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

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

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PREPARED FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

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DEFINITION OF TERMS

Because injecting drug users in the US tend to use syringes with non-removable needles, we use the terms "needle" and "syringe" interchangeably in this report. We use the term "needle exchange program" to refer to any establishment at which injecting drug users can exchange an old needle or syringe for a new one, because this term has become the most common way to refer to these programs.

EXECUTIVE SUMMARY

CONCLUSIONS

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 accommodate 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 programs.

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 program 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.

RECOMMENDATIONS

Recommendations for the federal government

- The federal government should repeal the ban on the use of federal funds for needle exchange services and substantial federal funds should be committed both to providing needle exchange services and to expanding research into these programs.

Recommendations for state governments

- State governments in the eleven states that have prescription laws should repeal these laws.*
- States should repeal the paraphernalia laws as they apply to syringes.**

Recommendations for local governments and communities

- Local governments should enter into discussions with local community groups to develop a comprehensive approach to preventing HIV in injecting drug users, their sex partners, and their offspring. This approach should include needle exchange programs and the expansion of drug treatment services.
- Local communities should seek to further increase sterile syringe availability by encouraging the sale, distribution, or exchange of syringes by pharmacists.

Recommendations for researchers

- Descriptions of the "kinetics" and determinants of needle use patterns: injecting drug users' sources of needles, methods of disposal of needles, frequency of needle re-use, and needle-sharing patterns. How do these change when a needle exchange program or other changes in needle availability are implemented?
- Evaluations of "natural experiments" in which needle availability laws change or pharmacists expand the over-the-counter sales of syringes.

*Prescription laws preclude the purchase of a syringe without a prescription, limiting sterile syringe availability and creating a risk of arrest for needle exchange program staff and clients.

**Paraphernalia laws exist in 46 states and require pharmacists to determine whether the purchaser intends to use the syringe for "legitimate medical purposes." Conviction under a paraphernalia law is a felony or a misdemeanor.

- Surveys of pharmacists to determine their willingness to participate in pharmacy-based syringe sale, distribution, or exchange and to identify the barriers to their participation.

- Assessments of the effects of design features of needle exchange programs (e.g., administering bodies, site characteristics, opening hours, and program rules) upon process measures of needle exchange program outcome (e.g., needles distributed, drug treatment referrals, discarding of needles).

- Ethnographic and other qualitative research to assess the factors involved in drug use initiation and in transitions between various routes of drug use.

- Case-control studies of the relationship between use of the needle exchange program and acute hepatitis B, particularly in cities with active surveillance for the infection.

- Large, multicenter case-control studies within existing cohorts of injecting drug users to assess whether use of the needle exchange program is associated with hepatitis B or HIV seroconversion.

- Mathematical modeling using program data and behavior change evaluations to determine which aspects of program design determine effectiveness and cost-effectiveness.

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

> [S]ubstance use plays a major role in the transmission of HIV disease—indeed, a much larger role than has been generally recognized. Clearly, our nation's drug control policies must recognize this inextricable linkage between drugs and HIV disease and be designed to address the two aggressively and simultaneously.
>
> —National Commission on AIDS, The Twin Epidemics of Substance Use and HIV, 1991[1]

> Because neither a vaccine nor a cure for HIV infection appears likely in the near future, planning is needed for the long term to limit the spread of HIV among drug injectors, their sexual partners, and their potential offspring.
>
> —National Research Council, AIDS: The Second Decade, 1990[2]

A. Background

Any assessment of the public health impact of needle exchange programs (NEPs) must commence with the recognition of the critical links between the epidemics of human immunodeficiency virus (HIV) and substance abuse, and the relationship between HIV infection among injecting drug users (IDUs) and transmission to sexual partners and offspring. Unless these phenomena are fully appreciated, the public health significance of HIV infection among IDUs cannot be fully comprehended, and the impact of measures to prevent HIV infection in this group will be underestimated.

Estimates of the numbers of IDUs in the US range from 1.1 to 1.5 million.[3,4] The societal costs of injection drug use include the costs of drug treatment, lost productivity, motor vehicle accidents, crime, and stolen property, and have been estimated at $58.3 billion per year.[5] With the lifetime cost of treating an HIV-infected person estimated at approximately $119,000,[6] and the number of IDU acquired immunodeficiency syndrome (AIDS) cases growing during the 1980s[7] HIV among IDUs will exact a growing economic toll in the years to come.

By early 1993, 253,448 people in the US had been diagnosed with AIDS. Of these, 73,311 (29%) were IDUs, 8,481 (3%) people with heterosexual contact with an IDU, and 2,420 (1%) children born to IDUs and their sex partners.[7] Thus cases related to injection drug use account for fully one-third of all AIDS cases in the US to date. The impact is felt disproportionately in communities of color; IDU-associated AIDS cases accounted for 52% of African-American and 45% of Latino cases in the US in 1991, while the corresponding percentage for whites was only 19%.[8]

The HIV seroprevalence among IDUs varies substantially according to geographic region. In studies of IDUs entering drug treatment centers in the US, seroprevalences ranging from 0% to 65% were recorded.[9-12] The highest rates were recorded in the northeastern US and in Puerto Rico. Using HIV seroprevalence rather than AIDS case rates reveals the same

disproportionate burden of disease among minority communities; approximately eight of 10 IDUs with HIV infection in the US are African-American or Latino.[13]

HIV is primarily transmitted between IDUs by the inoculation of an HIV-negative IDU with traces of blood from contaminated syringes and other drug paraphernalia previously used by an HIV-infected individual. Sexual transmission of HIV among IDUs and to their non-IDU sex partners, as well as transmission to their offspring are also important.[14] Decreases in HIV drug risk behavior in response to the epidemic have been documented since the mid-1980s. For example, cross-sectional studies of out-of-treatment IDUs in San Francisco between 1986 and 1989 revealed steadily decreasing rates of syringe sharing.[15] Between 1985 and 1987 the proportion of IDUs in San Francisco who reported usually or always using bleach to disinfect syringes rose from 6% to 47%.[16]

Risk reduction, however, is not the same as risk elimination, and the need for a comprehensive approach to disease prevention among IDUs remains as critical now as it was at the beginning of the HIV epidemic. Drug treatment resources remain woefully inadequate; fewer than 15% of IDUs are in treatment on any given day.[17] Many active IDUs express no interest in entering treatment.[18, 19] For active IDUs who will not or cannot stop injecting drugs, there are only three reliable methods of preventing HIV infection from injection drug use: 1) use a sterile syringe for each injection; 2) if you cannot use a sterile syringe for each injection, do not share syringes; and 3) if you do share syringes, disinfect with bleach. However, many IDUs do continue to share, at least occasionally, and recent guidelines from the Public Health Service indicate that "Disinfecting previously used needles and syringes... **is not as safe as always using a sterile needle and syringe** (emphasis in original)."[20]

It is in this milieu that NEPs have arisen. An NEP has been defined by one group of researchers as "a facility where drug injectors can obtain sterile needles and syringes and return used injecting equipment."[21] Although NEPs may make referral to drug treatment an important part of their services, they acknowledge that many IDUs, including some in drug treatment programs, continue to inject drugs and share injection equipment. They therefore seek to reduce the harm associated with these practices, a philosophy sometimes referred to as harm reduction or harm minimization.[22] The essential arguments in favor of NEPs are that they could decrease the transmission of HIV by increasing the probability that IDUs use uninfected syringes, produce reductions in HIV risk behaviors, and refer IDUs with little or no contact with the public health system to drug treatment or other public health services. Opponents of NEPs contest these assertions and counter that NEPs will increase drug use in the community, particularly in those communities of color already disproportionately affected by the drug trade, and condone drug use. Both beneficial and adverse effects of NEPs on the number of discarded syringes have been claimed.

In the US an additional complicating factor is the existence of two types of laws that restrict the possession, distribution, or sale of injecting equipment. Such laws do not exist in Canada or in the majority of Western

European countries. Paraphernalia laws make the manufacture, possession, or distribution of drug paraphernalia a misdemeanor or felony offense; such laws exist in 46 states and the District of Columbia.[23] Prescription laws require a physician's prescription in order to purchase a syringe; these laws exist in 11 states and the District of Columbia, although Maine recently revoked its prescription law and the prescription law in Connecticut has been modified (see below).[23]

Several lines of evidence suggest a potential connection between HIV infection and these laws. HIV seroprevalence among IDUs entering drug treatment tends to be higher in states that have prescription laws (median = 15.0%) than in states that do not have these laws (median = 2.7%), although this relationship may not be causal. Moreover, the repeal of such a law in France was followed by increased use of sterile injection equipment[24] and decreases in reported equipment sharing rates.[25] In Connecticut, where the paraphernalia and prescription laws were modified to permit the purchase of up to 10 syringes without a prescription, sales of syringes to IDUs appear to have increased.[26] Although Connecticut IDUs responding to a questionnaire reported no change in the proportion who had shared at least one, those in four focus groups reported fewer sharing episodes.[27] Finally, researchers in Baltimore, MD, a state without a prescription law, found a 2.5-fold higher HIV seroprevalence among non-diabetic compared to diabetic IDUs, a finding they attributed to diabetics having better access to sterile syringes.[28]

There is evidence that in the US IDUs may have difficulty purchasing syringes in pharmacies, even in states without prescription laws.[29, 30] No national survey of US pharmacists has been done, but several reports are available from Europe, Australia, and Canada.[21, 25, 31-38] In most studies, at least one-third of pharmacies or pharmacists were willing to sell syringes to IDUs, but many pharmacists were concerned about used syringe disposal and the potential adverse effects of IDUs' presence on their businesses.

Studies in the US and abroad demonstrate that, even when NEPs are operating, IDUs remain dependent upon a variety of primarily black market sources for their syringes.[39-43] It should be clear, therefore, that the NEPs are but one of several methods by which the availability of sterile syringes for IDUs could be enhanced. Schemes to promote the sale, distribution, or exchange of syringes in pharmacies have been a central element of the response to the HIV epidemic in Canada, Britain, Australia, New Zealand, Switzerland, Spain, France, and Germany.[25, 31, 44-48] The only pharmacy-based NEP in the US is in Tacoma and operates on a one-for-one exchange basis out of a health department pharmacy.[49] IDUs who obtain their syringes from pharmacists can be assured of sterile syringes, whereas syringes obtained on the street may be repackaged to appear new.[50] Finally, Germany, Italy, Denmark, and the Netherlands have taken the lead in developing vending machines which either sell or exchange syringes.[51-54]

B. Project Methods

The current evaluation was funded through a cooperative agreement between the Centers for Disease Control and Prevention (CDC) and the Association of Schools of Public Health, which contracted with University of California, Berkeley (UCB) to conduct the study. A significant amount of the work was subcontracted to the Institute for Health Policy Studies at the University of California, San Francisco (UCSF). The project began in April 1992 and was funded through October 1993.

We assembled a 12-person multidisciplinary research team in which no investigator was identified in his or her writing as either in favor of or opposed to NEPs. Community and expert input was sought by convening a 13-member Advisory Committee based in the San Francisco Bay Area and by contracting with seven outside experts to review draft chapters.

The goal of the project was: "To assess the public health impact of needle exchange programs." Fourteen research questions were identified; Chapters 5 through 18 of Volume I of the report each address one of these research questions. The study consisted of four components: 1) formal review of existing research, 2) NEP site visits; 3) mail surveys of NEPs not visited; and 4) cost-effectiveness modeling.

A total of 1,972 sources were reviewed during the study. These included 475 journal articles, 381 conference abstracts, 236 reports, 499 newspaper articles, and 159 unpublished materials.

Between May and September 1992 site visits to 15 cities with 23 NEPs were conducted: 10 cities in the US,* three in Canada,** and two in Europe.*** In all but three cities, site visits were at least three days in duration. Volume II of the report contains descriptions of the 12 cities with NEPs that were fully evaluated in our site visits. Following semi-structured interview guidelines,[55] project members interviewed a total of 239 individuals, including 25 NEP directors and staff, 14 public health officials, 22 IDU researchers, and 47 community leaders known for their support of or opposition to the local NEP. A total of 129 IDUs were also interviewed, most in 11 NEP client and seven non-client focus groups; a small number of IDUs were interviewed individually.

Twenty US NEPs not visited by project members were surveyed using a mail questionnaire. To our knowledge, all but four active NEPs in the US were either visited or surveyed by project members. These four NEPs were identified too late for inclusion in the evaluation.

Cost-effectiveness modeling involved a four-step process: 1) an assessment of NEP budgets; 2) the systematic evaluation of studies of NEP impact on HIV risk behaviors; 3) the assessment and further development of

*Berkeley, CA; Boston, MA; Boulder, CO; New Haven, CT; New York City, NY; Portland, OR, San Francisco, CA; Santa Cruz, CA; Seattle, WA; Tacoma, WA

**Montreal, PQ; Toronto, ON; Vancouver, BC

***Amsterdam, the Netherlands; London, England

existing mathematical models of NEP impact on HIV transmission; and 4) the use of mathematical models to estimate the cost-effectiveness of NEPs, defined as cost per HIV infection averted.

The research protocol was submitted to and approved by the Committee for Protection of Human Subjects at UCB. Two Draft/Interim report were completed and submitted to the CDC and the reviewers on April 1, 1993 and July 16, 1993. The drafts were extensively reviewed by the contracted experts and other reviewers.

C. How and Why did NEPs Develop?

The first NEP was established in Amsterdam, the Netherlands in 1984 by a drug users advocacy group called the Junkie Union that wished to prevent an epidemic of hepatitis B when an inner-city pharmacist planned to discontinue selling syringes to IDUs.[56] The first person to distribute drug injection equipment publicly in the US was Jon Parker, in New Haven, CT and Boston, MA in November 1986 (Dan Waldorf, personal communication, September 1, 1992).[57] The first NEP to provide comprehensive services was established in Tacoma, WA in 1988. As of September 1, 1993 there are at least 37 NEPs operating in 30 US cities (see Appendix and Figure 1). In addition, we are aware of three states (Florida, Minnesota, and Arkansas) and two cities (Cincinnati, OH and Baltimore, MD) that are considering establishing NEPs.

Figure 1: US NEPs Active in First Quarter 1993

Based on NEP staff interviews at 13 programs visited and mail surveys of 20 programs not visited

We discuss here four trends that characterize the evolution of NEPs in the US. Jon Parker, who states that he has been arrested 27 times in seven states and has publicly challenged the prescription laws in all states

that have them,[57] perhaps best exemplified the civil disobedience approach to NEPs. While this approach has succeeded in making NEPs a prominent public issue, it has at times alienated the very community groups whose support is critical to the establishment of NEPs—African-Americans and providers of drug treatment. Later NEPs, such as those in New Haven and Portland, OR were established only after prolonged periods of community consensus-building.

A second trend has been that NEPs are now more likely to be legal than in the past. Several programs that were initially illegal and underground, such as Prevention Point in San Francisco, CA, subsequently received approval and even funding from local governments. Nonetheless, of the 12 NEPs that opened in 1992, only five are legal.

A third trend has been the growing institutionalization of US NEPs. Several programs started by activists now receive government or foundation funding and some are run directly by health departments (e.g., Boulder, CO and Seattle, WA). NEPs are less reliant upon volunteer staff and have better linkages to other public health services.

A final trend has been increasing US federal funding of NEP research. A total of five bans on the use of federal funds for either providing NEP services or conducting research into the programs have existed. Although a ban on federal funding for NEP services remains, there have now been seven federally-funded studies of NEPs. Four of these, including the present study, are concerned primarily with the synthesis of existing information; three studies entail the collection of new data. In a 1993 report, the GAO concluded that "Existing statutory authority does, however, in our opinion, permit use of federal funds for studies or demonstrations of needle exchanges, which might involve the provision of needles."[58]

The Canadian experience with NEPs has been dramatically different from that in the US. As early as 1989, the Canadian federal government offered to co-fund comprehensive pilot IDU HIV prevention programs that included NEPs. By February 1993, a total of 28 Canadian cities had active NEPs (Betsy MacKenzie, personal communication, February 25, 1993). While some Canadian community and neighborhood groups have opposed NEPs, the debate has generally been less politically charged than in the US. The fact that pilot NEPs operate within a multifaceted approach to drug use that combines education, counseling, law enforcement and linkage to other services, including drug treatment, has helped minimize community opposition.

Conclusion:

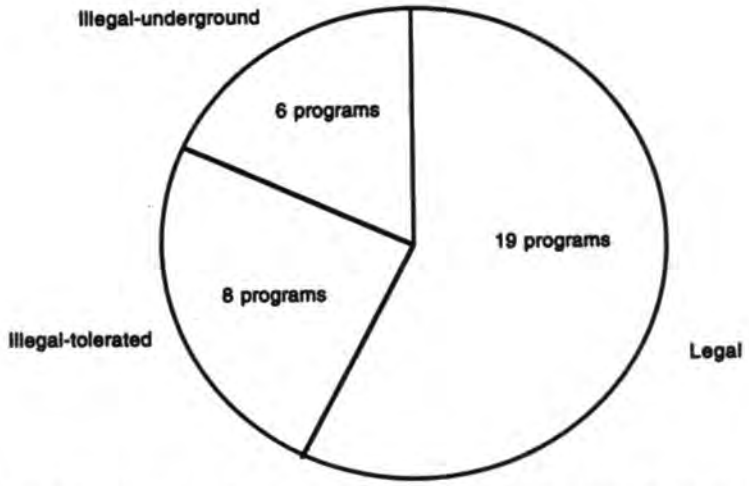
- *NEPs have continued to increase in number in the US and by September 1, 1993 at least 37 active programs existed. The evolution of NEPs in the US has been characterized by growing efforts to accommodate the concerns of local communities, increasing likelihood of being legal, growing institutionalization,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

D. How Do NEPs Operate?

There are almost as many NEP operating models as there are NEPs. Each is the unique product of an often extended interaction between the NEP, its clients, and the broader community. Four aspects of NEP operations can be delineated: 1) legal status; 2) organizational structures; 3) operating characteristics; and 4) services provided. We summarize here the results of information gathered on site visits and in the project mail survey.

Of the 33 NEPs visited or surveyed in this project, 19 are legal,* eight are illegal but have received the support of a local elected body, and six are illegal and operate without such support (see Figure 2). All Canadian NEPs are legal.

Figure 2: Legal Status of US NEPs



Based on NEP staff interviews at 13 programs visited and mail surveys of 20 programs not visited

Four distinct categories of NEP administering bodies can be delineated: activists (13 programs), community-based organizations (CBOs) without government sponsorship (eight programs), CBOs with government sponsorship (six programs), and state or local government-operated NEPs (six programs). For many NEPs, funding is secured from a patchwork of different sources, among which private donations and foundation grants are the most common. Fifteen US NEPs receive state or local government funds for operations, but no program receives federal funds.

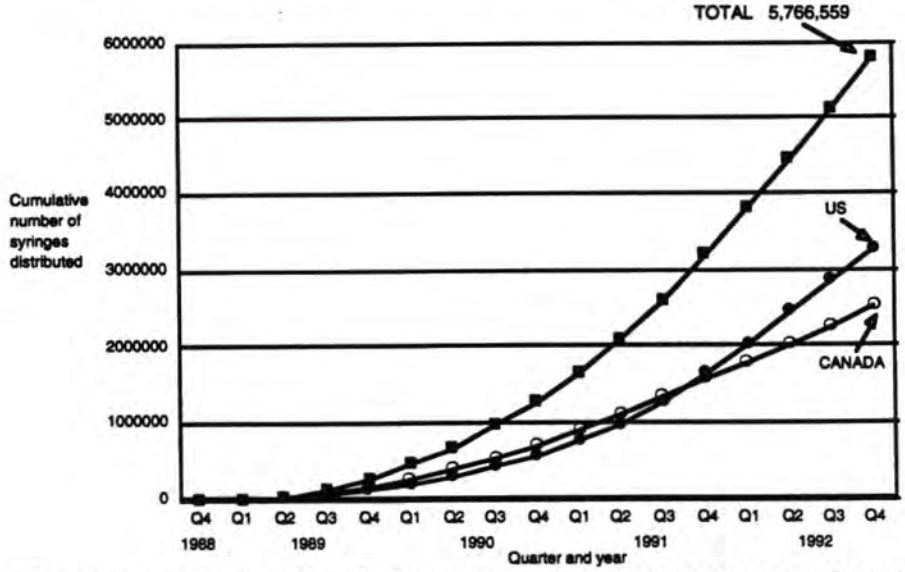
The 33 US NEPs operate a total of 102 sites, which can be divided into the more common fixed sites (65 sites) and less common mobile sites (37 sites). The most common fixed sites are scheduled van stops (27 sites)

*NEPs are defined as legal if they exist in a state without a prescription law or operate under an exemption to the prescription law.

and scheduled street exchanges (26 sites), while delivery services (20 sites) are the most numerous of the mobile sites. US NEPs are open a median of three days per week for a mean of 23.9 hours. Twenty-six NEPs use volunteers, including 15 that rely exclusively upon volunteers to provide services. Almost all US NEPs (27 NEPs) provide only one syringe for each syringe brought in to the NEP; about one-half (17 NEPs) provide small numbers of syringes to IDUs making their first visit to the NEP. For the most part, therefore, US NEPs take in as many syringes as they give out. At 11 NEPs restrictions on the number of syringes that can be exchanged exist. Minimum age limits and requirements to show evidence of current drug injection are rare characteristics of US NEPs, probably because they are difficult to enforce.

We estimate that over 5.4 million syringes have been distributed by US NEPs; due to missing data for some NEPs, this number is an underestimate (see Figure 3). US NEPs distributed more than 2.4 million syringes in 1992. Recognizing that sexual transmission of HIV is also a risk for IDUs, all US NEPs provide condoms to clients. Almost all programs also distribute bleach for syringe disinfection, health pamphlets, and alcohol wipes, with fewer programs providing cotton, water bottles, or cookers, items used in the preparation of drugs for injection. While most NEPs do refer clients to a variety of public health services, they have limited ability to provide these services on-site. Services provided by all US NEPs are thus considerably broader than simply the exchange of syringes, and emphasize links to other public health services, including drug treatment.

Figure 3: Cumulative Number of Syringes Distributed by Selected US and Canadian NEPs Through Fourth Quarter 1992



Based on 15 programs visited and Hawaii. Data missing for Boulder 10/92–12/92; Berkeley 10/92–12/92; Santa Cruz 7/92–12/92; and Toronto, Parkdale 4/92–12/92. Data interpolated for Toronto, The Works; Montreal, CACTUS; Vancouver; and San Francisco.

Conclusion:

- *About one-half of US NEPs are legal, but funding is often unstable and most NEPs rely on volunteer services to operate. All but six NEPs 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 NEPs provide a variety of services ranging from condom and bleach distribution to drug treatment referrals.*

E. Do NEPs Act as Bridges to Public Health Services?

As NEPs have become more institutionalized (see Chapter 5), they have increasingly been touted as a potential method for referring IDUs to the public health system. NEPs have contact with IDUs with limited or no prior experience with drug treatment (see Chapter 9); these IDUs could benefit from referrals not only to drug treatment, but also to HIV counseling and testing, primary medical care, tuberculosis and sexually transmitted diseases screening and treatment, and psychological counseling and support. NEPs would thus become one part of a comprehensive approach to the prevention of HIV in IDUs, an approach that would also emphasize the expansion of drug treatment and school- and community-based interventions to prevent the initiation of drug use.

A significant limitation on the ability of NEPs to refer IDUs to drug treatment is the paucity of drug treatment slots. As mentioned, fewer than 15% of IDUs are in drug treatment on any given day.[17] From a public health perspective, NEPs cannot be a meaningful bridge to treatment if all they can do is refer IDUs to waiting lists or help NEP clients displace others waiting for admission to drug treatment.

NEPs vary greatly with respect to the emphasis they place upon making referrals to drug treatment and other public health services. This stems in part from the desire to make the NEP "user-friendly," the recognition that many active IDUs express no interest in entering drug treatment,[18, 19] and the related belief that an overemphasis on drug treatment referral could alienate potential NEP clients. Many NEPs have therefore evolved an approach where they selectively refer clients to drug treatment, based on either staff perceptions of the client's readiness for treatment or the client's declared interest.

Staff of all but one of the 18 US and Canadian NEPs visited during this project stated that they refer clients to drug treatment. The six NEPs visited that maintained records of these referrals had made a total of 2,208 referrals to drug treatment, an underestimate because recent data are lacking for all (see Table 1). Although there are limited data on whether these referrals are completed, significant numbers of NEP clients have entered drug treatment in Hawaii,[59] Seattle, WA,[60] Tacoma, WA,[61] New Haven, CT,[62] and Vancouver, BC.[63]

Table 1: Referrals Made by Selected US and Canadian NEPs Visited

NEP	Dates	Referrals
New Haven NEP	11/90–6/91	186 drug treatment
Seattle NEP	2/90–3/92	179 drug treatment
Tacoma, Point Defiance	2/91–6/93	982 drug treatment
Montreal, CACTUS	7/89–12/90	94 medical care 160 detoxification 125 psycho-social support
Toronto, The Works	8/89–1/93	294 drug treatment 80 drug detoxification 226 medical services 663 "other" services
Vancouver, DEYAS	7/90–3/91	327 drug treatment 244 medical treatment 209 social services 66 youth worker

Source: NEP statistics

Only three of the 33 US NEPs are able to provide drug treatment services on-site. Ten NEPs provide on-site social services, eight on-site primary medical care, and seven on-site HIV testing and counseling and sexually transmitted diseases screening. Referral linkages appear to be stronger in the better-funded NEPs and those that are more integrated into the public health system.

Conclusion:

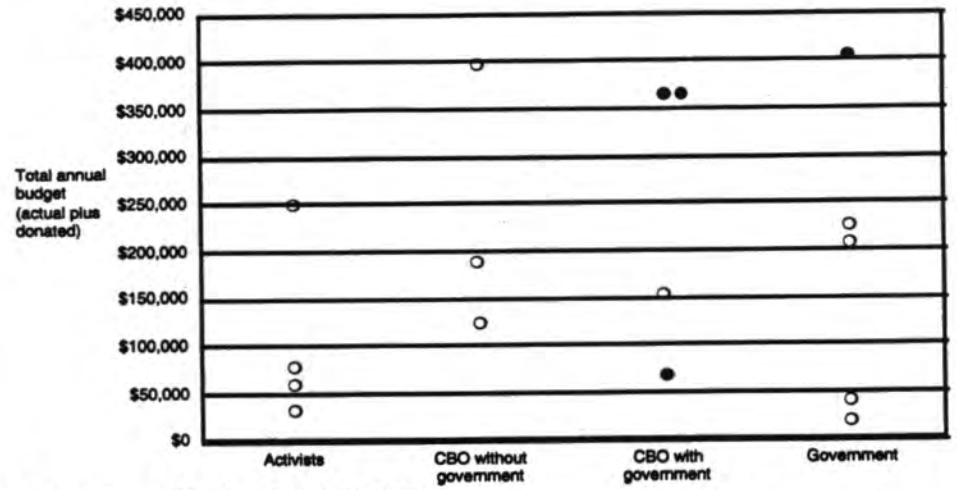
- *Some NEPs have made significant numbers of referrals to drug abuse treatment and other public health services, but referrals are limited by the paucity of drug treatment slots. Integrating NEPs into the existing public health system is a likely future direction for NEPs.*

F. How Much Does it Cost to Operate NEPs?

The diversity and continuing evolution of NEPs point to a need to assess program budgets and examine the key determinants of cost. In particular, the relationship between NEP administering body and budget is of great policy relevance.

NEPs in the US and Canada visited by project members vary greatly in total* annual budgets; these range from a low of $18,628 at Tacoma, WA's Pharmacy NEP to a high of $403,464 at Toronto, ON's The Works, with a median of $168,650 (see Figure 4). This relatively low median program budget could support about 60 methadone maintenance slots for one year.[64] Activist programs tend to be least expensive and government programs most expensive, with CBO-run programs in between. Much of the cost of the more expensive NEPs is for items that do not add directly to services (e.g., staff supervision and rent) and for non-exchange services (e.g., drug treatment referrals and counseling).

Figure 4: Total Annual NEP Budget, by Administering Body



● = One Canadian NEP ○ = One US NEP
Based on NEP staff interviews and budgets at 16 programs visited

The largest cost component is personnel, accounting for a median of 66% of total budgets. Syringe costs represent a median of 7% of total budgets.

Three indices permit assessment of NEP productivity. The median cost per syringe distributed is $1.35 and the median cost per hour open is $145. The median number of syringes distributed per hour is 205.

Conclusion:

- *The median annual budget of US and Canadian NEPs visited is relatively low at $169,000, with government-run programs tending to be more expensive. Some NEPs are more expensive because they also provide substantial non-exchange services such as drug treatment referrals. The annual cost of funding an average NEP would support about 60 methadone maintenance slots for one year.*

*Includes both actual expenditures and donated services and supplies

G. Who Are the IDUs Who Use NEPs?

A central assertion of NEP proponents is that NEPs provide services to "isolated IDUs": those with little contact with the public health system. Thus, NEPs may provide a point of contact to help IDUs get access to the public health services discussed in Chapter 7.

US NEPs serve an ethnically diverse clientele. The mean age of US NEP clients ranges from 33 to 41 years; the mean duration of drug use ranges between seven and 20 years. One-third to one-half of NEP clients have never been in drug treatment, and clients are primarily regular and frequent injectors. These clients are at substantial risk for HIV infection; approximately one-third report sharing syringes in the month preceding the interview.

Fifteen studies have compared NEP client and non-client samples.[36, 61, 65-79] These studies suggest that, compared to non-clients, NEP clients may be slightly more likely to be male, are somewhat less likely to be African-American, and are older. These findings generally hold in the US and abroad. NEP clients in the US appear to have been enrolled less often in drug treatment programs than non-clients, while the opposite seems to be true in foreign countries. In the US, NEP clients and non-clients appear to be at similar risk of acquiring HIV through their drug use; clients abroad are consistently at lower risk for drug-related HIV infection. HIV seroprevalences are similar in NEP clients and non-clients in the six studies that evaluated this outcome.[59, 72-75, 79, 80]

In focus groups with NEP clients and non-clients conducted for this report, IDUs identified several factors that influence their use of the NEP. These included fear of arrest or harassment by police, NEP locations and hours, NEP staff attitudes, the desire not to be identified as an IDU, and the existence of alternative sources of sterile syringes.

Conclusion:

- *Although NEP clients vary from location to location, NEPs generally reach a group of IDUs with long histories of injection drug use who remain at significant risk for HIV infection. NEP clients in the US have had less exposure to drug abuse treatment than IDUs not using the NEP.*

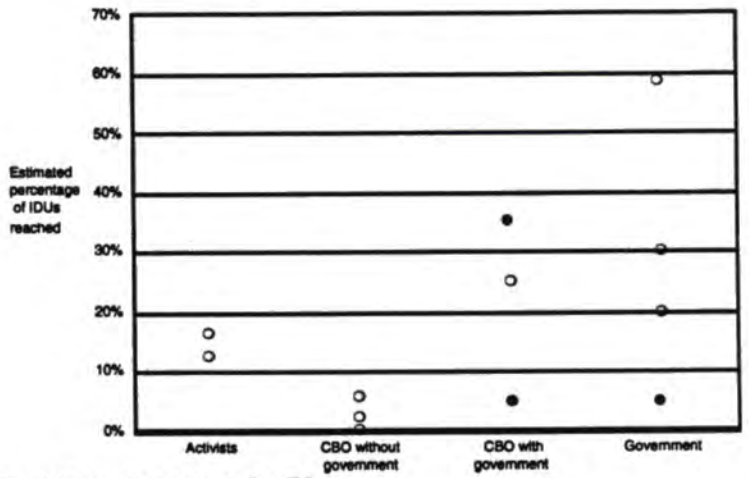
H. What Proportion of All IDUs in a Community Uses the NEP?

The overall public health impact of NEPs will be strongly related to the proportion of IDUs who use them. Studies from abroad indicate that NEPs, if adequately funded, have the capacity to reach significant proportions of the local IDU population. By 1988, over 50% of IDUs attending methadone or sexually transmitted diseases clinics in Amsterdam, the Netherlands were using the local NEPs as their sole source of syringes.[81] (In Amsterdam methadone maintenance therapy is frequently used to decrease injection frequency, not necessarily to induce abstinence.)

Thirty-four percent of opiate injectors in Manchester, England use NEPs regularly.[69]

Information gathered by project members suggests that, to date, coverage by US and Canadian NEPs has been more limited, perhaps due to funding and legal constraints. US and Canadian NEPs visited by project members have had contact on at least one occasion with a median of 14.5% of the estimated number of IDUs in those cities and have distributed a median of 2.3 syringes per IDU per quarter (see Figure 5). Because almost all US NEPs are distributing increasing numbers of syringes, it is also useful to consider the NEPs that perform most successfully on these measures, as they suggest the potential impact of NEPs. The New Haven, CT NEP is estimated to have reached between 49% and 68% of local IDUs and Tacoma, WA's Point Defiance distributes about 21 syringes per IDU per quarter.

Figure 5: Estimated Percentage of IDUs Reached by US and Canadian NEPs, by Administering Body



● = One Canadian NEP ○ = One US NEP
Overall median = 14.5%
Based on 12 programs visited. Data for the Point Defiance and Pharmacy NEPs in Tacoma are combined and presented as a CBO with government.

In considering these findings, it is critical to acknowledge the inherent uncertainty in estimates of the numbers of IDUs and to mention that estimates of total numbers of IDUs were only available by metropolitan area, thus underestimating the impact of NEPs in large cities that serve only IDUs in specific neighborhoods. Because many IDUs, particularly those in states without prescription laws, may have access to a regular supply of syringes, and because some IDUs may have others exchange on their behalf, the optimal proportion of IDUs that should be reached by NEPs remains unclear. However, it appears that NEPs alone cannot distribute sufficient numbers of syringes, and alternative methods of syringe distribution, such as pharmacy sale, distribution, or exchange, must be explored.

Conclusion:

- *Studies of adequately-funded NEPs suggest that NEPs do have the potential to serve significant proportions of the local IDU population. While some NEPs appear to have reached large proportions of the local IDU population at least once, others are reaching only a small fraction of local IDUs. Consequently, other methods of increasing sterile needle availability must be explored.*

I. What Are the Community Responses to NEPs?

Proposals to establish NEPs in US cities have frequently encountered vigorous opposition from a variety of individuals and community groups. The US community responses have been in marked contrast to those in foreign countries, including Canada, where debate over the issue was less contentious and often largely confined to the public health community.

Many US NEPs were initially proposed and/or established by activist groups, including the gay and lesbian activist group ACT-UP. Local elected officials who supported NEPs were opposing the stance of President George Bush[82] and some received letters from the federal Office of National Drug Control Policy (ONDCP) lobbying against the NEP.[83] Health department staff were critical in communicating the urgency of the HIV epidemic to policymakers, and some volunteered their time and skills to work with the local NEP.

Opposition often came from law enforcement authorities, drug treatment providers, local businesspeople, and residential groups. Although several police chiefs supported NEPs (e.g., Portland, OR; San Francisco, CA; and New Haven, CT), others saw the programs as inconsistent with the "War on Drugs." Drug treatment providers who opposed NEPs did so either because they saw the programs as being in conflict with the abstinence ethic of many drug treatment programs, or because they were concerned about competition for scarce program funds. Local business people and residents who opposed NEPs generally opposed the local presence of IDUs, not the NEP *per se*.

The most consistent sources of opposition to NEPs were African-American church and community leaders. There were four major reasons for African-American community opposition to NEPs. First, the repeated failure to provide sufficient drug treatment capacity led some to oppose NEPs. Second, activists at times failed to meet and consult with African-American community leaders. Third, African-American community leaders felt that NEP advocates did not understand the often ruinous effects of the drug market and drug use on communities of color. Fourth, if NEPs were to lead to increased drug use rates, African-American communities would bear a disproportionate share of the burden. This was described by some African-American leaders as "genocide."[84-87] However, newer African-American organizations established specifically to address HIV prevention (e.g., the Black Coalition on AIDS in San Francisco) generally supported NEPs as did several African-American mayors (e.g., New York City,

Baltimore, MD, New Haven, CT, and Washington, DC). African-American and Latino community leaders must be consulted if harm reduction and community-based HIV prevention strategies such as NEPs are to be effective.

Public opinion polls[88-101] indicate that approximately half of the general public has supported harm reduction efforts, including needle cleaning, legalization of needle sales, needle exchange, and needle distribution. Support has tended to grow with time and has been higher for needle exchange than for needle distribution schemes. African-Americans are about as likely to support needle exchange or distribution as the general public.

Conclusion:

- *Unlike in many foreign countries, including Canada, proposals to establish NEPs 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.*

J. Do NEPs Result in Changes in Community Levels of Drug Use?

The debate over whether NEPs facilitate drug use has probably been more hotly contested than any other issue regarding NEPs. A requirement that NEPs be shown to "not encourage the use of illegal drugs" before NEP services can be funded by the federal government has even been established by Congress.[102]

The intensity of the debate has tended to obscure the fact that the question of whether NEPs increase drug use can be divided into three sub-questions: 1) are NEPs associated with a change in the frequency of drug injection among IDUs who use the NEP? 2) are NEPs associated with changes in community levels of injection and non-injection drug use? and 3) do NEPs deter IDUs from seeking drug treatment? It is critical to address these three components of the question separately.

With respect to the first question, the studies reviewed in Chapter 14 as well as focus groups conducted with NEP clients and non-clients suggest that NEPs are not associated with a change in injection frequency among NEP clients.

To answer the second question definitively, one would have to establish large cohorts of IDUs and non-IDUs in numerous communities and follow these subjects prospectively for several years. Outcome measures would include the incidence and prevalence of drug use as well as assessments of changes in the frequency and routes of drug use. The multiple complex logistical, ethical, and political obstacles likely to be encountered would prevent such a study from ever being conducted.

Two studies in San Francisco, CA[76, 103] evaluated the second question by demonstrating that the mean age of drug users either rose or

stayed stable over time. In Amsterdam, the Netherlands, annual capture-recapture studies of "hard" drug users showed their numbers to be stable, the mean age of this population to be increasing, and the proportion under 22 years of age to be declining.[56] We also evaluated three national drug use indicators:[104] 1) Drug Abuse Warning Network (DAWN),which records emergency room and medical examiner mentions of drug use; 2) Drug Use Forecasting (DUF), which conducts random urine tests of arrestees or detainees; and 3) Uniformed Crime Reports (UCR), which summarize drug-related arrests. These data, while limited in their precision (making detection of small changes in drug use difficult), provide no evidence of any changes in community levels of drug use. Almost all IDU focus group members stated that NEPs would not affect the numbers of injecting and non-injecting drug users in the community.

No formal studies of the third question have been reported. Any assessment of the net effect of NEPs on drug treatment utilization would also have to factor in the substantial numbers of new referrals to drug treatment generated by some NEPs (see Chapter 7). Some public health officials and IDUs found the possibility of drug treatment deferral more plausible than the other two scenarios discussed.

Conclusion:

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

K. Do NEPs Affect the Number of Discarded Syringes?

The debate over the effect of NEPs on the number of discarded syringes is unique among the 14 research questions surrounding NEPs in that both opponents and advocates have claimed that the evidence favors their point of view. This question has been of concern both to members of the public and law enforcement officers, who fear needlestick injuries while searching suspects. Fortunately, theoretical analysis and empirical evidence can help resolve this issue.

Fifteen of the 33 US NEPs evaluated in this report operate on a one-for-one exchange basis and provide no syringes to IDUs presenting without a syringe at their first visit (see Chapter 6). These NEPs give clients one sterile syringe for every used syringe turned in to the NEP and thus cannot increase the total number of discarded syringes, although they could change the geographical distribution of the discarded syringes. Because a used syringe in a city with an NEP now has value, it is plausible that the discarding of syringes would decrease and that IDUs would even pick up discarded syringes to bring to the NEP to exchange. NEP staff confirm that this occurs.[105] Although 17 US NEPs do provide syringes to IDUs presenting to the NEP for the first time, these "starter needles" are few in

the local level and the fact that many cities already have NEPs make such a study unlikely. Blinding, at least of study subjects, is also impossible. Without randomization and blinding, comparison of NEP clients to non-clients, while useful, will always be imperfect.

We identified a total of 26 evaluations of the effect of NEPs on HIV drug and sex risk behavior. Study designs included seven cross-sectional analyses,[65, 66, 69, 76, 112-114] five serial community cross-sectional studies,[42, 45, 76, 103, 115-117] seven studies based on recall,[36, 65, 80, 106, 118-121] and six prospective cohort studies of NEP clients.[59, 68, 72, 73, 78, 122-127] Each study was evaluated and graded on a quality scale ranging from one (lowest quality) to five (highest quality).

Sixteen of the 26 evaluations provide credible evidence (quality rating ≥3) about NEP effects on behavior (see Table 2). Ten of the 16 studies included comparison groups. No study received a quality rating of five; limitations included lack of randomization, NEP client self-selection, dependence upon self-reported behaviors of IDUs, poor follow-up in prospective studies, and lack of detail in reporting of behavior. Formal meta-analysis was precluded by the use of differing research approaches and inconsistent measures of risk behavior change.

Table 2: Summary of Studies of Behavior Change With Quality Rating of Three or Greater

	Evaluations by finding and city		
Outcome measure	Beneficial NEP effect	Mixed or neutral NEP effect	Adverse NEP effect
Drug risk			
Sharing frequency	10 studies	4 studies	
Giving away used	3 studies	1 study	1 study
Needle cleaning	3 studies	1 study	
Injection frequency	3 studies	4 studies	1 study
Sex Risk			
Number of partners	2 studies*	1 study**	
Partner choice	1 study***	1 study†	
Condom use	1 study††	1 study†††	1 study*f*

References:
See text for drug risk references
* 68, 124, 125, 106
** 72, 126
*** 68, 124, 125
† 72, 126
†† 106
††† 36
f 68, 124, 125

Most of the 16 acceptable studies showed drug-related risk reductions during NEP participation. Of the 14 studies examining sharing,

number and are dwarfed by the overall number of syringes distributed by any NEP. Even those NEPs without one-for-one exchange rules or that provide starter needles do not diverge greatly from the one-for-one exchange condition; the NEPs in Portland, OR (one-for-one; provides three starter needles) and Vancouver, BC (not one-for-one; provides two starter needles) had 99% and 97% return rates in 1992. It is worth noting, however, that schemes that distribute or sell syringes through pharmacies do have the potential to increase the number of discarded syringes, although this problem can be at least partially addressed by either providing sharps containers with the syringes or providing a discount on syringe purchases if used syringes are returned.[45, 106]

Empirical studies confirm these theoretical predictions. The number of discarded syringes in the vicinity of the Portland NEP decreased by almost two-thirds after the NEP opened.[107] Because this research design cannot assess whether used syringes might have simply been discarded elsewhere in the city, it is useful to examine community-wide indices. In Toronto, ON the number of syringes collected by various community and governmental organizations appears to have decreased since the opening of the NEP.[108] In Amsterdam, the Netherlands, needlestick injuries reported by members of the general public to the Municipal Health Service have increased somewhat since the NEP opened, but a similar rise in reported needlestick injuries by the medical profession suggests that this is a reporting artifact due to increased awareness of needle-borne infections.[109]

Conclusion:

- *NEPs 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.*

L. Do NEPs Affect Rates of HIV Drug and/or Sex Risk Behaviors?

In part because changes in HIV infection rates are difficult to demonstrate empirically, a substantial amount of NEP research has sought to assess whether NEPs can affect the behaviors that result in the transmission of HIV. Such behavior change may include decreased sharing of used syringes, as well as other risk reductions (e.g., increased bleaching of used syringes or decreased sex risk). These changes would produce risk reduction in addition to that resulting from the essential rationale for establishing NEPs: removing contaminated syringes from circulation and replacing them with sterile ones.

Studies of behavior change associated with NEPs, like studies of many other HIV prevention strategies, can never satisfy the ideal standards of randomized controlled trials. For example, randomization of IDUs to NEP use or non-use raises significant ethical issues in the minds of some, and inevitable cross-over between NEP client and non-client groups would complicate interpretation.[110] Randomizing communities to having an NEP or not, another possible approach, is likely to be extremely expensive, probably costing in the tens of millions of dollars.[111] Political obstacles at

ten suggested reduced sharing[36, 65, 72, 76, 78, 80, 106, 115, 116, 118-120, 122, 123, 126] and four no effect.[66, 68, 69, 114, 124, 125] None found an increase in risk behaviors. Of the five studies looking at IDUs giving away used needles, three found beneficial effects,[72, 80, 119, 120, 126] one found mixed effects,[114] and one found adverse effects.[69] Of the four studies examining needle cleaning, three found a benefit associated with the NEP[78, 106, 120, 122, 123] and one found no effect.[66] Finally, of the eight studies considering the effect of NEPs on the frequency of injecting, three found reductions in injection,[36, 65, 80, 119] four found a mixed or no effect,[76, 103, 115, 116, 118, 120] and one found an increase in injection compared with controls.[72, 126]

The four evaluations of the effects of NEPs on HIV sex risk behaviors found no clear trend toward either a beneficial or adverse effect of NEPs on number of partners, choice of partners, or frequency of condom use.[36, 68, 72, 106, 124-126]

Conclusion:

- *The majority of studies of NEP clients demonstrate decreased rates of HIV drug risk behavior, but not decreased rates of HIV sex risk behavior.*

M. What is the Role of Studies of Syringes in IDU Research?

Although the data presented in Chapter 14 show a decrease in HIV drug risk behaviors, all of the behavioral data are self-reported. While we believe that self-reported data, if interpreted cautiously, can be used to assess IDU behaviors and behavior change, others, including the former Director of the ONDCP, have questioned the validity of such data.[128]

For these reasons, some have proposed the assessment of used syringes as a potential method for addressing the limitations of self-reported data. Such data could serve the following possible purposes: 1) validating self-reported needle sharing by IDUs;[79, 129] 2) estimating the prevalence of HIV antibody;[112, 130-137] 3) estimating the prevalence of HIV itself;[138-144] 4) evaluating syringe HIV infectiousness;[141] 5) estimating the prevalence of hepatitis B virus;[145] 6) detecting bleach (Guydish and Barnett, unpublished data); and 7) visually inspecting syringes to estimate circulation times.[146]

The validity of testing of syringes is limited by the following factors: 1) limited sensitivity due to the small amount of blood in the syringe; 2) dilution effects due to serial use of the syringe; 3) for some techniques, high cost; 4) changes in access to sterile syringes; 5) changes in client recruitment; and 6) decreased effectiveness in the presence of bleach or specific drugs for some testing methods.

Syringe HIV positivity rates should not, therefore, be used as simple proxies for IDU seroprevalence. In general, tests for HIV antibody or deoxyribosenucleic acid (DNA) are quite specific, but their sensitivity is limited. These limitations can be minimized by comparing syringe characteristics over time or between NEP clients and non-clients.

Researchers in New Haven, CT have made creative use of syringe testing to estimate HIV incidence in NEP clients.[147]

Conclusion:

- *The limitations of using the testing of syringes as a measure of IDU behavior or behavior change can be minimized by following syringe characteristics over time, or by comparing characteristics of syringes returned by NEP clients with those obtained from non-clients of the NEP.*

N. Do NEPs Affect Rates of Diseases Related to Injection Drug Use Other than HIV?

Researchers have considered examining rates of hepatitis B and C infection, subcutaneous abscesses, cellulitis, and sexually transmitted diseases as objective measures of NEP effectiveness. Only studies of abscesses and hepatitis B have been reported to date. Although much of the information related to abscess rates is anecdotal, that information is consistent with the ability of NEPs to decrease abscess rates, although abscess rates are also reflective of skin cleaning and drug preparation methods.[148-152]

The outcome of greatest interest in answering this question is the change in the hepatitis B seroconversion rate, which can only be measured in prospective studies. However, new cases of hepatitis B are relatively rare; thus cases are likely to be uncommon in any cohort regardless of the intervention, and differences between control and NEP arms will be difficult, if not impossible, to demonstrate. It is for this reason that we believe that case-control studies of hepatitis B represent the most fruitful line of research to address this question.

Six studies have examined the effect of NEPs on hepatitis B; three are serial community cross-sectional studies,[15, 117, 119, 153, 154] one is a serial NEP cross-sectional study,[155] one is a case-control study,[156] and one is an open cohort study.[78*] The sole case-control study demonstrates a strong protective effect against acute hepatitis B for IDUs who had used the Tacoma, WA NEP (odds ratio = 3.9; 95% confidence interval: 1.1-13.4). As differences between cases and controls other than their use of the NEP may explain these results, a multivariate statistical analysis of the data is now being conducted. The Portland, OR open cohort study is hampered by small sample size and short follow-up period, but the results demonstrate that attending an NEP is insufficient on its own to completely prevent cases of infections related to injection drug use.

*An open cohort study is one without prospective follow-up, but subjects may return periodically to the study site and be retested (e.g., at a drug treatment center).

Conclusion:

- *Studies of the effect of NEPs on injection-related infectious diseases other than HIV provide limited evidence that NEPs are associated with reductions in subcutaneous abscesses and hepatitis B among IDUs.*

O. Do NEPs Affect HIV Infection Rates?

Studies of the effects of NEPs on HIV infection rates are hampered by the methodological limitations mentioned in Chapter 16 as well as the fact that new HIV infections are even rarer and more difficult to detect than hepatitis B infections. Thus, studies with HIV infection as the outcome measure require still larger sample sizes; using favorable assumptions (50% decrease in new HIV infections due to the NEP; 5% baseline seroconversion rate; and 70% follow-up rate), we estimate that over 2,500 IDUs would have to be followed for one year to conduct such a study.

Our review has identified two case studies,[156, 157] seven community cross-sectional studies,[15, 34, 42, 59, 155, 158-161] six serial NEP cross-sectional studies,[72, 127, 155, 162-165] one case-control study,[166] two open cohort studies,[78, 163] and three prospective studies.[72, 119, 127] In this summary we focus on the case-control study and the prospective studies.

A case-control study in Amsterdam, the Netherlands failed to demonstrate a statistically significant relationship between HIV seroconversion and use of the NEP.[166] However, with only 31 HIV seroconverters (31), the study had limited statistical power to detect even relatively powerful NEP effects. In addition, in Amsterdam the use of NEPs is so widespread and pharmacy sales of syringes so large that even non-clients or infrequent clients of the NEP probably had substantial access to sterile syringes, potentially obscuring any NEP effect. In addition, a number of HIV seroconversions may have been due to sexual rather than drug risk behaviors.

Seroconversions have been rare in prospective studies of HIV incidence in NEP clients. In two such studies,[72, 119] no seroconversions were noted and in a third[127] the two seroconversions reported may have occurred prior to enrollment in the NEP. Two of these studies[72, 119] included control groups; no HIV seroconversions were detected in either control group.

It should be noted that all currently accepted HIV prevention interventions (e.g., condoms) were initially advocated in the absence of data suggesting that they had decreased HIV seroconversion rates. For most interventions, such data have never been generated and there is no HIV prevention intervention that has been shown to decrease HIV seroconversion rates in a randomized trial. Although having clearcut evidence that NEPs reduce HIV seroconversion rates is certainly optimal, public health officials frequently advocate (or oppose) interventions in the absence of such data. Such an approach is clearly justifiable, particularly when there is an epidemic of a highly lethal, potentially preventable infectious disease.

Conclusion:

- *Studies of the effect of NEPs 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 NEPs decrease HIV infection rates. However, NEPs do not appear to be associated with increased rates of HIV infection.*

P. Are NEPs Cost-effective in Preventing HIV Infection?

Four methods were utilized to assess NEP effectiveness and cost-effectiveness. In the first, the New Haven needle circulation model,[147] was reviewed and each of its assumptions evaluated. Based on this review, we conclude that the model is a significant, innovative, and sound addition to NEP evaluation efforts. Because it does not include estimates of risk behavior change (other than the act of exchanging), it probably underestimates the true impact of NEPs.

In a second model (see Table 3), a simplified version of the circulation model was combined with data collected for this report to estimate NEP effectiveness and cost-effectiveness in four hypothetical cities. HIV incidence in NEP clients is estimated to decline between 17% and 70% in these hypothetical cities. The cost per HIV infection averted ranges between $12,000 and almost $100,000.

Table 3: Comparison of Model Estimates of NEP Impact and Cost-effectiveness, in One Hypothetical City

	Simplified circulation model	Behavior change model	Combined model
Relative decrease in HIV incidence, NEP clients	17%	15%	17%
HIV infections averted during program operation, NEP clients	50	46	53
Additional HIV infections averted*	0	113	11
Cost per HIV infection averted	$12,000	$3,773	$9,375

*In NEP clients, their drug and sex partners, and their offspring over five years (one year of NEP operation and four years of delayed effects)

The third model used self-reported behavior change data from a separate study of IDUs in a city similar to one of the four hypothetical cities. An estimated total of 159 infections in NEP clients, their drug and sex partners, and their offspring would be prevented over five years at a cost per HIV infection averted of approximately $3,700.

The fourth model combined descriptions of HIV risk behaviors from the same dataset with the circulation model, and applied them to the same hypothetical city. This model predicts that, over five years, 64 infections in NEP clients, their drug and sex partners, and their offspring would be prevented at a cost of approximately $9,400 per HIV infection averted.

Conclusion:

- *Multiple mathematical models of NEP impact support the findings of the New Haven model. These models suggest that NEPs 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.*

Q. Recommendations

The preceding review demonstrates that needle exchange programs can provide a variety of public health services to significant numbers of injecting drug users who continue to inject drugs and who would otherwise not receive these services. Such services can be provided cost-effectively and have produced diminutions in HIV drug (but not sex) risk behavior. Although the data available are limited, they provide no evidence that needle exchange programs increase the amount of drug use by needle exchange program clients or change overall community levels of injection and non-injection drug use. Any controversy in local communities can be minimized by involving all interested communities in the planning of needle exchange services, both prior to opening the needle exchange program and after it is implemented, to address concerns such as program sites and hours of operation. Needle exchange programs should be conceptualized as an integral part of public health efforts to stem HIV infection among drug users and should be *part of a comprehensive approach to drug use*, that should also emphasize expanded access to drug treatment and school- and community-based interventions to prevent the initiation of drug use.

Needle exchange programs can be supplemented by the expanded sale of syringes by pharmacists, an approach that has the advantage of protecting client confidentiality while still guaranteeing the client that the syringe obtained is sterile. This is in marked contrast to the situation on the street, where syringes are often repackaged by unscrupulous dealers so as to appear new.[50] However, pharmacy schemes provide a weaker link to other public health services and pharmacists may be reluctant to participate because of concerns about syringe disposal and the effect of injecting drug users' presence on their businesses.

Although the research studies upon which this report's conclusions and recommendations are based have their weaknesses, needle exchange is an intervention based on the sound theoretical principle of seeking to eliminate the item (a contaminated syringe) that transmits infection from one person to another.[147] This is analogous to reducing the number of mosquitoes in an attempt to prevent malaria. With new HIV infections in injecting drug users and their offspring occurring daily, the time has arrived for federal, state, and local governments to remove the legal and administrative barriers to increased needle availability and to facilitate the expansion of needle exchange programs in the US.

Recommendations for the federal government

- *The federal government should repeal the ban on the use of federal funds for needle exchange services and substantial federal funds should be committed both to providing needle exchange services and to expanding research into these programs.*

Recommendations for state governments

- *State governments in the eleven states that have prescription laws should repeal these laws.**
- *States should repeal the paraphernalia laws as they apply to syringes.***

Recommendations for local governments and communities

- *Local governments should enter into discussions with local community groups to develop a comprehensive approach to preventing HIV in injecting drug users, their sex partners, and their offspring. This approach should include needle exchange programs and the expansion of drug treatment services.*
- *Local communities should seek to further increase sterile syringe availability by encouraging the sale, distribution, or exchange of syringes by pharmacists.*

Recommendations for researchers

Although we believe that the data reviewed in this report are sufficient to support the recommendations listed above, the proposed expansion of needle exchange services in the US will generate additional research questions that will have to be addressed. The implementation of our recommendations should not, however, be delayed pending the results of these studies, many of which will take years to complete. The following are the areas most critical for further research:

- *Descriptions of the "kinetics" and determinants of needle use patterns: IDUs' sources of needles, methods of disposal of needles, frequency of needle re-use, and needle-sharing patterns. How do these change when a needle exchange program or other changes in needle availability are implemented?*
- *Evaluations of "natural experiments" in which needle availability laws change or pharmacists expand the over-the-counter sales of syringes.*
- *Surveys of pharmacists to determine their willingness to participate in pharmacy-based syringe sale, distribution, or exchange and to identify the barriers to their participation.*
- *Assessments of the effects of design features of needle exchange programs (e.g., administering bodies, site characteristics, opening hours, and program rules) upon process measures of needle exchange*

*Prescription laws preclude the purchase of a syringe without a prescription, limiting sterile syringe availability and creating a risk of arrest for needle exchange program staff and clients.

**Paraphernalia laws exist in 46 states and require pharmacists to determine whether the purchaser intends to use the syringe for "legitimate medical purposes." Conviction under a paraphernalia law is a felony or a misdemeanor.

program outcome (e.g., needles distributed, drug treatment referrals, discarding of needles).

- *Ethnographic and other qualitative research to assess the factors involved in drug use initiation and in transitions between various routes of drug use.*
- *Case-control studies of the relationship between use of the needle exchange program and acute hepatitis B, particularly in cities with active surveillance for the infection.*
- *Large, multicenter case-control studies within existing cohorts of injecting drug users to assess whether use of the needle exchange program is associated with hepatitis B or HIV seroconversion.*
- *Mathematical modeling using program data and behavior change evaluations to determine which aspects of program design determine effectiveness and cost-effectiveness.*

R. Appendix

NEPs in the US Through August 1993

State	City	Name and Address	Month and Year Opened
Alaska	Fairbanks	The Exchange 1109 O'Connor Road Fairbanks, AK 99701	August 1989
California	Berkeley	Needle Exchange Emergency Distribution (NEED) 3884 Shafter Avenue Oakland, CA 94609	November 1990
	Los Angeles	Clean Needles Now (CNN) P.O. Box 128 Topanga Canyon, CA 90290	June 1992
	Monterey County	Monterey Needle Exchange 91 Chestnut Street Apt. 228 Santa Cruz, CA 95060	April 1992
	Novato	Marin County NEP 172 Escollonia Drive Novato, CA 94945	October 1992
	Oakland	Alameda County Exchange (ACE) 2512 Regent Street, #6 Berkeley, CA 94704	July 1992
	San Diego	San Diego Clean Needle Exchange Team ACT-UP San Diego P.O. Box 5341 San Diego, CA 92165	January 1992
	San Francisco	Prevention Point 1090 Eddy Street #604 San Francisco, CA 94109	November 1988
	San Jose	Risk Reduction Task Force* No mailing address Hotline telephone number: 408-236-2121	July 1992
	San Mateo	AIDS Prevention Action Network, Inc. (APN) 609 Edinburgh Street San Mateo, CA 94402	September 1990

NEPs in the US Through August 1993 (continued)

State	City	Name and Address	Month and Year Opened
California (continued)	Santa Cruz	Santa Cruz Needle Exchange Program 180 Dakota, Unit 6 Santa Cruz, CA 95060	December 1989
Colorado	Boulder	The Works Boulder County Health Department 3450 Broadway Boulder, CO 80304	May 1989
Connecticut	Bridgeport	Bridgeport NEP* 725 East Main Street Bridgeport, CT 06608	May 1993
	Hartford	Hartford NEP Hartford Health Department AIDS/HIV Program 80 Coventry Street Hartford, CT 06112	March 1993
	New Haven	New Haven Needle Exchange Program Department of Health 540 Ella Grasso Boulevard New Haven, CT 06519	November 1990
	Willimantic	Willimantic NEP P.O. Box 752 Willimantic, CT 06226	March 1990
Hawaii	Honolulu	Kalihi-Palama Health Care for the Homeless 350 Summer Street Honolulu, HI 96817	November 1991
		CHOW Project Needle Exchange 710 North King Street Honolulu, HI 96817	September 1901
		"Rubber Room" Life Foundation 81 North Hotel Street Honolulu, HI 96817	July 1990
Illinois	Chicago	Chicago Recovery Alliance P.O. Box 470688 Chicago, IL 60647	January 1992
Indiana	Indianapolis	National AIDS Brigade Prevention Point 111 East 16th Street #201 Indianapolis, IN 46202	October 1992

NEPs in the US Through August 1993 (continued)

State	City	Name and Address	Month and Year Opened
Massachusetts	Boston	ACT-UP/Boston I.V. League P.O. Box 483 Kendall Square Station Cambridge, MA 02142	February 1991
		National AIDS Brigade (currently exchanging in New York City, New Haven, Los Angeles, and Chicago) 492 East Broadway P.O. Box 201 Boston, MA 02127	November 1986
New York	Buffalo	Prevention Point of Buffalo, Inc. 593 Winspear Ave., upper apt. Buffalo, NY 14215-1209	April 1992
	New York City	Bronx-Harlem Needle Exchange Program c/o Bronx AIDS Services 1 Fordham Plaza #903 Bronx, NY 10458	February 1990
		Lower East Side Needle Exchange Program 39 Avenue C New York, NY 10009	February 1990
		Housing Works, Inc. 594 Broadway, Suite 700 New York, NY 10012	September 1992
		ADAPT Community Based Comprehensive Harm Reduction Needle Exchange Program 552 Southern Boulevard Bronx, NY 10455	December 1992
		St. Ann's Corner of Harm Reduction* 295 St. Ann's Avenue Bronx, NY 10454	August 1990
Oregon	Portland	Outside-In Needle Exchange/AIDS Prevention Program 1236 SW Salmon Portland, OR 97205	November 1989

NEPs in the US Through August 1993 (continued)

State	City	Name and Address	Month and Year Opened
Pennsylvania	Philadelphia	Prevention Point Philadelphia Health Center #5 1900 North 20th Street Philadelphia, PA 19121	December 1991
Washington	Olympia	Olympia Underground Exchange 114 Cherry St., NE Olympia, WA 98501	April 1992
	Seattle	Seattle-King County Department of Public Health Needle Exchange 400 Yesler Way, 3rd floor Seattle, WA 98104	March 1989
	Spokane	Outreach Center* 1025 West First Avenue Spokane, WA 99204	May 1991
	Tacoma	Tacoma Needle Exchange/Point Defiance AIDS Projects 535 East Dock Street #108 Tacoma, WA 98402	August 1988
		Tacoma-Pierce County Health Department Needle Exchange 3629 South D Street Tacoma, WA 98408	March 1989
	Yakima	Yakima Health District Needle Exchange 104 North 1st Street Yakima, WA 98901	November 1992

* Not included in the results of this report

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FYI
Needle exchange

THE WHITE HOUSE

WASHINGTON

November 10, 1993

MEMORANDUM

TO: CAROL RASCO, Special Assistant to the President for Domestic Policy

HOWARD PASTER, Legislative Affairs

FROM: KRISTINE M. GEBBIE, National AIDS Policy Coordinator M. Steve Cooper

RE: DRAFT LETTER TO SENATOR KENNEDY

There is some expectation that Senator Helms will introduce an amendment to the pending crime bill restricting further federal funding for needle exchange programs.

I and others have indicated that this Administration endorses the current law, which is to leave a determination of the public health effectiveness of needle exchange with the Surgeon General.

Attached is a draft letter to Senator Kennedy from me supporting the current law while we await CDC's further study of recent reports on needle exchange. I would send the letter if problem amendments were presented.

Please let me know if you have any comments or changes to the letter. I'll keep you posted if there is any legislative action.

Thank you.

THE WHITE HOUSE

WASHINGTON

Senator Edward M. Kennedy
315 Senate Russell Office Building
Constitution & Delaware Avenues NE
Washington, D.C. 20510

Dear Senator Kennedy:

Public Law 102-321 currently provides that "no funds appropriated under this Act shall be used to carry out any program of distribution of sterile needles for hypodermic injection of any illegal drug, unless the Surgeon General of the United States determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, except that such funds may be used for such purposes in furtherance of demonstrations or studies authorized in the ADAMHA Reorganization Act (Public Law 102-321)." That language for FY 1993 was substantially re-enacted for FY 1994.

As you are aware, a number of studies evaluating needle exchange programs in the United States and abroad have been recently concluded and are currently under evaluation by the Center for Disease Control and other agencies within the Department of Health and Human Services.

Until such evaluations are concluded and recommendations made, I strongly recommend that current law not be altered and would oppose any amendments to alter current law in either house of Congress.

Sincerely yours,

Kristine M. Gebbie, RN MN FAAN
National AIDS Policy Coordinator

January 5, 1994

file

MEMORANDUM

TO: KRISTINE M. GEBBIE
BOB JACKSON

FM: BEN MERRILL

RE: FUTURE STRATEGIES RE NEEDLE EXCHANGE

Here are some suggested strategies regarding advance needle exchange programs as funded by the Federal Government:

1. Delegation of Determination: Surgeon General should delegate the determination to be made under the legislation to a flag officer, preferably someone like Jim Curran. Delegation to Jim would make perfect sense since CDC funded the study upon which the determination rests.

2. Briefing of Congress, Justice and HHS:

A briefing should be made for the Secretary. I am available if you want to contract with me to do one. Once the Department is in line, you should brief key members of Congress: Tim Westmoreland, Mike Iskowitz, etc. Andrew and KG know the players.

The task force that I assembled to see this thing through are:

HHS	Patsy Fleming	690-5400
	Nan hunter	690-7780
CDC	Steve Jones	800-447-4784 PIN 3291655
DOJ	Grace Mastalli	514-4606
ONDCP	John Carnavali	467-9883

I believe that KG has another addition or two, but it should be kept small and workable.

On the Hill, of course, Tim Westmoreland and Rip Forbes have been invaluable: 226-7620 and Mike Iskowitz will be necessary: 224-2236.

I have spoken extensively with Grace Mastelli at DOJ. She is grateful for the breather, since they are busy getting some things together for Kristine that Janet Reno promised. She will continue to treat this as a public health issue.

With regard to drug paraphernalia laws, Larry Goston (202/662-9373) continues to be available to work with us and Justice to convince them that we need to move forward on this issue, Federally, and more importantly, state side. His chapter in the Kaiser Foundation booklet is the most concise treatment of this subject to date and Justice is aware of it.

Ideally, we would continue to:

1. Hold ONDCP to a health issue standard and keep Dr. Lee Brown out of the spotlight on it.

2. Work closely with Justice to continue their treatment of the issue as a health issue, and at the same time get them to buy in on the elimination of drug paraphernalia laws at least as those laws affect enrolled members of harm reduction programs. The best program is New York's, i.e. Alan Clear's Lower East Side Needle Exchange Program which enrolls members and has a working relationship with the NYPD so that if a person is stopped with needles on them, if they have a card showing their enrollment, they are then let go.

The big question still to be answered is, assuming that the federal government makes the determination, the next question is: then what happens? Does the government buy needles; fund on-going programs, etc. NIDA wants a build-in evaluation of the programs. We are not opposed to this, but Steve Jones and I agree that we should not delay for six months while this component part of the puzzle is worked out. Evaluation parts exist in on-going programs and it would be fastest to graft them onto programs that do not have such evaluation.

As an interim strategy, we have suggested that Federal monies be used to fund an "evaluative component" of community-based programs. It appears from a very limited legislative history, that if such evaluation was characterized as a "research initiative" that Federal dollars could be used. To that end, we could move toward Federally funding the evaluation of such programs, either on-going or start-up operations, and it would be better if we were asked to do so by the community's who have started such programs. [E.g., a letter from a community program that said: "We have had an on-going NEP for the last 24 months. We request that the Federal government undertake an evaluation of our program as it seeks an answer to the efficacy of such programs and in determining whether such programs stop the spread of the HIV/AIDS virus and whether or nor such programs increase drug use."

The Washington Times
THURSDAY, JANUARY 27, 1994 ★

White House considers funding needle exchanges to fight AIDS

A1

FROM COMBINED DISPATCHES

The Clinton administration is studying whether to allow federal funding for needle-exchange programs that aim to block the spread of AIDS among drug abusers, AIDS policy coordinator Kristine Gebbie said yesterday.

Ms. Gebbie wouldn't speculate on when a decision will be reached, but she said state and local officials don't have to wait for the federal government.

"What makes a difference is local commitment," Ms. Gebbie told the AIDS Task Force of the U.S. Conference of Mayors. "This administration isn't afraid to talk sex, to talk HIV prevention. But the real conversations have to happen at the state and local level."

Intravenous drug users are at high risk for infection with the human immunodeficiency virus, which causes AIDS. About one-third of U.S. AIDS patients are drug users or are the sex partners or children of users.

The idea of federal tax dollars being used to provide clean needles for drug addicts was immediately attacked by various sources. "It's an outrage," said Sen. Don Nickles, Oklahoma Republican. "If you have the federal government saying it's going to give free needles in an exchange program, it's almost a government acquiescence to intravenous drugs. This would be a serious mistake. ... Intravenous drugs are deadly."

Rep. Henry Hyde, Illinois Republican, said he fears that a government-sponsored needle-exchange program would "encourage the use of drugs rather than discourage drug use."

"I'd rather spend the money trying to get drug addicts cured rather

see NEEDLES, page A14

NEEDLES

From page A1

than facilitating their addiction," he said.

Kristi Hamrick, spokeswoman for the Family Research Council, said:

"Given what we know to be true about drugs in America — that they are addictive and dangerous — it's absolutely ludicrous that the administration is considering funding illegal, criminal and dangerous behavior. It's the kind of bad health policy that will get us more of something we don't need: people with drug addictions."

There are 37 programs around the country in which drug users can exchange dirty needles for clean ones. Laws ban federal funding of these programs until there is evidence of their effectiveness against the spread of HIV without increasing drug use.

A study sponsored by the Centers for Disease Control and Prevention (CDC) concluded in October that needle exchanges help prevent the transmission of HIV.

"Removing contaminated syringes from circulation is analogous to removing mosquitoes" that spread malaria, said chief investigator Dr. Peter Lurie of the University of California at San Francisco.

The study isn't perfect because there is no way to prove that drug users in needle-exchange programs won't eventually get AIDS because of other risks.

But Ms. Gebbie said opponents apply more rigorous standards to such preventive measures than to potential treatments. Often, new drugs are used on AIDS patients after a mere one or two studies.

"It's not a clear study that lawyers like me would like to have," said Hector Luis Acevedo, the mayor of San Juan, Puerto Rico, and the task force chairman. "But in an epidemic, we cannot wait.... We have to move with the evidence we have."

Mr. Hyde expressed discomfort with what he described as the "vague language" used to describe the study's results. He said Americans will want to see "some solid data" about the effectiveness of needle-exchange programs before their taxes are used for that purpose.

The administration's acknowledgment that it is studying the possibility of needle-exchange programs follows its kickoff of a condom advertising campaign earlier this month aimed at sexually active young people. The CDC said condoms are "highly effective" in preventing the sexual transmission of HIV.

But Mr. Hyde said he doesn't get much comfort from the condom campaign or the prospect of a government-sponsored needle-exchange program. "It doesn't provide much optimism that we're going to diminish drug addiction and promiscuous sexual conduct among people whose conduct is being subsidized by the federal government."

Instead, he said, it appears that "society is just surrendering to the lowest common cultural denominators."

"We seem to be surrendering to the needle and condom cultures," Mr. Hyde said.

● *Staff writer Joyce Price contributed to this report.*

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201
(202) 690-7780
Fax: 690-7998

Y19 C 400

MEMORANDUM

To: Kristine Gebbie
Patsy Fleming

From: Nan D. Hunter

Date: 3 January 1994

Re: Surgeon General's responsibilities re: studies of needle exchange programs

---

It appears from our initial research that the Surgeon General's responsibilies can be delegated along the lines we discussed at our recent meeting. Such a delegation can probably be made to anyone in the Public Health Service.

I have asked for a final opinion by 13 January. I will have my secretary contact your offices to schedule a further discussion among us after that date.

1/22 Post FYI

Needle Exchanges

An inexpensive weapon against AIDS.

In Alexandria, as in many urban areas, the face of AIDS is changing. Among new cases of HIV infection reported last year, only 35 percent reported that their risk factor was having sex with men, while 27 percent reported that they were intravenous drug users—a big increase over previous reportings. In March 1992 at least 66 Alexandrians were infected or sick from HIV as a result of injecting drugs; by May 1993, the number had reached 100.

The city's health department has tried to educate people about protecting themselves from infection by not sharing injection equipment; it has distributed bleach kits for drug users to clean their "works" since 1992. But the numbers of the infected continue to rise in Alexandria—140 cases of HIV infection because of injection of illegal drugs as of September.

The necessity for expanding the repertoire of tools available to combat this epidemic is made even more pressing by new research that shows that bleach is not as effective for viral inactivation as was once thought.

At the same time, reputable institutions—the National Commission on AIDS, the American Public Health Association, the U.S. General Accounting Office, Yale University, Johns Hopkins University and the University of California in a study for the Centers for Disease Control and Prevention—have released studies showing that needle-exchange programs merit implementation and can serve as a bridge to drug treatment programs.

So why is there a hold-up in making this inexpensive and effective tool available?

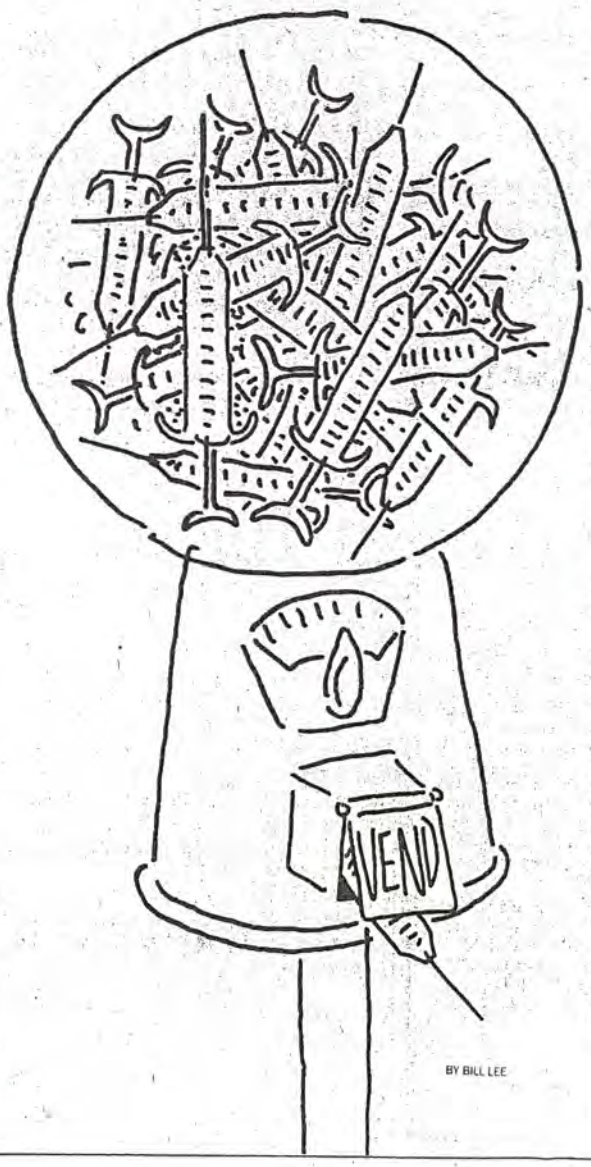
Those who insist that needle-exchange programs encourage drug use have no evidence to back such a claim. Further, the primary purpose of needle-exchange programs is the prevention of the spread of HIV, not the prevention of drug use. Many drug users are not ready or able to "just say no"; needle-exchange programs give them a chance to avoid infection with HIV and offer them the opportunity to consider treatment for drug use later.

Those who argue "not in my backyard" or "it will attract an undesirable crowd" must understand that needle-exchange programs can be provided discreetly and in ways that minimally disrupt other community activities, if at all.

And for those who question whether every drug user will quit sharing needles if an exchange program is offered, the answer is probably not, but the prevention of even one HIV infection with its associated human suffering and costs would be worth the limited price of such a program.

In Virginia, needle-exchange programs are at present a violation of drug paraphernalia laws. The state General Assembly should pass legislation to change that and to allow a locality such as Alexandria the option of establishing a needle-exchange program.

—Joshua Lipsman
is the director of the Alexandria Health Department.



BY BILL LEE

Tacit support for drug use.

The Maryland legislature is about to be put into a political Catch-22 regarding the passage of legislation that would allow Baltimore City to institute a needle-exchange program. City officials have been trying to sway both the public and the legislature into believing that if they don't support the program, then they are not serious about stopping the AIDS epidemic. I hope our lawmakers are concerned enough to ask two questions: First, is a needle-exchange program necessary? And second, how effective would it be?

One of the more troubling justifications for a needle-exchange program, other than the shortage of treatment resources, is that clean needles are necessary to protect those who "cannot stop using drugs." This argument implies that treatment will not work for some addicts and that society must accept and support their continued drug use. I find that hard to accept.

The proposed goal of needle exchange is to reduce the spread of the HIV virus among Intravenous drug users, a major cause for the spread of AIDS. It is not, however, the only cause, nor is it the most threatening.

The greatest increase in the spread of AIDS now is from heterosexual contact, and this occurs primarily through the transmission of the virus from intravenous drug users to their sexual partners. Clean-needle programs are unlikely to modify the irresponsible sexual behavior of IV drug users. Irresponsible and self-destructive behaviors are synonymous with being an addict and are hard to change without long-term treatment. In the New Haven, Conn., needle-exchange program, which Baltimore officials use as a model, fewer than one-third of the participating addicts were found to be practicing safe sex.

In addition, the New Haven program experienced a 60 percent dropout rate, which means that the government is putting thousands of new needles into the streets for addicts to share and possibly sell. Also, Baltimore City has more than 35,000 addicts, while New Haven's total population is only 130,000 people, so it's difficult to draw parallels between the two cities.

The support of a needle-exchange program puts government in an awkward position of supporting and even facilitating drug use. This is dangerous, given that reduction in demand is accepted as the best method to control our drug-abuse problem. Demand reduction involves prevention, education and treatment programs, especially for addicts. In order for education, prevention and treatment programs to work, society has got to give a clear message that drug abusers must stop using drugs. The support of a needle-exchange program sends a mixed message to both addicts and to our children.

I hope that the General Assembly of Maryland sends a clear no-use messages to all who are using drugs and to all who may be thinking about it.

—Michael M. Gimbel
is the director of Baltimore County's Office of Substance Abuse.

Author: Ben Merrill at ~ONAPC
Date: 12/22/93 3:57 PM
Priority: Normal
TO: Kristine Gebbie ✓
CC: Bob Jackson
CC: Andrew Barrer
CC: Carlos Velez
CC: Ben Merrill
Subject: NIDA Position on Needle Exchange Programs

---------- Message Contents ----------

A few follow up points on our discussions yesterday with Nan and Patsy on needle exchange programs.

1) Bob Jackson says he was in Steve Jones' office when Patsy called Steve to congradulate him on the letter that Patsy suggested yesterday she never saw. Bob says Patsy was on the phone for at least 15 minutes going over the letter.

2) I'm sending over, hard copy, NIDA's comments on NEP. NIDA continues to be the most defensive on this issue and I think their go slow position is the one driving NIH/CDC/and OS

Ben (copy to others)

1) no surprise in the Patsy info

2) I think you are over-reacting to the NIDA response — I don't read "include research/evaluation" as "go slow" — I read it as an accurate statement of what we need ——

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

TO: James W. Curran, M.D.
Associate Director HIV/AIDS, CDC

FROM: Deputy Director, Office of AIDS Research, NIH

SUBJECT: NIDA/NIH Comments on the University of California Report, "The Public Health Impact of Needle Exchange Programs in the United States and Abroad"

Please find attached additional comments provided by NIDA on the above referenced report. Please include these comments as part of the NIH response to the report.

If you have any questions, please call Paul Gaist at (301) 496-0353.

Jack Whitescarver, Ph.D.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute on Drug Ab
5600 Fishers Lane
Rockville, Maryland 20857

DEC 9 1993

TO: James W. Curran, M.D.
Associate Director HIV/AIDS, CDC
Through: Deputy Director
Office on AIDS Research, NIH

FROM: Acting Director, NIDA, NIH

SUBJECT: NIDA Comments on the University of California Report, "The Public Health Impact of Needle Exchange Programs in the United States and Abroad"

I find much of the CDC draft response to the "Review of the University of California Report on Needle Exchange and Recommendations on Needle Exchange" appropriate and supportable. The U.C. Report itself acknowledges substantial variations among Needle Exchange Programs (NEPs); acknowledges that accurate measurement of drug use patterns and numbers of drug users in communities is very challenging; calls for the Federal Government to repeal the ban on the use of Federal funds for needle exchange services; and calls for substantial Federal funds to expand research into these programs.

I endorse the CDC comments on the Report that it is important to have NEPs "as one possible component of a comprehensive HIV prevention program for drug users" and that increasing the availability of sterile needles and syringes is appropriate Federal policy, for the reasons enunciated.

I also agree with the Report, the CDC review, and Dr. Whitescarver's cover memorandum that evaluation components and future research of NEPs are needed. One practical suggestion is that made by Dr. Whitescarver which states, "until more is definitively known and has been time tested, any NSE service program funded should have appropriate research and/or evaluation components built into them as a prerequisite for Federal funding."

In April 1992, when NIDA funded its first extramural grant conducting research on mathematical modeling related to the effectiveness of needle and syringe exchange programs, we were perceived to be on one end of a spectrum, incorrectly characterized as support for NEPs. More accurately, we believe that research on NEPs is appropriate and supportable. Since that time we have funded two other needle exchange research projects and, in November 1993, released a Program Announcement (#94-010)

entitled "Research on Needle Hygiene and Needle Exchange Programs" (attached). NIDA continues to believe that NEPs bring with them a substantial research agenda and look forward to working with other PHS agencies to prevent the spread of HIV and contribute to the science of AIDS prevention.

Richard A. Millstein

Attachment

Back/AA thru file

MEMORANDUM

September 2, 1993

TO: KRISTINE GEBBIE, Director

FROM: BEN MERRILL

RE: **Needle Exchange Issues - Political**

You have asked for an update and over-view on Needle Exchange. I have spent this first day avoiding re-inventing the wheel. Here is a brief over-view:

BACKGROUND TO DATE

1. **Donna Shalala** requested a briefing on Needle and Syringe Exchange (NS Ex) on February 2, 1993.

2. On March 9 **Senator Patty Murray** asked the Secretary to include professionals directly involved in the development of such programs from the states to attend such a briefing.

3. In late March **GAO** released its report to the House Committee on Narcotics Abuse finding that needle exchange programs would be a promising strategy for reducing or preventing the spread of HIV/AIDS.

That report favorably reviewed the work of **Dr. Edward H. Kaplan**, in developing a model that assumed no behavior modification in the addict and assumed only the impacts on the length of time needles are available to be shared. Thus, conservatively, the rate of reduction between incidence and infection was found to be 33 percent. GAO concluded that the rate would increase further in the event that there was any opportunity in the program to modify behavior.

4. You have received a note from **Lee Brown** attaching the response to Dr. Kaplan's study that was set forth by former Drug Czar **Bob Martinez**. It concluded that there was no evidence supporting the contention that needle exchange programs reduce the spread of HIV.

I do not know if this is Brown's position or if he is looking for your input before he formulates one.

5. Kaplan's work was independently reviewed by GAO consultants, and Kaplan has recently rebutted each and every one of the ONDCP charges (see Pediatric AIDS and HIV Infection, Vol. 4, No. 2, pp. 92-96, 1993) and his model won the 1992 Franz Edelman Award from TIMS.

6. I have proposed draft letters responding to Senator Murray and the Conference of Mayors. Each of these letters takes a wait and see attitude. They refer to on-going studies.

7. I believe that the study that everyone is waiting for is the University of Southern California which has been in labor for some time. The oversight officer from NIH is **Steve Jensen.** The work is being done now by **Dr. Author Reingold.** It is important to note that Dr. Reingold's one-time Co-Principle Investigator was **Asst. Secretary Phil Lee.**

I believe that you have an early draft of the report. The report, which was to have been out in May, is now scheduled for September, but Jensen says he doubts that it will be out then. He says that he does not know when it will be out but is hopeful that it will be out soon. Other's who have reviewed drafts of the report, such as **Dr. Peter Hartsock** and **Dr. David Valahov** indicated that the report is very convoluted and difficult to read. They indicate that the report does not do Kaplan's work justice. Jenson himself, the Project Officer, told me that parts of the report would be helpful but that other parts of the report would not.

IN-HOUSE POLITICAL CONSIDERATIONS

Patsey Fleming told me today that the development of this issue should go slow. I asked her why and she said that they were waiting for the Berkeley study. She said that she did not think it should go outside of HHS at this time.

I don't know if Ms. Fleming is being cautious because Assistant Secretary Lee has a vested interest in the Berkeley study, or if the "political nature" of the decision is such that they do not want to get the President in hot-water over the issue. My sense is that cities are going to be moving forward on this and Maryland will probably pass legislation next year. The Connecticut experience as well as Dinkins reversal in New York and the strength of the Conference of Mayor's letter would tilt in that direction.

COST-BENEFIT ANALYSIS

I have obtained a hand-written letter from **Dr. Robert Heimer** of Yale's Department of Internal Medicine with a very impressive run at cost/benefit. He suggests:

> Kaplan's model suggests decrease in incidence from 6.4 cases/100 IDU/Yr to 3.9 cases over the first 19 months of the New Haven NEP. For about 500 regular program participants that means 20 cases prevented. If each injection cost 30K/year to treat, and a person is

infected for 10 years, then each case cost $300K. The total savings for 20 cases is $6 million. During these 19 months, it costs 150 K. to run the Needle Exchange Program (NEP). The return on investment is $6.5M/$150K or 40 fold.

Even if the CDC's conservative figure of 755 days from date of diagnosis to death is used, and we hold to a 2 year period, the cost of 20 people drops to $2.4M. An 18 instead of 40 fold return. GAO suggested that there Kaplan's model was conservative and that there would more than likely be some behavior modification at point of contact resulting in even greater savings.

This memo sets forth only political background. I will now start on the substantive stuff, generally outlined in the letter from ASTHO. I am scheduled to visit with Dr. David Valahof in Baltimore next Wednesday morning and that afternoon with the chief AIDS legislative counsel of the Maryland legislature. The meeting includes four recovering addicts who are working the trenches. The meeting should also include the chief medical examiner for the city. They all know this is backgrounding information but it should give us a very good insight into the trenches. I plan on taking the Metroliner into Baltimore for the day. Let me know if you consider this a waste of time.

KG
FYI

THE WHITE HOUSE

WASHINGTON

October 26, 1993

John T. Carnevale
Office of National Drug Control Policy
750 17th Street N.W., 8th Floor
Washington, D.C. 20503

OCT 27 1993

Dear John:

Thanks again for meeting with me this morning and for supporting us as we move toward resolving the needle exchange programs issue. As I explained, we appreciate the Director's position that this is a public health issue and it is in that forum that it needs to be addressed.

I am enclosing the Department of Justice release that I told you about, and hopes that it helps focus the issue in the next Congressional go-around. You have asked for, and I will discuss with Ms. Gebbie, her lending your office support for a budget that is realistic around prevention and treatment strategies.

Finally, as you complete your tactical plans for implementing the interim strategy, you have offered to get us early drafts for review and input, and we appreciate that very much. As I explained, Dr. Bob Jackson is slated for coming aboard in the near future and he will head up substance abuse. Please send me anything that you wish us to see.

Again, thank you for the meeting. And for the offer to help.

Sincerely yours,

Ben Merrill, J.D.
Special Assistant to
the Coordinator

cc: Kristine M. Gebbie, RN MN
National AIDS Policy Coordinator
Executive Office of the President
750 17th Street, N.W. Suite 1060
Washington, D.C. 20503

Carlos Velez, Lead, Prevention Group
ONAPC

Office of the National AIDS Policy Coordinator

Executive Office of the President
750 17th Street, N.W. Suite 1060
Washington, D.C. 20500

	17th ST. OFFICE	HUMPHREY BLDG
Phone:	(202)632-1090	(202) 690 5560
Fax:	(202)632-1096	(202) 690-7560

Deliver To: K GEBBIE, ANDREW, JOHN

Sent From: R. S. JACKSON, M.D.

Kristine Gebbie, RN, MN, National AIDS Policy Coordinator

Number of Pages: 2 + Cover Fax Number: 9-632-1096 Date: 3/10/94

Message:

F.Y.I.

MARYLAND BILL HAS PASSED 2 COMMITTEES

THEY EXPECT APPROVAL

BEILENSON'S FATHER IS IN CONGRESS

MIGHT BE VALUABLE ALLY

BOB

CITY OF BALTIMORE

KURT L. SCHMOKE, Mayor

HEALTH DEPARTMENT

PETER BEILENSON, M.D., M.P.H., Commissioner
303 East Fayette Street
Baltimore, Maryland 21202

BALTIMORE CITY
AIDS PREVENTION NEEDLE EXCHANGE-PILOT PROGRAM
FACT SHEET

Why the Need for Needle Exchange?

- **AIDS is the #1 killer of 25-44 year olds in Baltimore City.**
- **61% of new AIDS cases in Baltimore in 1993 were in injection drug users; 8% were their sex partners; and 3% were their babies.**
- **Four new infections with HIV occur each day in Baltimore.**
- **Needle sharing is the most common way of spreading HIV in Baltimore.**
- **Baltimore has 48,000 heroin and cocaine addicts, the majority injection drug users.**

Needle Exchanges are Effective

Several studies, including a comprehensive 1993 study, sponsored by the Centers for Disease Control, of all 37 needle exchanges currently operating in the United States have found that:

- **Needle exchange programs are effective at preventing th spread of HIV.**
- **When connected with drug treatment programs, as Baltimore's will be, needle exchanges serve as important bridges to treatment.**
- **Needle exchange programs do not increase either the frequency of drug use among current users, nor increase initiation rates in the rest of the community.**
- **Following implementation of a needle exchange, the number of dirty discarded needles decreases significantly in the surrounding area.**

Needle Exchanges are Cost-Effective

- **The total lifetime cost of treating a single adult AIDS patient is $102,000.**
- **The cost in the first year of life of treating a single child born with AIDS is $210,000.**
- **Baltimore's pilot needle exchange program will serve approximately 750 addicts at a total cost of $160,000 (all City General Funds). Therefore, if only two adult cases of AIDS are prevented, the pilot program will save the State money (since the vast majority of AIDS care ends up being covered by Medical Assistance or is passed on as uncompensated care).**
- **In New Haven, the needle exchange program which has been operating since 1990 has resulted in a 35% decrease in the risk of HIV transmission among participants. With a 4% seroconversion rate per year among injection drug users in Baltimore, such a result with Baltimore's proposed initial pilot would result in savings of approximately $1 million per year.**

(Continued)

- If just a third of Baltimore's uninfected injection drug users are eventually enrolled in a needle exchange program (far lower than the 60% of injection drug users enrolled in New Haven), **approximately 125-150 new HIV infections would be averted per year, saving approximately $12.5 to $15 million in public health care expenditures.**
- The money saved by this program would be well-used to provide additional substance abuse treatment slots to help more addicts go drug-free.

Organizations Supporting Baltimore's Needle Exchange Proposal

Medical and Chirurgical Faculty of Maryland, Baltimore City Medical Society, Maryland Chapter of American College of Emergency Physicians, Maryland Alliance for Healthcare (comprised of Med Chi, Maryland Hospital Association, Medical Data Analysis Corporation, Blue Cross Blue Shield of Maryland, Maryland Nurses Association, Maryland Association of Health Maintenance Organizations), Mid-Town Churches Community Association, Advocates for Children and Youth, Baltimore Jewish Council, National Black Women's Health Project/Maryland Public Policy Committee, Baltimore City Substance Abuse Directorate, University of Maryland School of Medicine Adult HIV Program, Johns Hopkins School of Hygiene and Public Health Program of Infectious Disease, Mayor's AIDS Coordinating Council, Liberty Medical Center, Mercy Medical Center, Bon Secours Hospital, Sinai Hospital of Baltimore, Francis Scott Key Medical Center, Mid-Atlantic Association of Community Health Centers, Baltimore Medical Systems, Inc., AIDS Service Providers Network, Maryland Nurses Association (partial listing).

C:Nee.fct
3/94

Kristine Gebbie -

Fyi.

Lisa Lewis
3/11

MAR 14 1994

PHS CORRESPONDENCE

T65170

REFERRAL DATE: 3-9 **DUE DATE:** 3-11

TO:

- ☐ ASH
- ☐ DEPUTY ASH
- ☐ SG
- ☐ DASH-MO
- ☐ DASH-SE
- ☐ DASH-C
- ☑ DASH-DPHP (2-)
- ☐ DASH-IGA / RHA
- ☐ DAS-IH
- ☐ DAS-MH
- ☐ DASH-PA
- ☐ DAS-PHP
- ☐ ADAMHA
- ☐ AHCPR
- ☐ ATSDR
- ☐ CDC
- ☐ FDA
- ☐ HRSA
- ☐ IHS
- ☐ NIH
- ☑ NAPO (1-) 3-2-94
- ☐ NVP
- ☐ PCPFS
- ☐ OEEO
- ☐ OEP
- ☑ OGC / H (3-)
- ☐ OHL
- ☐ OHPE
- ☐ OM
- ☐ OSIR
- ☐ OWH
- ☐ ES / PHS _____
- ☐ OTHER _____

ACTION:

- ☐ SECRETARY'S SIGNATURE
- ☐ ASH SIGNATURE
- ☐ DIRECT REPLY
- ☐ _____ SIGNATURE
- ☐ DRAFT FOR OS SIGNATURE (WHITE HOUSE REFERRAL)
- ☑ REVIEW / CLEARANCE (1-3)
- ☐ NECESSARY ACTION
- ☐ FOR YOUR INFORMATION

SPECIAL INSTRUCTIONS

PHS-5175
Rev. 4/92

PHS / ES
Rm. 710H

Phone: 690-8566

Routed by:

135

Ms. Frances Milberg
Chair
Ad Hoc Committee on AIDS
The Association of the Bar
of the City of New York
42 West 44th Street
New York, New York 10036-6090

Dear Ms. Milberg:

I am responding to your letter to Secretary Donna Shalala supporting the needle exchange programs as a potential means of reducing the spread of the human immunodeficiency virus (HIV) and other bloodborne disease agents.

We recognize that the Association of the Bar of the City of New York has been very active in the fight against HIV infection and AIDS, and appreciate your thoughtful discussion of needle exchange issues. As you know, the October 1993 report entitled "The Public Health Impact of Needle Exchange Programs in the United States and Abroad," was prepared for the Centers for Disease Control and Prevention (CDC) by researchers at the University of California. The final report, including findings, conclusions, and recommendations, was independently produced by the University of California project team.

This report represents a tremendous effort to examine an important health option for preventing transmission of HIV infection, and is presently under review by the Public Health Service.

We will consider your comments in evaluating needle exchange as a possible prevention strategy.

We appreciate your interest in HIV prevention. An identical letter is being sent to Mr. Edward Kornreich, who co-signed your letter.

Sincerely yours,

Philip R. Lee, M.D.
Assistant Secretary for Health

cc:
OD
CDC/W
H Official File
CDC Official File (Return to CDC, Atlanta)
Cleared by:JCurran, CDC, OHA, 02/17/94
OS No. 9401270047; Tracer No. T65170
CDC ID HCA83433; HIV/HCA 83472; Doc. Name MILBERG.ASH
CDC:DSatcher:pkg:03/04/94; (404) 639-3291; CNL/03/04/94
Spelling Verifier Used by:PGalusha:03/04/94
Prepared by:CO'Connell, CDC, OHA, (404) 639-0938
Contact:BCoker, CDC, OD, (404) 639-3322

IDENTICAL LETTER SENT TO:

Mr. Edward Kornreich
Chair
Health Law Committee
The Association of the Bar
of the City of New York
42 West 44th Street
New York, New York 10036-6090

THE ASSOCIATION OF THE BAR
OF THE CITY OF NEW YORK
42 WEST 44TH STREET
NEW YORK, N.Y. 10036-6690

(212) 382-6600

January 24, 1994

The Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Federal Policy on Needle Exchange Programs

Dear Secretary Shalala:

The Association of the Bar of the City of New York is a 19,000-member organization of attorneys dedicated to improving the administration of justice. Since the beginning of the HIV epidemic in New York City, the Association has taken great interest in the legal, social, public policy and medical aspects of the disease and its impact on the New York City metropolitan area. Through its various committees, including the Ad Hoc Committee on AIDS, and the Health Law Committee, the Association has issued reports and policy statements on many aspects of the epidemic, ranging from AIDS in correctional facilities to policies on HIV testing, medical confidentiality, and HIV prevention efforts.

We have been following with great interest the unfolding debate on needle exchange programs ("NEPs") as a potential means of reducing the spread of the human immunodeficiency virus ("HIV") and other blood-borne diseases among injecting drug users. It was, therefore, with great interest that we reviewed the study prepared for the Centers for Disease Control and Prevention by researchers at the University of California, entitled "The Public Health Impact of Needle Exchange Programs in the United States and Abroad," released September 30, 1993 ("CDC Study").

The CDC Study confirms our belief that NEPs can play an important role in moderating the spread of HIV, not only among the injecting drug user population, but from that population to their non-drug using sexual partners and offspring.

Based upon the conclusions of the CDC Study and those of other studies, we recommend that the federal government end current restrictions on the use of federal funds for NEPs. It is our considered opinion that the federal government should encourage and nurture NEPs as part of its effort to combat the spread of HIV and other diseases. The federal government's support of NEPs would create a bridge between the distribution of clean needles and the provision of other public health services for injecting drug users such as treatment for drug abuse and TB testing. It is our hope, as well, that federal support for NEPs would encourage states, such as New York, to repeal criminal sanctions for possession of non-prescription hypodermic instruments.

The CDC Study concluded that NEPs reach injecting drug users with long histories of drug abuse who remain at significant risk of HIV infection and who often have had less exposure to drug abuse treatment programs than other drug users. Some NEPs have made significant numbers of referrals for drug abuse treatment and other public health services when slots for those services were available. Greater availability of treatment opportunities will increase the possibility of referrals for treatment by NEPs.

However, even if drug use is not significantly decreased, NEPs can play a salutary role in protecting public health by decreasing HIV drug risk behavior. Access to clean needles reduces the likelihood of the spread of HIV infection between the drug using population or from that population to their sexual partners and offspring.

The CDC Study also revealed that available data offers no evidence that NEPs increase the amount of drug use by NEP clients or increases overall community levels of drug use. Furthermore, in terms of cost-benefit analysis, the relatively minimal investment for the operation of an NEP results in a far more efficient expenditure of resources than the high medical and social costs associated with each case of HIV infection.

The implications of the CDC Study and the majority of studies preceding it are clear: NEPs should be considered an important part of an overall strategy to combat the further spread of HIV, as well as an important part of an overall strategy to combat drug dependency. Thus, NEPs are important in advancing two of the federal government's major public health goals.

The federal government should respond to the CDC Study it commissioned by adopting a pragmatic public health strategy that will encourage states and localities to establish NEPs as part of their overall effort to combat the spread of blood-borne infectious diseases. In addition, we believe such support will, as urged by the CDC Study, encourage states and localities to repeal laws that make it a crime to possess non-prescription hypodermic instruments.

The CDC Study indicates that NEPs alone will not reach all injecting drug users and that alternative methods of syringe distribution to decrease the rate of HIV drug risk behavior must be considered. This conclusion supports the recommendation reached by the Association in 1986 that non-prescription sale of hypodermic needles should be legalized in those states that ban them, and, further, that paraphernalia laws as they relate to hypodermic equipment be similarly repealed. See *"Legalization of Non-Prescription Sale of Hypodermic Needles: A Response to the AIDS Crisis,"* 41 The Record of the Association of the Bar of the City of New York 809 (Nov. 1986) (A copy of this report is enclosed).

In sum, present restrictions on the use of federal health funds must be replaced with a program of federal encouragement and subsidization of NEPs. Funding for NEPs must include support for sorely needed counseling and treatment services for drug users. This will enable the bridge between the provision of clean needles and referral to public health services and drug abuse treatment to become a reality.

Finally, states and localities must be encouraged to repeal laws prohibiting non-prescription possession of hypodermic instruments and related paraphernalia laws.

Thank you for your consideration. Please feel free to contact our Committees if you think we can provide further information or be of any assistance with respect to these issues. Please be advised that this letter has also been sent to the Honorable Mario Cuomo, Governor of the State of New York, and to the Honorable Rudolph W. Giuliani, Mayor of the City of New York and their respective Commissioners of Health.

Very truly yours,

Frances Milberg
Chair
Ad Hoc Committee on AIDS

Edward Kornreich by F.M.
Edward Kornreich
Chair
Health Law Committee

cc: The Honorable Jocelyn Elders
The Honorable Kristine Gebbie

NATIONAL AIDS POLICY OFFICE
OFFICE OF THE COORDINATOR

ROUTING SLIP

DATE: 1/19

TO: Kristin

FROM: ✓ W. STEVE LEE

✓ For your information
copy sent to Ben

____ For your action ____

____ Review and comment by (date) ____

____ Prepare reply for Coordinator's signature

____ Reply directly and blind copy Coordinator

____ Circulate/forward to: ____

____ File

COMMENTS: ____

Needle Exchanges

FAX

DATE: FAX # (212) 264-1324

FROM : Barry R. Gordon
Regional AIDS Coordinator

NUMBER OF PAGES:

TO: KRISTINE GEBBIE
AIDS POLICY COORDINATOR

REGARDING: SYRINGE EXCHANGE (MY)

NOTE: ANY PROBLEMS CALL (212) 264-2535

THOUGHT THIS INFO
WOULD BE OF INTEREST

REGARDS
Barry Gordon

NEW YORK STATE DEPARTMENT OF HEALTH — AIDS INSTITUTE

HARM REDUCTION INITIATIVE UPDATE
NYS-Authorized Needle Exchange Programs

RECENT RESEARCH AND EVALUATION OF NEEDLE EXCHANGE PROGRAMS

Last month, researchers from the School of Public Health at the University of California-Berkeley and the Institute for Health Policy Studies at the University of California-San Francisco released the results of an 18-month study of legal and illegal needle exchange programs in the U.S., Canada, and eight other countries. This evaluation, sponsored by the U.S. Centers for Disease Control and Prevention (CDC), is the most comprehensive study ever conducted on the effectiveness of needle exchange programs in preventing the spread of HIV among injection drug users (IDUs). The 500-page report entitled, "The Public Health Impact of Needle Exchange Programs in the United States and Abroad", covers 37 programs currently operating in the U.S., more than half of which are legal. The report concluded:

> "With new HIV infections occurring daily in injecting drug users, their sex partners and their children, the time has arrived for federal, state and local governments to remove the legal and administrative barriers to increased needle availability and to facilitate the expansion of needle exchange programs. These programs should be an integral part of public health efforts to stem HIV infection drug users and should be part of a comprehensive approach to drug use that should also emphasize expanded access to drug treatment and school- and community-based interventions to prevent the initiation of drug use."

The major findings of the report include:

- **Effect on drug use.** There is no evidence that needle exchange programs increased the amount of drug use by clients or changed overall community levels of non-injection and injection drug use.
- **Effect on HIV risk behaviors.** Studies of needle exchange clients show decreased rates of HIV drug risk behaviors, which should translate into decreased HIV infections.
- **Effect on HIV and hepatitis B infection rates.** Multiple mathematical models developed for this project support the findings of researchers in New Haven, Connecticut, which estimated a 33 percent decrease in the rate of new HIV infections among needle exchange program clients. 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.
- **Discarded syringes.** Needle exchange programs in the U.S. have not been shown to increase the total number of discarded syringes and can be expected to result in fewer discarded syringes.

- **Services.** In addition to distributing syringes, U.S. programs provide a variety of services, ranging from distributing bleach (for disinfecting syringes) and condoms, to providing drug treatment referrals. Six U.S. and Canadian programs have referred over 2,200 individuals to drug treatment programs.

- **Users of exchange programs.** Needle exchange programs generally reach a group of injecting drug users at significant risk for HIV infection who have long histories of drug injection. One-third to one-half of U.S. needle exchange program clients have had no exposure to drug abuse treatment programs.

The report recommended that:

- the federal government should repeal the ban on the use of federal funds for needle exchange services and substantial federal funds should be committed both to providing needle exchange services and to expanding research into the programs.

- state governments in the eleven states that have prescription laws for obtaining syringes should repeal these laws.

- local governments should enter into discussions with local community groups to develop a comprehensive approach to preventing HIV in injecting drug users, their sex partners, and their offspring. This approach should include needle exchange programs and the expansion of drug treatment services.

Other Needle Exchange Research and Evaluation. Needle exchange programs have been extensively studied, both in the United States and abroad, and have consistently demonstrated that they:

- help drug injectors significantly reduce drug-using behaviors which put them or someone else at risk for contracting HIV[1];

- serve as an effective gateway to drug treatment and health and social services for program participants[2];

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[1] For a sampling of available studies, see Don C. Des Jarlais and Samuel R. Friedman, "AIDS and Legal Access to Sterile Drug Injection Equipment," *Annals, American Academy of Political and Social Science* 1992; Holly Hagan, Don C. Des Jarlais, *et al.*, "Multiple Outcome Measures of the Impact of the Tacoma Syringe Exchange," Poster #4238, Proceedings of the VIII International Conference on AIDS, 1992; J.A.R. van den Hoek, H.J.A. van Haastrecht, *et al.*, "Risk Reduction among Intravenous Drug Users in Amsterdam under the Influence of AIDS," *American Journal of Public Health* 1991; and Graham J. Hart, Andrea L.M. Carvell, *et al.*, "Evaluation of needle exchange in central London: behavior change and anti-HIV status over one year," *AIDS* 1992.

[2] See, for instance, Holly Hagan, Don C. Des Jarlais, *et al.*, "The Tacoma Syringe Exchange," in *Cocaine, AIDS and Intravenous Drug Use* (Samuel R. Friedman and Douglas S. Lipton, Eds.), Binghamton, NY: Harrington Park Press (1991); Andrea L.M. Carvell and Graham J. Hart, "Help-seeking and referrals in a needle exchange: a comprehensive service to injecting drug users," *British Journal of Addiction* 1990; and Elaine O'Keefe, Edward Kaplan, *et al.*, *Preliminary Report: City of New Haven Needle Exchange Program*, New Haven Department of Health (July 31, 1991).

- do not cause an increase in injection drug use or a decrease in drug treatment admissions in communities where they operate[3];
- reduce the risk of HIV exposure to the larger public by lessening the number of potentially-contaminated needles discarded in public places[4]; and
- are a cost effective HIV prevention measure.

In addition, data from several U.S. programs suggest that needle exchange programs have reduced or stabilized HIV seroconversion and hepatitis-B seroprevalence rates among IDUs in the locales in which they operate.[5]

EVALUATION OF THE NEW YORK-BASED NEPs

Description. The American Foundation for AIDS Research (AmFAR) is sponsoring an evaluation of the five legal New York City NEPs being conducted by Drs. Don C. Des Jarlais and Denise Paone of the Chemical Dependency Institute of Beth Israel Medical Center.

Preliminary Findings. The initial findings of the needle exchange program evaluation are promising, generally showing a decrease in HIV risk behaviors and an increase in "protective" behaviors such as alcohol and use prior to injection. The following data, based on the sharing practices of interviewees before and during their participation in the exchange, demonstrates this trend.

The evaluation team have conducted 2,849 interviews and analyzed 1752 of the interviews conducted between the months of October 1992 and June 1993. The following excepts are quoted verbatim from a draft paper entitled "New York City Syringe Exchange: An Overview", that was presented at a workshop on needle exchange and bleach distribution programs on September 27-28, 1993 in Baltimore, Maryland. This paper will be published in final form in December of 1993.

- **Demographics:** Of the 1752 subjects included in this analysis 70% were male and 30% were female. IDUs participating in this study were ethnically diverse (38% Latino, 35% African American, 28% White). The mean age of participants was 36 and ranged from 18 to 67 years old.

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[3] See, for example, Joseph Guydish, Jesse Gusardo, *et al.*, "Evaluating needle exchange: are there negative effects?" *AIDS* 1993; Joel Wolk, Alex Wodak, *et al.*, "The effect of a needle and syringe exchange program on a methadone maintenance unit," *British Journal of Addiction* 1990; and Des Jarlais and Friedman, *op. cit.* (1992).

[4] See, for example, Kathy Oliver, Samuel R. Friedman, *et al.*, "Impact of a Needle Exchange Program on Potentially Infectious Syringes in Public Places," *Journal of AIDS* 1992.

[5] Holly Hagan, Don C. Des Jarlais, *et al.*, "The Incidence of HBV Infection and Syringe Exchange Programs," *JAMA* 1991; and Blaine O'Keefe, Edward Kaplan, *et al. op cit.* 1991.

- **Drug History:** The mean age of first injection was 19. Respondents had long histories of injecting drug use; the average length of injection was 16 years.

- **Risk Taking Behaviors:** Participants reported that in 30 days prior to using the syringe exchange, they injected with previously used works an average of 11.6% of the time compared to 3.9% of the time in the last 30 days. There was a significant decrease in the number of participants who reported sharing syringes in the last 30 days compared with 30 days prior to using the exchange; (rented or bought used syringes, 21.7% prior, 5.8% current, borrowed or used works, 29.3% prior, 12.1% current). The number of IDUs who reported using alcohol pads to clean their skin when injecting increased significantly. (33.0% prior, 80.0% current)

- **Renting or Buying:** A total of 1337 participants responded to questions about renting or buying used syringes both 30 days prior to using the exchange and during the past 30 days. Of these, 1047 (78%) did not rent or buy prior to using the exchange and 290 (22%) did. In comparison, among the 290 who did rent or buy used works prior to using the exchange, 223 (77%) no longer do so.

- **Borrowing or Using Used Works:** A total of 1328 participants responded to questions about borrowing or using used works. Of these, 939 (71%) did not practice these behaviors in the 30 days prior to using the exchange and 389 (29%) did. Among those who did not, only 23 (2%) initiated this behavior. In comparison, among those who previously borrowed or used used works, 251 (65%) have not in the last 30 days.

- **Alcohol Pad Use:** A total of 1269 participants responded to queries about using alcohol pads while injecting. Of these, 851 (67%) did not use alcohol pads prior to using the exchange and 418 (33%) did. 808 (71%) have begun since using the exchange.

- **Sexual Behavior:** Of the 1752 participants interviewed, 60% reported that they had anal, oral, or vaginal sex in the last 30 days. Seventy on percent (or 753) of the 1056 sexually active respondents reported having had sex with a primary partner of the opposite sex in the last 30 days. Of these 753 participants, 733 responded to a question about condom use. Fifty two percent reported that they never used a condom, 31.5% always used a condom, and 17% reported that they sometimes used a condom in the last 30 days.

ROLE OF THE NYS DEPARTMENT OF HEALTH AIDS INSTITUTE

The main function and responsibility of the NYS AIDS Institute is to monitor the operation of the programs and provide oversight in accordance with the State regulations. In addition to providing regulatory oversight, the NYS AIDS Institute has:

- implemented a protocol for handling occupational exposure;
- developed procedures in consultation with the State Department of Environmental Conservation regarding the disposal of hazardous waste;
- ensured that each program adheres to procedures for handling the ordering, receipt, storage, dispensing, and disposal of syringes and other supplies. These procedures include appropriate security precautions;
- assisted the existing NEPs with program development, community relations, and technical assistance matters;
- developed a uniform database for approved NEPs to facilitate required data collection and reporting, and trained NEP staff on the use of database software;
- played an active role in soliciting the cooperation and support of law enforcement, and in meeting with community groups to inform them about the Harm Reduction Initiative; and
- helped the programs develop referral relationships with other providers and assisted in the coordination of NEP staff and volunteer training.

PARTICIPANT DATA OF THE NYS-AUTHORIZED NEPs

As of June 30, 1993, the five NYC-based programs had enrolled a total of 11,004 clients. Of those, approximately 77% are male and 33% are female. The racial and ethnic composition of the enrolled clients is 46% Latino/a, 30% African-American, and 23% white. Seventy-nine percent (79%) of enrolled participants were over the age of 30 and less than one percent (1%) were under 20.

Services Provided Directly or by Referral to Other Providers. As part of the comprehensive harm reduction model, the needle exchange programs refer participants to health care, drug detoxification and treatment, HIV counseling and testing, and other services. To date the programs have collectively provided over 1,200 referrals. Over 530 of those referrals have been to detox and drug treatment services; over 200 for HIV testing and counseling; about 110 for health care, including HIV/AIDS services; and over 100 for entitlements.

NYS-Authorized Needle Exchange Programs

LOCATIONS AND HOURS OF OPERATION

as of 10/27/93

PROGRAM NAME	EXCHANGE SITES	DAY(S)	HOURS
ADAPT Needle Exchange Program Contact: Hector Garduno (212) 289-1957 (718) 665-5421, x 22 5000 participants ?	302 Bedford Avenue, Brooklyn	Mon. - Fri.	10:00 - 12:00 PM
	109th Street between Lexington and Third Avenues	Mon.	9:30 - 11:30 AM
		Fri.	5:00 - 7:00 PM
	South Fifth Street & Marcy Avenue Williamsburg, Brooklyn	Sat.	12:00 - 2:00 PM
	Corner of Putnam & Knickerbocker Aves., Bushwick, Brooklyn	Sat.	2:30 - 4:30 PM
		Tues.	9:30 - 11:30 AM
Bronx-Harlem Needle Exchange Program Contact: Paul Carvajal (718) 842-6050	Clinton Street and Jerome Avenue	Sat.	8:00 - 11:00 AM
	126th Street between Lexington & 3rd Aves.	Sat.	9:00 - 12:00 PM
	Corner of 110th Street & Park Avenue	Tues.	1:00 - 4:00 PM
	147th Street & Bergen Avenue	Thurs.	11:00 - 2:00 PM
Housing Works, Inc. Needle Exchange Program Contact: Alfredo Miranda (212) 966-0466, x 286	Main Office, 594 Broadway, Suite 700 (between Prince and Houston Streets) **NOTE: Only Housing Works' clients may participate in their needle exchange program. Housing Works serves homeless people who are HIV positive.**	Mon. - Fri.	9:00 - 5:00 PM
		Sat.	10:00 - 4:00 PM
Lower East Side Needle Exchange Program Contact: Allan Clear (212) 477-6863 (212) 228-7734	Storefront 39 Avenue C (between 3rd and 4th Streets)	Mon.	5:00 - 7:00 PM
		Wed. & Sat.	11:00 - 2:00 PM
		Thurs.	2:00 - 5:00 PM (Women Only)
		Thurs.	6:00 - 8:00 PM (All Clients)
		Fri.	7:00 - 10:00 PM
	Roving teams in the general areas of Essex, Delancey, and Pike Streets and under the Manhattan Bridge (locations subject to change)	Wed. & Sat.	11:00 - 2:00 PM
St. Ann's Corner of Harm Reduction Needle Exchange Program Contact: Joyce Rivera-Beckman (718) 585-5544 (718) 585-5632	139th Street and St. Ann's Avenue, Bronx	Tues.	12:30 - 2:30 PM
		Sat.	9:30 - 11:30 AM

For more information, please contact the New York State Dept. of Health AIDS Institute at (212) 613-4345.