

# **The Public Health Impact of Needle Exchange Programs in the United States and Abroad**

## **Summary, Conclusions and Recommendations**



(This logo was developed by the Centre québécois de coordination sur le SIDA of the Ministry of Health and Social Affairs of Quebec, in conjunction with injecting drug users (IDUs), local hospitals, community health centers, and pharmacists. It can be displayed at any site providing HIV prevention or education services for IDUs, including needle exchange and distribution.)

**-- Prepared by the School of Public Health,  
University of California, Berkeley  
and the Institute for Health Policy Studies,  
University of California, San Francisco**

**-- 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.

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## 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 children. 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 a contaminated syringe or 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 10 states and the District of Columbia; Maine recently revoked its prescription law and the prescription law in Connecticut has been modified.[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 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 (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), three in Canada (Montreal, PQ; Toronto, ON; Vancouver, BC), and two in Europe (Amsterdam, the Netherlands; London, England). 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 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 US 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. 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.

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 now 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 linkages 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, [NEPs are defined as legal if they exist in a state without a prescription law or operate under an exemption to the prescription law] eight are illegal but have received the support of a local elected body (illegal-tolerated), and six are illegal and operate without such support (illegal-underground). All Canadian NEPs are legal.

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) 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 by June 1993; due to missing data for some NEPs, this number is an underestimate. US NEPs distributed more than 2.4 million syringes in 1992. Figure 3 displays data on syringes distributed by the 15 US and Canadian NEPs visited and Hawaii that provided us with detailed breakdowns of syringes distributed.

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.

### **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, 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; 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. Although there are limited data on whether these referrals are completed, at least 794 NEP clients have entered drug treatment in Hawaii,[59] Seattle, WA,[60] Tacoma, WA,[61] New Haven, CT, [62] and Vancouver, BC.[63]

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 (includes both actual expenditures and donated services and supplies); 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. 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).

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.

**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 gain access to the public health services discussed in Section E.

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. 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.

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 resources. Local businesspeople 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 Section L 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) Uniform 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. 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. 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 can be exchanged for a sterile syringe), it is plausible that the discarding of syringes would decrease in much the same way as "bottle bills" have decreased discarded bottles and cans. IDUs might 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 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 total number of discarded syringes, although this problem can be at least partially addressed by either distributing 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 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) based on its ability to assess behavior change due to the NEP.

Sixteen of the 26 evaluations provide credible evidence (quality rating >3) about NEP effects on behavior. 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.

Most of the 16 acceptable studies showed drug-related risk reductions during NEP participation. Of the 14 studies examining sharing, 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 syringes, 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 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, right-sided endocarditis, 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] (An open cohort study is one without formal prospective follow-up, but subjects may return periodically to the study site and be retested (e.g., at a drug treatment center).) 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.

### **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 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, 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. 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, 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.

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 children would be prevented over five years at a cost per HIV infection averted of approximately \$3,800.

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 children 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 children. 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 may otherwise not receive these services. Such services can be provided cost-effectively and are associated with 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 and continuation of drug use.

Needle exchange programs should 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 cannot definitively prove that needle exchange programs decrease HIV infection rates, four lines of evidence suggest that this is likely. First, needle exchange is an intervention based on the sound theoretical principle of eliminating 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. Second, there is clear evidence of decreases in HIV drug risk behavior among needle exchange program clients, which should translate into decreased HIV infection rates. Third, hepatitis B infections appear to be reduced by needle exchange programs. Fourth, mathematical modeling by this project and other researchers consistently estimate substantial decreases in HIV transmission rates.

We believe that the data reviewed in this report meet the criteria established by the US Congress for lifting the ban on the use of federal funds for needle exchange program services. Federal law currently requires that "the Surgeon General of the United States [determine] that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs." [102] 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.
- 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 ten states and the District of Columbia that have prescription laws should repeal these laws.\*
- States should repeal the paraphernalia laws as they apply to 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 the District of Columbia and preclude the possession or distribution of syringes except for "legitimate medical purposes." Conviction under a paraphernalia law is a felony or a misdemeanor.**

### **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 programs (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.

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## Project Personnel

Principal investigators	<a href="#">Peter Lurie, MD, MPH</a> Arthur L. Reingold, MD
Co-Investigators	Benjamin Bowser, PhD Donna Chen, MPH Jill Foley, BA <a href="#">Joseph G. Guydish, PhD, MPH</a> <a href="#">James G. Kahn, MD, MPH</a> Sandra Lane, PhD, MPH, RN James Sorensen, PhD
Project Assistants	<a href="#">Pamela DeCarlo, BA</a> Nicholas Harris, BA
Project Officer	T. Stephen Jones, MD Office of the Deputy Director for HIV Centers for Disease Control and Prevention

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For questions regarding the report, call Peter Lurie at (415) 597-9138, or write to the address below.

### [Peter Lurie, MD, MPH](#)

University of California, San Francisco  
Prevention Sciences Group  
74 New Montgomery Street, Suite 600  
San Francisco, CA 94105  
Fax: (415) 597-9213

Copies of this Summary booklet, Volume I (a 500-page document addressing the essential policy questions on needle exchange programs), and Volume II (a 200-page document providing case studies of 12 cities visited by the project) can be obtained by calling (800) 458-5231 or writing to the address below.

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P.O. Box 6003  
Rockville, MD 20849-6003

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