NLWJC - Kagan

DPC - Box 016 - Folder 004

Drugs - Needle Exchange [1]

Drugs - Needle exchange

L/HHS/Ed General Provisions for FY 2000 Budget
"Side-by-Side" Comparison for Selected Provisions
Titles II and V of L/HHS Bill

	FY 1999 President's Budget	FY 1999 Enacted	Recommended FY 2000
Needle Exchange	Sec. 505. Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug *unless the Secretary of Health and Human Services determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.*	Repeated FY 98 enacted language, as follows: Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.	"No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug unless the Secretary of Health and Human Services, having determined that such distribution is effective in preventing the spread of HIV and does not encourage the use of illegal drugs, establishes distribution criteria for such programs for preventing the spread of HIV and for ensuring that the distribution does not encourage the use of illegal drugs."
Needle Exchange	**[Sec. 506. Section 505 is subject to the condition that after March 31, 1998, a program for exchanging such needles and syringes for used hypodermic needles and syringes (referred to in this section as an "exchange project") may be carried out in a community if . . .]**	**Provision deleted.**	**No provision.**

drugs - needle exchange

I

105TH CONGRESS
2D SESSION

H. R. 3717

To prohibit the expenditure of Federal funds for the distribution of needles or syringes for the hypodermic injection of illegal drugs.

IN THE HOUSE OF REPRESENTATIVES

APRIL 23. 1998

Mr. SOLOMON (for himself, Mr. WICKER, Mr. HASTERT, Mr. BARR of Georgia, and Mr. DELAY) introduced the following bill; which was referred to the Committee on Commerce

---

A BILL

To prohibit the expenditure of Federal funds for the distribution of needles or syringes for the hypodermic injection of illegal drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROHIBITION REGARDING ILLEGAL DRUGS AND DISTRIBUTION OF HYPODERMIC NEEDLES.

Part B of title II of the Public Health Service Act (42 U.S.C. 238 et seq.) is amended by adding at the end the following section:

"PROHIBITION REGARDING ILLEGAL DRUGS AND DISTRIBUTION OF HYPODERMIC NEEDLES

"SEC. 247. Notwithstanding any other provision of law, none of the amounts made available under any Federal law for any fiscal year may be expended, directly or indirectly, to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.".

SEC. 2. CONFORMING AMENDMENT.

Section 506 of Public Law 105–78 is repealed.

○

drugs - needle exchange

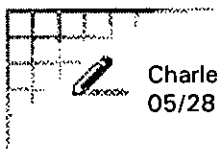
Richard Socarides 05/30/98 09:24:02 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Re: Coverdell Bill

---------- Forwarded by Richard Socarides/WHO/EOP on 05/30/98 09:26 AM ----------



Charles M. Brain
05/28/98 05:05:16 PM

Record Type: Record

To: Richard Socarides/WHO/EOP

cc:
Subject: Re: Coverdell Bill

Richard: The Coverdell bill (S. 1959) is sitting in the Labor Committee and is unlikely to be acted upon.

The Senate is more likely to act on the Solomon bill (H.R. 3717) which passed the House on Arpil 29 and is now on the Senate Legislative Calendar. There is also a rumor that Coverdell might offer his bill as an amendment to the tobacco bill now pending in the Senate.

Chuck

Message Sent To:

Sylvia M. Mathews/WHO/EOP
Maria Echaveste/WHO/EOP
Sandra Thurman/OPD/EOP
Bruce N. Reed/OPD/EOP
Elena Kagan/OPD/EOP

Drugs-needle exchange

Sandra Thurman 05/13/98 02:59:57 PM

Record Type: Record

To: Sylvia M. Mathews/WHO/EOP, Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:

Subject: Coverdell Bill

On Friday Senator Lott rule 14nd the Coverdell bill (which is pending in the Labor Committee, and bans federal funding for programs which support needle exchange either directly or indirectly) which means that the bill has been placed on the Senate calendar for consideration but for the Kennedy hold.

The Senate Democratic cloak room has notified the Kennedy staff that given his hold on the bill freestanding he should be prepared for it to be offered as an amendment to some other pending legislation. Labor Committee Republicans, including Jeffords and Frist are probably inclined to be helpful but will be looking for cues from the White House. The Kennedy folks are also looking for cues from us.

Folks on the Hill are most interested in having Drs. Varmus and Satcher speak to Jeffords, Frist and others regarding the issue. I also spoke to Kevin Thurm about this and he, too, was looking for some direction on how to proceed.

Do we happen to have any cues give them, by chance?

Thanks.

Tob - ... -
needle exchange

Needle Exchange Q&As
May 5, 1998

Q: What is your position on the Solomon Amendment to prohibit any Federal funding for needle exchange programs?

A: The Administration strongly opposes this legislation because it is unnecessary and unwarranted. We believe that this legislation serves only to further politicize this issue. Congress should focus on those issues that immediately impact the health and well being of the nation: youth smoking, quality shortcomings, and Americans ages 55 to 65 that have been failed by the insurance market.

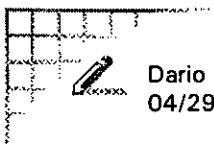
Q: If you believe that needle exchange is an issue that should be decided at the local level why does the Secretary need any authority to authorize Federal funding?

A: It has been the longstanding position of Congress to give the Secretary of Health and Human Services the authority to determine the scientific and public health merits for a wide range of public health activities. We believe it is unwarranted and unnecessary to take away the Secretary's authority and that this legislation is being pursued for purely political -- not policy -- reasons.

Q: If the science concludes that needle exchange programs reduce the transmission of HIV and do not increase drug use, why didn't you release federal funds for needle exchange programs?

A: We have always said that communities should make their own decisions on this issue, based on their own circumstances and using the best available scientific information. Releasing federal funding for needle exchange would have inappropriately shifted the focus away from communities -- where these decisions should be made -- to the national level. That could have severely undermined or threatened local programs that are currently in place, and hindered additional communities from deciding to put these programs into place. At the same time, such federal action could send an inappropriate message about the acceptability of drug use -- a message that is not sent when an individual community decides, on the basis of its unique circumstances, that a particular, carefully designed needle exchange program advances public health interests. For these reasons, the Administration concluded that it should simply give the scientific guidance that is necessary for communities to make their own decisions, rather than federalize the needle exchange issue.

Drugs - needle exchange



Dario J. Gomez
04/29/98 11:22:43 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Marjorie Tarmey/WHO/EOP, Suzanne Dale/WHO/EOP, Mindy E. Myers/WHO/EOP, Jessica L. Gibson/WHO/EOP

Subject: Needle Exchange

Chuck Brain wanted to make sure that everyone had a copy of Pelosi's Motion to Recommit:

Motion to Recommit H.R. 3717

Offered by Ms. Pelosi of California

Ms. Pelosi of California moves to recommit the bill, H.R. 3717, to the Committee on Commerce with instructions to report the same back to the House with the following amendment: Page 2, line 8, insert before the period the following: ", unless the Governor, State health officer, or local municipal health authority determines that the use of Federal funds for such a program would reduce the rate of transmission of the human immunodeficiency virus (commonly known as HIV), would not encourage the use of illegal drugs, and is accptable to the affected State, city or other unit of local government, or community".

Message Sent To:

Maria Echaveste/WHO/EOP
Mickey Ibarra/WHO/EOP
Janet Murguia/WHO/EOP
Elena Kagan/OPD/EOP
Sandra Thurman/OPD/EOP
Richard Socarides/WHO/EOP
Christopher C. Jennings/OPD/EOP
Andrew J. Mayock/WHO/EOP
Peter Rundlet/WHO/EOP
Minyon Moore/WHO/EOP
Lynn G. Cutler/WHO/EOP
Robert N. Weiner/WHO/EOP

Drugs - needle exchange

DRAFT – NOT FOR RELEASE

April 28, 1998
(House)

H.R. 3717 - Prohibition Regarding Illegal Drugs and the Distribution of Hypodermic Needles
(Rep. Solomon (R) NY and four cosponsors)

The Administration strongly opposes H.R. 3717 because it is unnecessary and unwarranted. As the Nation's chief appointed health official, the Secretary of Health and Human Services should have the authority to determine the scientific and public health merit of needle exchange programs as they affect rates of HIV transmission and injection drug use. The Administration believes that the Secretary is the appropriate official to determine which HIV prevention strategies should be supported with Federal funds, and that the decision on which HIV prevention strategies to use should rest with State and local officials.

* * * * * * * * * *

(Do Not Distribute Outside Executive Office of the President)

This Statement of Administration Policy was developed by the Legislative Reference Division (Pellicci) in consultation with HLTH (Turman/Ip) , OMB Associate Director Mendelson, National AIDS Policy Office Deputy Director Todd Summers, and Deputy Assistant to the President Chris Jennings. HHS (Per Richard Tarplin, Assistant Secretary for Legislation) agrees with the proposed position. The Department of Justice (per Greg Jones) and the Office of National Drug Control Policy (per Ross Deck) have no objection.

OMB/LA Clearance:_____

H.R. 3717 was introduced on April 23rd. There have been no hearings or committee action on the bill. The House Rules Committee is scheduled to consider the bill at 2 p.m. on Tuesday, April 28th. House floor action is expected on Wednesday, April 29th.

Background

Public Law 105-78 (the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act for FY 1998) continues the prohibition on the use of Federal funds for the distribution of needles, but allows for such funds to be used for needle-exchange programs after March 31, 1998, if the Secretary of HHS certifies that such programs are: (1) effective in preventing the spread of HIV; (2) operated in accordance with criteria established by the Secretary; and (3) not encouraging the use of illegal drugs.

On April 20th, HHS Secretary Shalala announced that "based on the findings of extensive scientific research . . . 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." The Secretary noted, however, that the current law restriction on Federal funding of

needle exchange programs would not be lifted administratively. (Since 1989, the use of Federal funds for needle exchange programs has been restricted by the Congress.)

Description of H.R. 3717

H.R. 3717 states that "[n]otwithstanding any other provision of law, none of the amounts made available under any Federal law for any fiscal year may be expended, directly or indirectly, to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug."

H.R. 3717 would also repeal the provision in P.L. 105-78, which was discussed above, that would permit the use of appropriated funds to be used after March 31, 1998, for needle exchange programs.

Pay-As-You-Go Scoring

According to HLTH (Chin-Chin Ip), H.R. 3717 would not affect revenues or direct spending; therefore, it is not subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990.

LEGISLATIVE REFERENCE DIVISION DRAFT
04/28/98 - 9:15 a.m.

Drugs - needle exchange

Congress of the United States

House of Representatives

Washington, DC 20515

April 27, 1998

Federal Funds for Drug Needles?

Dear Colleague:

As you know, the Clinton Administration recently endorsed needle exchange programs for drug addicts. This is an outrage and that is why we have just introduced legislation, H.R. 3717, to permanently ban the use of federal funds for needle distribution.

Numerous studies – including those done by General McCaffrey's Office of National Drug Control Policy – have concluded that needle exchange programs increase illegal drug use. In addition, they do not reduce the spread of HIV. A recent study published in the prestigious *American Journal of Epidemiology* confirmed this: drug addicts who participate in needle exchange programs are 2.2 times more likely to contract HIV than addicts who do not participate.

We have led the fight against illegal drug use and we are not going to allow the pro-drug contingent in this Administration to reverse the progress we have made.

Please support our legislation when it comes to the floor this week.

Sincerely,

GERALD B. H. SOLOMON
Member of Congress

TOM DELAY
Member of Congress

DENNIS HASTERT
Member of Congress

BOB BARR
Member of Congress

ROGER WICKER
Member of Congress

Drugs-needle exchange

HUMAN
RIGHTS
CAMPAIGN

April 28, 1998

Via Facsimile

Dear Member of Congress:

On behalf of the Human Rights Campaign, I am writing to ask you to oppose H.R. 3717, a bill which would permanently ban the use of any federal funds for needle exchange programs. The bill is scheduled to be considered by the House on Wednesday. As you know, on Monday, April 20th, Secretary Shalala announced that there is unequivocal support from the scientific literature that needle exchange programs reduce HIV infection and do not contribute to illegal drug use. Nevertheless, the Administration clearly stated its commitment to maintain the current prohibition on federal funding for needle exchange programs. H.R. 3717 is redundant and unnecessary, given the Administration's clear position.

As the attached article reports, AIDS deaths have declined significantly in the last two years primarily due to the success of new drug treatments which help keep people with HIV disease alive and healthy for longer periods of time. New HIV infections, however, continue to occur at an unacceptable rate. The article highlights that injection drug use is increasingly fueling this epidemic. In fact, over 50% of new HIV infections can be attributed to injection drug use and recent data indicate that 74% of all AIDS cases among women and over 50% of all AIDS cases among children are connected directly or indirectly to injection drug use. In the African American community, 48% of AIDS cases are related to injection drug use.

As the HIV epidemic continues to grow, it is vital that public health considerations drive the debate on funding and policy decisions. Instead of legislating a ban on federal funding for needle exchange programs, Congress should be taking affirmative and bold actions to reduce the numbers of new infections by increasing HIV prevention funding and expanding the options communities have to address their growing infection rates. Legislation banning federal funding for needle exchange programs would only serve to further politicize an issue that should appropriately be addressed by scientists and state and local public health officials.

Please do not politicize HIV prevention and take public health determinations out of the hands of scientists and public health experts. Amending the Public Health Service Act is a serious matter and should not be done hastily on the House floor without careful consideration from the Committee with jurisdiction. Please vote no on the rule and return this issue to Committee for the appropriate attention it deserves and vote no on H.R. 3717. Thank you for your attention to this urgent matter.

Sincerely,

Winnie Stachelberg
Political Director

WORKING FOR LESBIAN AND GAY EQUAL RIGHTS.

1101 14th Street NW, Suite 200 Washington, D.C. 20005
phone (202) 628 4160 *fax* (202) 347 5323 *e-mail* hrc@hrc.org

HIV's Spread Is Unchecked

AIDS-Slowing Treatments Eclipse Rising Infection Rate, Study Says

By Rick Weiss
Washington Post Staff Writer

Although the number of new AIDS cases in the United States has declined substantially in recent years, HIV continues to spread through the population essentially unabated, according to data released yesterday by the Centers for Disease Control and Prevention.

The first direct assessment of HIV infection trends shows that the recent decline in U.S. AIDS cases is not due to a notable drop in new infections. Rather, improved medical treatments are allowing infected people to stay healthy longer before coming down with AIDS, overshadowing the reality of an increasingly infected populace.

"The findings of this report give us a very strong message, that mortality may be going down—therapy is working—but HIV continues its relentless march into and through our population," said Thomas C. Quinn, an AIDS specialist at the National Institute of Allergy and Infectious Diseases. "These data tell us we have a lot of work to do."

The findings also confirm previously identified trends showing that women and minorities are increasingly at risk. Especially worrisome, officials said, is that the annual number of new infections in young men and women 13 to 24 years old—a group that has been heavily targeted for prevention efforts—is virtually unchanged in recent years.

HIV Spread Not Slowed in U.S.

AIDS. *From A1*

"It certainly documents that we have ongoing new infections in young people," said Patricia L. Fleming, chief of HIV/AIDS reporting and analysis at the CDC in Atlanta.

The report also shows continuing high numbers of new infections among intravenous drug users, a population that has recently been the focus of a political debate over the value of needle exchange programs that offer drug users clean syringes to prevent the spread of HIV, the virus that causes AIDS. [International financier George Soros yesterday offered $1 million in matching funds to support needle exchange programs around the country, the Associated Press reported.]

CDC officials would not comment directly on President Clinton's decision this week to extend a ban on federal funding of needle exchanges. But both Fleming and Quinn said that AIDS prevention programs in this population need to be improved.

"It's clear that something stronger is needed to slow this epidemic," Quinn said.

The new figures, in today's issue of the CDC's Morbidity and Mortality Weekly Report, are based on HIV test results compiled by 25 states from January 1994 to June 1997. They indicate that the number of new infections during that period remained "stable," with just a "slight" decline of 2 percent from 1995 to 1996, the most recent full year included in the new analysis. By contrast, deaths from AIDS declined 21 percent in 1996 and dropped an additional 44 percent in the first six months of last year.

From 1995 to 1996, the number of HIV infections increased by 3 percent among women. And it jumped 10 percent among Hispanics, although officials said that figure was imprecise. Infections declined by 2 percent in the white and 3 percent in the African American populations.

All told, the study tallied 72,905 infections during the survey period. The number nationwide is much higher, since participating states account for only about 25 percent of U.S. infections.

The single biggest risk category was men having sex with other men, but heterosexual transmission continued its steady increase. Most of those cases involved women contracting the virus through sex with male drug users, Fleming said.

The survey is the first to track infection trends by looking directly at HIV test results in people coming to clinics and other health care outlets. That's a major change from the previous system, in which officials simply estimated the number of new infections by counting the number of people newly diagnosed with AIDS.

The old "back calculation" method worked fine during the first 15 years of the epidemic, when HIV infection progressed predictably to disease over a period that averaged about 10 years. With drug therapies now slowing disease progression, however, the number of new AIDS cases no longer reflects the number of new infections, and public health officials were becoming uncertain about how they were doing in prevention efforts.

The new reporting system, now spreading to other states, has helped officials regain those bearings, Fleming said. And although everyone wishes the numbers were more encouraging, she said, at least officials now have a clearer picture of the task at hand.

FOR MORE INFORMATION

To read Post coverage about the AIDS academic, click on the above symbol on the front page of The Post's Web site at www.washingtonpost.com

HUMAN
RIGHTS
CAMPAIGN

1101 14th Street NW
Washington, DC 20005
website http://www.hrcusa.org
phone 202 628 4160
fax 202 347 5323

SYRINGE EXCHANGE

Needle Exchange Does Not Divert Resources

- Needle exchange programs are in no way meant to divert resources away from drug treatment. They cannot be seen as a low cost substitute for such treatment. They can and should be seen as a part of an overall strategy to connect people to systems of care. Needle exchange programs provide a linkage to drug treatment in addition to other health care, counseling, and psychosocial services. Needle exchange programs are a component of a drug treatment and outreach strategy, they are not a substitute.

- No one doubts the effectiveness of drug treatment. The long term solution for injection drug users to reduce their HIV risk and put their lives back on track is to get off drugs. No policy or funding decisions should contradict that message. Because drug treatment on demand is not available in this country, it is imperative that we keep people alive until they can get into treatment. Needle exchange programs not only help people stay alive (through avoiding HIV infection), they also help many drug users start their long journey toward a drug free life.

    * In Tacoma, WA the needle exchange program was the source of 43% of new recruits into methadone treatment

    * Seattle's treatment slots have increased by 350 since needle exchange began.

    * The 90 treatment slots reserved for participants in the Baltimore needle exchange program were rapidly filled.

- No one is advocating for the use of drug treatment funds to support needle exchange programs. The money at issue is in the CDC HIV prevention budget. These funds flow through a community planning process which would have to support needle exchange as a component of the community's HIV prevention plan.

Support for Needle Exchange Is Not A Double Message

- It is not a double message to advocate for drug abstinence, drug treatment programs, and needle exchange. All of those efforts are directed at keeping people, old and young, alive and healthy.

    * Studies show that the mean age of injection drug users rises over time even in places where needle exchange programs operate.

Needle Exchange Should Be Continually Monitored

- The language in the FY 1998 Labor/HHS Appropriations bill requires any federally supported needle exchange programs to cooperate with federal efforts to evaluate and monitor the programs.

- Contrary findings to the general scientific consensus that needle exchange programs reduce HIV transmission and do not increase drug use should be examined carefully. One study in Montreal found an increase in seroconversion rates in the study population. Some have questioned whether those increases were related needle sharing as opposed to unsafe sexual behavior on the part of study participants, many of whom were prostitutes.

Alternative Approaches

- Data from Connecticut, which recently relaxed it laws restricting access to syringes, suggest that access to clean needles reduces HIV transmission. Whether that access comes through an exchange program or a pharmacy, the data show that when people can use clean needles, they reduce their risk for HIV. Pharmacy access and other means of obtaining clean needles may not, however, also provide referrals to drug treatment and support services, as do most needle exchange programs.

Impact of Drug Use on Treatment Regimens and Risk Behavior

- Drug use absolutely is detrimental to one's ability to maintain complicated treatment regimens and reduce risky behavior. The best long term solution is to free one's self from drug use. The linkage that needle exchange programs provide to drug treatment and support services helps, not hinders, the ability of people to maintain their health and reduce their risk.

Impact on Women and Children

- 74% of all AIDS cases among women are connected directly or indirectly to injection drug use (34% of the cases are those who inject drugs; 40% of the cases are among those who had sexual contact with an injection drug user).

- More than 50% of the cases of AIDS among children can be traced back to injection drug use.

Americans Support Needle Exchange and Local Control

- A poll commissioned by the Human Rights Campaign found that 55% of the American public favors needle exchange programs. (Source: The Tarrance Group and Lake, Sosin, Snell and Associates, April 1997)

- A Kaiser Family Foundation poll found that 61% of Americans favor changing federal law to allow state and local governments to decide for themselves whether to use their federal funds for needle exchange programs. (Source: Kaiser Family Foundation Omnibus Survey, November 1997)

HUMAN
RIGHTS
CAMPAIGN

VOTE NO ON H.R. 3717

A VOTE IN THE HOUSE TO PERMANENTLY BAN FEDERAL FUNDING FOR NEEDLE EXCHANGE PROGRAMS MAY OCCUR AS EARLY AS WEDNESDAY APRIL 29

- On Monday, April 20th, Secretary Shalala announced that there is unequivocal support from the scientific literature that needle exchange programs reduce HIV infection and do not contribute to illegal drug use. Nevertheless, the Administration clearly stated its commitment to maintain the current prohibition on federal funding for needle exchange programs.

- On Thursday, April 23rd, the federal Centers for Disease Control and Prevention reported that there has been no measurable decrease in the rate of new HIV infections, over half of which are directly or indirectly related to intravenous drug use.

- Legislation banning federal funding for needle exchange programs is unnecessary and redundant given the clear position prohibiting funding taken by the Clinton Administration. It would only serve to further politicize an issue that should appropriately be addressed by scientists and state and local public health officials.

- Legislation banning federal funding for needle exchange programs does nothing to respond to the AIDS epidemic which continues to disproportionately strike young people, women and communities of color. Instead of legislating a ban on federal funding for needle exchange programs - already prohibited by the Clinton Administration, Congress should be taking affirmative and bold actions to reduce the numbers of new infections by increasing HIV prevention funding and expanding the options communities have to address their growing infection rates.

- Regardless of your individual beliefs about the appropriateness of federal funding for needle exchange, we encourage you to resist affirming a vote that has everything to do with politics and nothing to do with public health.

- Amending the Public Health Service Act is a serious matter and should not be done hastily on the House floor without careful consideration from the Committee with jurisdiction. Vote no and return this issue to Committee for the appropriate attention it deserves.

4/28/98

WORKING FOR LESBIAN AND GAY EQUAL RIGHTS.

1101 14th Street NW, Suite 200 Washington, D.C. 20005
phone (202) 628 4160 *fax* (202) 347 5323 *e-mail* hrc@hrc.org

Drug-needle exchange

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR SYLVIA MATHEWS AND BRUCE REED

From: Sandra L. Thurman
Director, Office of National AIDS Policy
(202) 632-1090

Cc: Elena Kagan
Chris Jennings

Date: April 29, 1998

Re: **Needle exchange debate and ONDCP**

Attached is a press statement released by the authors of legislation that makes permanent the ban on federal support for needle exchange programs. You will note that Barry McCaffrey is cited as a supporting source. Also attached is a letter from Mr. McCaffrey to me, and my response outlining some of the errors and distortions it includes.

I am concerend about the damage that is done when someone from this Administration so publicly contradicts established policy. It is certainly making it rather difficult to manage the issue. The publication today by *The Washington Times* of a "study" done by ONDCP staff of a needle exchange program in Vancouver is yet one more example of this kind of public bashing of our own decision.

Anything you can to do to insure that ONDCP's public statements are consistent with this Administration's policy (and are factually accurate) would be greatly appreciated!

Congress of the United States

House of Representatives

Washington, DC 20515

April 27, 1998

Federal Funds for Drug Needles?

Dear Colleague:

As you know, the Clinton Administration recently endorsed needle exchange programs for drug addicts. This is an outrage and that is why we have just introduced legislation, H.R. 3717, to permanently ban the use of federal funds for needle distribution.

Numerous studies – including those done by General McCaffrey's Office of National Drug Control Policy – have concluded that needle exchange programs increase illegal drug use. In addition, they do not reduce the spread of HIV. A recent study published in the prestigious *American Journal of Epidemiology* confirmed this: drug addicts who participate in needle exchange programs are 2.2 times more likely to contract HIV than addicts who do not participate.

We have led the fight against illegal drug use and we are not going to allow the pro-drug contingent in this Administration to reverse the progress we have made.

Please support our legislation when it comes to the floor this week.

Sincerely,

GERALD B. H. SOLOMON
Member of Congress

TOM DELAY
Member of Congress

DENNIS HASTERT
Member of Congress

BOB BARR
Member of Congress

ROGER WICKER
Member of Congress

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

April 23, 1998

The Honorable Sandra L. Thurman
Director
White House Office of National AIDS Policy
808 17th St., N.W., 8th Floor
Washington, D.C., 20503

Dear Ms. Thurman: Sandy —

The President's courageous decision not to authorize federal funding for needle exchange programs (NEPs) reflected both the continuing controversy over the efficacy of NEPs as a means to prevent the transmission of HIV and widespread concern that such programs encourage illegal drug use.

While all of us at ONDCP are encouraged by CDC studies showing that the number of new HIV cases in the U.S. appears to be declining, we share your commitment to policies that would help accelerate this decline. As you know, injecting drug use was an exposure category for 15 percent of new HIV cases reported between July 1996 and June 1997. Clearly, this problem needs to be addressed. However, NEPs are an inappropriate tactic that would undermine the President's multi-faceted, balanced *National Drug Control Strategy*.

We look forward to supporting future efforts against HIV/AIDS. Surely, our shared commitment to protecting all Americans from drug abuse and its consequences can result in mutually supportive public-health and law-enforcement strategies.

Sincerely,

Barry R. McCaffrey
Director

A sensible, prudent decision by the Administration which maintains focus of Federal efforts on supporting effective drug treatment.

THE WHITE HOUSE

WASHINGTON

April 28, 1998

Barry R. McCaffrey
Director
Office of National Drug Control Policy
Washington, DC 20503

Dear Mr. McCaffrey: Barry

Thank you for your letter of April 23, 1998 regarding needle exchange programs (NEPs). Unfortunately, its perpetuation of factual errors and statements that directly contradict scientific determinations just made by HHS is troubling. The President is not well served when policy positions are predicated on misinformation.

The letter refers to the "continuing controversy over the efficacy of NEPs." As you well know, the Secretary of Health and Human Services with the support of the President, resolved that issue only last Monday. The position of this Administration is that needle exchange programs reduce HIV transmissions without encouraging the use of illegal drugs. We have both committed publicly to following the science on this issue, and now that the scientific determination has been made, I believe we have an obligation to respect it. I have certainly defended the Administration's decision not to fund needle exchange, despite the fact that it wouldn't have been my choice.

Also included in the letter are statements relative to the spread of HIV in this country, and particularly among injection drug users, that are erroneous. Unfortunately, we do not know, as is stated, that the number of new HIV infections in the U.S. are declining. Similarly, it is said that, "injecting drug use was an exposure category for 15 percent of new HIV cases." Both errors come from the use of HIV infection data published by the Centers for Disease Control and Prevention but only available for the 29 states that collect such data. As we have explained in the past, these are almost entirely low-incidence and prevalence states and using their data to characterize the spread of HIV in our country as a whole is deceptive.

Finally, continued distortions of the implications of studies completed on needle exchange programs in Montreal and Vancouver are also of great concern to me. The scientists who directed these studies, in an op-ed published in the *New York Times* (see attached), directly refuted the misinterpretation of their studies that has been used to argue that NEPs are ineffective in reducing HIV transmissions. Not only have these distortions continued but the pretext of an objective review of those programs by ONDCP staff was done to substantiate those misinterpretations.

If there is a misunderstanding about the facts that you and I have discussed at length in person, or the discussions between our staff, I am more than willing to work to clarify them. Our work together can only be effective when we adhere to our commitments to follow the science and stick to the facts.

I appreciate and admire your passionate dedication to reducing the use of drugs in this country and look forward to continuing to work with you to address the both the AIDS and drug epidemics.

Sincerely yours,

Sandra L. Thurman
Director
Office of National AIDS Policy

Drugs - needle exchange

EK -
For your
Honest Broker file.
-BR

THE WHITE HOUSE
WASHINGTON

April 19, 1998

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed

SUBJECT: Needle Exchange

You should try to make a final decision on needle exchange today. If you decide to go forward with the "demonstration" option, Shalala would like to announce it tomorrow to ward off a press conference AIDS groups have called for tomorrow morning to demand her resignation. If you decide to certify the science but rule out federal funds, we should announce that soon to stop Republican attacks over the issue.

Under the demonstration proposal, HHS would certify that needle exchange programs reduce HIV transmission without increasing drug use, and allow federal prevention funds to be used for those programs in up to 8 communities hardest hit by drug-related HIV. Communities that ranked among the highest in the overall rate or number of drug-related HIV cases or drug-related HIV cases among women of childbearing age would be eligible, but only 8 would be permitted to use federal funds. Over the next year, CDC would evaluate these 8 communities to determine whether their programs were working and whether they were making an effective link to drug treatment before deciding whether to expand the number of eligible communities.

A program would also have to 1) be legal in that state and community; 2) make referrals to drug treatment; 3) comply with hazardous waste disposal standards; 4) replace syringes on a one-for-one basis; and 5) agree to research and evaluation. HHS estimates that only about 27 communities have the capacity to meet these requirements.

You still have the option to certify the science but rule out the use of federal funds on the grounds that this should be a local decision, not a national political debate. Contrary to her earlier statement to Erskine, Shalala opposes this option, as would the AIDS community. (We do not know how much the AIDS and scientific communities will criticize the demonstration option.)

Several Republican members of Congress and the RNC have already issued statements attacking the Administration over needle exchange. They will almost certainly attach a ban on federal funds to the supplemental bill, to tobacco legislation, and to the Labor/HHS appropriations bill in the fall. The AIDS community would want you to veto legislation over this issue, but we have always refused to do so in the past.

Whatever you decide, we will inform Shalala and McCaffrey, and roll out the decision to key members and groups.

Drugs - needle exchange

Sex Orient. Exec Order -
Talk to Sylvia/
Tohn

Needle Exchange - To Do 4/21/98

1. Phone calls -

A. Erskine → Willie Brown
B. Erskine → Scott Hitt
C. Bruce → Daniel Zingale
D. Bruce → Winnie Stachelberg
E. Sandy → Jeff Levi

Maria → Becerra
Minyon → Waters

2. Legislation

(Larry - who's doing?) (minority caucus)

3. Private funding?

Sylvia has talked to Soros (not the right person)

Talk to other people < Donna / Sandy

- Bruce to talk to Donna
- I'll talk to Sylvia - Soros?

4. Radio address?? (1 yr anniv of vaccine)

Todd & etc.

5. Other AIDS stuff

- Medicaid expansion (Chris)
- Drug treatment/prevention funds (Chris)

6. HHS to produce data — to communities

• Sandy → Kevin
(Chris)

Drugs-needle exchange

DRAFT – NOT FOR RELEASE

April 28, 1998
(House)

H.R. 3717 - Prohibition Regarding Illegal Drugs and the Distribution of Hypodermic Needles
(Rep. Solomon (R) NY and four cosponsors)

The Administration strongly opposes H.R. 3717 because it is unnecessary and unwarranted. As the Nation's chief appointed health official, the Secretary of Health and Human Services should have the authority to determine the scientific and public health merit of needle exchange programs as they affect rates of HIV transmission and injection drug use. The Administration believes that the Secretary is the appropriate official to determine which HIV prevention strategies should be supported with Federal funds, and that the decision on which HIV prevention strategies to use should rest with State and local officials.

****

To: TODD SUMMERS

VERSION being circulated for final review.

Bob P.

Drugs - needle exchange

W:Needle.vte

NEEDLE EXCHANGE

Ds who voted for Hastert but may be willing to change their vote	Ds who voted against Hastert who may wish to change their vote	Rs who voted against Hastert
Costello (IL) - *	Allen (ME) - ?	Campbell (CA)
Gordon (TN) - C, ?	Boucher (VA) - C	Cooksey (LA)
Green (TX) - C	Brown (CA)- ?, *	Foley (FL)
Hamilton (IN)- *,R	DeGette (CO) - C, *	Frelinghuysen (NJ)
Johnson (WI) - *,?	Deutsch (FL) - C,*	Ganske (IA)
Klink (PA) - C, *	Eschoo (CA) - C, *	Greenwood (PA)
LaFalce (NY) - *	Evans (IL) - ?, *	Horn (CA)
Lipinksi (IL) - *	Furse (OR) - C, R,*	Houghton (NY)
Lurther (MN) - *, ?	Gejdenson (CT) - ?, *	Johnson (CT)
10. Karen McCarthy (MO) - *, C	Hinchey (NY) - ?, *	Kolbe (AZ)
McNulty (NY) - *	Hooley (OR) - ?, *	Leach (IA)
Minge (MN) - *	Kind (WI) - ?, *	McCrery (LA)
Oberstar (MN) - *	Kuchinich (OH) - ?*	Morella (MD)
Pascrell (NJ) - *, ?	Lampson (TX) - ?	Shays (CT)
Peterson (MN) - *,	Maloney (CT) - ?, *	Thomas (Ca)
Poshard (IL) - HO, *	Manton (NY) - C, *	Young (FL)
Roemer (IN) - *	McGovern (MA) - ?, *	
Strickland (OH) - *, C, ?	Olver (MA) - ?, *	
Stupak (MN) - *, C	Pallone (NJ) - C, *	
Visclosky (IN) - *	Pomery (ND)- ?	

	Price (NC) - ?, *	
	Sawyer (OH)- C, ?	
	Sherman (CA) - ?, *	
	Smith, Adam (WA) - ?, *	
	Snyder (Ark)- ?	
	Stabenow (MI) - , ?, *	
	Tierney (MA)- ?, *	

C- Commerce Committee member
* State has needle exchange program
? - Difficult Race
R- retiring
HO- seeking higher office

House Vote Detail

CONGRESS: 105 **SESSION:** 1
ROLL CALL NUMBER: 391
RESULT: Passed
VOTE DATE: 09-11-97
CONGRESSIONAL RECORD PAGE:7233
BILL-AMEND NUMBER:H.R. 2264 - A028
SPONSOR: Hastert
VOTE TYPE: Recorded Vote
QUESTION: On agreeing to the Hastert amendment (A028)
TITLE: An amendment to delete the provisions of the bill to allow implementation of hypodermic needle exchange programs, if the Secretary of Health and Human Services determines such programs to be effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

Vote Matrix: H.R. 2264 - A028

	Y	N	PRESENT	NOT VOTING
Democratic	59	141	0	6
Republican	207	16	0	3
Other	0	1	0	0
Total	**266**	**158**	0	**9**

Information Services | Votes Search

House Votes

Member Response List
Bill Number: H.R. 2264
Congress: 105-1
Roll Call: 391
View: Democrats voting AYE

Member	ST	CD	Party	Response
Baesler	KY	06	D	AYE
Barcia	MI	05	D	AYE
Bentsen	TX	25	D	AYE
Boswell	IA	03	D	AYE
Boyd	FL	02	D	AYE
Clement	TN	05	D	AYE
Condit	CA	18	D	AYE
Costello	IL	12	D	AYE
Cramer	AL	05	D	AYE
Danner	MO	06	D	AYE
Davis (FL)	FL	11	D	AYE
Doyle	PA	18	D	AYE
Edwards	TX	11	D	AYE
Etheridge	NC	02	D	AYE
Goode	VA	05	D	AYE
Gordon	TN	06	D	AYE
Green	TX	29	D	AYE
Hall (OH)	OH	03	D	AYE
Hall (TX)	TX	04	D	AYE
Hamilton	IN	09	D	AYE
Hefner	NC	08	D	AYE
Hinojosa	TX	15	D	AYE
Holden	PA	06	D	AYE
John	LA	07	D	AYE
Johnson (WI)	WI	08	D	AYE
Kildee	MI	09	D	AYE
Kleczka	WI	04	D	AYE
Klink	PA	04	D	AYE
LaFalce	NY	29	D	AYE
Lipinski	IL	03	D	AYE
Luther	MN	06	D	AYE
Mascara	PA	20	D	AYE
McCarthy (MO)	MO	05	D	AYE
McIntyre	NC	07	D	AYE
McNulty	NY	21	D	AYE
Minge	MN	02	D	AYE

Mollohan	WV	01	D	AYE
Murtha	PA	12	D	AYE
Oberstar	MN	08	D	AYE
Ortiz	TX	27	D	AYE
Pascrell	NJ	08	D	AYE
Peterson (MN)	MN	07	D	AYE
Poshard	IL	19	D	AYE
Reyes	TX	16	D	AYE
Rodriguez	TX	28	D	AYE
Roemer	IN	03	D	AYE
Sandlin	TX	01	D	AYE
Sisisky	VA	04	D	AYE
Skelton	MO	04	D	AYE
Spratt	SC	05	D	AYE
Stenholm	TX	17	D	AYE
Strickland	OH	06	D	AYE
Stupak	MI	01	D	AYE
Tanner	TN	08	D	AYE
Taylor (MS)	MS	05	D	AYE
Traficant	OH	17	D	AYE
Turner	TX	02	D	AYE
Visclosky	IN	01	D	AYE
Wise	WV	02	D	AYE

Information Services Votes Search

House Votes

Member Response List
Bill Number: H.R. 2264
Congress: 105-1
Roll Call: 391
View: Republicans voting NO

Member	ST	CD	Party	Response
Campbell	CA	15	R	NO
Cooksey	LA	05	R	NO
Foley	FL	16	R	NO
Frelinghuysen	NJ	11	R	NO
Ganske	IA	04	R	NO
Greenwood	PA	08	R	NO
Horn	CA	38	R	NO
Houghton	NY	31	R	NO
Johnson (CT)	CT	06	R	NO
Kolbe	AZ	05	R	NO
Leach	IA	01	R	NO
McCrery	LA	04	R	NO
Morella	MD	08	R	NO
Shays	CT	04	R	NO
Thomas	CA	21	R	NO
Young (FL)	FL	10	R	NO

Information Services | Votes Search

--- NOES 158 ---

Abercrombie	*Furse*	Morella
Ackerman	Ganske	*Nadler*
Allen	*Gejdenson*	*Neal*
Andrews	*Gephardt*	*Obey*
Baldacci	Greenwood	*Olver*
Barrett (WI)	*Gutierrez*	*Owens*

Becerra	*Harman*	*Pallone*
Berman	*Hilliard*	*Pastor*
Berry	*Hinchey*	*Pelosi*
Bishop	*Hooley*	*Pickett*
Blagojevich	Horn	*Pomeroy*
Blumenauer	Houghton	*Price (NC)*
Bonior	*Hoyer*	*Rahall*
Boucher	*Jackson (IL)*	*Rangel*
Brown (CA)	*Jackson-Lee (TX)*	*Rivers*
Brown (FL)	*Jefferson*	*Rothman*
Brown (OH)	Johnson (CT)	*Roybal-Allard*
Campbell	*Johnson, E. B.*	*Rush*
Capps	*Kanjorski*	*Sabo*
Cardin	*Kaptur*	*Sanchez*
Carson	*Kennedy (MA)*	Sanders
Clay	*Kennedy (RI)*	*Sawyer*
Clayton	*Kennelly*	*Schumer*
Clyburn	*Kilpatrick*	*Scott*
Conyers	*Kind (WI)*	*Serrano*
Cooksey	Kolbe	Shays
Coyne	*Kucinich*	*Sherman*
Cummings	*Lampson*	*Skaggs*
Davis (IL)	*Lantos*	*Slaughter*
DeFazio	Leach	*Smith, Adam*
DeGette	*Levin*	*Snyder*
Delahunt	*Lewis (GA)*	*Stabenow*
DeLauro	*Lofgren*	*Stark*
Deutsch	*Lowey*	*Stokes*
Dicks	*Maloney (CT)*	*Tauscher*
Dingell	*Maloney (NY)*	Thomas
Dixon	*Manton*	*Thompson*
Doggett	*Markey*	*Thurman*
Dooley	*Martinez*	*Tierney*
Engel	*Matsui*	*Torres*
Eshoo	*McCarthy (NY)*	*Towns*
Evans	McCrery	*Velazquez*
Farr	*McDermott*	*Vento*

Fattah	*McGovern*	*Waters*
Fazio	*McHale*	*Watt (NC)*
Filner	*McKinney*	*Waxman*
Flake	*Meehan*	*Wexler*
Foglietta	*Menendez*	*Weygand*
Foley	*Millender-McDonald*	*Woolsey*
Ford	*Miller (CA)*	*Wynn*
Frank (MA)	*Mink*	*Yates*
Frelinghuysen	*Moakley*	Young (FL)
Frost	*Moran (VA)*	

--- NOT VOTING 9 ---

Bonilla	*Gonzalez*	*Payne*
Borski	*Hastings (FL)*	Schiff
Dellums	*Meek*	Taylor (NC)

HR 3717 IH

105th CONGRESS

2d Session

H. R. 3717

To prohibit the expenditure of Federal funds for the distribution of needles or syringes for the hypodermic injection of illegal drugs.

IN THE HOUSE OF REPRESENTATIVES

April 23, 1998

Mr. SOLOMON (for himself, Mr. WICKER, Mr. HASTERT, Mr. BARR of Georgia, and Mr. DELAY) introduced the following bill; which was referred to the Committee on Commerce

---

A BILL

To prohibit the expenditure of Federal funds for the distribution of needles or syringes for the hypodermic injection of illegal drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROHIBITION REGARDING ILLEGAL DRUGS AND DISTRIBUTION OF HYPODERMIC NEEDLES.

Part B of title II of the Public Health Service Act (42 U.S.C. 238 et seq.) is amended by adding at the end the following section:

'PROHIBITION REGARDING ILLEGAL DRUGS AND DISTRIBUTION OF HYPODERMIC NEEDLES

'SEC. 247. Notwithstanding any other provision of law, none of the amounts made available under any Federal law for any fiscal year may be expended, directly or indirectly, to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.'.

SEC. 2. CONFORMING AMENDMENT.

Section 506 of Public Law 105-78 is repealed.

END

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.

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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.

###

American Medical Association
Physicians dedicated to the health of America

Statement

Statement attributable to: Nancy W. Dickey, MD
President-Elect
American Medical Association

"The American Medical Association recognized one year ago, in a policy statement adopted by our House of Delegates, that important advances to arrest the AIDS epidemic could be made through responsible needle exchange and drug treatment programs. Traditionally, AMA policy follows science, and as Secretary Shalala notes scientific evidence clearly shows that needle exchange is effective in curtailing HIV transmission and that the availability of clean needles does not increase drug abuse.

"We hope that drug treatment programs review the growing body of evidence concerning these serious public health issues, and take appropriate actions in intervene effectively."

-4-20-98-

For further information, contact: James Stacey 202 789-7419

1101 Vermont Avenue, NW
Washington, DC 20005
202 789-7400

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:

- Appendix A: The Department's February 1997 Report to Congress
- Appendix B: Recent data analysis completed since February 1997
- Appendix C: Summary document reviewing the scientific literature by outcome measures of interest
- 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 creats 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.

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,

Donna E. Shalala

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

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

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

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

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

Introduction

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

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

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

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

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

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

I. Review of Published Studies

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

Report of the U.S. General Accounting Office

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

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

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

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

One concern surrounding needle exchange programs is whether they lead to increased injection drug use. Seven of the nine projects looked at this issue, and five had strong evidence for us to report on outcomes. All five found that drug use did not increase among users; four reported no increase in frequency of injection and one found no increase in the prevalence of use. None of the studies that addressed the question of whether or not the needle exchange progams 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:

- 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.

- The lower the fraction of needles in circulation that are contaminated, the lower the risk of new HIV infections.

- 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.

- 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.

- The available scientific literature provides evidence that needle exchange programs have public support, depending on locality, and that public support tends to increase over time." Preventing HIV Transmission: The Role of Sterile Needles and Bleach, Executive Summary, page 4.

Other Recent Studies

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

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

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

- Findings HIV incidence among continuing exchange users in the Syringe Exchange Evaluation was 1.58 per 100 person-years at risk (95% CI 0.54, 4.65) and among continuing exchange users in the Vaccine Preparedness Initiative it was 1.38 per 100 person-years at risk (0.23, 4.57). Incidence among non-users of the exchange in the Vaccine Preparedness Initiative was 5.26 per 100 person-years at risk (2.41, 11.49), and in the National AIDS Demonstration Research cities (non-exchange users) 6.23 per 100 person-years at risk (4.4, 8.6). In a pooled-data multivariate proportional-hazards analysis, not using the exchanges was associated with a hazard ratio of 3.35 (95% CI 1.29, 8.65) for incident HIV infection compared with using the exchanges.
  Interpretation We observed an individual-level protective effect against HIV infection associated with participation in a syringe-exchange programme. Sterile injection equipment should be legally provided to reduce the risk of HIV infection in persons who inject drugs." p. 987.

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

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

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

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

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

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

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

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

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

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

II. Current Federally Supported Research on Needle Exchange Programs

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

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

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

III. National Survey on the Regulation of Syringes and Needles

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

Summary

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

IV. Appendices

Appendix A. Needle Exchange Programs: Research Suggests Promise as an AIDS Prevention Strategy. U.S. General Accounting Office. 1993

Appendix B. The Public Health Impact of Needle Exchange Programs in the United States and Abroad, Volume 1. San Francisco, CA: University of California. 1993

Appendix C. Preventing HIV Transmission: The Role of Sterile Needles and Bleach. National Research Council and Institute of Medicine. 1995.

Appendix D. Des Jarlais DC, Marmor M, Paone D et al. HIV Incidence Among Injecting Drug Users in New York City Syringe-Exchange Programmes. Lancet. 1996;348:987-991.

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

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

1) Vlahov D. et al. Evaluation of the Baltimore Needle Exchange Program: Preliminary Results. Abstract Mo.D.361

2) Schoenbaum, E. et al. Needle Exchange Use Among a Cohort of Drug Users. Abstract Tu.C.2523

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

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

GAO

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

GAO/HRD-93-60

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

Attachment C

Preventing HIV Transmission

The Role of Sterile Needles and Bleach

NATIONAL RESEARCH COUNCIL • INSTITUTE OF MEDICINE

APPENDIX D

thromboembolic disease. *Lancet* 1995; 346: 1582–85.
23 Jick J, Jick SS, Gurewich V, Myers MW, Vasilakis C. Risk of idiopathic cardiovascular death and non-fatal venous thromboembolism in women using oral contraceptives with differing progestagen components. *Lancet* 1995; 346: 1589–93
24 Bloemenkamp KWM, Rosendaal FR, Helmerhorst FM, Buller HR, Vandenbroucke JP. Enhancement by factor V Leiden mutation of risk of deep-vein thrombosis associated with oral contraceptives containing a third-generation progestagen. *Lancet* 1995; 346: 1593–96.
25 Nachtigall LE, Nachtigall RH, Nachtigall RD, Beckman EM. Estrogen replacement therapy II: a prospective study in the relationship to carcinoma and cardiovascular and metabolic problems. *Obstet Gynecol* 1979; 54: 74–79.
26 Sampler MJ, Goldhaber SZ, Manson JE, et al. A prospective study of exogenous hormones and risk of pulmonary embolism in women. *Circulation* 1992; 86 (suppl I): I-476 (abstr).
27 Poller L, Thomson JM, Cooper J. Conjugated equine oestrogens and blood clotting: a follow-up report. *BMJ* 1977; i: 935–36.
28 Stangel JJ, Innerfield I, Reynick J, Seane ML. The effect of conjugated estrogens on coagulability in menopausal women. *Obstet Gynecol* 1977; 49: 314–16.
29 Nesheim M, Kitchens CS, Ware MD. Coagulation and fibrinolysis in estrogen-treated surgically menopausal women. *Obstet Gynecol* 1984; 63: 621–25.
30 Nesheim M, Kitchens C, Ware MD, Hirschberg K, Coone L. Combination estrogen and progestin replacement therapy does not adversely affect coagulation. *Obstet Gynecol* 1983; 62: 596–600.
31 Postmenopausal Estrogen/Progestin Interventions Trial Writing Group. Effects of estrogen/progestin regimens on heart disease risk factors in postmenopausal women. *JAMA* 1995; 273: 199–208.
32 Grady D, Rubin SM, Petitti DB, et al. Hormone therapy to prevent disease and prolong life in postmenopausal women. *Ann Intern Med* 1992; 117: 1016–37.

HIV incidence among injecting drug users in New York City syringe-exchange programmes

Don C Des Jarlais, Michael Marmor, Denise Paone, Stephen Titus, Qiuhu 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.[3-5] 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.[1]

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.[6] 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.[7-10]

Lancet 1996; 348: 987–91

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

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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

Schoenbaum, Ellie E*, Hartel DM, Gourevitch MN. Montefiore Med Center, Albert Einstein College of Medicine, Bronx, New York, USA.

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

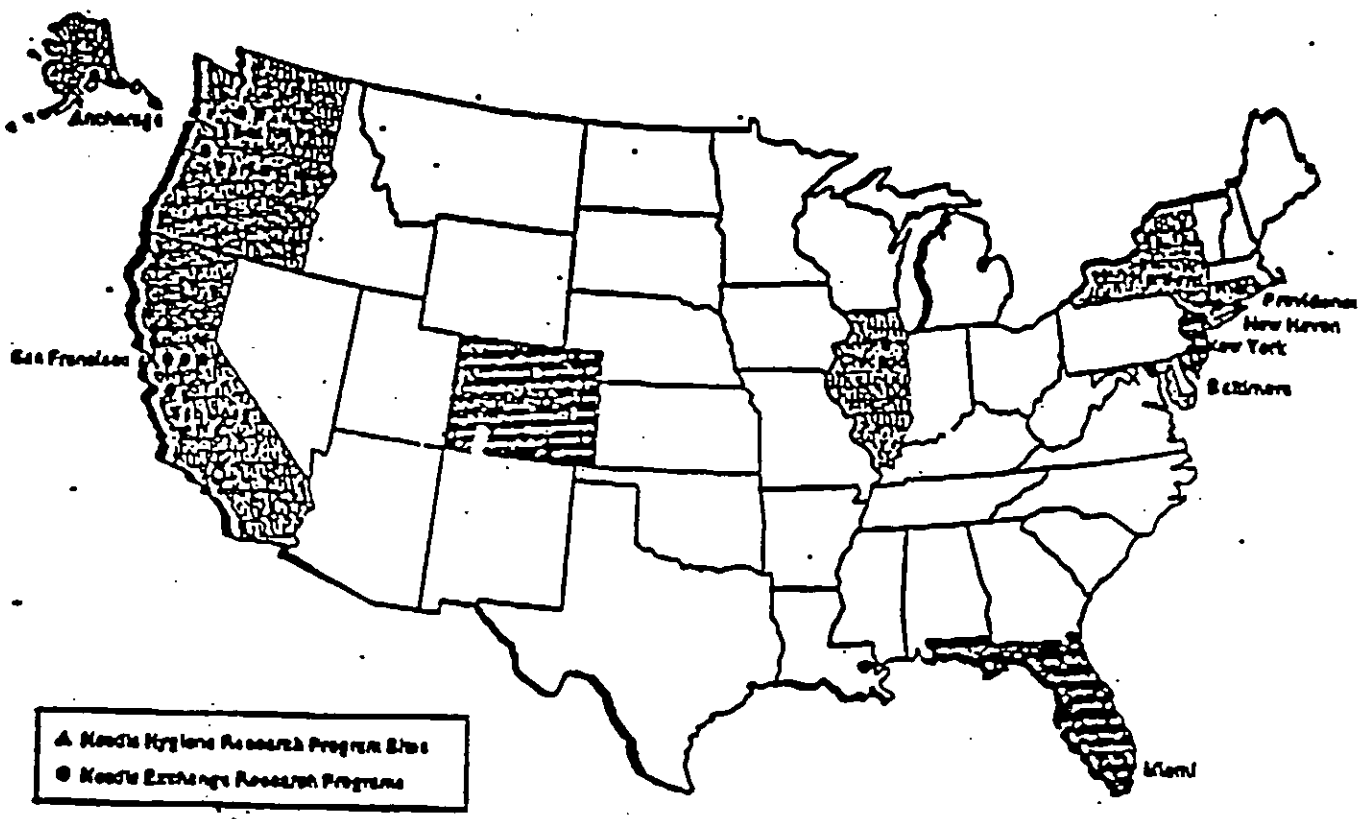
First Year of the Pilot Needle Exchange Program in Massachusetts

October 1995

The Medical Foundation
95 Berkeley Street
Boston MA 02116

NIDA's Needle Hygiene and Needle Exchang Evaluation Research Program Portfolio 1992-Present

Needle Hygiene and Needle Exchange Evaluation Research Program Site



Needle Exchange 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 van 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 paradoxic 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

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

Authors/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.

Authors/Purpose	Sample/Design	Results/Findings	Comment
Paone et al., 1996 To describe cahracteristics 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.

[1]Note: 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.

Table 1.3: HIV Infection Rates (Continued)

Authors/Purpose	Sample/Design	Results/Findings	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
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 Preparednss 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.

*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.
*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 counseling & 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 counseling & 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 serostaus, - 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 user were 2.2 times more likely to be positive at baseline. - The cohort analysis showed that the cummulative 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.
*Lurie & Drucker, 1997, The Lancet, 349:605-608. Estimate the number of HIV infections that could have been averted (and associated cost) between 1987 and 1995 in the US had NEPs been implemented.	Implement a mathematical model using empirical data from available epidemiological data from the US and Australia.	- Estimates that between 4,304 and 9,666 HIVinfection could have been averted between 1987 and 1995. - The cost to trhe health care system for treating these preventable infections range between 244 to 538 million.	Estimates are based on mathematical modeling which make stringent assumptions (it is appropriate to use empirical estimate from Australia to estimate US experience).
*Singer et al.,1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	3,050 randomly selected needles r 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 1.4: Hepatitis B (HBV) and Hepatitis C (HCV) Infection Rates (2 studies: 2 found significant reductions)

Authors/Purpose	Sample/Design	Results/Findings	Comments
Hagan et al., 1991 To report on HBV incidence and determination of risk behaviors for observed new HBV infections.	All incident HBV cases among IDUs, 1985-90 CDC HBV case reports: sentinel surveillance pre-post needle exchange	Outbreak of HBV among IDU in 1985 (40 incident cases) dropped rapidly a few months following the opening of the NEP to 9 incident cases in 1990	Low HIV prevalence site. NEP began in Amsterdam to reduce risk of hepatitis.
Hagan et al., 1995 To examine the association between syringe exchange use and hepatitis B and C in IDUs.	Cases: • 28 HBV IDUs • 20 HCV IDUs Controls: • 38 No-HBV IDUs • 26 No-HCV IDUs Case control study	• Non-NEP use associated with a 5.5 greater risk of HBV • Non-NEP use associated with a 7.3 greater risk of HCV	Low HIV prevalence area.

Table 2.1: Reductions in Injection Frequency (9 studies: 4 had significant reductions, 3 had mixed findings, and 2 were not significant)

Authors/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%)	
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	
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)	Median daily frequency of injection declined: • from 1.9 to 0.7 injections per day	
Paone 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	

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., 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 Pre-exchange / Post-exchange < 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.

*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: Reductions in Multiperson Reuse of Works (8 studies: 7 had significant reductions, 1 had mixed findings)

Authors/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-section study. Data on records 2 years preceding NEP (1987-1988) and 2 years following NEP	Percent of IDUs who report sharing in 30 days before admission to methadone detoxification clinic (n=5,532) • Decreased steadily over time (36.5% in 1987; 30.1% in 1988; 29.2% in 1989; 24.8% in 1990) • NEP implemented in 6/88	
Hagan et al., 1993 To assess the potential effectiveness of the Tacoma NEP	204 needle exchange participants Retrospective cohort study (pre-post measure)	Mean monthly frequency of rented or borrowed syringe • Pre-NEP 56/month, while in NEP 30/month ($p<.05$) Mean monthly frequency of lending used syringe • Pre-NEP 100/month, while in NEP 62/mo ($p<.05$)	
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)	Proportion of IDUS who reported sharing, last 30 days • Frequent NEP users (i.e., used > 25 times in last year) were 0.71 times less likely to report sharing than those who used NEP less often or not at all	
Paone et al., 1994 To evaluate NYC lower East side NEP.	1,752 IDUs, randomly selected needle exchange participants Multiple random cross-sections of needle exchange participants with recapture feature using retrospective data collection over 8 months (10/92- 6/93)	Percentage of injection episodes that involved using a previously used works: • Pre-NEP 11.6%, while in NEP 3.9% Percent IDUs who used used works: • Rented or bought: Pre-NEP 22%, while in NEP 6% • Borrowed: Pre-NEP 29%, while in NEP 12%	

Table 2.2 continues on next page.

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	Percentage of IDUs who shared prior to using NEP compared to percentage who did while using NEP: ▸ 9% decrease sharing (65% vs 56%) ▸ 6% decrease renting (9% vs 3%) ▸ 13 % decrease borrowing (20% vs 7%)	
Hagan et al., 1994 To update the evaluation of Tacoma NEP.	426 needle exchange participants Retrospective cohort study (pre-post NEP measure)	▸ Proportion not using a used syringe in month & those who did at least once (OR=.36, p<.05). ▸ Proportion not passing on a used syringe in month and those who did at least once (OR=.33, p<.05). Pre-exchange / Post-exchange Re-used syringe None 42% 68% At least once 57% 33% Passed used syringe None 28% 54% At least once 72% 46%	
Des Jarlais et al., 1994	1,115 IDUs admitted to drug detoxification program Ecological study with 2 randomly selected cross-sectional samples, 1984 and 1992	Decrease significant for one behavior and not significant for another: ▸ Negative correlation (-.67) between NEP use and using used needles (p<.02) ▸ Negative correlation (-.44) between NEP use and passing needles (p<.13)	
*Singer et al.,1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	315 needle exchange participants Prospective cohort study with pretest and posttest measures	Percentage of NEP users who share needles: ▸ 74% do not share at baseline, 16% discontinued or decreased needle sharing at posttest Percent of NEP users who share injection equipment: ▸ 14% do not share at baseline, 37% discontinued or decreased sharing injection equipment at posttest ▸ NEP use < 2 yrs: mean decrease of 10 times/month ▸ NEP use ≥ 2 yrs: mean decrease of 48 times/month	

Table 2.3: Increases in Needle Disinfection (2 studies: 2 found significant increases)

Authors/Purpose	Sample/Design	Results/Findings	Comments
Hagan et al., 1993 To assess the potential effectiveness of the Tacoma NEP	204 needle exchange participants Retrospective cohort study (pre-post measure)	Mean monthly frequency of used bleach to disinfect syringe • Used bleach: Pre NEP 69 per mth During NEP 105 per mth ($p<.05$)	
Oliver et al., 1994 Evaluate NEP in Portland, OR.	77 needle exchange participants Prospective cohort study with pre-post measures (baseline and six month follow-up)	Percentage of IDUs who cleaned their needles. Percentage of IDUs who re-used works without cleaning. Compared cleaning prior to attending NEP with behavior while using NEP: • 14% increase in % who cleaned (65% vs 51%) 11% Decrease in % who re-used works without cleaning (12% vs 23%)	

Table 2.4: 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 2.5: Unsafe Disposal of Injection Equipment (2 studies: 1 found significant reduction, 1 not significant)

Authors/Purpose	Sample/Design	Results/Findings	Comments
Oliver et al., 1994 Evaluate NEP in Portland, OR	77 needle exchange participants Prospective cohort study with pre-post measures (baseline and six month follow-up)	Percentage of IDUs who used syringes and threw away: • 14% decrease in % IDUs who used syringes and threw them away (54% vs 40%) Mean number of syringes found on street per month: • Before NEP implementation: 5.2 • After NEP implementation: 1.9	
*Doherty et al., 1997 Examine effect of NEP on quantity of discarded needles.	Random sample of city blocks in high areas of drug use Prospective study with pre-post needle exchange implementation measures	• At 2 month follow-up, no increase in discarded syringes following NEP implementation • At 2 year follow-up, the number of discarded syringes was reduced	

Table 2.6: 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/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: 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)	
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	

References

1. Bruneau, J., Lamothe, F., Franco, E. et al. (1997). 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, 146:994-1002.*

2. Des Jarlais, D.C., Friedman, S.R., Sotheran, J.L., Wenston, J., Marmor, M., Yancovitz, S.R., Frank, B., Beatrice, S., & Mildvan, D. (1994). Continuity and change within an HIV epidemic: Injecting drug users in New York City, 1984 through 1992. *Journal of the American Medical Association, 271 (2)*:121-127.

3. Des Jarlais, D.C., Marmor, M., Paone, D., Titus, S., Shi, Q., Perlis, T., Jose, B., & Friedman, S.R. (1996). HIV incidence among injecting drug users in New York City syringe-exchange programmes. *The Lancet, 348*:987-991.

4. Doherty, M.C., Garfein, R.S., Junge, B., Beilenson, P., & Vlahov, D. (1997). Discarded Needles Do Not Increase With a Needle Exchange Program. *American Journal of Epidemiology*, 145, 730-737.

5. Guydish, J. Bucardo, J., Young, M., Grinstead, O., & Clark, W. (1993). Evaluating needle exchange: Are there negative effects? *AIDS, 7 (6)*:871-876.

6. Hagan, H., Des Jarlais, D.C., Purchase, D., Friedman, S.R., Reid, T.R., & Bell, T.A. (1991). The incidence of HBV infection and syringe exchange programs [letter]. *Journal of the American Medical Association, 266 (12)*:1646-1647.

7. Hagan, H., Des Jarlais, D.C., Purchase, D., Friedman, S.R., Reid, T.R., & Bell, T.A. (1993). An interview study of participants in the Tacoma, Washington syringe exchange. *Addiction, 88*;1691-1697.

8. Hagan, H., Des Jarlais, D.C., Friedman, S.R., & Purchase, D. (1994). Risk for human immunodeficiency virus and hepatitis B virus in users of the Tacoma syringe exchange program. Pp. 24-34 in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs*. National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

9. Hagan, H., Des Jarlais, D.C., Friedman, S.R., Purchase, D., & Alter, M.J. (1995). Reduced risk of hepatitis B and hepatitis C among injecting drug users participating in the Tacoma syringe exchange program. *American Journal of Public Health, 85 (11)*:1531-1537.

10. Heimer, R., Kaplan, E.H., & Cadman, E.C. (1992). Prevalence of HIV-infected syringes during a syringe-exchange program. *The New England Journal of Medicine, 327 (26)*:1883-1884.

11. Heimer, R., & Lopes, M. (1994). Needle exchange hastens entry into drug treatment [letter]. *Journal of the American Medical Association, 271 (23)*:1825-1826.

12. Hurley, S., Jolley, D.J., Kaldor, J.M. (1997). Effectiveness of needle-exchange programmes for prevention of HIV infection. *The Lancet, 349:1797-1800.*

13. Kaplan, E.H. (1994). Operational modeling of needle exchange programs. Pp. 202-249 in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs*. National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

14. Kaplan, E.H., & Heimer, R. (1994). HIV incidence among needle exchange participants: Estimates from syringe tracking and testing data. *Journal of Acquired Immune Deficiency Syndromes, 7 (2)*:182-9.

15. Kaplan, E.H., & Heimer, R. (1995). HIV incidence among New Haven needle exchange participants: Updated estimates from syringe tracking and testing data. *Journal of Acquired Immune Deficiency Syndromes & Human Retrovirology, 10 (2)*:175-176.

16. Kaplan, E.H., & O'Keefe, E. (1993). Let the needles do the talking! Evaluating the New Haven needle exchange. *Interfaces, 23 (1)*: 7-26.

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

18. Oliver, K., Maynard, H., Friedman, S.R., & Des Jarlais, D.C. (1994). Behavioral and community impact of the Portland syringe exchange program. Pp. 35-46 in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs*. National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

19. Paone, D., Des Jarlais, D.C., Caloir, S., Friedmann, P., Ness, I., & Friedman, S.R. (1994). New York City Syringe Exchange: An Overview. Pp. 47-63.in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs*. National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

20. Paone, D., Des Jarlais, D., Clark, J. & Shi, Q. (1996). Syringe-Exchange Programs in the United States: Where Are We Now? *AIDS & Policy Policy Journal, 11 (3):* 144-147.

21. Paone, D., Des Jarlais, D., Clark, J. & Shi, Q. et. Al. (1997). Update: Syringe-Exchange Programs - United States 1996. *MMWR, 46:565-568.*

22. Schoebaum, E.E., Hartel, D.M., & Gourevitch, M.N. (1996). Needle Exchange Use Among a Cohort of Injecting Drug Users. *AIDS, 10 (14)*:1729-1734.

23. Singer, M., Horowitz, S., Weeks, M., & Radda, K. (1997). New needles for old: Preventing AIDS among injection drug users in Hartford, CT. *Medical Anthropology Quarterly,18:1-24.*

24. Strathdee, S.A., Patrick, D.M., Currie, S.L. et al. (1997). Needle Exchange is not enough: lessons from the Vancouver injection drug use study. *AIDS. 11:F59-F65.*

25. Vlahov, D. et al. (1997). Reductions in high risk drug use behaviors among participants in the Baltimore needle exchange. *Journal of AIDS and Human Retrovirology, 16:400-406.*

26. Watters, J.K. (1994). Trends in risk behavior and HIV seroprevalence in heterosexual injection drug users in San Francisco, 1986-1992. *Journal of Acquired Immune Deficiency Syndromes, 7 (12)*:1276-1281.

27. Watters, J.K., Estilo, M.J., Clark, G.L. & Lorvick, J. (1994). Syringe and needle exchange as HIV/AIDS prevention for injection drug users. *Journal of the American Medical Association, 271 (2)*:115-120.

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 Have 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	Sample/Design	Report/Findings	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 NBP 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 counseling & 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 counseling & 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 user were 2.2 times more likely to be positive at baseline. - The cohort analysis showed that the cummulative 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 r 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)**

[illegible]	[illegible]	[illegible]	[illegible]
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)

Author/Period	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)**

Authors/Purpose	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)	Median daily frequency of injection declined: • from 1.9 to 0.7 injections per day	
Paone 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 Pre-exchange / Post-exchange < 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	Reviewer
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 whetherthey 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."	

References

1. Bruneau, J., Lamothe, F., Franco, E. et al. (1997). 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, 146:994-1002.*

2. Des Jarlais, D.C., Friedman, S.R., Sotheran, J.L., Wenston, J., Marmor, M., Yancovitz, S.R., Frank, B., Beatrice, S., & Mildvan, D. (1994). Continuity and change within an HIV epidemic: Injecting drug users in New York City, 1984 through 1992. *Journal of the American Medical Association, 271 (2)*:121-127.

3. Des Jarlais, D.C., Marmor, M., Paone, D., Titus, S., Shi, Q., Perlis, T., Jose, B., & Friedman, S.R. (1996). HIV incidence among injecting drug users in New York City syringe-exchange programmes. *The Lancet, 348*:987-991.

4. Doherty, M.C., Garfein, R.S., Junge, B., Beilenson, P., & Vlahov, D. (1997). Discarded Needles Do Not Increase With a Needle Exchange Program. *American Journal of Epidemiology*, 145, 730-737.

5. Guydish, J. Bucardo, J., Young, M., Grinstead, O., & Clark, W. (1993). Evaluating needle exchange: Are there negative effects? *AIDS, 7 (6)*:871-876.

6. Hagan, H., Des Jarlais, D.C., Purchase, D., Friedman, S.R., Reid, T.R., & Bell, T.A. (1991). The incidence of HBV infection and syringe exchange programs [letter]. *Journal of the American Medical Association, 266 (12)*:1646-1647.

7. Hagan, H., Des Jarlais, D.C., Purchase, D., Friedman, S.R., Reid, T.R., & Bell, T.A. (1993). An interview study of participants in the Tacoma, Washington syringe exchange. *Addiction, 88*:1691-1697.

8. Hagan, H., Des Jarlais, D.C., Friedman, S.R., & Purchase, D. (1994). Risk for human immunodeficiency virus and hepatitis B virus in users of the Tacoma syringe exchange program. Pp. 24-34 in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs*. National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

9. Hagan, H., Des Jarlais, D.C., Friedman, S.R., Purchase, D., & Alter, M.J. (1995). Reduced risk of hepatitis B and hepatitis C among injecting drug users participating in the Tacoma syringe exchange program. *American Journal of Public Health, 85 (11)*:1531-1537.

10. Heimer, R., Kaplan, E.H., & Cadman, E.C. (1992). Prevalence of HIV-infected syringes during a syringe-exchange program. *The New England Journal of Medicine, 327 (26)*:1883-1884.

11. Heimer, R., & Lopes, M. (1994). Needle exchange hastens entry into drug treatment [letter]. *Journal of the American Medical Association, 271 (23)*:1825-1826.

12. Hurley, S., Jolley, D.J., Kaldor, J.M. (1997). Effectiveness of needle-exchange programmes for prevention of HIV infection. *The Lancet, 349:1797-1800.*

13. Kaplan, E.H. (1994). Operational modeling of needle exchange programs. Pp. 202-249 in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs.* National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

14. Kaplan, E.H., & Heimer, R. (1994). HIV incidence among needle exchange participants: Estimates from syringe tracking and testing data. *Journal of Acquired Immune Deficiency Syndromes, 7 (2)*:182-9.

15. Kaplan, E.H., & Heimer, R. (1995). HIV incidence among New Haven needle exchange participants: Updated estimates from syringe tracking and testing data. *Journal of Acquired Immune Deficiency Syndromes & Human Retrovirology, 10 (2)*:175-176.

16. Kaplan, E.H., & O'Keefe, E. (1993). Let the needles do the talking! Evaluating the New Haven needle exchange. *Interfaces, 23 (1)*: 7-26.

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

18. Oliver, K., Maynard, H., Friedman, S.R., & Des Jarlais, D.C. (1994). Behavioral and community impact of the Portland syringe exchange program. Pp. 35-46 in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs.* National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

19. Paone, D., Des Jarlais, D.C., Caloir, S., Friedmann, P., Ness, I., & Friedman, S.R. (1994). New York City Syringe Exchange: An Overview. Pp. 47-63.in *Proceedings, Workshop on Needle Exchange and Bleach Distribution Programs.* National Research Council and Institute of Medicine. Washington, DC: National Academy Press.

20. Paone, D., Des Jarlais, D., Clark, J. & Shi, Q. (1996). Syringe-Exchange Programs in the United States: Where Are We Now? *AIDS & Policy Policy Journal, 11 (3):* 144-147.

21. Paone, D., Des Jarlais, D., Clark, J. & Shi, Q. et. Al. (1997). Update: Syringe-Exchange Programs - United States 1996. *MMWR, 46:565-568.*

22. Schoebaum, E.E., Hartel, D.M., & Gourevitch, M.N. (1996). Needle Exchange Use Among a Cohort of Injecting Drug Users. *AIDS, 10 (14)*:1729-1734.

23. Singer, M., Horowitz, S., Weeks, M., & Radda, K. (1997). New needles for old: Preventing AIDS among injection drug users in Hartford, CT. *Medical Anthropology Quarterly, 18:1-24.*

24. Strathdee, S.A., Patrick, D.M., Currie, S.L. et al. (1997). Needle Exchange is not enough: lessons from the Vancouver injection drug use study. *AIDS. 11:F59-F65.*

25. Vlahov, D. et al. (1997). Reductions in high risk drug use behaviors among participants in the Baltimore needle exchange. *Journal of AIDS and Human Retrovirology, 16:400-406.*

26. Watters, J.K. (1994). Trends in risk behavior and HIV seroprevalence in heterosexual injection drug users in San Francisco, 1986-1992. *Journal of Acquired Immune Deficiency Syndromes, 7 (12)*:1276-1281.

27. Watters, J.K., Estilo, M.J., Clark, G.L. & Lorvick, J. (1994). Syringe and needle exchange as HIV/AIDS prevention for injection drug users. *Journal of the American Medical Association, 271 (2)*:115-120.

Drugs - needle exchange

April 17, 1998

Via Facsimile

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear President Clinton:

We, the undersigned national organizations, write to you to condemn the failure to date of your Administration to lift the federal funding restrictions on needle exchange programs. We urge you to act immediately so that federal funds can be made available for these life saving interventions in communities that choose to implement them.

Despite the high rates of HIV infection related to injection drug use and the lack of a sufficient number of drug treatment slots, your Administration has failed to put forth a coherent plan to increase access to substance abuse treatment and to combat the spread of HIV among injection drug users, their partners and their children. The absence of a commitment to addressing these issues is further reflected in the funding cuts for HIV prevention and substance abuse treatment in your FY 1999 budget.

We affirm and support the Presidential Advisory Council on HIV and AIDS in their vote of no confidence in your Administration's commitment and willingness to achieve your own stated goal of reducing the number of new HIV infections annually, until there are no new infections. To accomplish this goal, your Administration must follow the science and make an immediate determination on needle exchange. We expect that federal support for these life saving programs will be made available this fiscal year and incorporated into a comprehensive, fully-funded plan to address the twin epidemics of HIV and substance abuse in the United States. Inaction on these issues is unacceptable, if your Administration is truly committed to protecting the public health.

A wealth of scientific evidence, including six federally funded studies, demonstrates that needle exchange programs reduce HIV transmission and do not encourage the use of illegal drugs. Not to act on this scientific evidence which supports a life saving intervention is both immoral and unethical. The organizations which have reviewed this science are: the National Institutes of Health (1997 Consensus Statement), the Office of Technology Assessment (1995), the National Academy of Sciences (1995), the University of California, San Francisco (1993 CDC funded study), the General Accounting Office (1993), and the National Commission on AIDS (1991).

The continuation of restrictions on federal funding for needle exchange programs is also inconsistent with your recently announced Race Initiative to reduce racial disparities in health outcomes. Given the significant role drug addiction plays in fueling the AIDS epidemic in communities of color, better access to clean needles would undoubtedly reduce the level of HIV infection in these populations and help reduce racial disparities in health outcomes. In their letter to the Secretary urging her to take immediate action, the Chairs of the House Black and Hispanic Caucus state, "Minority populations are disproportionately affected by HIV/AIDS and this scientifically proven intervention is one way to stop this trend".

The statistics speak for themselves. An estimated 40,000 Americans will become infected with HIV this year. Over 50% of new HIV infections can be attributed to injection drug use. Recent data indicate that 74% of all AIDS cases among women and over 50% of all AIDS cases among children are connected directly or indirectly to injection drug use. In 1996 AIDS death rates declined by 32% for whites, but only 13% for African Americans, and 20% for Latinos. As of June 1997, people of color represent 72% of the male and 78% of the female AIDS cases directly and indirectly related to injection drug use. In the African American community, 48% of AIDS cases are related to injection drug use. While the epidemic rages in the injection drug using community, only 475,000 treatment slots are available at any given time to the estimated 1.5 million active drug users in the United States.

Your Administration has consistently ignored the advice of the Director of National AIDS Policy and the Presidential Advisory Council on HIV and AIDS. It has further ignored the nation's leading public health organizations, including the American Medical Association, the American Nurses Association, the American Public Health Association, the American Academy of Pediatrics, and the Association of State and Territorial Health Officials. All of these organizations support needle exchange programs and the lifting of federal restrictions.

In the interest of public health, we call on your Administration to develop a plan to address the interconnected epidemics of HIV and substance abuse. Such a plan must include: federal funding for needle exchange programs, comprehensive HIV and drug prevention services to those at high risk of becoming infected, accessible drug treatment services to those who are ready to enter treatment, and high quality primary care and supportive services to substance abusers at risk for or living with HIV and AIDS.

As the leading national organizations representing people living with HIV disease and the organizations that serve them, we are united in our message to you that your Administration must exercise leadership which will save the lives of tens of thousands of Americans.

Sincerely,

A. Cornelius Baker, Executive Director
National Association of People With AIDS

Elizabeth Birch, Executive Director
Human Rights Campaign

David Harvey, Executive Director
AIDS Policy Center for Children, Youth,
and Families

Paul A. Kawata, Executive Director
National Minority AIDS Council

Jerome Radwin, Executive Vice President
Chief Executive Officer
American Foundation for AIDS Research

Julie Scofield, Executive Director
National Alliance of State and Territorial
AIDS Directors

Daniel Zingale, Executive Director
AIDS Action

cc: Vice President Albert Gore
Secretary Donna Shalala
Erskine Bowles
Rahm Emanuel
John Podesta
Sylvia Mathews
Bruce Reed
Chris Jennings
Sandra Thurman
Kevin Thurm
Maria Echaveste
Richard Socarides
Ron Klain
Elena Kagan
Marsha Martin
Eric Goosby
Bob Dreier
Toby Donenfeld

HUMAN
RIGHTS
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Drugs - needle exchange

MEMO

DATE: April 9, 1998

TO: White House Domestic Policy Staff
Office of National AIDS Policy
HHS Policy Staff

FROM: Winnie Stachelberg

SUBJECT: Needle Exchange

Despite rumors of a forthcoming decision regarding needle exchange, HRC and the entire public health and AIDS community remain deeply concerned about the Administration's lack of action. Many, if not all, of the organizations working on this issue are poised to take further action if a clear, simple announcement is not made this week. Clarity on the Administration's position and course of action is more important than ever at this critical juncture.

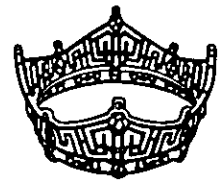
I also want to state clearly HRC's position regarding the use of federal funds to support the Secretary's scientific determination. It is our view that making federal funds available to local communities for needle exchange is an administrative function that should not be part of a public determination on the science. The Congressional criteria guiding the operation of needle exchange programs should be re-iterated and explained in the CDC guidance to state and local health departments on the eligible uses of HIV prevention funds. Such a process would be consistent with the process used to enforce Congressional intent in other federal grant programs.

More important, the Administration should not make the necessary scientific determination and then defer the decision about the actual use of federal funds back to Congress. In addition to being inconsistent with how HHS administers other federal HIV prevention funds, such a deferral could lead to a total ban on federal funding for needle exchange. Many in the AIDS advocacy and public health community would view such a deferral as an abdication of responsibility on the part of the Administration and a purposeful subversion of the scientific determination.

In summary, the Secretary should make an immediate, public determination that needle exchange programs reduce HIV transmission and do not encourage illegal drug use. Setting up the administrative structure within HHS to make federal funds available should begin thereafter with no explicit public statement on that process or deferral of HHS administrative authority to Congress.

Thank you for your attention to this matter. Please do not hesitate to call me or Seth Kilbourn if you have any questions or concerns.

Drugs - needle exchange



Kate Shindle
MISS AMERICA 1998

April 6, 1998

The Honorable William J. Clinton
The White House
1600 Pennsylvania Avenue, NW
Washington D.C. 20500

Dear President Clinton:

I am aware that your administration is once again reviewing the issue of federal funding for needle exchange programs, which affects the lives and futures of thousands of American men, women, and children each year. Once again, organizations across the country have been discouraged and frustrated at the outcome of one of these reviews. I am asking you to use federal funds to support needle exchange programs and prevent the spread of the HIV/AIDS epidemic.

It has been eighteen years since AIDS began to decimate American families, and the epidemic shows no sign of slowing. Despite recent breakthroughs in AIDS treatment, the number of new infections continues to explode. Every day, 16,000 people, somewhere, contract HIV. And as you know, the epidemic is undergoing a dramatic demographic shift. Women, minorities, and the young are being infected at unprecedented rates. Every hour of every day, two American teenagers contract HIV. And heterosexual women account for the fastest-rising group of new infections. AIDS is no longer restricted to any one social group. It's happening to all of us.

But a unique phenomenon continues to sweep our nation. It is the dynamic created by a desire to end the AIDS epidemic and a hesitance to implement the programs which will eradicate it. *We know exactly how to stop the spread of HIV.* In the absence of a cure, scientists, educators, and public health officials agree upon the need for strong and proactive programs which empower individuals to protect themselves from this virus.

Statistics regarding the prevalence of HIV infection among IV drug users are astounding. 63% of all AIDS cases among women are related to the sharing of needles—these women contract HIV either through IV drug use or through sex with an IV drug user. Similarly, 58% of pediatric AIDS cases are attributable to a parent's drug use. Clearly, drugs are killing Americans in more ways than one.

But needle-exchange programs are overwhelmingly effective in combating HIV infection. By providing clean syringes in exchange for used ones, we can easily prevent the sharing of contaminated drug paraphernalia. *Needle exchange programs prevent HIV from being spread.*

But needle-exchange programs are overwhelmingly effective in combating HIV infection. By providing clean syringes in exchange for used ones, we can easily prevent the sharing of contaminated drug paraphernalia. *Needle exchange programs prevent HIV from being spread.* In Baltimore, the HIV seropositivity rate was reduced by 40% during the program's three-year trial period. And the community benefits as well. The lifetime cost of treating *just one* person with AIDS is estimated to be $119,000, while the median cost of running an exchange is just $169,000—eliminating a significant financial burden on taxpayers. And by providing the opportunity for a one-to-one syringe exchange, we can all but ensure that there are no contaminated needles lying around in streets, on playgrounds, or in other places where children can find them and hurt themselves.

President Clinton, we are all familiar with the so-called arguments against needle exchange. Quite frankly, the idea that these programs promote drug abuse is unreasonable, and outdated, and has already been categorically disproven. Seven different independent agencies, including the Centers for Disease Control and the University of California at San Francisco, have shown unquestionably that there is no increase in the incidence of drug use in communities where needle-exchange programs have taken hold. In fact, the rate of use can actually decline when staff are able to counsel drug users into treatment. *No one wants more drugs on our streets.*

It's time to take action. Every 5.4 seconds, someone contracts HIV. While we bide our time and weigh our options, people are still dying. There seems to be a lot of "morality" talk surrounding HIV/AIDS prevention. Ironically, we have forgotten our moral obligation to save lives. We need to provide the information and tools which will empower all Americans to protect themselves. I am twenty-one years old, and my generation is dying.

It's time for us, finally, to have an intelligent and substantive dialogue about needle exchange. No more stalling. No more "looking into the issue." We no longer have the luxury of time. The facts are on the table. The AIDS-services community has done what you asked by providing these findings. Approximately 60% of Americans approve of needle exchange, and are watching. *Mainstream America cares about this.* Now you need to hold up your end of the deal.

There is still a lot of fear when it comes to talking about this issue, and dozens of warring factions. No one ever said ending a global pandemic would be easy. America needs money for needle exchange. We need to let scientists and public health officials determine the need for such programs on a community-by-community basis, and then we need funding to support their efforts. At this point, there is no more room for excuses. Americans are still dying, and we are to blame unless we protect them.

Sincerely,

Kate Shindle

Kate Shindle
Miss America 1998

Drugs - needle exchange

JANET MURGUIA [redacted]
04/22/98 11:15:54 PM

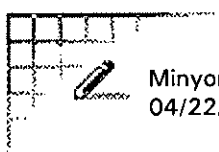
Record Type: Record

To: See the distribution list at the bottom of this message

cc: Charles M. Brain/WHO/EOP, Broderick Johnson/WHO/EOP, Peter G. Jacoby/WHO/EOP
Subject: Feedback from the Caucuses on Needle Exchange

White House Legislative Affairs and HHS Legislative Affairs will do a conf. call tomorrow to discuss both the needle-exchange outreach efforts and the tobacco minority health statistics roll out plan. Mindy my assistant is setting this up for early afternoon. If you are interested in joining let me or Mindy know. Thanks.

---------- Forwarded by Janet Murguia/WHO/EOP on 04/22/98 10:01 PM ----------



Minyon Moore
04/22/98 07:50:37 PM

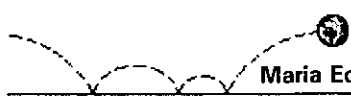
Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Feedback from the Caucuses on Needle Exchange

There appears to be a press conference in the works for Friday by the CBC on this issue. I will provide more details as they come in. As anyone other than myself been in touch with them to help articulate our position?

---------- Forwarded by Minyon Moore/WHO/EOP on 04/22/98 07:51 PM ----------



Maria Echaveste 04/21/98 06:16:28 PM

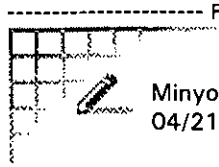
Record Type: Record

To: Elena Kagan/OPD/EOP, Richard Socarides/WHO/EOP

cc: Janet Murguia/WHO/EOP, Minyon Moore/WHO/EOP, Sylvia M. Mathews/WHO/EOP, Sandra Thurman/OPD/EOP
Subject: Feedback from the Caucuses on Needle Exchange

I spoke with Becerra on this issue--he said he spoke with Shalala yesterday and indicated to her that he was glad that the science had been affirmed but where was the money? He did say that while he hadn't really heard from members, he didn't anticipate a Caucus statement or press conference saying that some of the members were conservative and not in favor of the needle exchange program. He did suggest that matching localities with private sources of funding would be a good thing. Below is Minyon's note re her conversation with Waters.

---------- Forwarded by Maria Echaveste/WHO/EOP on 04/21/98 06:13 PM ----------



Minyon Moore
04/21/98 05:41:37 PM

Record Type: Record

To: Maria Echaveste/WHO/EOP

cc: Janet Murguia/WHO/EOP, Richard Socarides/WHO/EOP, Sylvia M. Mathews/WHO/EOP, Robert B. Johnson/WHO/EOP

Subject: Needle Exchange Q&A's- note correction!

As a follow-up to your call, I spoke with Maxine. They haven't taken an official position on the Administrations announcement, but anticipate meeting late tonight or tomorrow to discuss their response. She indicated that she has rec'd pressure from many members re: federal funding and the impact on minority communities. She further stated she wanted to have a longer discussion with Charles Rangel. She indicated that more than likely they will issue a press statement or do a press conference once consensus has been met. Asked if I wanted a heads up (response why course).

Maria she and Becerra will be talking.

---------- Forwarded by Minyon Moore/WHO/EOP on 04/21/98 05:23 PM ----------

Maria Echaveste 04/21/98 04:00:31 PM

Record Type: Record

To: Minyon Moore/WHO/EOP

cc:

Subject: Needle Exchange Q&A's- note correction!

fyi

---------- Forwarded by Maria Echaveste/WHO/EOP on 04/21/98 04:05 PM ----------

Laura Emmett 04/21/98 01:22:02 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Sarah A. Bianchi/OPD/EOP

Subject: Needle Exchange Q&A's- note correction!

Q&A-NEED.4 Note the correction is the answer to the first question:

Because the science is now there to make these findings. We already knew that needle exchange programs can **help reduce the rate of HIV transmissions**, and yesterday, the Secretary made clear that the scientists, including all the respected leadership within the National Institutes of Health, have concluded that these programs do not increase drug use.

Drugs - needle exchange

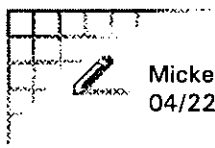
Richard Socarides 04/23/98 09:18:34 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, Andrew J. Mayock/WHO/EOP

cc:
Subject: Needle Exchange

---------- Forwarded by Richard Socarides/WHO/EOP on 04/23/98 09:20 AM ----------



Mickey Ibarra
04/22/98 08:07:00 PM

Record Type: Record

To: Sandra Thurman/OPD/EOP, Christopher C. Jennings/OPD/EOP, Richard Socarides/WHO/EOP

cc: Lynn G. Cutler/WHO/EOP, Suzanne Dale/WHO/EOP, Mona G. Mohib/WHO/EOP
Subject: Needle Exchange

I spoke to Elena this evening regarding yesterday's meeting on our Needle Exchange policy. I regret IGA was not at the meeting however, we are interested in teaming with you to get the research information out to local and state elected officials and the organizations that represent them. Lynn Cutler has agreed to assist on this subject for IGA since mayors and county officials have such a large stake. Please let me know how we can help as well. Thanks.

Drugs - needle exchange

Sandra Thurman 04/24/98 04:45:41 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP

cc:
Subject: And more bad news..

We're going to run over copies of Maxine Water's statement today--woosh! I also heard that McAffrey is going to be meeting with the Washigton Times editorial board Tuesday. Now do you think that's a coincidence with the vote scheduled Wednesday on the Solomon needle exchange bill???? This is getting a little tedious.

Drugs - needle exchange

Sandra Thurman 04/24/98 04:36:24 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:
Subject: McAffrey op-ed

As Todd mentioned earlier, Mr. McAffrey has been seeking to place op-eds in leading papers apparently arguing that needle exchange programs take advantage of African Americans and Latinos. We understand the Wall Street Journal is going to print it on Monday. We don't know if it's going in under his signature or someone else's.

This is just not right. The statement released by Maxine Waters, and the letter to the President from the CBC, criticize McAffrey's role in this. An op-ed is only going to inflame the racial divisiveness. Help!!!

Drug - needle exchange

Questions and Answers on Washington Times Story on Needle Exchange
April 17, 1998

Q: Has General McCaffrey been left out of the needle exchange decision?

A: No, because a decision has not been made. It's important to note, however, that Congress has specifically placed authority for making this decision with the Secretary of Health and Human Services. Congress has prohibited the use of Federal AIDS prevention funds to support needle exchange programs unless the Secretary of Health and Human Services certifies that needle exchange programs reduce the transmission of HIV and do not 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." And while HHS continues to look at this issue, Secretary Shalala has not yet concluded that needle exchange programs do not encourage drug use – the standard set by Congress if the ban on federal funds is to be lifted.

Q: But the Washington Times reported that Secretary Shalala could announce a decision as early as Monday. Is this true?

A: Secretary Shalala will make an announcement when she feels that the science is there.

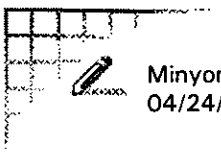
Q: Is the Administration split on this issue?

A: No. We all share the view that the Administration should not take any action that might send young people conflicting signals about the use of illegal drugs. The intravenous use of drugs is illegal, unhealthy and wrong. It is clearly a major health problem as well as a law enforcement concern. And while HHS continues to look at this issue, Secretary Shalala has not yet concluded that needle exchange programs do not encourage drug use -- the standard set by Congress if the ban on federal funds is to be lifted.

Q: But General McCaffrey says that needle exchange programs will have a "nutball effect" attracting drug users and other undesirables to areas that implement needle exchange programs. Is this true?

A: Congress has made clear that needle exchange programs must not encourage drug use, and Secretary Shalala shares that concern. That's why she has been studying this issue so thoroughly for so long. And while HHS continues to look at this issue, Secretary Shalala has not yet concluded that needle exchange programs do not encourage drug use – the standard set by Congress if the ban on federal funds is to be lifted.

Drugs - needle exchange



Minyon Moore
04/24/98 10:14:08 AM

Record Type: Record

To: Sylvia M. Mathews/WHO/EOP, Janet Murguia/WHO/EOP, Elena Kagan/OPD/EOP

cc: See the distribution list at the bottom of this message
Subject:

As I mentioned an earlier e-mail, the CBC was scheduled to respond to our position on needle exchange today. As I write, they should be holding a press conference on the Hill.
As I understand it, there position will be to support Shalaha, blast McCaffrey and send a strongly worded letter to the President reflecting their views.

I went back and forth with them on a number of issues ------won a few lost one or two.

Message Copied To:

Robert B. Johnson/WHO/EOP
Michelle Crisci/WHO/EOP
Maria Echaveste/WHO/EOP
Sandra Thurman/OPD/EOP
Richard Socarides/WHO/EOP

Drugs-needle exchange

Todd A. Summers
04/24/98 02:47:41 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: See the distribution list at the bottom of this message
Subject: HR 3712 - Solomon bill on needle exchange funding

Rep. Solomon is fast-tracking a bill to prohibit federal funds from directly or indirectly funding needle exchange. It was our understanding from the meeting earlier this week with Bruce, Elena, Chris et al that we were going to stay the course on protecting the Secretary's authority, though we would have to modify the justification. Reps. Waxman, Morella, and Pelosi are wanting to know what we're going to do.

Our assumption, Elena, is that OMB can prepare a SAP in opposition to HR 3712 and similar bills. Can we threaten veto?

FYI, here's the text of the bill. I understand it's going to sail through rules and may hit the floor the middle of next week.

H. R. 3712

To prohibit the expenditure of Federal funds to provide or support programs to provide individuals with hypodermic needles or syringes for the use of illegal drugs.

IN THE HOUSE OF REPRESENTATIVES

April 22, 1998

Mr. SOLOMON introduced the following bill; which was referred to the Committee on Commerce

A BILL

To prohibit the expenditure of Federal funds to provide or support programs to provide individuals with hypodermic needles or syringes for the use of illegal drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROHIBITION ON USE OF FUNDS FOR HYPODERMIC NEEDLES.

Notwithstanding any other provision of law, no Federal funds shall be made available or used to carry out or support, directly or indirectly, any program of distributing sterile hypodermic needles or syringes for the hypodermic injection of any illegal drug.

Message Copied To:

Christopher C. Jennings/OPD/EOP
Joshua Gotbaum/OMB/EOP
Daniel N. Mendelson/OMB/EOP
Richard J. Turman/OMB/EOP
Robert J. Pellicci/OMB/EOP
Sandra Thurman/OPD/EOP

Drugs - needle exchange

Todd A. Summers
04/24/98 02:44:27 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: ondcp/needle exchange

---------- Forwarded by Todd A. Summers/OPD/EOP on 04/24/98 02:46 PM ----------

Daniel C. Montoya

04/24/98 02:37:24 PM

Record Type: Record

To: Sandra Thurman/OPD/EOP, Todd A. Summers/OPD/EOP

cc:
Subject: ondcp/needle exchange

FYI -

i was told that mccaffrey is gearing up for op-eds on needle exchange to say that it exploits communties of color and that these areas do not/will not develop economically due to the encouragement of drug use.

they will probably start to appear next week.

dcm