
Journal of Urban Health: Bulletin of the New York Academy of Medicine Vol. 81, No. 1, March 2004

A Syringe Prescription Program to Prevent Infectious Disease and Improve Health of Injection Drug Users

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ABSTRACT *Injection drug users (IDUs) are at increased risk for many health problems, including acquisition of human immunodeficiency virus (HIV) and hepatitis B and C. These risks are compounded by barriers in obtaining legal, sterile syringes and in accessing necessary medical care. In 1999, we established the first-ever syringe prescription program in Providence, Rhode Island, to provide legal access to sterile syringes, reduce HIV risk behaviors, and encourage entry into medical care. Physicians provided free medical care, counseling, disease testing, vaccination, community referrals, and prescriptions for sterile syringes for patients who were not ready to stop injecting. We recruited 327 actively injecting people. Enrolled participants had limited stable contact with the health care system at baseline; 45% were homeless, 59% were uninsured, and 63% did not have a primary care physician. Many reported high-risk injection behaviors such as sharing syringes (43% in the last 30 days), reusing syringes (median of eight times), and obtaining syringes from unreliable sources (80%). This program demonstrates the feasibility, acceptability, and unique features of syringe prescription for IDUs. The fact that drug use is acknowledged allows an open and frank discussion of risk behaviors and other issues often not disclosed to physicians. The syringe prescription program in Providence represents a promising and innovative approach to disease prevention and treatment for IDUs.*

KEYWORDS *Injection drug users, HIV, Hepatitis B, Hepatitis C, Syringe prescription program.*

BACKGROUND

Injection drug users (IDUs) face tremendous health problems, including risk for infection with human immunodeficiency virus (HIV) and hepatitis viruses from sharing and reusing injection equipment. Injection drug use accounts for about one third of all reported acquired immunodeficiency syndrome (AIDS) cases[1] and 50%

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of all new HIV cases.[2] It is estimated that 50% to 95% of IDUs are infected with hepatitis C virus,[3–5] and the prevalence of hepatitis B virus is somewhat less.[6] Bacterial infections and complications from reusing syringes include cellulitis, endocarditis, tetanus, wound botulism, and abscesses.[7–12] In addition, many IDUs have other complex medical, social, and psychological problems and receive limited preventive care.[13–16]

Despite these health care needs, IDUs often face obstacles to accessing health care services. The stigma that surrounds injection drug use can lead IDUs to fear and mistrust physicians.[17] Many physicians report having negative attitudes toward IDUs and view addicted patients as "incurable" and "unmotivated."[18] Economic and social barriers, such as homelessness, poverty, unemployment, lack of health insurance, and lack of transportation, also inhibit the access of IDUs to medical care. Often, chaotic and unstable living situations make keeping appointments difficult.[19–22] Successful models for providing care to drug injectors address these issues by offering low-threshold services (e.g., appointment flexibility, low-cost or free care, transportation vouchers) in accessible settings such as storefront clinics, mobile health clinics (vans), drug treatment facilities, and as part of needle-exchange programs (NEPs).[23,24]

Numerous studies have shown that one component of the HIV prevention effort among IDUs is providing access to sterile syringes. High-risk injection behaviors have repeatedly been associated with restricted syringe access, and programs that increase syringe access have been shown to reduce HIV transmission without increasing drug use.[25–30] Approaches to improving syringe access include NEPs and changing laws to allow the purchase and possession of syringes. Although successful in increasing syringe access and reducing risk behaviors, these approaches have been limited by an ongoing federal ban on funding for provision of sterile syringes and by limited local support.[31–36] A third approach to increasing access to sterile syringes that is legal in 48 states but has not previously been implemented on a large scale involves physician prescription of sterile syringes for IDUs.[37,38] The prescription of syringes to IDUs by physicians is a prevention-and-treatment strategy that provides legal access to sterile syringes in the context of health care services.

Syringe Access in Rhode Island

Rhode Island has a history of very stringent and strictly enforced legal control of syringes. Until 1998, possession of a single syringe was a felony offense punishable by up to 5 years in prison, and syringes could not be purchased without a prescription. These legal barriers resulted in syringe scarcity and sharing and spread of HIV. Rhode Island IDUs reported among the highest rates of reuse in the country (average of 24 times per syringe),[26] and Rhode Island was one of only four states where over 50% of AIDS cases were associated with injection drug use.[39]

Several steps have been taken in Rhode Island to address the HIV/AIDS epidemic among IDUs. In 1994, Rhode Island passed legislation permitting a pilot NEP that has been in operation since that time. In 1998, the penalty for syringe possession was reduced from a felony to a misdemeanor without jail time. In 2000, the purchase and possession of syringes without a prescription finally became legal.

In 1999 (when syringe possession was a misdemeanor), with broad support from the medical and public health communities, the director of the Department of Health, Dr. Patricia Nolan, invited all licensed physicians in the state to participate in a clinical program to offer syringes by prescription to IDUs to prevent infection and transmission of blood-borne pathogens.[40] This allowed the creation of a program of prescribing syringes to IDUs to prevent disease. We describe here the methodology,

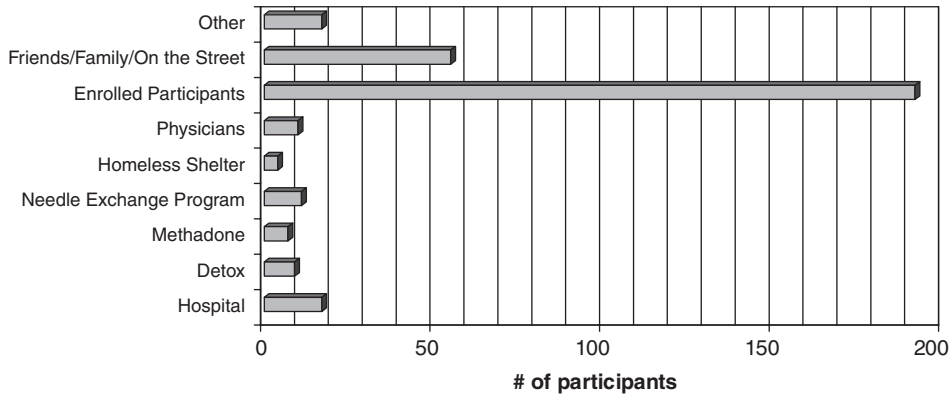

FIGURE. Referral source for IDUs enrolled in syringe prescription pilot study.

implementation, baseline characteristics, and a brief overview of program usage by participants enrolled in the syringe prescription program.

METHODS

In the summer of 1999, we implemented a pilot demonstration project to examine the feasibility, acceptability, and outcome of physician syringe prescription (PSP) to IDUs.[40] The project was designed to provide low-threshold medical services, access to sterile syringes, risk-reduction counseling, and referrals for a high-risk population. The program objectives were to provide legal access to sterile syringes, to reduce syringe sharing and reuse, to provide access to health care services, and to increase access to substance abuse treatment and other IDU-related services.

The PSP Study was designed as a research study with written, informed consent and full approval by the Miriam Hospital Institutional Review Board.

Recruitment and Eligibility

We recruited active IDUs through community agencies; emergency departments, and specialty clinics at the two major hospitals in Providence; drug treatment centers, including detoxification and methadone treatment facilities; community health clinics; homeless shelters; and meal programs. On enrollment, all PSP Study participants received referral cards to distribute to other IDUs as a means to reach IDUs not already linked to services. Cards were color coded to track origin of referral (Figure).

Potential participants called a toll-free number or "dropped-in" during clinic hours and underwent a brief phone screen to assess eligibility. Screening questions included the following categories: demographics, drug use, syringe reuse and sharing. Inclusion criteria for the study were age 18 years or older, anticipate living in the state for the next year, active injection drug use (self-reported injection in past 30 days), and self-reported insufficient access to sterile syringes (defined as any sharing, reuse, or desire for more syringes to inject safely).

Enrollment Procedures

When possible, enrollment visits were arranged during clinic hours (see details of the clinic procedures below) to facilitate participants' enrollment and attendance of their first clinic visit on the same day. Potential participants met with an interviewer who reviewed the consent document and explained the details of the program. Study staff

conducted the baseline interview, which included sections on basic demographics, smoking, alcohol use, drug use, injection drug use behaviors (e.g., syringe sharing, reuse, acquisition, carrying, disposal, and utilization of NEP), sexual activities and HIV risk assessment, alcohol/drug treatment history, and access to health care. The enrollment process (consent, baseline interview, etc.) lasted approximately 1 hour.

Following the baseline interview, the participant had the opportunity, and was encouraged, to see a physician. If the enrollment visit did not occur during clinic hours or if the participant was unable to stay and see the doctor, a medical appointment was scheduled for a later date. Participants received $10 reimbursement for completing the baseline interview, bus tokens for transportation, and an appointment card detailing both their next clinic appointment and their next assessment visit.

Clinic Procedures

Physicians saw participants at two clinic sites, the Miriam Hospital or a community-based medical building, both in Providence, Rhode Island. HIV-positive participants were referred and followed through the Miriam Hospital, but the majority of participants attended clinic at the community site, which was easily accessible and operated 2 days per week. The community site was also utilized by other medical clinics, a dental office, and an HIV/AIDS multiservice agency, thus providing anonymity to participants who were concerned about identification as an IDU.

After the baseline interview, the first visit consisted of the physician taking a general and focused medical and psychosocial history and performing a physical exam. History taking included an extensive discussion of current and past drug use, including type of drugs used, drug of choice, route of administration, and the different types of drug treatment tried. Physicians encouraged participants to undergo HIV, hepatitis B and C, and syphilis testing and, if appropriate, hepatitis B vaccination, all available for free at the clinic. Physicians worked with participants to assess the need for drug treatment, housing, medical, mental health, and other community services. When the participant reported the need for additional services, an outreach worker arranged referrals or gave participants the necessary information to arrange the appointment themselves.

For those participants who reported that they would continue to inject despite recommendations not to, the physician provided a prescription for syringes with instructions not to share or reuse and to dispose of each syringe properly. Physicians generally prescribed 100 syringes at a time, which was sufficient to provide most participants with sterile syringes for 1 month. However, syringes were prescribed according to the needs of the participant. For instance, some homeless participants preferred to receive fewer syringes because they had difficulty storing them.

Physicians discussed safer injection practices, such as cleaning the injection site with an alcohol wipe, using a tourniquet, rotating injection sites, and recognizing abscesses, cellulitis, and endocarditis. Participants also received counseling and education on overdose prevention and safe disposal of used syringes, along with a free biohazard bucket or handheld syringe disposal device. Participants were encouraged to return to the clinic as often as needed for medical care, referrals, or a prescription for syringes. Although the first prescription for syringes was only available after a medical appointment with the doctor, participants could request prescription refills over the telephone. Follow-up clinic appointments were scheduled as needed, with many participants returning 3 weeks after their baseline visit to receive serologic test results.

Certain amenities were available to participants during all clinic and interview appointments. These included hygiene products such as toothbrushes, toothpaste,

combs, soap, and shampoo and risk-reduction materials such as clean cotton balls, "cookers" (metal bottle caps), condoms (male and female), and lubricants. Snacks were always available, as were transportation vouchers to get to and from clinic or interview appointments and to referral appointments.

Each clinic was staffed by two doctors, a clinic coordinator, two interviewers and an outreach worker. Five internists and one family practitioner staffed the program during its first 3 years of operation, including one infectious disease and one addiction medicine specialist. In addition, the clinic served as a rotation site for two medical residents who were mentored in addiction medicine. Basic training for all nonmedical staff included Rhode Island Health Department–sponsored "HIV 101" and HIV pre- and posttest counseling training, and Miriam Hospital/Brown University–sponsored consent process training/review. Ongoing in-service trainings and seminars focused on issues such as overdose prevention; risk-reduction strategies; comorbid conditions, including hepatitis B and C; and homeless services.

The Pharmacies

Throughout the project, we worked with two pharmacies located near the clinic sites.[40] We established a billing agreement with the corporate office of these pharmacies and the PSP Study paid for syringe prescriptions filled at either of these two locations; participants could take their prescriptions elsewhere, but had to pay for their syringes if they did. Private foundation monies were used to pay for syringes. We periodically met with each of the participating pharmacists. In addition, pharmacy staff were given the pager number of the project director in case of problems.

Clinic and Assessment Follow-up

Follow-up clinic appointments were briefer than the baseline physician visit and included risk-reduction counseling, referrals, and prescriptions for syringes by the physicians. Physicians continued to encourage and offer HIV and other tests as appropriate, especially if participants had not undergone testing at baseline. They also offered the series of hepatitis B vaccination shots for those participants who had not completed them. PSP Study staff scheduled follow-up clinic appointments, but many participants dropped in during clinic hours rather than coming at a prearranged time.

Participants' follow-up interviews were targeted for 3, 6, and 12 months after baseline. Study staff contacted participants with reminder letters and phone calls when they were due for a follow-up interview. As with the baseline interview, these appointments were scheduled to occur during clinic hours to facilitate participants completing their interview and seeing the doctor. Participants received a graduated monetary reimbursement for each interview; the total reimbursement was $100 after completion of all four interviews.

Although the majority of interviews occurred within their targeted time frames (i.e., 3, 6, and 12 months), some participants did not return for their first follow-up interview until several months after the target date (and in a few cases, over 1 year later). Even if the participant was very late for his or her first follow-up interview, they were asked to return for the second follow-up interview 3 months later and for the third follow-up interview 6 months after the second.

RESULTS

Between June 1999 and December 2000, we enrolled 327 participants, with an average enrollment of 18 new participants a month. Within a few months of program

TABLE 1. Active IDUs enrolled in syringe prescription pilot study, Rhode Island, 1999–2000

Parameter	
Average age, years (n = 327)	Mean 38.3 (SD 9.84)
Gender (n = 327)	
Female (109)	33.3%
Male (218)	66.7%
Race (n = 326)	
White (179)	54.9%
African American/black (80)	24.5%
Hispanic/Latino (44)	13.5%
Native American or Alaskan Native (6)	1.8%
Other (17)	5.2%
Homelessness	
Ever homeless (n = 323)	79.9%
Currently homeless (n = 319)	45.4%
Education (n = 324)	
Less than high school (144)	44.4%
High school graduate or GED (104)	32.1%
Some college or technical school (76)	23.5%
Ever been in prison or jail overnight (n = 324)	89.5%
Average age first injected drugs, years (n = 322)	Mean 22.3 (SD 7.62)
Mean duration of injection, years (n = 322)	Mean 16.0
Last time injected drugs (n = 325)	
Today	45.9%
1–3 days ago	40.6%
4–6 days ago	3.4%
1–2 weeks ago	6.8%
Longer than 2 weeks	3.4%
Median daily injection frequency (n = 321)	Mean 4.0
Drug of choice to inject (n = 314)	
Heroin (278)	88.5%
Cocaine (31)	9.9%
Speedballs (4)	1.3%
Average cost of syringe, $ (n = 257)	Mean 4.6 (SD 1.98)
Primary syringe source in the last 3 months (n = 324)	
Friend/relative/partner (181)	55.9%
Person selling on street or from house (69)	21.3%
Needle-exchange program (58)	17.9%
Pharmacy (6)	1.9%
Other (10)	3.1%
Ever used needle-exchange program in Rhode Island? (n = 318)	Yes 40.9%
Syringe sharing	
Ever shared a syringe (n = 325)	Yes 76.0%
Shared a syringe in the last 30 days? (n = 322)	Yes 42.9%
Syringe reuse: number of times participant reuses a syringe (n = 319)	
Median	8
Minimum	1
Maximum	200

TABLE 1. ***Continued***

Parameter	
Health services use	
Have a doctor (n = 325)	37.2%
Have medical insurance (n = 318)	41.2%
Use emergency room for basic health service needs (n = 318)	41.8%
Visited the emergency room within the last year (n = 307)	68.1%
Number of emergency room visits within the last year (n = 305)	Mean 2.0 (SD 3.01)
Drug treatment ever?* (n = 316)	83.5%
Currently in some type of drug treatment* (n = 327)	31.2%
Results of most recent HIV test (self-report) (n = 298)	
Negative	81.2%
Positive	13.4%
No result/refused	5.4%
Reported using condom during last sexual encounter (n = 317)	34.4%

*Methadone, detoxification, 12-step program, or outpatient counseling.

initiation, the primary source of referral (79%) was word of mouth. Table 1 is an outline of the baseline characteristics of the participants.

The demographic makeup of the study cohort was 25% African American, 14% Latino, 55% white, and 33% female. Almost 80% of PSP Study participants reported homelessness in their lifetime, and 45% reported homelessness at time of enrollment. At baseline, a large proportion (43%) of participants reported sharing syringes within the previous 30 days, and participants reused each syringe a median of eight times. Only 20% of participants reported obtaining syringes from a reliable source, such as an NEP or a pharmacy. Only 37% reported having a primary care physician; 41% reported having insurance; 68% reported going to the emergency room in the last year; and 42% reported using the emergency room for their basic health care needs.

Over the course of participation in the study, 86% of the 327 enrolled participants saw a physician at least once, 68% at least twice, and 51% three or more times, with an average number of 3.2 visits (SD 3.18) per participant. A total of 68,990 syringes were picked up at the pharmacy. Of the participants, 71% picked up syringes at least once, 46% at least twice, and 32% three or more times. The median number of syringes picked up per participant was 100, with a minimum of 0 and a maximum of 3,600.

DISCUSSION

We describe here the first program to offer IDUs syringes by prescription in the context of medical care. We found that a PSP program is feasible; can attract a high-risk, underserved, and diverse population; and provides unique and synergistic benefits for IDUs in comparison to other approaches to improve syringe access. At baseline, participants reported unstable housing, high risk for injection-related illness, and lack of access to sterile syringes and primary health care services. Study participants were demographically similar in composition to those in the IDU-associated AIDS cases in Rhode Island.[41] The PSP Study had a greater minority representation than area methadone treatment programs (82% white)[42] and IDUs attending the state-funded

detoxification facilities (76% white) and NEP (85% white).[31] Less than half of participants reported having ever attended the Rhode Island NEP, suggesting that we successfully outreached to a different network of users or possibly pointing to NEP limitations, such as inadequate accessibility.

We received the support and ongoing participation of not only a group of physicians, but also pharmacists. Participating pharmacists appreciated the disease prevention rationale for providing syringes to IDUs and said that their involvement in this program made it easier for them to adjust to the subsequent deregulation and over-the-counter sale of syringes (in 2000). Throughout the duration of the study, there was cooperative interaction between IDUs and the pharmacists.

Syringe Prescription as a Means of Legal Syringe Access

Syringe prescription can provide IDUs with legal access to sterile syringes in places where such access is otherwise restricted. A prescription is currently required for sale or possession of syringes in six states: California, Delaware, Massachusetts (except NEPs), Nevada, New Jersey, and Pennsylvania. Seven states allow some sale or possession of syringes without a prescription (e.g., no more than 10 syringes), and 30 states or territories have drug paraphernalia laws that could be applied to syringes; 14 more have laws that exempt some possession of syringes. Prescription of syringes to IDUs is legal in 40 of these 44 jurisdictions and possibly legal in 2 more.[43]

In some cases, prescribing syringes may be the *only* available approach to provide legal syringe access for IDUs, for example, in places where NEPs are not allowed and possession of syringes requires a prescription. Even in places with NEPs, there are additional advantages of PSPs. PSPs may serve as an alternative for IDUs unable or unwilling to attend NEPs because of other barriers.[32] Also, in states where prescription is not legally mandated, having a prescription can improve access by reducing IDUs' fear of harassment by pharmacists. Pharmacy associations, corporations, and individual pharmacists retain considerable discretion with regard to sales of nonprescribed syringes.[44] Many pharmacists are eager to contribute their valuable services to preventing the spread of HIV; others have concerns about providing syringes to IDUs and may refuse service or make additional requirements (such as showing identification) for customers they think are IDUs.[40,45]

Physician–Patient Relationship

Perhaps the most remarkable feature of the program is that the relationship between the physicians and patients encompassed an acknowledgement of the patients' drug use. In more traditional health care settings, IDUs are unlikely to reveal their injection behavior to their physicians; consequently, physicians are unlikely to offer care and services related to drug use and injection.[46] The acknowledgment of drug use sets the stage for an open discussion about drug use and related issues. Physicians participating in the program reported that it served as a "window" into the life of addiction and allowed them to serve the needs of their addicted patients more thoroughly. Further, they reported that these experiences carried over into their other clinical practices. Anecdotally, participants appreciated the physician–patient relationship that encompassed an honest dialogue of their drug use.

We nurtured this relationship by providing low-threshold services such as drop-in hours, appointment flexibility, language and cultural competency, child care, and transportation tokens. The PSP clinic was organized for patients who injected, addressing their specific needs and creating a comfortable space for them. Participants

were welcome whether they arrived for a prescheduled appointment or just dropped in. Snacks and harm-reduction paraphernalia and pamphlets were always available, and all services were provided free of charge. Most important, PSP Study physicians, several of whom had years of experience treating addicted patients, offered nonjudgmental interactions and invited patients to discuss their drug use and its impact on their lives.[47]

The discussions that ensued included issues such as participation in the underground economy; exchanging sex for drugs or money; child custody issues; support and barriers to reducing or quitting drug use; and problems with violence and abuse. These discussions underscored how chaotic the lives of some of these individuals were and how many of them were at extremely high risk for transmission of infectious diseases as well as other medical, psychiatric, and psychological illnesses and violence. They also created unique opportunities for intervention and referral.

Linking Injecting Drug Users to Care

The syringe prescription program offered a "hook" into care for IDUs and encouraged an ongoing clinical relationship, establishing a basis for medical, substance abuse treatment, and social service interventions and linkages. Clinical staff provided much-needed medical care (such as HIV, hepatitis, tuberculosis, and syphilis screenings and hepatitis B vaccinations), as well as community referrals. Referrals varied widely and included drug treatment services such as detoxification and methadone, primary and specialty health care, domestic violence shelters, mental health services, meal programs, housing services, and financial assistance programs. Having a regular health care provider who was aware of, and concerned about, injection-related health risks facilitated continuity of care for patients who were passing in and out of drug treatment programs and incarceration.

Therefore, promoting access to sterile syringes is important in preventing the spread of disease and improving the health of IDUs. As IDUs vary in their ability to access syringes, implementing a number of approaches to syringe availability is crucial. Syringe prescription can serve as a complement to NEPs and over-the-counter pharmacy sales in providing access to sterile syringes for people who inject.

Limitations of the Study

The impact of syringe prescription depends, in part, on providers' ability to attract IDUs into care. We were quite successful in recruiting high-risk IDUs into care; however, the intervention took place in a somewhat artificial environment. Syringes were paid for and participants received monetary incentives over the course of their participation. In addition, the clinical services were geared specifically toward IDUs and not integrated into an already existing clinical practice. There was no control arm to evaluate thoroughly the impact of the intervention.

Finally, other limitations of the study include that we attracted a high-risk sample population as a result of our eligibility criteria, which selected for participants who currently had insufficient access to syringes. Nearly half our participants were homeless, and this may have affected program use and made participants less likely to follow up. In addition, the two pharmacies involved with our study were located near the clinics, and although this was convenient during interview or clinic visits, this may have been a barrier for other participants who lived further away and wished to call in for a prescription renewal.

Although participants received monetary incentives for their interview visits only, we arranged those visits, whenever possible, during clinic hours. However, participants were not required to see the doctor; they were paid for the interview

regardless, and 14% never made a physician visit. Despite the confounding factor of incentives, the study successfully distributed almost 69,000 syringes and provided an average of three medical visits per participant and voluntary disease screenings for half of the participants, all indicating that participants actively engaged in the intervention. Further analysis of the intervention (including which participants visited the doctor, underwent testing, and picked up syringes at the pharmacy), its impact on high-risk behaviors, and participant evaluation of the intervention is ongoing and will be presented at a later date.

To understand fully the potential of syringe prescription, implementation in other settings and further evaluations are required. The purpose of this demonstration study was to assess feasibility, including utilizing strategies that attract IDUs into care. Although recreating a clinic designed for IDUs may not be practical for most communities, adopting many of the strategies discussed may be possible and has been successfully employed in other settings[23,24] The steps recommended for implementing a syringe prescription program are listed here:

1. Know the local legal status of prescribing syringes in the state (the Temple School of Law website is a good place to start: http://www.temple.edu/lawschool/aidspolicy/apolicy.htm).
2. Obtain local support for syringe prescription. We built up a substantial amount of local support, including that of the state's medical society, pharmacists' association, and health department.
3. Provide low-threshold, nonjudgmental, culturally sensitive access to care and create links to other programs—especially substance abuse treatment programs—that can assist this population.
4. Include other harm-reduction strategies in the patient's care, such as advice not to share or reuse syringes or other injection equipment; to clean the injection site with an alcohol wipe; information on using a tourniquet, rotating injection sites, and preventing overdose. See the Harm Reduction Coalition Web site: http://www.harmreduction.org/index.html.
5. Assist patients in disposing of used syringes safely.
6. Engage pharmacist partners. This partnership mitigates problems that could arise, encourages a consistent message to patients, and utilizes an invaluable human resource.
7. Document this care in a medical record, including the assessment of risk, disease transmission, and ongoing substance abuse management. Document the need and rationale for prescribing syringes (disease prevention) and verify that attempts at alternative approaches were tried (i.e., referral to substance abuse treatment).
8. Evaluate outcomes if possible. With any new, unproven strategy, it is helpful to have data to evaluate the strategy to convince others to support it.

CONCLUSION

We have attracted a high-risk, diverse population of IDUs to an intervention that provides legal access to sterile syringes and a "hook" into medical care. This intervention does not need to be adopted by many physicians to have a significant impact in the injection drug–using community. PSP is an innovative intervention that has potential for a significant public health impact, as well as for changing the lives of individual patients. This may be an ideal component of a comprehensive

prevention intervention for HIV-infected individuals, as recently recommended by the Centers for Disease Control and Prevention.[48] The ability of this intervention to improve health outcomes, reduce risk behavior, and enhance linkage to substance abuse treatment services should be studied further.

ACKNOWLEDGEMENT

The project described was supported by the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration (1KD1 TI12037–01); the National Institutes of Health, Center for AIDS Research (P30-AI-42853); the American Foundation for AIDS Research (10630-EG); and the Open Society Institute/ Lindesmith Center (282941581). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the awarding agencies. We would also like to acknowledge and thank our dedicated staff, Christina Anastacio and Zoraida Torres; all the team members over the last 3 plus years who have contributed invaluably to the work of the project; and our Community Advisory Board, which has guided us throughout. Special thanks are given to Paul Fitzgerald and the staff of AIDS Care Ocean State, who provided space for clinical services and weekly camaraderie. Finally, we thank the study participants, whose enthusiasm and trust made this work possible.

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