changes in their current levels of drug use.
- An October 1997, study of needle exchange programs in Baltimore, Maryland, (Brooner et al., Abstract presented to the American Public Health Association, October 1997) reported that needle exchange programs that are closely linked to or integrated with drug treatment programs actually reduce the incidence of drug use with high levels of retention in drug treatment. A 1998 NIH Consensus Conference report on the effectiveness of treatment for heroin addiction found that drug treatment programs can assist heroin users in halting their drug use.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

APR 20 1998

MEMORANDUM TO THE SECRETARY

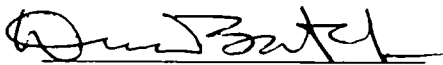
SUBJECT: Review of Scientific Data on Needle Exchange Programs

At your request, we have reviewed the scientific studies on the effectiveness of syringe and needle exchange programs. Attached is our review. It includes:

- o Appendix A: The Department's February 1997 Report to Congress
- o Appendix B: Recent data analysis completed since February 1997
- o Appendix C: Summary document reviewing the scientific literature by outcome measures of interest
- o Appendix D: Data summary specifically addressing the criteria established by Congress as conditions for federal funding for needle exchange programs

After reviewing all of the research, we have unanimously agreed that there is conclusive scientific evidence that needle exchange programs, as part of a comprehensive HIV prevention strategy, are an effective public health intervention that reduces the transmission of HIV and does not encourage the use of illegal drugs. In addition, when properly structured, needle exchange programs can provide a unique opportunity for communities to reach out to the active drug injecting population and provide for the referral and retention of individuals in local drug treatment and counseling programs and other important health services.

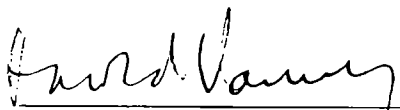
Therefore, based on the scientific data, we strongly recommend that you certify that needle exchange programs are effective in reducing the transmission of HIV and do not encourage the use of illegal drugs.



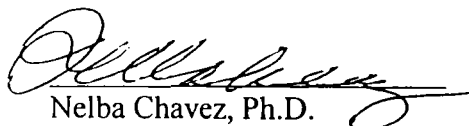
David Satcher, M.D., Ph.D.
Assistant Secretary for Health
Surgeon General



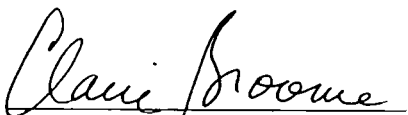
Margaret Hamburg, M.D.
Assistant Secretary for
Planning and Evaluation



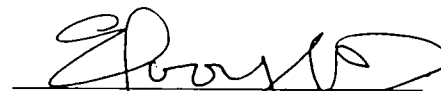
Harold Varmus, M.D.
Director
National Institutes of Health



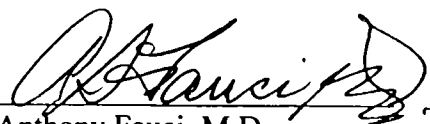
Nelba Chavez, Ph.D.
Administrator
Substance Abuse and Mental Health
Services Administration



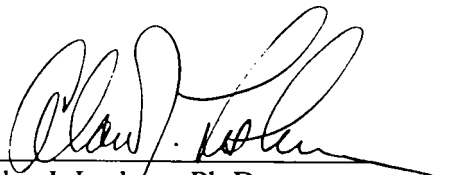
Claire Broome, M.D.
Acting Director
Centers for Disease Control and Prevention



Eric P. Goosby, M.D.
Director
Office of HIV/AIDS Policy



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



Alan I. Leshner, Ph.D.
Director
National Institute on Drug Abuse



Helene Gayle, M.D., M.P.H.
Director
National Center for HIV, STD and
TB Prevention, CDC

NEEDLE EXCHANGE PROGRAMS IN AMERICA: REVIEW AND EVALUATION OF SCIENTIFIC RESEARCH

Introduction

In September 1996, the Committee on Appropriations for the Departments of Labor, Health and Human Services, Education and Related Agencies requested the Secretary of the Department of Health and Human Services to provide a review of the scientific research on needle exchange programs. In response to that request, the Department provided a report to Congress in February 1997 with an overview of the status of scientific research on needle exchange programs, including a compilation of relevant studies and abstracts pertinent to the efficacy of needle exchange programs in reducing HIV transmission and their effect on utilization of injection drugs.

The February 1997 report included two extensive summaries (National Academy of Science/Institute of Medicine 1995, and University of California at Berkeley/San Francisco 1993) evaluating the research literature on the effectiveness of needle exchange programs for the prevention of HIV transmission among injection drug users and their effect on utilization of illegal drugs. An earlier report by the General Accounting Office (1993) reviewed the results of studies addressing the effectiveness of needle exchange programs in the United States and abroad, with an assessment of 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. The conclusion provided in the February 1997 report stated 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, and 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.

Since the completion of the February 1997 report to Congress, a number of researchers have published data in peer-reviewed journals or presented research findings at national conferences. The National Institutes of Health also published an NIH Consensus Development Statement, Interventions to Prevent HIV Risk Behaviors, in March 1997. That document summarized the proceedings of an NIH Consensus Development Conference, which evaluated the available scientific information regarding the effectiveness of interventions designed to prevent HIV transmission, including needle exchange programs.

Consistent with the February 1997 report to the Congress, this report is limited to those studies conducted in the United States, with the exception of the inclusion of Canadian research data from Vancouver and Montreal. The National Academy of Sciences/Institute of Medicine previously reviewed the unpublished data from Montreal, now published in final form. Other international studies are not reviewed here, as drug use patterns are highly context sensitive in terms of both social, cultural and economic factors and findings could not be generalized to the U.S. population.

This report builds upon the February 1997 report to Congress, expanding on that summary to include newly available data and the implications for policy.

HIV Transmission Through Injection Drug Use

The consequences of injection drug use have become the driving force in the HIV epidemic in the United States. Half of all new infections are caused by the sharing of injection equipment contaminated with HIV, either due to injection drug use or through unprotected sex with an injection drug user or birth to a mother who herself, or whose partner, was infected with HIV through drug use. The proportion of AIDS cases and new HIV infections attributable to injection drug use has been rising steadily. Over 75% of new HIV infections in children result from injection drug use by a parent. The impact has been most devastating in communities of color, which accounted for 65% of newly reported AIDS cases between July 1996 - June 1997.

The primary goal of needle exchange programs is to reduce the transmission of HIV and other blood borne infections, such as hepatitis B (HBV) and hepatitis C (HCV), associated with drug injection by providing sterile needles in exchange for potentially contaminated ones. Researchers from Yale University empirically demonstrated that provision of sterile syringes results in removing from circulation contaminated syringes that could potentially be re-used, thereby decreasing the transmission risk associated with sharing contaminated equipment. In addition to exchanging syringes, needle exchange programs are effective access points for populations with multiple high risk behaviors for HIV infection to receive other services. Many needle exchange programs provide an array of other services including referrals to drug treatment and counseling, HIV testing and counseling, and screening for sexually transmitted diseases and tuberculosis. There are more than 100 needle exchange programs now operating in 71 cities and 28 states and one territory in the United States.

Summary of Research Findings on Needle Exchange Programs

This section summarizes in brief the primary research findings regarding needle exchange programs. A more extensive review of the studies included in the February 1997 DHHS Report to the Appropriations Committee can be found at Appendix A; an analysis of those studies completed since February 1997 is provided at Appendix B. A summary table of needle exchange research studies examining specific outcomes of interest is provided at Appendix C. A subset of this table identifying those studies reporting on the two criteria established in the Public Law 105-78 Appropriations legislation is provided at Appendix D.

Empirical Studies in the United States Needle exchange programs have been implemented in low, moderate and high HIV prevalence sites in an attempt to reduce the spread of HIV and other blood borne infectious diseases among injection drug users. A discussion of some of the methodological issues pertinent to studies on needle exchange is provided later in this document.

In brief, findings from a comprehensive review of the literature indicate that needle exchange programs: increase the availability of sterile injection equipment and reduce the proportion of contaminated needles in circulation (Kaplan and Heimer 1992, Kaplan 1994, and Heimer et al. 1993); reduce drug-related risk behaviors such as multi-person re-use of syringes (Hagan et al. 1991 and 1993, Guydish et al. 1993, Oliver et al. 1994, Paone et al. 1994, DesJarlais et al. 1994, Watters et al. 1994, Singer et al. 1997, and Vlahov et al. 1997); increase drug treatment referrals (Heimer 1994) and entry into drug treatment (Hagan et al. 1993, Singer et al. 1997, and Vlahov et al. 1997); have successfully referred participants to drug treatment with resulting high drug treatment retention rates and reduced HIV risks (Brooner and Vlahov 1997); have shown small improvements in reducing sexual risk behaviors among needle exchange participants (Watters et al. 1994, DesJarlais et al. 1994, and Paone et al. 1994); have maintained low prevalence of blood borne HBV and HCV infections (Heimer et al. 1993, DesJarlais et al. 1995, Hagan et al. 1994, and Paone et al. 1994); have reduced HIV seroprevalence rates in certain cities (Hurley, Jolley and Kaldor 1997); and have reduced the rate of new blood borne infections like HIV and HBV among program participants (Hagan et al. 1991 and 1995, and DesJarlais et al. 1996). Additional information on the study design and findings of the studies listed above can be found in the summary documents at Appendices C and D.

Empirical Studies in Canada Two recent observational studies from Vancouver (Strathdee et al. 1997) and Montreal (Bruneau et al. 1997) reported a higher incidence of HIV among injection drug users participating in needle exchange than non-exchange participants. In Vancouver, HIV seroprevalence was estimated to be stable at 1%-2% among the injection drug using population from 1988, when the needle exchange program was established, through 1993. In 1994, a rapid expansion of the HIV epidemic took place, with a baseline seroprevalence of 23.2% observed in a prospective cohort study of injection drug users. Preliminary analysis from this cohort study found an HIV incidence rate of 18.6 per 100 person years. This study reported on a number of behavioral and social risk factors associated with HIV seropositive status, including a high level of injectable cocaine use, prostitution and longer histories of injection drug use. The presence of multiple behavioral risk factors confounded the ability to isolate participation in needle exchange as a predominant or predictive factor for HIV infection. Subsequent 1997 data from this cohort have showed a decline in HIV incidence to 4.4 per 100 person years.

An observational cohort study of injection drug users was conducted in Montreal. In a baseline assessment of HIV seroprevalence, individuals who attended a needle exchange program reported higher frequencies of risk behaviors associated with drug injection and more frequent involvement in prostitution activities. In a prospective HIV seroincidence analysis, HIV incidence among persons attending the needle exchange program was 7.9 per 100 person years, compared to 3.1 per 100 person years among non-attenders. As in the Vancouver study, demographic, behavioral and social factors were identified that in aggregate defined the high risk profile of those persons also attending needle exchange programs. A more complete review and analysis of these two studies is provided at Appendix B.

Synthesis Reports

Institute of Medicine

In 1995, the National Academy of Sciences/Institute of Medicine published a report, Preventing HIV Transmission: The Role of Sterile Needles and Bleach, reviewing the cumulative body of scientific literature available at that time. A summary of the conclusions of the NAS/IOM panel on the scientific assessment of needle exchange program effectiveness is provided as follows:

“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 drug 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.” p.4

The IOM concluded that “ needle exchange programs should be regarded as an effective component of a comprehensive strategy to prevent infectious disease.” (p.4)

NIH Consensus Development Statement

In March 1997, the National Institutes of Health published the Consensus Development Statement on Interventions to Prevent HIV Risk Behaviors, summarizing the proceedings of a Consensus Development Conference. A panel of non-Federal experts evaluated the available scientific information regarding behavioral interventions to reduce risk for HIV/AIDS. Presentations of scientific data were made to the panel by distinguished researchers, including ongoing evaluation studies of needle exchange programs. Specific behaviors and community contexts that produce elevated risks for HIV infection were reviewed, as well as the spectrum of available interventions to reduce behavioral risks. After reviewing the data on needle exchange programs, the panel concluded that these programs have beneficial effects on reducing behaviors

such as multi-person re-use of syringes. They reported that “studies show a reduction in risk behaviors as high as 80% in injecting drug users, with estimates of a 30% or greater reduction of HIV.” (p.11) The panel also concluded that the preponderance of evidence shows either a decrease in injection drug use among participants or no changes in their current levels of use.

University of California at Berkeley and San Francisco Study for the CDC

In 1993 the University of California published a review and analysis of the literature on needle exchange programs to answer a number of research questions, including the effect of needle exchange programs on HIV infection rates and HIV risk behaviors. Study findings reported included the following: needle exchange programs served as a bridge to other health services, particularly drug abuse treatment; needle exchange programs generally reached a group of injecting drug users with long histories of drug injection and limited exposure to drug abuse treatment; there was no evidence that needle exchange programs increased the amount of drug use in participants or changes in overall community levels of drug use; needle exchange programs did not result in an increase in the number of discarded syringes in public places; the rates of HIV drug risk behaviors were reduced in needle exchange participants; needle exchange programs were associated with reductions in hepatitis B among injection drug users; and, the data were too limited at that time to draw conclusions about needle exchange programs and reductions in HIV infection rates.

Summary of New Research Findings

Since completion of the Department of Health and Human Services' February 1997 report to the Congress on needle exchange programs, several scientific studies have added new data on the effects of needle exchange programs, corroborating and expanding knowledge about the role needle exchange programs play in reducing HIV transmission. In addition, these new data continue to demonstrate that needle exchange programs do not encourage drug use, and in fact will increase referrals into drug treatment for hard-to-reach populations. A more complete description of these studies is provided at Appendix B.

In a study by Vlahov et al. (1997), reductions in high risk drug use behaviors and an increase in enrollment in drug treatment were observed in a cohort participating in the needle exchange program. In a study by Brooner et al (in press), a high rate of acceptance of substance abuse treatment and retention in treatment was demonstrated among injection drug users referred from needle exchange programs, despite greater severity of drug use and high risk behaviors for HIV and psychosocial problems in this group. Hurley et al (1997) identified decreased HIV seroprevalence among 29 cities with needle exchange programs compared to 52 cities without these programs, with cities selected according to the availability of HIV prevalence data for their injection drug using population for 2 or more years. Two studies from Canada reported increased HIV incidence among injection drug users also using needle programs, but the design of these studies and the behavioral characteristics of the study populations limit the

generalizability of the findings to the United States populations. Subsequent data from one Canadian study (Vancouver) has shown a significant decrease in HIV incidence since publication of the first study.

Methodological Considerations

In reviewing the scientific data on needle exchange, it is relevant to note the wide range of methodologic approaches utilized and the impact of these study design choices on the conclusions drawn. As was noted in the 1995 report by the National Academy of Sciences/Institute of Medicine, some of the studies that examine needle exchange and bleach distribution programs have various limitations including inadequate sample size, improper controls and problematic measures including self-reporting instruments. In behavioral research, these study designs and instruments are the best available tools to describe complex behaviors. In addition, multiple behavioral risk factors, including drug choices such as cocaine, confound the ability to isolate cause and effect relationships for HIV transmission among injection drug users. This whole body of research is burdened by these constraints.

Nevertheless, as the NAS/IOM report states "... the limitations of individual studies do not necessarily preclude us from being able to reach scientifically valid conclusions based on the entire body of literature available. The situation resembles the exploration of the relationship between cigarette smoking and lung cancer; virtually every individual study was vulnerable to some particular objection, yet collectively those studies justified a compelling conclusion. It was essential for the panel first to distinguish between studies of high quality and those of lesser quality, and then to weigh the credibility of the findings, according to their completeness and soundness. Using this approach, the panel based its conclusions on the pattern of evidence provided by a set of high-quality studies, rather than relying on the preponderance of evidence across less scientifically sound studies." p. 3-4

Maximizing the Public Health Benefits of Needle Exchange Programs

In assessing the public health benefits gained from needle exchange programs, certain characteristics have consistently emerged from the research data that confirms the unique role that needle exchange programs can play as part of the public health response to an epidemic driven by injection drug use. To ensure that federal dollars are maximized in this effort, a careful consideration of those factors most predictive of public health benefit must be heeded. To this end, it is critical that no reduction in drug treatment capability occur, as substance abuse treatment remains the long term strategy for reducing injection drug use and the associated risk of HIV transmission. Needle exchange programs are appropriately supported as an HIV prevention activity in those communities that choose to develop them. Other important factors include local support of health department leaders and affected communities for needle exchange as a necessary component of a broader, comprehensive HIV prevention plan. Those programs which consistently provide referral to medical and drug treatment afford the greatest opportunity

to reduce HIV infection and decrease injection drug use. Concerns among communities have highlighted the need for appropriate disposal of hazardous wastes. Where collection and disposal of used syringes has been implemented, and syringes are provided on a replacement basis only, community support has been achieved. Those programs that operate in accordance with state and local laws, or which are granted waivers from applicable laws, have shown the greatest success in linking together the range of medical and drug treatment services needed by their clients. Finally, there is an important role for ongoing evaluation of needle exchange programs to maximize their effectiveness in reaching high risk populations and providing the means for injection drug users to eliminate or reduce both their risks for HIV and injection drug use.

Public Health Implications

The scientific data now available have established the utility of needle exchange programs in reducing new HIV infections with no evidence of increasing injection drug use. The data supports the unique role needle exchange programs can play in creating an access point into social services, drug treatment and medical care for the population most responsible for new HIV seroconversions. This role as a conduit into care is amplified in that needle exchange programs offer, at multiple points in time, repeated opportunities for prevention intervention as well as an ongoing opportunity to develop trusting relationships between professional staff and the injection drug-using population. This is often the most significant social connection in an active drug user's life and creates a foundation with which future interventions may depend. In addition to the immediate replacement of a contaminated needle with a clean one, we see the efficacy of a needle exchange program as dependent on its relationship to a constellation of services that are directed at identifying high risk populations and creating formal conduits into care.

The public health need to target high risk populations most responsible for driving HIV seroconversion rates is evident. Our understanding of how HIV moves through communities must be structured into responses to epidemiologic surveillance data that describe modes of transmission. This includes allowing States and localities to coordinate their resources and target them to those population groups that cannot stop participating in high risk behaviors. However, federal funding is only appropriate for those programs that provide the critical linkages with drug treatment and health care services and incorporate the spectrum of prevention services that have proven effective HIV prevention tools.

We remain committed to exploring through research those factors that affect the demonstrated utility of needle exchange programs in curtailing transmission of HIV in communities and the relative effects on drug use and entry into drug treatment.

Attachments

- Appendix A: 1997 Report to Congress
- Appendix B: Analysis of Recent Data
- Appendix C: Summary Tables of Research Studies
- Appendix D: Summary of Data by Statutory Criterion



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

**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
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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 use; 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

AL-100-10 C

PREVENTING

HIV

TRANSMISSION

The Role of
Sterile Needles
and Bleach

NATIONAL RESEARCH COUNCIL • INSTITUTE OF MEDICINE

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

Don C Des Jarlais, Michael Marmor, Denise F. Kline, Stephen Titus, Qihui 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,² whereas that participation is associated with lower rates of drug-injection HIV-risk behaviour.^{3,4} 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.⁵

New York City had rapid transmission of HIV among drug injectors between 1978 and 1984, with seroprevalence reaching about 50%.⁶ 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 1990.⁷ 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

Lancet 1996; 348: 987-91

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**[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.

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[Tu.C.2523] NEEDLE EXCHANGE USE AMONG A COHORT OF DRUG USERS

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Objective: To prospectively study injection behaviors among IDU who did and did not utilize a local needle exchange in the Bronx, New York City.

Methods: Starting in 1985, IDUs attending a methadone maintenance program were enrolled in a prospective study of HIV-related risk behaviors. Since 1989, when a needle exchange opened near the methadone program, data were collected regarding the number and percent of needles obtained at the needle exchange. By end of 1993, 12.6% had died and 23.7% were lost to follow-up.

Results: Of 904 IDUs who injected between 1985 -1993, 21.9% used the needle exchange. Male gender (ORadj 1.57), HIV seropositivity (ORadj 1.39) and younger age (ORadj/10 yrs of age 1.66) were independently associated with needle exchange use. The percent injecting declined each year, preceding the needle exchange opening and concurrent with its operation (from 64.6% in 1985 to 43.6% in 1993). The proportion of active injectors using the needle exchange increased from 38/398 (9.6%) in 1989 to 140/251 (55.8%) in 1993. Among the 329 IDU who injected in 1988, the year before the exchange opened, 53/124 (42.7%)($p<.001$) who went on to use the needle exchange and 168/205 (81.9%)($p<.001$) non-users stopped or decreased injecting by 1993. Needle exchange users reported less needle sharing than non-users ($p<.05$ in 1993). HIV infected and uninfected IDUs were equally likely to decrease or stop injecting.

Conclusions: 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 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.

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THE MEDICAL FOUNDATION

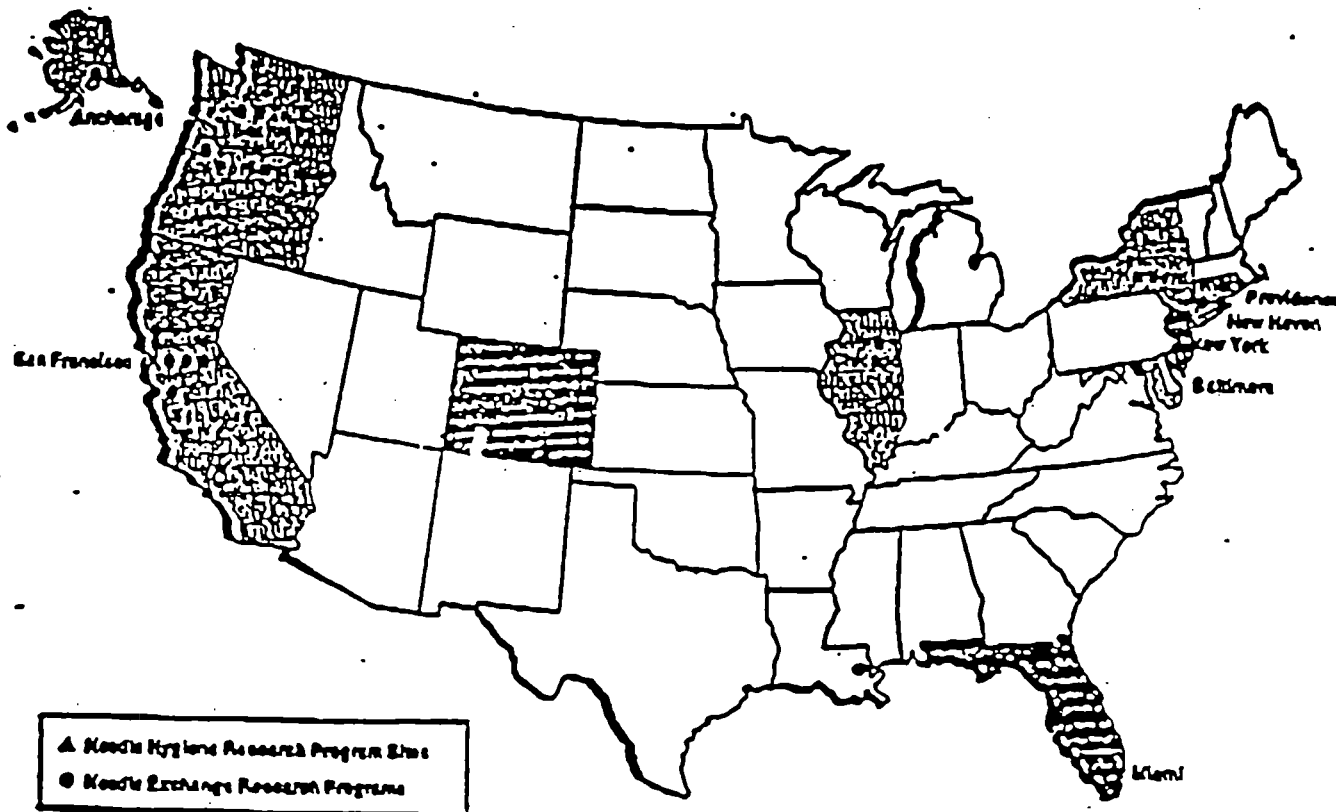
Final Report
First Year of the Pilot Needle Exchange Program
in Massachusetts

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 SITE:



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Dennis G. Fisher, Ph.D., Anchorage, AK; David R. Gibson, Ph.D., San Jose, CA; Holly Hagan, Ph.D., Seattle-King County, WA;
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Merrill C. Singer, Ph.D., Hartford, CT; Thomas W. Valente, Ph.D., Baltimore, MD; David Vlahov, Ph.D., Baltimore, MD;
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Needle Hygiene Research Program Grantees

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**NEEDLE EXCHANGE PROGRAMS:
ANALYSIS OF SCIENTIFIC DATA COMPLETED
SINCE FEBRUARY 1997**

NEEDLE EXCHANGE PROGRAMS: ANALYSIS OF SCIENTIFIC DATA COMPLETED SINCE FEBRUARY 1997

On February 18, 1997, the Secretary provided a report to the Committee on Appropriations reviewing all published studies on needle exchange programs in the United States and the status of federally-supported research. Since completion of that report, a number of researchers have published data in peer-reviewed journals or presented research findings at national conferences. The National Institutes of Health published a Consensus Development Statement, Interventions to Prevent HIV Risk Behaviors, in March 1997. Additional data have been submitted in abstract form to the 12th World AIDS Conference to be held in Geneva in the summer of 1998, but peer-review has not been completed at this time.

This report will review this recent body of data relevant to the issues of efficacy of needle exchange programs in reducing HIV transmission and their effect on utilization of illegal drugs. Consistent with the February 1997 report to the Congress, this analysis will be limited to those studies undertaken in the United States, with the exception of inclusion of the Canadian research data from Vancouver and Montreal. The National Academy of Sciences/Institute of Medicine previously reviewed the data from Montreal, and it is included here in published form. Scientific data relevant to needle exchange programs reviewed during the NIH Consensus Development Conference, which was published in March 1997, overlaps with the Department of Health and Human Services' February 1997 report to the Appropriations Committee. The conclusions drawn from the NIH Consensus Development Conference are reviewed.

NIH Consensus Statement: Interventions to Prevent HIV Risk Behaviors Volume 15, Number 2 February 11-13, 1997

The purpose of the consensus conference was to examine what is known about behavioral interventions that are effective with different populations in various settings for the two primary modes of HIV transmission: unsafe sexual behavior and nonsterile injection practices.

The consensus statement concluded that the scientific evidence shows that needle exchange program participants have a decrease in needle sharing, a decrease in drug use among participants, an increased likelihood of entering drug treatment programs, and in the vast majority of studies reviewed, no observed increase in used needles discarded in public places. The consensus development conference summary conclusion was that needle exchange programs are an effective public health intervention for decreasing seroconversions in injection drug users and do not increase drug use.

Paone D, Des Jarlais D, Clark J et al. Update: Syringe-Exchange Programs - United States, 1996. Morbidity and Mortality Weekly Review 1997; Vol 46, No. 24: 565-568.

This report summarizes a survey of needle exchange programs in the United States regarding their activities during 1995 and 1996. A questionnaire was mailed to 101 syringe exchange programs

who were members of the North American Syringe Exchange Network, followed by a structured telephone interview. Eighty seven needle exchange programs participated in the survey (86% response rate), operating in 71 cities in 28 States and one territory. Fifty one syringe exchange programs began operating before 1995, with an additional 22 starting in 1995 and 14 in 1996.

In 1996, 84 needle exchange programs reported exchanging approximately 14 million syringes. Approximately 9.4 million syringes (69%) were exchanged in the 10 most active needle exchange programs. Fifty needle exchange programs (57%) reported exchanging 55,000 fewer syringes apiece, with 23 programs exchanging fewer than 10,000 syringes each. Data on the number of syringes exchanged was not available from 3 programs.

Ninety seven percent of needle exchange program respondents (84 programs) provided client referral to substance abuse treatment programs. Instruction to reduce sexual transmission of HIV and other STDs was provided by 97% of needle exchange programs. Health services offered on-site included HIV counseling and testing (40%), primary health care (17%), tuberculosis skin testing (26%) and STD screening (20%). All programs provided injection drug users information about safer injection techniques and/or use of bleach to disinfect injection equipment.

Fifty three percent (46) of needle exchange programs operated legally, in that they operated in a State without a law requiring a prescription to purchase a hypodermic syringe or had an exemption to the State prescription law allowing the needle exchange program to function. Twenty three percent (20) of needle exchange programs were defined as illegal-but-tolerated, as they operated in a State with a prescription law but had received a formal vote of support or approval from a local elected body. Twenty four percent (21) of needle exchange programs were defined as illegal underground programs. The legal needle exchange programs were more likely than illegal ones to offer on-site HIV counseling and testing (63% of legal vs. 20% of illegal needle exchange programs) and TB skin testing (41% of legal programs vs. 7% of illegal programs). The three needle exchange programs that did not refer clients to substance abuse treatment programs were illegal underground programs.

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

Using systematic sampling, a subset of needle exchange program enrollees was recruited to participate in an evaluation study of injection practices among needle exchange program clients. The study hypothesis was that participation in a needle exchange program should reduce the frequency of high risk injection practices, contributing to a reduced risk for acquiring blood borne infections. All participants (2965) of the Baltimore needle exchange program were given a brief interview by needle exchange program staff at their first visit, covering demographic information and drug injection behavior for the previous 6 months. A subset of 422 (14.2%) recruited into the evaluation study were statistically similar to the larger cohort with respect to most demographic and drug use variables; however, the evaluation group were more likely to be female (33.2% vs 26.9%), had a higher proportion of daily speedball (heroin mixed with cocaine) injectors (72.1%

vs 64.3%), and had initiated injection drug use at a younger age (20.1 years vs. 20.8 years old). A follow-up interview at 2 weeks was completed by 335 (79.4%), and at 6 months by 221 (66%). Demographic and drug use characteristics of those returning at 2 weeks were similar to the original evaluation group, with the exception that drop-outs were 10% more likely to have used a needle after someone else. Comparison of the 221 clients studied at 6 months with the 114 who did not return were statistically similar with respect to demographic and drug use variables.

Drug use patterns and related behaviors before and after enrollment were compared for the 335 participants who completed the baseline and 2-week follow-up interviews. After joining the needle exchange program, the proportion of evaluation participants who injected at least daily declined (97% vs 88%, $p < .001$). Declines were observed in the use of syringe previously used by another person (20% vs 11.7%, $p < .001$), lending one's used syringe to a friend (27.7% vs 20.1%, $p = .003$), sharing cookers (60.5% vs 42.5%, $p < .001$), and sharing cotton (45.8% vs 33.5%, $p < .001$).

Injection frequency and syringe use variables were also examined. The mean injections per day decreased from 5.9 in the two weeks before enrollment to 4.9 in the two weeks after enrollment in the needle exchange program (mean change = -1.09, 95% confidence interval = -1.5, -0.68). The mean number of injections per syringe was 12.4 in the 2 weeks before and 8.5 in the 2 weeks after entry into the needle exchange program (mean change = -3.98, 95% CI -5.85, -2.11), and the median injections per syringe decreased from 6 to 4.3.

Regarding related practices, declines were reported in the proportion of evaluation participants who discarded needles in a street, alley, sewer or gutter (28.2% vs 15.6%, $p < .001$) and in the garbage or a dumpster (42.2% vs 29.1%, $p < .001$) at baseline and at 2 weeks. Injection settings also changed significantly, with declines in injections performed in friends' places (53.2% vs 41.7%, $p < .001$); streets, parks and restrooms (24% vs 16.2%, $p < .001$), empty houses and abandoned buildings (38.1% vs 21.6%, $p < .001$); and shooting galleries (22.9% vs 12.4%, $p < .001$).

Regarding experience with drug treatment, at baseline 5.9% of the injection drug user enrolled in the needle exchange program reported that they were in treatment. Two weeks after enrollment, 9.6% needle exchange participants reported having been in treatment, increasing to 15.9% reporting being in treatment at 6 months.

Data for participants completing the 6-month interview showed a sustained reduction in the proportion engaging in high risk injection practices at the 6-month visit. With the exception of syringe backloading ($p = .238$), all other behavioral changes from baseline to 6 months were statistically significant with $p < .001$. The number of daily injections decreased from 5.6 to 4.1 from baseline to 6 months ($p < .001$). The number of syringes used per day increased from 1.1 to 1.6 ($p < .001$). Accordingly, the mean number of injections per syringe declined substantially from 12.4 at baseline to 8.5 at 2 weeks, and 3.6 at the 6-month follow-up visit (median numbers 6.0, 4.3, and 2, respectively).

Baseline HIV seropositivity in the evaluation group was 29.9% at enrollment, and slightly higher

among the subgroup of 335 returning at 2 weeks (32.5%). It is important to note that the difference was not statistically significant, and does not reflect any change in infection status given the smaller size of the returning group and the short two week time interval. This reflects the change in drop outs and is not indicative of an alteration in the baseline seroprevalence. HIV seropositive persons were more likely than HIV seronegative persons to be older, unemployed, to share cookers and cotton, and to inject at a shooting gallery.

Study design issues of note include the reliance on self-report and the absence of an external comparison group. To study the concern that self-reported data may reflect distortion based on concern for socially acceptable responses, the authors undertook a supplemental analysis of those injection drug users who reported no decrease in injection frequency. Among this subgroup of injection drug users who admitted continuing a socially undesirable risk behavior, the levels of decline for other drug-use related variables measured were similar to the overall evaluation group. This result increases the confidence that behavioral change, not socially conditioned responses, were responsible for the observed findings.

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

An ecological study design was used to compare changes HIV seroprevalence over time among injecting drug users in 29 cities with needle exchange programs and 52 cities without needle exchange programs. The purpose of the design was to overcome methodological limitations of observational studies reliant on self-reported behavior. Cities were included in the analysis if HIV seroprevalence had been measured in injecting drug users in 2 or more calendar years, and basic information on needle exchange program implementation was available. Forty four of the study cities were in North America (54%), 32% in Europe, and 12.4% were in Asia and the South Pacific. The data from this study are included in this series due to the proportion of data coming from North America and the perspectives offered by the alternative study design. Of the North American cities, 17 had needle exchange programs and 27 did not.

Data from 214 published studies, and unpublished data from the CDC on HIV seroprevalence among injection drug users entering treatment between 1988-1993, were used in this study. The term HIV seroprevalence survey was defined as a measurement of HIV seroprevalence among injection drug users in a single city at a single point in time. The rate of change of HIV seroprevalence over time was estimated by regression analysis. Average slopes, or the rate of change in HIV seroprevalence, were calculated for cities with established needle exchange programs during the period spanned by the surveys and those without needle exchange programs. In the study cities, 1046 surveys of HIV seroprevalence involving 332,892 drug users had been done between 1980 and 1993, with 75% conducted in drug treatment centers. Some serum specimens had been collected and stored, and analyzed when HIV tests became available. The regression model showed that seroprevalence increased on average by 5.9% per year in the 52 cities without needle exchange programs, and decreased by 5.8% per year in the 29 cities with needle exchange programs ($p=.004$).

Study design issues limiting the analysis include different protocols used to collect seroprevalence data among diverse populations; however, it is unlikely that a systematic error would exist across cities with and without needle exchange programs. Selection of the cities studied may also reflect a bias in that decisions were made to conduct HIV seroprevalence surveys. HIV seroprevalence may also have remained low in some of the cities with needle exchange programs irrespective of their operation, and implementation of other HIV prevention strategies potentially confounds the study findings. Nevertheless, a plausible explanation for the differences in HIV prevalence across cities is that needle exchange programs lead to a reduction in HIV incidence in injection drug users.

Brooner R, Kidorf M, King V et al. Drug Abuse Treatment Success Among Needle Exchange Participants. Abstract Presented at APHA, Oct 1997. Accepted for publication Pub Health Rep: Special Supplement (Summer 1998)

New admissions to a Baltimore outpatient opioid substitution program were classified by their referral source (needle exchange program n=82, standard referral n=243) and followed for 3 months to assess early treatment response. Data on demographic characteristics, substance use and other psychiatric disorders were collected for each participant as well as prior history of treatment. Current psychiatric and substance use diagnoses were made using the Structured Clinical Interview for DSM-III-R (SCID). Dimensional data on severity of drug use and psychosocial impairment was obtained using the Addiction Severity Index-Fifth Edition (ASI). Outcome measures included retention in treatment rates, self-reported drug use and injection frequency, self-reported illegal activities for profit, and weekly urine tests for drugs. All patients admitted to this community-based drug treatment program received routine opioid agonist treatment and weekly individual and group counseling.

Patients in the needle exchange group were referred by the Baltimore City Needle Exchange Program. Out of a total of 160 out-of-treatment opioid abusers who were offered referral and guaranteed admission to the treatment program, 82 (51%) presented to the treatment program for admission. There were no significant demographic differences between the 82 referrals who entered treatment and the 78 referrals who did not seek admission.

There were significant differences in demographic characteristics, self-reported drug use patterns and psychosocial problems between the needle exchange program-referred group and standard referral group. Compared to baseline information for individuals in the standard referral group (SRS), the needle exchange program-referred group were older (40.6 yrs vs. 37.6 yrs, $p=.001$), more likely to be African American (85.4% vs. 49.8%, $p<.001$), had a greater proportion of men (69.5% vs 43.6%, $p<.001$) and higher rates of unemployment (93.9% vs 71.2%, $p<.001$). Significantly more referrals from needle exchange had cocaine dependence (74.1% vs 41.1%, $p<.001$) and reported remarkably higher rates of heroin and cocaine use than SRS referrals (for heroin 28.8 days vs. 17.2 days, $p<.001$). The needle group also reported significantly more days of injecting drugs (26 vs. 14 days, $p<.001$) and sharing of injection equipment (5.1 vs 1.8 days, $p=.01$). Needle exchange program referrals also reported higher severity scores for drug use, alcohol use and legal difficulties compared to SRS referrals (all p -values $<.001$). Needle exchange

program referrals also reported spending more days in the past month engaged in illegal activity than SRS referrals (12.1 vs 3.2 days, $p < .001$) and earning more illegal income during this period (\$637 vs \$181, $p = .001$).

Retention rates at the completion of 13 weeks of treatment were 88% for the standard referral group and 76% for the needle exchange program group ($p = .004$); these rates compare favorably to published data on retention rates among new admissions to opioid substitution programs in the greater Baltimore area. Self-reported data comparing pre-treatment baseline data with data collected after 30 days of treatment showed significant short-term reductions in opioid and cocaine use, number of days engaged in illegal activity, and number of days injecting all drugs (all p values $< .01$). Patients in the needle exchange program group also had significant reductions in the amount of illegal income and number of days sharing injection equipment. There was a significantly higher proportion of opioid and cocaine-positive urine specimens among the needle exchange program referral group, but there were comparable reductions in opioid positive urine specimens between months 1 and 3 for the needle exchange program group (9%) and the SRS group (11%).

This data documented that significant acceptance of referral, and retention in drug treatment with an opioid agonist component, can be achieved among injection drug users referred from needle exchange programs, in the face of greater severity of drug use, high risk behaviors for HIV, and psychosocial problems common among this population. Limitations of the study design include use of self-report, self selection among those accepting referral to treatment, lack of self-reported data for 2 and 3 month follow-up intervals, and limited sample size.

CANADIAN STUDIES

Vancouver, British Columbia

One published study, one study in press, and one abstract presented at the 5th Conference on Retroviruses and Opportunistic Infections in February 1998 reporting on the Vancouver Injection Drug Use Study are reviewed here. The study by Strathdee et al. reports on HIV incidence among a cohort of injection drug users and risk factors associated with HIV infection. The characteristics of the users of the Vancouver needle exchange program were further defined in a follow-up report by Archibald et al. The abstract by Raboud et al. describes a computer simulation model able to predict the outbreak of HIV in the Vancouver Injection Drug Use Study that was observed after years of stable incidence rates, coincident with a switch from heroin to injection cocaine among the injection drug using population.

Strathdee SA, Patrick DM, Currie SL et al. Needle Exchange Is Not Enough: Lessons From the Vancouver Injecting Drug Use Study. AIDS 1997;11:F59-F65.

Between May 1996 and February 1997, a cohort of 1006 injection drug users were continuously recruited for a study of HIV and hepatitis C (HCV) incidence and prevalence, and associated risk

behaviors. Study participants provided blood samples for HIV and HCV antibody testing, and underwent an interviewer-administered questionnaire at baseline and semi-annually. The questionnaire collected data on risk behaviors, demographic information, non-injection and injection drug use practices, substance abuse treatment history, self-reported frequency of HIV tests, sexual behavior and condom use, incarceration, housing, and a variety of mental health and social issues. Information on needle exchange program attendance was also collected as: a) ever attended needle exchange program, and b) frequent use of needle exchange program (i.e. more than once a week) or less frequent use of needle exchange programs (i.e. less than once a week). Referrals were provided for medical care, HIV/AIDS care, available drug and alcohol treatment, and counseling at each study visit.

Prevalence study Prior baseline estimates of HIV prevalence in 1988 among the Vancouver injection drug using population was 1-2%, which remained stable until 1994. For the injection drug using study cohort, baseline HIV prevalence was 23.2%; HCV prevalence was 88%. HIV positive injection drug users were more likely to be women ($p = .02$), significantly more likely to have less than a high school education, unstable housing, and to reside in a downtown Vancouver neighborhood which is the poorest district in Canada. HIV positive injection drug users were also significantly more likely to be established injection drug users (> 2 years), more likely to report engaging in commercial sex work, and more likely to inject with others. The most frequently injected drug among the cohort was cocaine, with HIV positive injection drug users reporting cocaine use more commonly than HIV seronegative injection drug users ($p < .001$). The proportion of HIV-positive and HIV-negative injection drug users who reported lending and borrowing used needles in the previous 6 months were nearly identical; almost one-half (45%) reported sharing other injection paraphernalia. HIV-positive injection drug users were more likely to have ever attended needle exchange programs (96% vs 91%, $p = .01$), and to attend needle exchange programs on a more regular basis, i.e. more than once a week (81% vs 71%, $p = .002$), compared with HIV-negative injection drug use.

Multiple logistic regression was used to identify independent predictors of HIV-positive serostatus. Behavioral variables independently associated with positive HIV serostatus were commercial sex work, borrowing used needles, injecting with others, being an established injection drug user, and attending a needle exchange program more than once per week. Sociodemographic variables independently associated with positive HIV serostatus were unstable housing and low education.

Incidence At the time of the first follow-up, 83% of the initially enrolled cohort returned. Of the 257 individuals who were seronegative at baseline, 24 HIV seroconversions had occurred yielding an estimated HIV incidence of 18.6 per 100 person years. The small number of new seroconversions precluded formal statistical analysis, but similarities with the larger HIV positive cohort included the proportion who were established injection drug users, high usage of cocaine as the most commonly injected drug, residence in unstable housing (primarily single room occupancy hotels), and the proportion who were women. Needle exchange programs were the most frequent source of syringes for all but one new HIV seroconverter.

Study design and context considerations include the possibility of self-selection bias among those returning for follow-up, if individuals suspecting an HIV exposure disproportionately returned. While cocaine injection was not an independent risk factor for HIV, cocaine was more frequently the drug of choice for HIV-positive injection drug users and is commonly associated with more frequent injections. The estimated 6000 -10,000 injection drug users in Vancouver, conservatively estimated to have 2.5 injections per day, exceeded the capacity of the needle exchange program to provide sterile injection equipment. The finding that frequent needle exchange program attendance was independently associated with HIV prevalence should not be interpreted as a causal factor, as the majority of subjects attended needle exchange programs at least once. The absence of significant change in HIV prevalence between 1988, when the needle exchange program was established, and 1994 is relevant.

NOTE: The HIV incidence rate in the injection drug use cohort was 18.6 per 100 person years between December 1996 to June 1997. Since June 1997, the incidence rate has been stable at 4.4 per 100 person years. Personal Communication from S. Strathdee.

Archibald CP, Ofuer M, Strathdee S et al. Factors Associated with Frequent Needle Exchange Program Attendance in Injection Drug Users in Vancouver, Canada. In Press. JAIDS.

A case control study to identify factors associated with frequent needle exchange program attendance was conducted among a community of injection drug users in Vancouver. Cases (n=89) were defined as those injection drug users with a newly positive HIV test result after January 1994 and who had a negative HIV test result within the prior 18 months. Controls (n=192) were HIV seronegative injection drug users who had two HIV-negative test results during the same period. Participants were recruited through street outreach, HIV testing sites, local health care providers and inner city service agencies. A questionnaire was used by trained interviewers to collect participant responses on the following issues, focused on the interval between the two HIV tests: demographic information, drug injection and sexual behavior, needle exchange program attendance, history of incarceration, mental health, and social factors such as housing and source of income. Information requested on needle exchange program attendance included if the injection drug user had attended the fixed site needle exchange programs and/or the mobile van, and the average frequency of their visits to either during the inter-test interval. Logistic regression analysis was used to examine the effects of a range of variables on needle exchange program attendance.

Of 274 participants providing information on frequency of needle exchange program attendance, 31% (84) attended the needle exchange programs daily, 27% (75) once every 2 to 6 days, 15% (42) once per week, 9% (25) one to three times per month, and 8% (23) did not use the needle exchange programs in the inter-test interval. Frequent attendees of the needle exchange programs were more likely to cite the needle exchange program as their main source of needles; about one fourth of participants reported difficulty obtaining new needles.

Cocaine was the drug of choice among study participants, with 90% of injection drug users

reporting cocaine injection during the inter-test interval; 70% injected heroin during this time. For men and women, frequent needle exchange program attendance was associated with injecting any drug >4 times/day ($p<.001$), injecting cocaine >4 times/day ($p<.004$), and borrowing used needles ($p=.003$ for women). For women, four additional variables were associated with frequent needle exchange program attendance: having a nonlegal source of income ($p=.03$), living in unstable housing ($p<.001$), using shooting galleries ($p=.003$), and not having a regular heterosexual sex partner ($p=.02$).

After adjusting for HIV serostatus, residence in Vancouver, and use of a mobile needle exchange program in multivariate analysis, frequent cocaine injection was the only variable significantly related to needle exchange program attendance for men (adjusted odds ratio (AOR) 3.9; 95% confidence interval (CI) 1.8 - 8.3). Variables independently associated with needle exchange program attendance among women were: frequency of any drug injection (AOR=5.5, CI 1.7-17), shooting gallery attendance (AOR=1.5, CI 2.2-66), and having a nonlegal source of income (AOR=3.4; CI 1.0-12).

Study design and context issues include reliance on self reported data with a recall period of up to 18 months, potential underrepresentation of male injection drug users who have sex with men, and limitation to those injection drug users with at least two HIV tests in the prior 18 months. The prevalence of cocaine use is a probable factor in the increased demand for needles, consistent with the observation that men who were frequent needle exchange program attendees were four times more likely to be frequent injectors of cocaine. The study design does not determine the effect of needle exchange program attendance on behavior, but it does document that the Vancouver needle exchange program appears to attract high risk persons. The finding that needle exchange programs attract high risk injection drug users could explain a paradoxical association between needle exchange program attendance and HIV prevalence and incidence, as sharing patterns and injection frequency among this population contribute to HIV risk independently of needle exchange program utilization.

Raboud JM, Thorne AE, Strathdee SA et al. Explosive HIV Epidemics in Injection Drug Users - What are the Causes and Controls? Abstract presented at 5th Conference on Retroviruses and Opportunistic Infections, Chicago, IL February 1998.

The purpose of this study was to determine the role of various factors in explosive outbreaks of HIV among injection drug users in cities such as Vancouver, where incidence rapidly increased to 18.6/100 person years following a long stable period with annual HIV incidence rates of 1%-2%. Computer simulations were run to study the effects of the following factors on the rates of HIV seroprevalence and seroincidence among injection drug users: number of needle-sharing partners, rate of change of partners, pattern of social networks in the injection drug user community, and high rates of infectivity in the first 3 months after seroconversion (acute phase of infection). Infectivity in the acute phase was set at 50-100 fold relative to the chronic phase, based on acute phase viral load data collected at the BC Center for Excellence in HIV/AIDS in Vancouver. The outbreak of HIV was simulated by approximately doubling the contact rates among injection drug users, as likely occurred when injection drug users switched from heroin to cocaine injection use.

in 1994. This effect was observed in the model only when a high rate of infectivity was postulated for the acute viral infection stage; reducing infectivity (as would occur with aggressive screening and antiretroviral therapy) limited the epidemic significantly. The presence of a "core group" of high risk individuals and the number of concurrent needle-sharing partners were also very influential.

Montreal, Quebec

Bruneau J, Lamothe F, Franco E et al. High Rates of HIV Infection Among Injection Drug Users Participating in Needle Exchange Programs in Montreal: Results of a Cohort Study. American Journal of Epidemiology 1997; 146 No.12:994-1002

A cohort of 1599 active injection drug users were recruited for an observational study of the association between use of needle exchange programs and baseline HIV seroprevalence and cumulative HIV seroincidence. Participants were recruited on an ongoing basis between September 1988 - January 1995 from a hospital detoxification unit, community-based social service agencies and city outreach workers. Injection drug users were eligible if they had injected drugs within the last 6 months. Participants completed a baseline questionnaire-based interview that included sociodemographic characteristics, knowledge and attitudes concerning HIV infection, drug use and sexual behavior, and had an HIV test performed. A similar questionnaire and repeat HIV test was included at a first follow-up visit at 3 months and at 6 month follow-up visits thereafter. Data were analyzed using three risk assessment scenarios: seroprevalence

analysis, seroincidence analysis, and a nested case control study. Adjusted odds ratios were calculated to address the potential confounding effects of drug utilization and sexual practices.

Seroprevalence analysis Baseline HIV seroprevalence among the full cohort of 1599 was 10.7% (171 HIV+). The majority of subjects were male (79.7%); mean age at entry was 32.2 years, although women were slightly younger with mean age of 28.9 yrs. Half of the women reported involvement in prostitution. Most participants reported consumption of multiple drugs lasting an average of 9.1 years, with cocaine the drug of choice for 64.2% of subjects; 82% reported having injected drugs in the previous month. Differences between needle exchange program attenders and non-attenders were analyzed, with needle exchange program attenders defined as subjects who reported having obtained equipment from a needle exchange program at least once in the 6 months prior to study enrollment. Needle exchange program attenders were significantly more likely to be HIV seropositive, younger, of lower income, and to have been in treatment for addiction less frequently. Needle exchange program attenders also reported higher frequencies of risk behaviors related to drug injection and more frequent involvement in prostitution activities. The odds ratio for HIV seropositive status associated with participation in needle exchange programs was 3.0 (95% confidence interval 2.2-4.5). Further adjustment for potential confounders reduced the magnitude of the association but consistent risk elevation was observed for needle exchange program attenders.

Seroincidence analysis The study cohort used for the seroincidence analysis included 974

HIV-negative subjects with a mean follow-up period of 21.7 months (median 15.4 months). Subjects differed from those initially seronegative persons (377) who were lost to follow-up on the following parameters: proportion of male subjects (81% vs. 74% lost to follow-up), cocaine as drug of choice (64% vs 57% lost to follow-up), sharing of equipment in last 6 months (78% vs 68%), having two or more sharing partners in the last month (23% vs 17%), getting syringes and needles at the drug dealer (57% vs 33%), proportion who were francophones (80% vs 72%) and declaring a lower income (11.5% vs 21%). Persons lost to follow-up more often reported sharing with an HIV-positive partner (11% vs 7%). There were 89 incident cases of HIV seroconversion during follow-up for an overall incidence was 5.1 /100 person years. Among needle exchange program attenders, incidence was 7.9/100 person years (95% CI 6.0-10.2), and 3.1/100 person years among non-needle exchange program attenders (95% CI 2.1-4.4). The cumulative probability of HIV seroconversion for persons using a needle exchange program in the 6 months prior to study enrollment remained significant after adjustment for potential confounders.

Nested case-control analysis The case-control analysis was done using 88 new seroconversion cases (1 was dropped due to matching difficulties) and 320 matched controls. Substantial HIV risk elevations among needle exchange program users were observed for both those persons obtaining their intravenous equipment exclusively from the needle exchange program and those also obtaining equipment from other sources (i.e. friends, pharmacies, drug dealers, shooting galleries). The consistency of reported needle exchange program attendance was also evaluated for an effect on HIV seroconversion; consistent attenders were defined as those who reported some needle exchange program attendance at all visits, and intermittent attenders were those reporting needle exchange program attendance at some but not all visits. Compared with non-attenders and intermittent attenders, consistent needle exchange program attenders were more likely to identify cocaine as their drug of choice (84.6%), had injected more often in the last month (76% with 30 injections or more), and had more sharing partners in the last month. There was a clear tendency for risks of seroconversion to increase with frequency of needle exchange program use over time; this remained significant only among consistent needle exchange program users and for males, after adjustment for potential confounders.

Study considerations include the observational study design which was not structured to address a possible causal relationship between needle exchange program attendance and HIV infection. Possible limitations include reliance on self-reported data, subject recruitment relying heavily on informal word-of-mouth advertisement which may have over sampled high-risk individuals, and different baseline HIV prevalence among groups of injection drug users. Limitations on the number of needles exchanged per visit may have underestimated the need for clean equipment among this population with substantial cocaine use. The ready availability of clean equipment through neighborhood pharmacies may also have resulted in needle exchange programs attracting existing core groups of marginalized, high risk individuals.

Note: Commentary on the Bruneau study by Lurie, and Bruneau's response are included in this same journal issue.

Discussion

The empirical data reviewed by the GAO report (1993), UCSF (1993), NAS/IOM (1995), NIH Consensus Development Conference (1997) and the Department's own reviews of February 1997 and April 1998, indicate that needle exchange programs are an effective component of a comprehensive HIV prevention strategy that will limit the spread of HIV and other blood borne diseases. The data presented in the recent articles reviewed here increase the confidence among the Department's senior scientists that needle exchange programs can be an effective component of a comprehensive HIV prevention strategy and do not increase drug use. Studies reviewed in the February 1997 report to Congress indicate that needle exchange programs significantly reduce HIV seroincidence, as well as seroincidence of Hepatitis B and Hepatitis C. In addition, those studies demonstrated that needle exchange participants reduce needle sharing and thereby reduce the circulating time of contaminated syringes in a given community.

The data reviewed in this analysis indicates that, where formal links are created between a needle exchange program and drug treatment with dedicated treatment slots available, injection drug users referred by a needle exchange program are more likely to enter drug treatment and be retained. In addition, short term reductions in high risk behavior were highly significant in the needle exchange program referred group. These data demonstrate an enhanced ability to decrease new HIV seroconversions when needle exchange programs are implemented in concert with drug treatment and medical services and are a solid component of a comprehensive HIV prevention plan. It is critical to keep in mind that injection drug users are not only at risk for HIV themselves, but they are a bridge to other individuals, their sexual partners and their children. Data showing an increased incidence of HIV in needle exchange users in two sites demonstrates the ability of these programs to target and engage the highest risk populations, even when compounded by the use of cocaine. When that same cohort was followed over time, HIV incidence moved down for needle exchange program participants (Strathdee, HIV incidence 18.6 per 100 person years declining to 4.4 per 100 person years).

Targeting the injection drug using population may well become a priority for those States and municipalities where injection drug use is driving their HIV epidemics. Needle exchange programs are often the only prevention intervention available to impacted States and cities that successfully creates an interface with this most difficult to reach population. The preponderance of evidence clearly shows HIV transmission is preventable in injecting drug user populations when exchange programs are linked to drug treatment and medical care. These "linked" needle exchange programs demonstrate higher rates of referral, entry and retention.

NEEDLE EXCHANGE PROGRAMS: AN UPDATED REVIEW OF RESEARCH ON THE EFFECTS OF NEPs

Findings from 27 published studies of Needle Exchange provide data on the following endpoints/outcomes:

- ▶ Characteristics of US Needle Exchange Programs
- ▶ Risk of HIV and other blood borne infections in IDUs
- ▶ Risk behaviors associated with HIV in IDUs
- ▶ Protective behaviors against HIV among IDUs
- ▶ Discarding of dirty needles on the streets
- ▶ Initiation of drug injection by non-IDUs
- ▶ Linking IDUs to drug treatment

Contents		
Table	Outcome	Page
Table 1.1:	Description of US NEP Activities	2
Table 1.2:	NEP Legal Status and Referrals to Drug Treatment	2
Table 1.3:	HIV Infection Rates (prevalence and incidence)	3-6
Table 1.4:	HBV and HCV Infection Rates (prevalence and incidence)	7
Table 2.1:	Reductions in Injection Frequency	8-10
Table 2.2:	Reductions in Multiperson Reuse of Works	11-12
Table 2.3:	Increases in Needle Disinfection	13
Table 2.4:	Entry into Drug Treatment	14
Table 2.5:	Unsafe Disposal of Injection Equipment	15
Table 2.6:	New Initiates to Drug Injection	16
References		17-19

NIDA/DEPR/CRB

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**Includes studies* published since Secretary's report 02/18/97*

***Revised 2/25/98 to*

***Include updated summaries of Strathdee et al., 1997 and Bruneau et al., 1997*

Reviewed and revised 4/6/98

Table 1.1: US Needle Exchange Programs Characteristics

Author/Purpose	Sample/Design	Results/Findings	Comments
*Paone, Des Jarlais, et al., 1997, MMWR, 46:565-568. Identify activities of US NEPs for 1995/96	National survey of all 101 NEP programs that were members NASEN in 1996	- 84 NEPs exchanged 14 Million syringes - 97% refer to Tx - 97% provide info on sexual risk - 81% provide STD prevention ed - 40% testing & counseling - 26% TB testing - 20% STD screening - 17% primary health care	- Current estimate of 120 NEP - 53% operate legally - NEPs provide ancillary services

Table 1.2: Effects of NEP Legal Status on Referrals to Drug Treatment.

Author/Purpose	Sample/Design	Results/Findings	Comment
Paone et al., 1996 To describe characteristics of US NEPs.	Review of 60 NEP programs in U.S. (46 cities in 21 states)	Provided formal referrals to drug treatment ▸ 79% of legal programs (26 of 33) ▸ 48% of illegal programs (13 of 27)	Fully legal status was associated with providing formal referrals to drug treatment services, always having a sufficient syringe supply, having funding for biohazardous waste disposal, and having longer hours of operation.

Table 1.3: HIV Infection Rates (11 studies: 3 found significant reductions in HIV seroincidence, 1 found no seroincidence associated with NEP participation, 1 found increases in HIV incidence, 3 found reductions in seroprevalence, and 2 found stable seroprevalence, and 2 found increases in seroprevalence)¹

Authors/Purpose	Sample/Design	Results/Findings	Comments
Heimer et al., 1992 To assess the prevalence rates of HIV in needles/syringes used by New Haven IDU.	1,860 randomly selected needles distributed and returned to the needle exchange Prospective open cohort	HIV seroprevalence rates • Pre-NEP: prevalence at 68% • NEP in 1st 2 months: prevalence at 64% • NEP after 4 months: prevalence stable at 43% (reflecting a 33% decrease)	Independent reviews of model support conclusions about HIV infections averted by NEP.
Kaplan & O'Keefe, 1993; Kaplan, 1994 Estimate change in seroincidence rate among IDUs following their enrollment in New Haven NEP	Randomly selected syringes Mathematical models using unique Syringe Tracking and Testing System	HIV seroincidence: • 33% reduction among program participants • 0.7 to 1.6 infections prevented per 100 person years	
Kaplan & Heimer, 1994, 1995 Provide more accurate estimates (Maximum likelihood model) of change HIV incidence rates among IDUs who use NEP.	2,813 tested needles that were distributed and returned between November 1990 and June 1992 Maximum likelihood change point model applied to empirical data gathered in Syringe Tracking and Testing System	HIV seroincidence • Incidence rate of 1.63 per 100 person years among program participants which was found not to differ from zero which means that the best estimate of new infection among needle exchange participant is zero	

Table 1.3 continues on next 3 pages.

¹Note: One of the 11 studies (i.e., Bruneau et al., 1997) examined both Incidence and Prevalence of HIV, making total number of finding equal to 12.

CRITERIA 1

**Section 505(1) The Secretary of Health and Human Services
determines that exchange projects are effective in preventing
the spread of HIV ... (PL 105-78)**

Table 1.1: HIV Infection Rates (11 studies: 5 found significant reductions in HIV seroincidence, 2 found increases in HIV incidence, 3 found stable seroprevalence, and 2 found reductions in seroprevalence)

Author/Purpose	Sample/Design	Results/Findings	Comments
Heimer et al., 1992 To assess the prevalence rates of HIV in needles/syringes used by New Haven IDU.	1,860 randomly selected needles distributed and returned to the needle exchange Prospective open cohort	HIV seroprevalence rates • Pre-NEP: prevalence at 68% • NEP in 1st 2 months: prevalence at 64% • NEP after 4 months: prevalence stable at 43% (reflecting a 33% decrease)	Independent reviews of model support conclusions about HIV infections averted by NEP.
Kaplan & O'Keefe, 1993; Kaplan, 1994 Estimate change in seroincidence rate among IDUs following their enrollment in New Haven NEP	Randomly selected syringes Mathematical models using unique Syringe Tracking and Testing System	HIV seroincidence: • 33% reduction among program participants • 0.7 to 1.6 infections prevented per 100 person years	
Kaplan & Heimer, 1994, 1995 Provide more accurate estimates (Maximum likelihood model) of change HIV incidence rates among IDUs who use NEP.	2,813 tested needles that were distributed and returned between November 1990 and June 1992 Maximum likelihood change point model applied to empirical data gathered in Syringe Tracking and Testing System	HIV seroincidence • Incidence rate of 1.63 per 100 person years among program participants which was found not to differ from zero which means that the best estimate of new infection among needle exchange participant is zero	

Table 1.1 continues on next 3 pages.

Table 1.1: HIV Infection Rates (Continued)

Author/Purpose	Study Design	Regions/Countries	Comments
Watters, 1994 To examine change in HIV risk behaviors and prevalence among IDUs between 1986 & 1992.	5,956 IDUs recruited from street settings and detoxification clinics Ecological study with 13 semiannual cross-sectional surveys over 6.5 years, 1986-1992	HIV seroprevalence rates - Needle exchange was implemented in 1988 - HIV prevalence rate doubled between 1986 and 1987 and remained stable between 1987 and 1992 (12%)	Cross-sectional data
Des Jarlais et al., 1994 Examine trends HIV risk behaviors & HIV prevalence among IDUs between 1984 & 1992.	1,115 IDUs admitted to drug detoxification program Ecological study with 2 randomly selected cross-sections, 1984 and 1992	HIV seroprevalence rates Stable HIV prevalence at slightly more than 50%	Cross-sectional data
*Hurley, Jolley, & Kaldor, 1997, 349:1797-1800. Compare changes over time in HIV seroprevalence among IDUs for cities with and without NEPs.	Ecological study of 81 cities across Europe, Asia, and North America	Seroprevalence among increased by 5.9% per yr in the 52 cities without NEPs, and decreased by 5.8% per yr in cities with NEPs. The average prevalence rate was 11% lower in cities with NEPs.	Cities in Europe, Asia, and the US with NEPs report seroprevalence decrease. Due to the study design, no causal link between the presence of NEP and HIV prevalence reductions can be made.

Des Jarlais et al., 1996 Compare HIV incidence among IDUs who use NEPs with that among IDUs who do not participate.	2,630 IDUs from • Syringe Exchange Evaluation (SEE) • Vaccine Preparedness Initiative (VPI) • National AIDS Demonstration Research (NADR) Meta-analytic technique combining HIV incident data across 3 studies	HIV seroincidence • SEE: among continuing NEP users, incidence was 1.58 per 100 person years at risk (pyar) • VPI: among continuing NEP users, incidence was 1.38 per 100 pyar; among non-NEP users, incidence was 5.26 per 100 pyar • NADR: among non-NEP users, incidence was 6.23 per 100 pyar • Pooled 3-study data indicate that non-NEP use was associated with a 3.35 greater risk of HIV infection	Causal link can not be made between NEP use and seroincidence. Data does show that NEP participation is protective of HIV seroconversion Dose response relationship between NEP participation and HIV infections averted.
*Strathdee, et al., 1997, AIDS, 11:F59-F65. Describe HIV prevalence and incidence among prospective cohort of IDUs	1,006 IDUs were recruited through street outreach. Prospective cohort study with baseline, semi-annual data collection.	Predictors of HIV + status were: - low education, unstable housing, commercial sex, borrowing needles, injecting with others, and frequent NEP attendance. - 23 of the 24 HIV Seroconverters reported NEP as their most frequent source of needles and only 5 reported having difficulty accessing sterile syringes.	• Despite availability of NEPs, high incidence was reported • NEP user most frequently report cocaine use • Comprehensive services such as counselling & testing, drug treatment appear not to have been &/or insufficient to prevent HIV • Study is epidemiologic in nature, was not intended to evaluate NEP (92% of study participant attended NEP) • Can not establish causal relationship between NEP use and HIV infection. • Comprehensive services such as counselling & testing, drug tx appear not to be available or insufficient to prevent HIV infection.

*Bruneau et al., 1997, Am J of Epidemiol, 146:994-1002. Assess the association between risk behaviors and HIV seroprevalence and incidence among IDUs in Montreal.	1,599 IDUs were recruited to participate in this open prospective cohort study. Data analyses included: - Cross-sectional analyses of baseline data to assess association of NEP use and serostatus, - Cohort analyses of NEP use at baseline as predictor of conversion, - Nested case-control analysis of NEP use during follow-up as predictor of conversion.	- NEP users were 2.2 times more likely to be positive at baseline. - The cohort analysis showed that the cumulative probability of HIV conversion was found to be 33% for NEP users versus 13% for Nonusers. - Nested case-control study revealed that consistent NEP users was associated with seroconversion (odds ratio = 10.5).	NEP users were at higher risk at baseline than non-NEP users. Study was not designed or intended to evaluate NEP. Epidemiologic study. No causal link between NEP participation and HIV infection can be made.
*Singer et al., 1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	3,050 randomly selected needles & Prospective open cohort with pretest and posttest measures returned to NEP	HIV seroprevalence rates: • Baseline NEP: prevalence at 58% • NEP after 2.5 years: prevalence relatively stable at <40%	

Table 1.3: Expert reports (2 studies: 2 found significant reductions)

Author/Institution	Sample/Method	Results/Findings	Comments
GAO, 1993 To assess the effectiveness of NEP in reducing HIV infection rates.	Reviewed all publications on the topic.	The report stated the following, based on a thorough review of the only study at the time that reported HIV incidence findings (Kaplan and O'Keefe, 1993): "Based on our expert consultant review, we found the model to be technically sound, its assumptions and data values reasonable and the estimated 33% reduction in new infections defensible."	
NRC/IOM To evaluate the effectiveness of NEP programs.	Reviewed all published and unpublished studies of NEPs.	The report states: "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. The lower the fraction of needles in circulation that are contaminated, the lower the risk of new HIV infections."	

CRITERIA 2

**Section 506(1) The Secretary of Health and Human Services
determines that exchange projects ... do not encourage the use
of illegal drugs (PL 105-78)**

Table 2.1: Increases in Mean Age of NEP Users Indicate NEP Did Not Encourage New IDUs (2 studies: 1 found significant increase, 1 had some significant increase)

Authors/Population	Sample/Design	Results/Findings	Comments
Watters et al., 1994 To evaluate a syringe exchange in San Francisco.	5,644 IDUs recruited from street settings and detoxification clinics Ecological cross-sectional study using 11 semiannual cross-sectional surveys over 5.5 years (12/86-6/92)	1987: Mean age of IDUs was 38.5 years 1992: Mean age of IDUs was 41.6 years The mean age of youngest NEP participants did not significantly over the 5.5 year study	
Guydish et al., 1993 To evaluate potential negative effects of the San Francisco NEP	35,460 drug treatment admissions: 24,120 IDUs 11,340 non-IDUs Ecological cross-section study. Data on records 2 years preceding NEP (1987-1988) and 2 years following NEP.	IDUs • Mean age at admission increased steadily over time • Mean age at first injection remained stable over time Non-IDUs • Pre-NEP, 31.6% switched to injection by time of 2nd treatment admission • Post-NEP, 35.4% switched to injection by time of 2nd treatment admission (not significant)	

Table 2.2: Reductions in Injection Frequency (9 studies: 5 had significant reductions, 2 had some significant reductions, 2 not significant)

Author/Year	Sample/Design	Results/Findings	Comments
Walters et al., 1994 To evaluate a syringe exchange in San Francisco.	5,644 IDUs recruited from street settings and detoxification clinics Ecological cross-sectional study using 11 semiannual cross-sectional surveys over 5.5 years (12/86-6/92)	Median daily frequency of injection declined: • from 1.9 to 0.7 injections per day	
Phone et al., 1994 To evaluate NYC lower East side NEP.	1,752 IDUs, randomly selected needle exchange participants Multiple random cross-sections of NEP participants with recapture feature using retrospective data collection over 8 month (10/92- 6/93)	Mean monthly frequency of injections declined: • from 95.2 to 85.6 times per month.	
Oliver et al., 1994 Evaluate NEP in Portland, OR.	• 83 participants attending NEP ≥ 4 times • 32 participants attending > 4 times Prospective cohort study with pre-post measures	Mean monthly frequency of Injection • Frequent NEP attenders: Baseline 28.7 reduced to Follow-up 8.9 • Infrequent NEP attenders: Baseline 33.0 reduced to Follow-up 30.7	
*Singer et al., 1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	233 NEP participants Prospective cohort study with pretest and posttest measures	Mean monthly frequency of Injection • IDU injecting < 5 times/day at baseline: Increase of 57 injections at posttest • IDU injecting ≥ 5 times/day at baseline: decrease of 90 injections at posttest	

Table 2.2 continues on next 2 pages.

Table 2.2: Reductions in Injection Frequency (Continued)

Author/Purpose	Sample/Design	Results/Findings	Comments									
Guydish et al., 1993 To evaluate potential negative effects of the San Francisco NEP	35,460 drug treatment admissions of which 24,120 were IDUs Ecological cross-sectional study. Data on records 2 years preceding NEP (1987-1988) and 2 years following NEP implementation.	Decrease significant and stable not significant: Proportion (%) of IDUs in various categories of frequency of injection in last 30 days • Decrease % of IDU injecting 2-3 times a day (before NEP 41% vs after NEP 28%) • Stable % of IDUs injecting once a day or less (before NEP 17% vs after NEP 17%) • Increase % of IDUs more than 3 times a day (before NEP 40.7% vs after 55.4%)										
Des Jarlais et al., 1994 Examine trends HIV risk behaviors & HIV prevalence among IDUs between 1984 & 1992.	1,115 IDUs admitted to drug detoxification program Ecological study with 2 randomly selected cross-sectional samples, 1984 and 1992	Decrease significant and stable not significant: Mean Frequency of injection per month • Decrease cocaine injections per month (55 vs 43) • Stable heroin injections per month (46 vs 44) • Stable speedball injections per month (43 vs 41)										
Hagan et al., 1993 To assess the potential effectiveness of the Tacoma NEP	204 needle exchange participants Retrospective cohort study (pre-post measure)	Decrease not significant: Mean monthly injection frequency • Stable injections at 155 a month prior to first use of NEP and 152 a month while participating in NEP										
Hagan et al., 1994 To update the evaluation of Tacoma NEP.	426 needle exchange participants Retrospective cohort study	Decreases not significant (OR=.83, p>.05) Proportion of IDUs who inject < 37 times per month and injectors who inject ≥ 37 times per month <table><tr><td></td><td><u>Pre-exchange</u></td><td><u>Post-exchange</u></td></tr><tr><td>< 37 per month</td><td>42.2%</td><td>46.9%</td></tr><tr><td>≥ 37 per month</td><td>57.8%</td><td>53.1%</td></tr></table>		<u>Pre-exchange</u>	<u>Post-exchange</u>	< 37 per month	42.2%	46.9%	≥ 37 per month	57.8%	53.1%	
	<u>Pre-exchange</u>	<u>Post-exchange</u>										
< 37 per month	42.2%	46.9%										
≥ 37 per month	57.8%	53.1%										

Schoenbaum, Hartel, and Gourevitch, 1996, AIDS, 10:1729-1734. To compare prospectively injection behaviors of IDUs in methadone Tx who did and did not use local NEP.	904 IDUs who injected between 1985 and 1993 and attended a methadone treatment program in the Bronx were recruited. Bronx NEP opened in 1989. Prospective study.	Among active IDUs, there were declines in the proportion of IDUs who injected 30 or more times per month. That proportion decreased for NEP participants from 72% in 1989 to 49% in 1993 compared with reductions of 70% to 45% among nonusers of NEP.	Study documents more substantial reductions in injection frequency and sharing among methadone Tx participants who also used NEP compared to IDUs in Tx who did not use NEP while in Tx.. Ongoing injection drug use while in methadone treatment is documented in this study and others in the literature. NEP and TX are compatible interventions.
*Vlahov et al., 1997 To determine whether enrollment in NEP was associated with short-term reduction in risk behaviors.	221 IDUs in NEP Prospective study, baseline and 2 follow-ups (at 2 weeks and at 6 months)	Significant reductions were reported in the mean number of injections per syringe and mean number of injections per day at follow-up (from 5.9 to 4.9 per day).	

Table 2.3: Entry into Drug Treatment (4 studies: 4 found significant effects)

Authors/Purpose	Sample/Design	Results/Findings	Comments
Hagan et al., 1993 To assess the potential effectiveness of the Tacoma NEP	530 patients admitted to methadone treatment Ecological, all drug treatment admissions during 17-month period	Health Dept. methadone referral source for all patients during study period • NEP was the largest referrals source (43%) followed by self-referrals (38%), other outreach (8%), and other source (13%)	
Heimer & Lopes, 1994 To report on the increase in drug treatment associated with opening of NEP	1,512 IDUs using New Haven's NEP Prospective open cohort, compared treatment entry during first 7.5 mths (1990) to 11 mths experience 2-3 yrs later.	Number of monthly drug treatment entries • Drug treatment entries doubled (14.4 to 28.8 persons per month)	
*Singer et al., 1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	315 needle exchange participants Prospective open cohort with pretest and posttest measures	After using NEP for more than 6 months, 58% report having enrolled in detox or drug treatment	
*Vlahov et al., 1997 To determine whether enrollment in NEP was associated with short-term reduction in risk behaviors.	221 IDUs in NEP Prospective study, baseline and 2 follow-ups (at 2 weeks and at 6 months)	Drug treatment participation tripled between baseline (5% of NEP users in treatment) and 6-month followup (15% of NEP users in treatment)	

Table 2.4: Expert reports (2 studies: 2 found significant reductions)

Author/Year	Study Design	Results/Findings	Comments
GAO, 1993 To assess the effectiveness of NEP in reducing HIV infection rates.	Reviewed all publications on the topic.	The report states: "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."	
NRC/IOM To evaluate the effectiveness of NEP programs.	Reviewed all published and unpublished studies of NEPs.	The report states: "There is no credible evidence to date that drug use increased among participants as a result of programs that provide legal access to sterile equipment. 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 drug use."	

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