



MAY 20 1998

**The Honorable Pete Stark
House of Representatives
Washington, D.C. 20515**

Dear Mr. Stark:

It was a pleasure to meet and talk with you at the Ways and Means Health Subcommittee hearing on April 23, 1998. Nancy-Ann Min DeParle and I appreciate your strong support for the Health Care Financing Administration (HCFA), and I look forward to working with you as we strive to improve the Medicare program.

At the conclusion of the April 23 hearing on Medicare appeals, you asked a question relating to the Medicare Conditions of Participation (CoP). Specifically, you asked whether the various Medicare statutory CoP provisions permit HCFA to require the use of a particular safety device that accompanies hollow-bore needles so as to mitigate the risk to health care workers of acquiring occupational blood borne infections caused by needle sticks.

The Medicare statutory requirements include broad CoP authority that would allow HCFA to mandate, by regulation, that hospitals and other providers use a particular kind of safety device when hollow-bore needles are used for venipuncture. We are concerned, however, that such an action would be counter-productive to our philosophy of encouraging provider flexibility in meeting quality standards. HCFA is committed, under the Administration's regulatory reform initiatives, to revising many of its quality regulations to focus on outcomes of care and eliminate unnecessary, burdensome, and costly procedural requirements. Although our current regulations rely heavily on structure and process requirements to achieve quality, the direction we are taking in our revised CoPs is to focus on health care outcomes and encourage flexibility in meeting standards, while eliminating outdated measures where possible.

The proposed hospital CoP, for example, are designed to give hospitals maximum flexibility to assimilate innovations in health care practice. We will impose specific process requirements only where there is industry-wide consensus or empirical evidence that these processes are predictive of desired outcomes for patients or safety for health care workers.

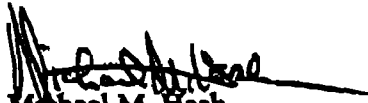
Page 2 - The Honorable Pete Stark

Over the past few years, many new safety devices to prevent percutaneous injuries have become available. Studies conducted by the Centers for Disease Control and Prevention have demonstrated the effectiveness of certain phlebotomy devices with safety features in reducing the number of health care workers' injuries. However, there are few data regarding the efficacy of other available safety devices, or their acceptability to health care workers.

Prevention of occupational injuries requires an institutional commitment to provide a safer work place that includes, but is not limited to, the use of safety devices. HCFA is committed to working with hospitals and other providers to foster safe environments for workers and patients, and we believe our more flexible CoP are the best means to ensure that providers promote the safety of their health care workers and patients.

HCFA shares your goal of protecting the safety of our Nation's health-care workers and the beneficiaries served by our programs. I appreciate your inquiry and encourage you to contact me if I can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael M. Hash", with a long horizontal line extending to the right.

**Michael M. Hash
Deputy Administrator**

To:

Chris Jennings

Fax:

Aug 9, 1995 456-5557

From:

Madeleine Golde

Date:

Aug. 9, 1995

Pages:

, including cover sheet.**fax**

Amended-
please disregard
previous memo.

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MHA

From the desk of...

Madeleine Golde

Senior Legislative Advocate, Legislative Dept.

Service Employees International Union

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U105-1000

August 9, 1999

Chris -

Approximately two weeks ago Carol Regan contacted you requesting your help with HHS regarding their lack of support for H.R. 1899/S.1140, the Health Care Worker Needlestick Prevention Act. I am following up since Carol is on vacation and the Office of the Secretary staff have informed us that they will respond to our request for clarification of HHS' position after Labor Day. We need your help to ensure that HHS does not come out opposing the bill. We have expressed willingness to meet with staff to clarify what we perceive as misinformation (see Andy Stern's letter).

SEIU, as well as a number of other unions, have been working on efforts to expand requirements for the use of safer needles in health care facilities for many years. We have been very active on this issue in the states and have had some success in getting legislation passed. This year, working with Reps. Pete Stark and Marge Roukema, H.R.1899 was introduced in May. The bill would amend OSHA's Bloodborne Pathogens standard to require the use of safe needles. Sens. Boxer and Reid have introduced it on the Senate side. There are 107 cosponsors on the House bill. We have not pushed the Senate bill until we have some Republican cosponsors.

OSHA and NIOSH support the bill. Alexis Herman stated her support for the use of safer needles at an AFL-CIO Executive Council Meeting. Vice President Gore also expressed his support at a recent SEIU conference.

At a conference call held on July 12 with HCFA, HRSA, NIH, FDA, and CDC staff a number of issues were raised that were the focus of their opposition (only NIOSH disagreed):

- The health care industry is already moving in the direction of using safer needles
- The requirement would cause major disruptions and involve huge costs
- There are not enough devices on the market
- Would require massive retraining
- Tort liability and workers comp will force the industry in the direction of safer needles.

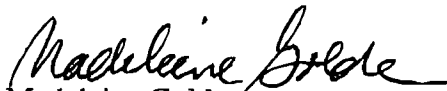
They clearly do not have good information with regard to costs, availability and training. Yes, there is movement in the right direction in the industry, but after 10 years of safer needles being on the market only 15% of hospitals are using some of the safer needles. Needlestick injuries are a very serious problem (a million a year) and are causing life threatening diseases, such as hepatitis C and HIV.

There is a tremendous amount of support for this legislation. It is very important to the health care unions. We could use your help in talking to Kevin Thurm, who Carol Regan originally talked to about this issue. The Assistant Secretary for Planning and Evaluation, Peggy Hamburg, apparently has the responsibility to set up a meeting between DOL and HHS to talk through the issues, but because of vacations this meeting can't take place until after Labor Day. I have talked with ASPE staff person Lesley Hardy who assures me that they want to address the issues as soon as possible.

Additionally, I would add that over the last year about 23 states have considered needlestick prevention legislation. Legislation has been signed into law in California, Tennessee, Maryland, and Texas. There is also legislation on the Governor's desk in New Jersey.

I have enclosed some additional material. Please feel free to call me at 202-898-3264.

Thank you for your help.


Madeleine Golde
Senior Legislative Advocate, SEIU



ANDREW L. STERN
International President

BETTY BEDNARCZYK
International Secretary-Treasurer

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8105-1000

July 19, 1999

The Honorable Secretary Donna Shalala
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

Ensuring a safe and healthy workplace is a top priority for the 675,000 health care members of SEIU. Yet 2,000 healthcare workers needlessly suffer preventable needlestick injury each day; some contracting hepatitis and HIV. Following a decade-long struggle in California, we were successful in gaining passage of a new law which gives healthcare workers access to needles and other sharps with integrated safety features.

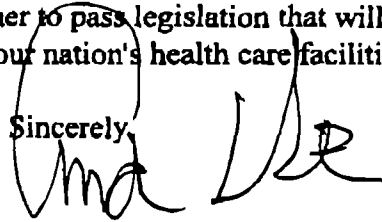
This law has received widespread bipartisan support as safer needles both minimize risk and save hospitals millions of dollars. CDC has found that such life-saving devices can reduce needlestick injuries by up to 76%. The State of California estimates that California alone will save nearly \$100 million due to the decreased need to test and treat needlestick victims.

Similar legislation was passed this year in Texas and Tennessee; the Governor of New Jersey will likely sign legislation this month, and many other states are considering similar action. However this is a national problem and federal legislation is desperately needed. SEIU with a number of groups have worked to introduce HR 1899/S. 1140. These measures are rapidly gaining co-sponsors from both sides of the aisle, and both Secretary Herman and NIOSH's Dr. Linda Rosenstock are supportive as well.

I understand that some HHS staff have raised potential concerns with the legislation. I want to stress that we are available to meet with HHS staff at any time to discuss this legislation, the supporting economic and medical research, and to address what we believe may be the industry's distortions.

I look forward to working together to pass legislation that will have a major impact on the quality of care in our nation's health care facilities.

Sincerely,


Andrew L. Stern
International President

cc: John Podesta
Chris Jennings

HR 1899, Health Care Worker Needlestick Prevention Act
Cosponsors as of 8/3/99

- | | |
|---------------------------------|---------------------------------------|
| 1. Pete Stark (D-CA) | 52. John McHugh (R-NY) |
| 2. Marge Roukema (R-NJ) | 53. Rosa DeLauro (D-CT) |
| 3. George Miller (D-CA) | 54. Ron Klink (D-PA) |
| 4. Rob Andrews (D-NJ) | 55. Mike Doyle (D-PA) |
| 5. Phil English (R-PA) | 56. Sam Farr (D-CA) |
| 6. Bob Matsui (D-CA) | 57. Martin Frost (D-TX) |
| 7. Robert Ehrlich (R-MD) | 58. Ben Gilman (R-NY) |
| 8. Mike Thompson (D-CA) | 59. Patrick Kennedy (D-RI) |
| 9. John Lewis (D-GA) | 60. John Larson (D-CT) |
| 10. Barney Frank (D-MA) | 61. Jim Turner (D-TX) |
| 11. Jan Schakowsky (D-IL) | 62. Barbara Lee (D-CA) |
| 12. Steve Rothman (D-NJ) | 63. Carolyn Maloney (D-NY) |
| 13. Peter DeFazio (D-OR) | 64. David Bonior (D-MI) |
| 14. Joseph Crowley (D-NY) | 65. Bennie Thompson (D-MS) |
| 15. Anthony Weiner (D-NY) | 66. Juanita Millender-McDonald (D-CA) |
| 16. Jim Maloney (D-CT) | 67. Elliot Engel (D-NY) |
| 17. Jim McDermott (D-WA) | 68. Christopher Smith (R-NJ) |
| 18. Mike McNulty (D-NY) | 69. Nick Lampson (D-TX) |
| 19. Brian Baird (D-WA) | 70. Nick Rahall (D-WV) |
| 20. Jim McGovern (D-MA) | 71. James T. Walsh (R-NY) |
| 21. Curt Weldon (R-PA) | 72. Danny Davis (D-IL) |
| 22. Donald Payne (D-NJ) | 73. Marcy Kaptur (D-OH) |
| 23. Nancy Pelosi (D-CA) | 74. Julian Dixon (D-CA) |
| 24. Jim Traficant (D-OH) | 75. George Brown (D-CA) |
| 25. Dale Kildee (D-MI) | 76. Jim Davis (D-FL) |
| 26. Louise Slaughter (D-NY) | 77. Peter King (R-NY) |
| 27. Collin Peterson (D-MN) | 78. Darlene Hooley (D-OR) |
| 28. Karen McCarthy (D-MO) | 79. Tom Udall (D-NM) |
| 29. Steven C. LaTourette (R-OH) | 80. Max Sandlin (D-TX) |
| 30. Bart Gordon (D-TN) | 81. Jose Serrano (D-NY) |
| 31. Lois Capps (D-CA) | 82. Jay Inslee (D-WA) |
| 32. Jerry Kleczka (D-WI) | 83. Major Owens (D-NY) |
| 33. David Wu (D-OR) | 84. Robert Wexler (D-FL) |
| 34. John Tierney (D-MA) | 85. William Delahunt (D-MA) |
| 35. Gary Ackerman (D-NY) | 86. Luis Gutierrez (D-IL) |
| 36. Jack Quinn (R-NY) | 87. Sheila Jackson Lee (D-TX) |
| 37. Carolyn Kilpatrick (D-MI) | 88. Jim Oberstar (D-MN) |
| 38. Maurice Hinchey (D-NY) | 89. Patsy Mink (D-HI) |
| 39. Michael Forbes (D-NY) | 90. Martin Meehan (D-MA) |
| 40. Frank Mascara (D-PA) | 91. Rush Holt (D-NJ) |
| 41. Nancy Johnson (R-CT) | 92. Elijah Cummings (D-MD) |
| 42. Tom Lantos (D-CA) | 93. Loretta Sanchez (D-CA) |
| 43. Carolyn McCarthy (D-NY) | 94. Ed Markey (D-MA) |
| 44. Bob Brady (D-PA) | 95. Eddie Bernice Johnson (D-TX) |
| 45. Michael Capuano (D-MA) | 96. Sue Kelly (R-NY) |
| 46. Bob Borski (D-PA) | 97. Dennis Kucinich (D-OH) |
| 47. Bruce Vento (D-MN) | 98. Earl Hilliard (D-AL) |
| 48. Neil Abercrombie (D-HI) | 99. Brian Bilbray (R-CA) |
| 49. Henry Waxman (D-CA) | 100. Donna Christianson (D-VI) |
| 50. Richard Neal (D-MA) | 101. Bob Filner (D-CA) |
| 51. Brad Sherman (D-CA) | |

OVER

102. Frank LoBiondo (R-NJ)
103. John Baldacci (D-ME)
104. Tom Cambell (R-CA)
105. Sam Gejdenson (D-CT)

106. Joe Barton (R-TX)
107. John Olver (D-MA)



Why We Need A Federal Needlestick Law

"It's too late for these devices to save my life now. Please don't wait for the list of others to grow and grow before effective action is taken."

—Peggy Ferro, San Francisco health care worker infected with HIV from a needlestick, in testimony to Congress February 2, 1992. Six years later, when Peggy died of AIDS at age 49, she was still working to pass a safer needles law in Congress.

Representatives Pete Stark (D-CA) and Marge Roukema (R-NJ) and Senators Barbara Boxer (D-CA) and Harry Reid (D-NV) have introduced the Health Care Worker Needlestick Prevention Act (HR 1899/S 1140), which would require health care facilities to use safer needles. Health care workers are dedicated to providing quality patient care, but with safety devices available they should not have to put their lives on the line every time they use a needle.

Needlesticks are a growing threat to health care workers.

- 600,000 to a million health care workers are accidentally stuck by needles each year.
- More than 1,000 of these workers will contract serious diseases, such as HIV, or Hepatitis B or C.
- If stuck by contaminated needles, workers and their families must live through a terrifying six months or longer to find out if they are infected.

Safer needles exist today that can prevent the spread of disease.

- There are a wide variety of safer needles on the market that have such features as a protective shield or a mechanism that automatically retracts the needles into the barrel after use.
- The FDA has cleared more than 250 such devices for marketing, yet only 15% of hospitals today use safer needles.
- Most hospitals are not buying or even evaluating safer needles, and regulatory agencies are not requiring them to use safer products.

Safer needles save lives and money for health care facilities.

- Hospital studies report that more than 80% of needlestick injuries are prevented when safer needles are used.

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- Even where no infection occurs, it costs up to \$3,000 to treat an injured health care worker with prophylactic drugs when they have had a high-risk exposure.
- One case of HIV can cost \$100,000 and one case of Hepatitis C, involving a liver transplant, can cost as much as \$750,000 (Hepatitis C is the leading cause of liver transplants).
- California, the first state to pass safer needle legislation, estimates it will save up more than \$100 million a year by using safer needles.
- As more health care facilities use safer needles, manufacturers will be able to reduce the price because of increased production volume.

States are leading the efforts to reduce needlestick injuries and deaths.

- In September, 1998, California became the first state to pass legislation requiring the California Occupational Safety and Health Administration to issue regulations mandating all health care facilities to evaluate and purchase safer needles by July 1, 1999.
- Tennessee and Maryland have also passed safer needle legislation and at least 17 other states are considering needlestick prevention legislation.
- The widespread bipartisan interest in state legislatures and the strong public support on this issue demonstrates that strong action should be taken immediately. Federal legislation is the only way to establish uniform national standards to prevent needlestick injuries.

The Health Care Worker Needlestick Prevention Act would...

- Amend the federal Occupational Safety and Health Administration's (OSHA) standards on bloodborne pathogens to require safer needles in health facilities.
- Require the involvement of workers who provide direct patient care in determining which safer needles and sharps to use in their workplaces.
- Provide for more accurate documentation of needlestick injuries.
- Create a national clearinghouse to collect data and develop evaluation and training guidelines.
- Require that public sector employees receive the same protections as private sector employees by requiring Medicare-funded hospitals to use safer needles.

**"For the price of a postage stamp, for 33 cents,
we could save health care workers lives."**

**—Andrew L. Stern, President
SEIU, Service Employees International Union**

Demand That Congress Act Now to Protect Health Care Workers!

Mike Hash

UPDATE ON NEEDLESTICK LEGISLATION

Representatives Pete Stark and Marge Roukema and Senators Barbara Boxer and Harry Reid have introduced the Health Care Worker Needlestick Prevention act, which would: amend OSHA standards on bloodborne pathogens to require safer needles in health facilities; require more accurate documentation of needlestick injuries; include a requirement that safer needles be used in the Medicare Conditions of Participation. The legislation has 107 cosponsors on the House side and three cosponsors on the Senate side (the third is Chuck Schumer).

According to the SEIU, more than one million health care workers are accidentally stuck by needles annually. Of those injured, more than 1,000 workers will contract serious diseases, such as Hepatitis B and C and HIV. More than 100 workers will die from these diseases.

Safe needles legislation has now been introduced in 25 states and the District of Columbia and has been signed into law in California, Tennessee, Maryland and Texas. In New Jersey, the bill is awaiting the governor's signature.

CURRENT HHS OBJECTIONS

HHS staff from FDA, HCFA, NIH, and CDC met with representatives of SEIU in June to discuss the Department's concerns about the Health Care Worker Needlestick Prevention Act. Although they have yet to take a formal position opposing the legislation, they raised the following concerns about requiring the use of safer needles:

- **May increase patient discomfort.** Because the sheath over the needle in the "safe needles" is bulky, it may make it difficult for the provider to position and insert the needle in a manner that causes the least amount of pain.
- * • **May increase costs.** HCFA is concerned that at a time where Medicare providers are struggling financially, to require the use of a new type of needle will increase their costs.
- **Dictating the practice of medicine is not within HCFA's jurisdiction.** HCFA is concerned that it is not appropriate to use the Medicare Conditions of Participation to dictate the practice of medicine, and would prefer to let market forces dictate the use of this new product.

It is also important to note that on May 20, 1998, Mike Hash sent a letter to Representative Stark stating that although they had concerns about the legislation, HCFA is open to imposing specific process requirements through the Medicare Conditions of Participation when there is industry-wide consensus or empirical evidence that these processes are predictive of desired outcomes for patients or increase safety for health care workers.

CURRENT OMB POSITION

OMB does not oppose this bill, since it would not increase Medicare or Medicaid expenditures.

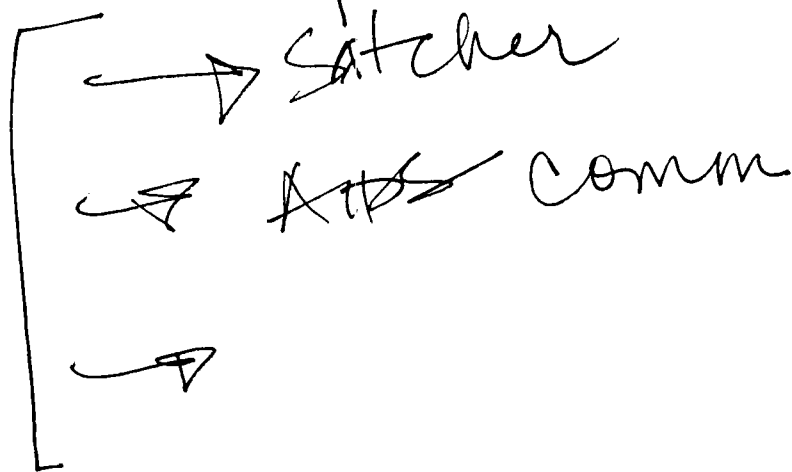
POSITION OF PROVIDER AND CONSUMER ADVOCACY COMMUNITIES

No one at HHS or OMB knows where the provider and consumer advocates are on this issue.

* cost estimate from Maryland Hosp Assn &
industry reps is ~~\$100,000~~ \$100,000 to outfit a hosp
with the new needles (old needles 47 cents; new 33 cents)

Federation pos

strongly validated
by ph community



410 205 5157 P.01/07

FAX TRANSMISSION

HEALTH CARE FINANCING ADMINISTRATION

Office of Legislation
Washington, D.C. 20201
202-690-5510
Fax: 202-690-8168

To: Devorah Adler

Date: August 10, 1999

Fax #: 456-5557

Pages: , including this cover sheet.

From: Julie Salz

Subject: Hollow-borne Needles

COMMENTS:

H.R. 1899 (Stark): Summary of HHS Concerns**Summary of bill:**

- Requires the Secretary of Labor (through OSHA), within a year of enactment, to amend the bloodborne pathogen standard to require use of "needleless systems" by all employers whose employees are exposed to human blood or bloodborne pathogens.
- Permits exceptions only where an employer demonstrates to the Secretary's satisfaction that, in that employer's circumstances, use of needleless systems would not promote employee safety, would interfere with patient safety or with the success of a medical procedure, or the devices are not commercially available.
- Requires HHS to apply the OSHA regulations to Medicare hospitals.
- Authorizes appropriation of \$15 million to NIOSH for a national clearinghouse on safer needle technology, which would develop a model training curriculum and establish a national data monitoring system.

HHS VIEWS

Background and overview: All HHS staff agree that transmission of bloodborne disease through needlestick injury is a serious public health concern, and measures should be taken to reduce the numbers. The disagreement is over whether the Stark bill is a step in the right direction or instead would create more problems than it solved.

Note attached statement by Vice President Gore, saying we need to address the issue. It's unclear whether he's indicating endorsement of a particular approach. On the one hand he mentions ongoing OSHA review of current guidelines. On the other he says "we are going to build on your historic victory in California last year", a reference to enactment of a State law mandating needleless technology, on which the Stark bill was modeled.

In favor: NIOSH

- A federal mandate is needed because the medical profession is moving too slowly toward adoption of new technology.
- The higher costs of the new technology will be (partly) offset by reduced costs of prevention and post-exposure treatment.
- DOL/OSHA has authority now to require this change by regulation, but a statutory mandate would dramatically reduce the time required, because OSHA would not need to justify the requirement.

Opposed: NIH, CDC/NCID, FDA, HCFA, ASPE, ASMB.

- It's bad policy and bad precedent to dictate the practice of medicine by federal statute.
- It's not justified here, where numbers of needlestick injuries are dropping, and the shift to alternative technologies is gradually happening without this intervention.
- It's a particularly bad idea to bypass rulemaking, which would provide a process for determining the merits and details of the federal standard, given the many issues on medical appropriateness (see below).
- Far less drastic measures can prevent most cases of transmission of disease through needlesticks, notably more aggressive vaccination of health care workers against Hepatitis A and B. Nor will a technology shift alone solve the problem: available devices generally protect against injury only after prescribed use, but not during prescribed use, when about half of needlestick injuries occur.
- The preferred approach is to increase education and training efforts, and to address the factors that have impeded change to new technology.
- Neither the technology nor health care professionals are yet ready for an across-the-board change.
 - FDA has not yet approved alternative needleless systems for all situations. We have not yet accumulated sufficient post-approval data to give us a clear picture on safety and effectiveness issues. However, some of the approved new technologies have proved to have design defects that either caused worker or patient injury or rendered them ineffective.
 - Massive numbers of health care workers must be trained in correct use of the new devices. Mandating a changeover before this has been accomplished is dangerous, as misuse of the new devices can render them ineffective or positively harmful. Numerous serious patient infections from injections have been traced to improper use of the new devices by inadequately trained health care workers.
 - There has been resistance to some of the new devices by both health care workers (who find the new devices harder to use) and patients (who find them more painful).

Undecided: OPHS/Office of HIV/AIDS

This office has advised that, since the information on the issue is conflicting, they are continuing to study the issue and have no position at this time.

Unanswered questions:

On a number of important points, the impact of the Stark bill is unclear:

- **Cost:** To what extent would increased costs (for the devices, training, etc.) be offset by savings from avoidance of exposure and injury?
- **Net payoff in injury reduction:**
 - The new devices could only be expected to reduce needlestick injury by about half.
 - Where new devices are being used, so many other factors are also involved (training, new safety procedures, etc.) that there are no good data on how much of the injury reduction is attributable to the new devices themselves.
- **Tort liability:** Could this legislation be invoked by a patient claiming injury through prohibited use of the old technology? By a health care provider to shield itself against suit for injury from improper use of the new technology?

(NOTE: Under workers' compensation laws, workers injured by needlesticks cannot sue their employers.)

Changes needed to Stark bill to eliminate (or at least reduce) HHS objections.

- No mandate to use alternative technologies should take effect until there has been rulemaking jointly by HHS and DOL to provide for exceptions to the requirement.
 - It should not be left either to the Congress or to DOL to decide when exceptions to the mandate should be granted. This concerns standards for the practice of medicine, not just worker safety. The HHS Secretary and the medical profession need to be consulted.
 - The bill's current exception provision (requiring individual employer appeals to DOL) seems patently designed to be an insuperable barrier, and is unacceptable. There will be many situations, particularly in the near term, when exceptions are appropriate. It should not be an individual physician's or facility's burden to prove this on a case-by-case basis.
- In order to minimize disruptive impact, the effective date of the mandate should be delayed until at least [a year] after promulgation of the final regulations, to allow time for worker training and public education, adjustment of supply contracts, etc.
- Criteria for exceptions should be broader, including considerations such as cost (as well as availability) of new devices, needs for worker training and public education, safety and efficacy in given circumstances, and other factors that come to the attention of the

SECRETION

Secretaries of HHS and Labor in the rulemaking process.

The provisions to require employer records and a national data bank on needlestick injuries must include adequate information security and privacy safeguards.

**MAY 20 1998**

The Honorable Pete Stark
House of Representatives
Washington, D.C. 20515

Dear Mr. Stark:

It was a pleasure to meet and talk with you at the Ways and Means Health Subcommittee hearing on April 23, 1998. Nancy-Ann Min DeParle and I appreciate your strong support for the Health Care Financing Administration (HCFA), and I look forward to working with you as we strive to improve the Medicare program.

At the conclusion of the April 23 hearing on Medicare appeals, you asked a question relating to the Medicare Conditions of Participation (CoP). Specifically, you asked whether the various Medicare statutory CoP provisions permit HCFA to require the use of a particular safety device that accompanies hollow-bore needles so as to mitigate the risk to health care workers of acquiring occupational blood borne infections caused by needle sticks.

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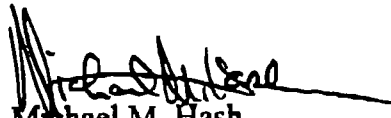
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HCFA shares your goal of protecting the safety of our Nation's health-care workers and the beneficiaries served by our programs. I appreciate your inquiry and encourage you to contact me if I can be of further assistance.

Sincerely,



Michael M. Hash
Deputy Administrator



March 17, 2000

NOTE TO BRUCE REED AND CHRIS JENNINGS

Chris

For your information.

Mary Beth

Mary Beth Donahue

Attachment



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 17 2000

The Honorable Nancy Pelosi
House of Representatives
Washington, DC 20515

Dear Ms. Pelosi:

Thank you for your letter of inquiry regarding the state of scientific knowledge of the public health effects of syringe exchange programs. As you know, HIV transmission related to injection drug use remains a serious public health concern, since many new HIV infections result from behaviors associated with injection drug use.

In response to your inquiry, I asked the Assistant Secretary for Health and Surgeon General, Dr. David Satcher, to provide me with an update on the scientific research regarding the effects of syringe exchange programs. I am attaching his response, which includes the Department's updated review of the published scientific literature on the public health effects of syringe exchange programs.

Thank you for your interest and commitment to the issue of slowing the HIV/AIDS epidemic in our country. I look forward to working together with you on this common goal.

Sincerely,

A handwritten signature in black ink, appearing to be "Donna E. Shalala", is written over the word "Sincerely,". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Donna E. Shalala

Enclosure

EVIDENCE-BASED FINDINGS ON THE EFFICACY OF SYRINGE EXCHANGE PROGRAMS: AN ANALYSIS FROM THE ASSISTANT SECRETARY FOR HEALTH AND SURGEON GENERAL OF THE SCIENTIFIC RESEARCH COMPLETED SINCE APRIL 1998

Introduction

The issues of substance abuse addiction and HIV transmission related to injection drug use remain serious public health challenges, and the need to define and implement effective public health interventions remain urgent. The scientific research continues to define the unique role that syringe exchange programs can play in curtailing the expansion of the HIV epidemic in vulnerable communities affected by substance abuse, as part of a well designed and implemented comprehensive HIV prevention strategy.

This paper provides a review of recently published peer-reviewed research on syringe exchange programs completed by senior scientists and public health experts within the Department of Health and Human Services. An overview of the research studies is followed by an annotated bibliography providing the published abstracts, directly quoted, and relevant commentary. In summary, the new studies contribute substantially to the strength of the data showing the following effects of effective syringe exchange programs: a decrease in new HIV seroconversions; an increase in the numbers of injection drug users referred to and retained in substance abuse treatment; and well documented opportunities for multiple prevention services and referral and entry into medical care. The data indicate that the presence of a syringe exchange program does not increase the use of illegal drugs among participants in syringe exchange programs, and in many cases, a decrease in injection frequency has been observed among those attending these programs.

Throughout the literature, the terms syringe exchange programs and needle exchange programs have been used interchangeably in characterizing programs providing sterile injection equipment to injection drug users. This paper will use the term syringe exchange program, except where a published abstract has specified needle exchange program.

Overview

Numerous studies have shown that syringe exchange programs reach and serve the most disenfranchised populations at high risk for HIV infection. In this regard, syringe exchange programs play a unique role in facilitating the engagement of these populations in meaningful prevention interventions and treatment opportunities, when implemented as part of a comprehensive HIV prevention and substance abuse strategy. The scientific evidence accumulated to date provides a basis on which municipalities that are heavily affected by an HIV epidemic driven by injection drug use should consider syringe exchange programs as a tool

for the identification, referral and retention of active users of injection drugs into these services, as part of a comprehensive HIV prevention plan.

Serious discussions about syringe exchange programs must be placed in the context of the HIV epidemic in this country. The urgency to address the consequences of substance abuse is clear, as injection drug use continues to fuel the HIV epidemic in the United States. As many as half of new HIV infections are caused by the sharing of injection equipment contaminated with HIV, either directly due to injection drug use, through unprotected sex with someone who acquired HIV infection through injection drug use, or birth to a mother who acquired HIV infection through these means (CDC, 1999). Women of color and their children continue to be disproportionately affected by HIV/AIDS due to injection drug use. An estimated three out of four AIDS cases among women are due to injection drug use or heterosexual contact with someone infected with HIV through injection drug use, and over 75% of new infections in children result from the consequences of injection drug use in a parent (CDC, 1999). All too often women are unaware of their risk, due to a distant history of drug use in a partner. The ability to halt this devastating epidemic, particularly among minority women and children, requires a three part strategy: (I) preventing substance abuse ; (ii) facilitating entry of those with addictions into substance abuse treatment; and (iii) establishing effective outreach to engage active and former drug users in HIV prevention strategies that will protect them, their partners and families from exposure to HIV, and bring them into substance abuse treatment and medical care. HIV prevention and treatment programs targeting HIV-infected injection drug users and their partners, and similar programs within criminal justice institutions, are also important components in preventing the transmission of HIV.

In the Department's prior reviews of the literature on syringe exchange programs in 1997 and 1998, there was discussion of the methodological issues and constraints present across most published studies in this area. These include self-reported measures and difficulty in establishing proper control groups. However, the Department's senior scientists continue to concur with the conclusion of the Institute of Medicine that the pattern of evidence is sufficiently strong to support scientifically clear conclusions regarding the utility of syringe exchange programs, in communities that choose to adopt them, as part of a comprehensive HIV prevention strategy.

A recent national survey of syringe exchange programs (Paone et al, 1999) found that a growing number of local communities have chosen to implement a syringe exchange program to reach injecting drug users who are not in substance abuse treatment, in order to reduce the transmission of HIV through reduction in drug use behaviors and unsafe injection practices. This survey also documented that, in addition to exchanging sterile syringes for contaminated ones, 97% of syringe exchange programs provide a range of other services including referral to substance abuse treatment, prevention education for sexually transmitted diseases, HIV counseling and testing, tuberculosis screening, and primary health care. These trends also were found in a 1997 national survey (CDC, 1998).

The biological rationale for removing contaminated injection equipment from circulation has been demonstrated in a new study by Abdala et al (1999), confirming empirical observations of previous studies. This study showed that HIV-1 can survive over 4 weeks in a contaminated syringe, remaining infectious to individuals who reuse that syringe over this prolonged period. Riley et al (1998) found that 10.9% of used syringes discarded in needle boxes at community locations tested positive for the HIV antibody, while Robles et al (1998) reported that 27% of contaminated syringes returned to a new needle exchange program were positive for HIV. The longevity of the HIV-1 virus, combined with its prevalence in used equipment in some communities, is basic to the public health rationale for removal of used syringes from the community environment.

Knowledge of the effectiveness of syringe exchange programs in reducing the sharing of injection equipment and reuse of contaminated syringes among injection drug users has recently been reinforced by a number of new studies (Heimer et al, 1998; Robles et al, 1998; Bluthenthal et al, 1998). Conversely, the closing of an established syringe exchange program in Connecticut was associated with an increase in reuse and sharing of contaminated equipment among injection drug users, exposing these individuals and their partners and families to an increased risk of preventable bloodborne diseases (Broadhead et al, 1999).

Recent research studies document the role that effective syringe exchange programs serve as mechanisms to engage very high risk and hard to reach individuals in substance abuse treatment services. Brooner et al (1998) found that half of syringe exchange program clients referred for substance abuse treatment actually entered treatment, with 76% completing the first 13 weeks of treatment. These results were achieved despite the fact that these clients had more severe drug use, more HIV risk behaviors, less employment and greater engagement in illegal activities than clients referred to substance abuse treatment from traditional sources. Hagan et al (In Press) reported reduced frequency of injection drug use among current and former users of a needle exchange program, and entry into methadone treatment programs among former, current and new users of a syringe exchange program. Strathdee et al showed that attendance at a syringe exchange program was positively associated with individuals entering detoxification services independent of other variables, again representing an important bridge that facilitates entry into substance abuse treatment.

Concerns about elevated HIV seroconversion rates linked to the use of syringe exchange programs remain scientifically unfounded, as the data primarily reflect the impact of multiple high-risk factors among individuals who participate in these programs – a population at extremely high risk that is not engaged in appropriate interventions through traditional mechanisms of outreach and treatment referral. Studies of HIV incidence among two study cohorts in Canada, and some recent data on the incidence of hepatitis B and hepatitis C in Seattle, are relevant as these relate to syringe exchange programs. In the Department's internal review of these data in 1998, careful attention was given to the study data on these Canadian cohorts, with the conclusion that syringe exchange programs were not associated with an increase in HIV seroconversions. Subsequent data from the

Montreal cohort (Bruneau et al, 1999) have confirmed this lack of association between HIV seroconversion and attendance at a syringe exchange program, with longer follow-up of the study participants and appropriate availability of sterile injection supplies. Efforts to identify any grounds for a causal relationship continue to show negative results (Schechter et al, 1999), when controlling for risk factors in the statistical model.

Public health scientists have long known about the incidence of hepatitis B (HBV) and hepatitis C (HCV) among injection drug users. These are highly infectious bloodborne diseases that are endemic among some drug-using populations. In Seattle, where there is a high prevalence of hepatitis C among injection drug users (70%-80%), participation in the syringe exchange program did not appear to be protective against new HCV or HBV infection (Hagan et al, 1999). Because of the high background prevalence of HCV in this population, a single exposure to a syringe used by an injection drug user carries a high level of risk that it will be contaminated with HCV. Although syringe exchange programs can greatly reduce the reuse of contaminated syringes, maximal prevention of HCV transmission among this population would require distribution of a sufficient volume of sterile syringes to preclude any reuse of injecting equipment. In contrast to this scenario, since HIV seroprevalence is yet low in this population, the empirical data support the potential of a protective effect for HIV among individuals seeking clean injection equipment at the syringe exchange program.

In summary, injection drug use is a driving force for new HIV infections, disproportionately affecting minority populations. Yet, HIV transmission via injection drug use is preventable. Efforts to halt the HIV epidemic are in part dependent on effective prevention interventions targeted to this population. Prevention will require successfully engaging injection drug users and bringing them into systems of care that offer substance abuse treatment, mental health, medical, and social support services. The availability of medical, social and preventive services alone are often not enough to engage the highest risk populations of active injection drug users, absent effective methods of outreach to this population. The scientific research has shown that well designed and implemented syringe exchange programs have demonstrated efficacy in engaging populations at severe risk for HIV and reducing the further spread of HIV among injection drug users, their sexual partners and children. Furthermore, these programs have not been shown to encourage the use of illegal drugs, and fit well into comprehensive substance abuse treatment strategies.

After reviewing all of the research to date, the senior scientists of the Department and I have unanimously agreed that there is conclusive scientific evidence that syringe exchange programs, as part of a comprehensive HIV prevention strategy, are an effective public health intervention that reduces the transmission of HIV and does not encourage the use of illegal drugs. In many cases, a decrease in injection frequency has been observed among those attending these programs. In addition, when properly structured, syringe exchange programs provide a unique opportunity for communities to reach out to the active drug injecting population and provide for the referral and retention of individuals in local substance abuse treatment and counseling programs and other important health services. The scientific evidence accumulated to date provides a basis on which

municipalities that are heavily affected by an HIV epidemic driven by injection drug use should consider syringe exchange programs as a tool for the identification, referral and retention of active users of injection drugs into these services, as part of a comprehensive HIV prevention plan.

ANNOTATED BIBLIOGRAPHY: SCIENTIFIC RESEARCH ON SYRINGE EXCHANGE PROGRAMS PUBLISHED SINCE APRIL 1998

Needle Exchange in the U.S. - National Surveys

Paone D, Clark J, Shi Q, Purchase D, Des Jarlais DC. Syringe exchange in the United States, 1996: A national profile. Am J Public Health 1999 Jan; 89(1):43-6.

ABSTRACT Objectives: This paper provides 1996 information on the status of US syringe exchange programs and compares these findings with data from our 1994 survey. Methods: In November 1996, questionnaires were mailed to 101 syringe exchange programs. Program directors were contacted to conduct telephone interviews based on the mailed questionnaires. Data collected included number of syringes exchanged, syringe exchange program operations, legal status, and services offered. Results: Eighty-seven programs participated in the survey. A total of 46 (53%) were legal, 20 (23%) were illegal but tolerated, and 21 (24%) were illegal-underground. Since 1994, there has been a 54% increase in the number of cities and a 38% increase in the number of states with syringe exchange programs. Eighty-four programs reported exchanging approximately 14 million syringes, a 75% increase from 1994. Syringe exchange programs also provided a variety of other services and supplies, and legal programs were more likely than illegal ones to provide these services. Conclusion: Despite continued lack of federal funding, syringe exchange programs expanded in terms of the number of syringes exchanged, the geographic distribution of programs, and the range of services offered.

COMMENT Many syringe exchange programs provide a range of preventive health services and health care, directly and through referrals. Of those programs surveyed, 97% provided referral to substance abuse treatment, 80% provided education to reduce risks of STDs, while many others provided HIV counseling and testing, primary health care, and tuberculosis screening in addition to exchanging sterile syringes for contaminated ones. The finding that legal programs are more likely to provide health services may reflect their ability to establish more regular hours and locations and to more formally refer clients to existing health, mental health and substance abuse treatment services. It has recently been estimated (Des Jarlais, 1999) that only 10% of injection drug users have access to needle exchange programs and their associated ancillary services, despite evidence that these programs are effective in reaching populations at very high risk for HIV and in need of substance abuse treatment services.

Centers for Disease Control and Prevention. Update: Syringe Exchange Programs – United States, 1997. Morbidity and Mortality Weekly Report, August 14, 1998, Vol 47 (31); 652-655.

(NO PUBLISHED ABSTRACT)

COMMENT This report provides an updated survey of the number and characteristics of syringe exchange programs (SEPs) in operation in the United States. The findings indicate continued expansion in the number, geographic coverage, and activity of SEPs in the United States. Of 113 SEPS contacted, 100 (89%) participated in the survey. These 100 SEPs reported operating in 80 cities in 30 States, the District of Columbia, and Puerto Rico. In 1997, 96 of the SEPs provided information about the number of syringes and reported exchanging approximately 17.5 million syringes (median; 57,343 syringes per SEP). The 10 largest volume SEPs (i.e. those that exchanged greater than or equal to 500,000 syringes) exchanged approximately 10.3 million (59%) of all syringes exchanged. Most of the 100 SEPs provided other public health and social services: 99% offered instruction to prevent sexual transmission of HIV and other sexually transmitted diseases; 96% provided IDUs with information about safer injection techniques and/or use of bleach to disinfect equipment; and 94% referred clients for substance abuse treatment programs. Health care services offered on site included HIV counseling and testing (64%), tuberculosis skin testing (20%), STD screening (20%), and primary health care (19%). The 100 SEPs operated in various settings, with 69% operating in multiple settings. SEPs reported receiving financial support from various sources including foundations, individuals, and state and local governments.

Risks Associated with Re-use of Syringes: A Laboratory study

Abdala N, Stephens PC, Griffith BP, Heimer R. (1999). Survival of HIV-1 in Syringes. J Acquir Immune Defic Syndr Hum Retrovirol 1999 Jan 1;20(1):73-80

ABSTRACT Summary: We performed a study to determine the duration of survival of HIV-1 in syringes typically used by injectors of illicit drugs (IDUs). We describe the effectiveness of a microculture assay in detecting viable virus in volumes of blood typical of those commonly found inside used syringes. Using this assay and modeling the worse-case situation for syringe sharing, we have recovered viable, proliferating HIV-1 from syringes that have been maintained at room temperature for periods in excess of 4 weeks. The percentage of syringes with viable virus varied with the volume of residual blood and the titer of HIV-1 in the blood. These experiments provide a scientific basis for needle exchange schemes, harm reduction, and other interventions among IDUs that support the nonsharing and removal of used syringes from circulation.

COMMENT Since the early years of the epidemic, researchers have documented that sharing of blood-contaminated equipment carries a substantial risk for transmission of HIV, and hepatitis B and C. These newly reported findings which document the long survival time of HIV-1 in syringes have implications for needle exchange program, in that the study confirms that a substantial

proportion of needles removed from circulation may have viable HIV and could transmit the infection. This data provides a scientific virologic rationale for the role syringe exchange programs play in reducing HIV transmission via used injection equipment, as these programs are organized to provide new, sterile injection equipment and remove from circulation potentially infectious needles and syringes.

Effectiveness of Needle Exchange Programs

Brooner R., Kidorf M., King V., Bielensohn P., Svikis D., Vlahov D. A Drug Abuse Treatment Success among Needle Exchange Participants. Public Health Reports, 113; Supplement 1: pp. 130-139, June 1998.

ABSTRACT Objective: Although lowering incidence rates of human immunodeficiency virus (HIV) transmission is the primary goal of needle exchange programs (NEPs), other desirable outcomes are possible. Referring exchange participants to more comprehensive drug abuse treatment programs has the potential to reduce or eliminate the use of drugs. This possibility was evaluated by comparing the treatment responses of new admissions with an outpatient opioid agonist treatment program in Baltimore, Maryland. Methods: New admissions (1994-1997) to an opioid agonist treatment program were first grouped by referral source (needle exchange, $n = 82$, vs. standard referrals, $n = 243$) and then compared on admission demographic and clinical variables and response to treatment during the first three months. Outcome measures included retention rates, self-reported drug use and injecting frequencies, self-reported illegal activities for profit, and results from weekly urinalysis testing for opioids and cocaine. Results: Patients from the NEP were significantly older and more likely to be male, African American, and unemployed than standard referral patients. Needle exchange patients also had a greater baseline severity of drug use than patients in the standard referral group. Despite these baseline differences, both groups achieved comparably good short-term treatment outcomes (including reduced drug use and criminal activity for profit); treatment retention was also good, although slightly better in the standard referral group (88% vs. 76%). Conclusion: These data demonstrate the feasibility and merits of creating strong linkages between NEPs and more comprehensive drug abuse treatment clinics.

COMMENT Two significant findings of this study are the ability of a NEP to successfully refer NEP clients to a substance abuse treatment program (51% of referrals were admitted to treatment) and the relatively high treatment retention rates for NEP-referred clients, despite greater severity of baseline drug use among this population compared to clients from standard referral sources. Establishing linkages between syringe/needle exchange programs and substance abuse treatment programs may lead to meaningful reductions in, or the elimination of, drug use among NEP clients in addition to the primary goal of reducing the risk of bloodborne infectious diseases in this population.

Hagan H, McGough JP et al. Reduced Injection Frequency and Increased Entry and Retention in Drug Treatment Associated with Needle Exchange Participation in Seattle Drug Injectors. In Press, Journal of Substance Abuse Treatment

ABSTRACT Objectives: The association between needle exchange, change in drug use frequency and enrollment and retention in methadone drug treatment was studied in a cohort of Seattle injection drug users (IDUs). Methods: Participants included IDUs classified according to whether they had used a needle exchange by study enrollment and during the 12-month follow-up period. The relative risk (RR) and the adjusted RR (ARR) were estimated as measures of the association. Results: IDUs who had formerly been exchange users were more likely than never exchangers to report a substantial ($\geq 75\%$) reduction in injection (ARR=2.85, 95% CL 1.47-5.51, to stop injecting altogether (ARR=3.5, 95% CL 2.1-5.9), and to remain in drug treatment. New users of the exchange were five times more likely to enter drug treatment than never-exchangers. Conclusions: Reduced drug use and increased drug treatment enrollment associated with needle exchange participation may have many public health benefits, including prevention of blood-borne viral transmission.

COMMENT The frequency of drug injection among active IDUs using a needle exchange program decreased during the time of this study. Both current users and new users of the needle exchange program were more likely to enter methadone treatment programs than IDUs who did not use the needle exchange program. Retention in methadone treatment at 12-month follow-up was 68% for former users of the NEP, 60% of current users of the exchange, and 45% of new users of the NEP. These findings support the role NEPs can play as a conduit into sustainable substance abuse treatment among heroin injectors.

Strathdee S, Celentano D et al. Needle Exchange Attendance and Health Care Utilization Promote Entry into Detoxification. In Press, Journal of Urban Health

ABSTRACT This study was undertaken to identify factors associated with entry into detoxification among injection drug users (IDUs), and to assess the role of needle exchange programs (NEPs) as a bridge to treatment. IDUs undergoing semi-annual human immunodeficiency virus (HIV) tests and interviews were prospectively studied between 1994 and 1998, during which time a NEP was introduced in Baltimore. Logistic regression was used to identify independent predictors of entry into detoxification, stratifying by HIV serostatus. Of 1490 IDUs, similar proportions of HIV-infected and uninfected IDUs entered detoxification (25% vs. 23%, respectively). After accounting for recent drug use, hospital admission was associated with four-fold increased odds of entering detoxification for HIV-seronegative subjects. Among HIV-infected subjects, hospital admission, outpatient medical care and having health insurance independently increased the odds of entering detoxification. After accounting for these and other variables, needle exchange attendance also was independently associated with entering detoxification for both HIV-infected (adjusted odds ratio [AOR]=3.2) and uninfected IDUs (AOR=1.4). However, among HIV-infected subjects, the increased odds of detoxification associated with needle exchange diminished significantly over time, concomitant with statewide

reductions in detoxification admissions. These findings indicate that health care providers and NEPs represent an important bridge to drug abuse treatment for HIV-infected and uninfected IDUs. Creating and sustaining these linkages may facilitate entry into drug abuse treatment and serve the important public health goal of increasing the number of drug users in treatment.

COMMENT This study provides a quantitative measure of the association between NEP attendance and subsequent entry into drug abuse treatment in an out-of-treatment population. NEP attendance was independently associated with entry into detoxification programs for both HIV-negative and HIV-infected clients. The researchers noted that the decreased strength of the association over time was likely due to external factors, such as the increased difficulty in obtaining admission for detoxification in Maryland and third party reimbursement barriers that differentially affected HIV-infected IDUs previously eligible for social security benefits. The research supports previous observations that NEPs can be a conduit to drug abuse treatment for very high risk populations.

Heimer R, Khoshnood K, Bigg D, Guydish J, Junge B. Syringe Use and Reuse: Syringe Exchange Programs in Four Cities. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 1998; 18(Suppl 1): S37-S44.

ABSTRACT Summary: We determined the effect of syringe exchange programs (SEPs) on syringe reuse patterns. Five methods were employed to estimate injections per syringe made by exchange clients in four cities. In San Francisco, Chicago, and Baltimore, self-reported data on the number of injections per syringe were obtained. In New Haven, self-reported injection frequencies were combined with syringe tracking data to derive two methods for estimating the mean injections per syringe. The average number of injections per syringe declined by at least half after establishment of SEPs in New Haven, Baltimore, and Chicago, all cities where such an analysis could be made. There were significant increases in the percentages of exchangers reporting once-only use of their syringes in San Francisco, Baltimore and Chicago, all cities where the data were amenable to this form of analysis. Self-report and syringe tracking estimates were in agreement that SEP participation was associated with decreases in syringe reuse by drug injectors. SEP participation was associated with increases in the once-only use of syringes. These findings add to earlier studies supporting the role of SEPs in reducing the transmission of syringe-borne infections such as HIV and hepatitis.

COMMENT This study uses several methods to assess syringe reuse among participants of syringe exchange programs, including syringe tracking data to minimize potential response bias associated with self-reported data. The decreased reuse of contaminated syringes observed over time in these study cohorts is significant in light of the previous study by Abdala et al, irrespective of the absence of a control group of non-SEP clients.

Bluthenthal RN, Kral AH, Erringer EA, and Edlin BR. Use of an Illegal Syringe Exchange and Injection-Related Risk Behaviors among Street-Recruited Injection Drug Users in Oakland, California, 1992-1995. Journal of AIDS and Human Retrovirology, 1998.

ABSTRACT Objective: To determine factors associated with syringe and injection supply sharing among injection drug users (IDUs) in a community with an illegal underground syringe exchange program. **Methods:** From 1992-1995, semi-annual cross-sectional samples of IDUs were recruited in Oakland, CA. To account for multiple observations from the same individual, we used general estimating equations with logit transformations to determine factors associated with sharing syringes and other injection works. **Results:** 1304 IDUs were interviewed; 684 (53%) returned for more than one interview. 2830 interviews were available for analysis. SEP use increased and syringe and supply sharing declined from 1992 to 1995 among study participants. In multivariate analysis, SEP users were less likely to share syringes than non-SEP users (adjusted odds ratio [AOR] = 0.57; 95% confidence interval [CI] = 0.46-0.72). SEP use was not significantly associated with the sharing of injection supplies (AOR = 0.85; 95% CI = 0.68 - 1.07). Syringe sharing and injection supply sharing were significantly less likely to occur among African American and HIV-positive IDUs. **Conclusions:** These data suggest that illegal SEPs can be effective HIV prevention programs. Lower rates of syringe-based risk factors among African American and HIV-positive IDUs are encouraging.

COMMENT The researchers re-examined seven semi-annual waves of interviews from both the baseline and follow-up assessments of IDUs who lived in a community with an illegal SEP. Variables that previous research has suggested would have an impact on syringe sharing, such as substance abuse treatment, marital status, gender, and income were included in the models to control for potential confounding factors, as well as control for the potential effects of temporal trends in use of NEPs and syringe sharing. Substantial declines in syringe sharing were observed over the interview periods among users of the SEP compared to non-SEP users. Use of the SEP increased from 5% in 1992 to 36% in 1995 despite arrests of program volunteers during the study period. The study adds to the literature in that it shows a decrease in syringe reuse is also associated with an illegal SEP, whereas most other reported studies come from legal or community-tolerated SEPs.

Bruneau J, Lachance N et al. Changes in HIV Seroconversion Rates of IDUs Attending Needle Exchange Programs in Montreal: The Saint-Luc Cohort. Canadian Journal of Infectious Diseases, [Supplement] May 1999.

ABSTRACT Objectives: From 1988 to 1995, we observed a positive association between NEP attendance and HIV seroconversion. Since 1995, modifications have been implemented in needle exchange programs (NEPs) in Montreal, including the opening of new distribution sites and the lifting of the syringe quota. The objective is to examine the association between NEPs and HIV seroconversion in the Saint-Luc Cohort after January 1995. **Methods:** Recent injection drug users (IDUs) were recruited by word-of-mouth and through substance abuse treatment agencies.

Information was collected and HIV status was assessed at each visit. The association between factors on demographics, drug and sexual behaviours and HIV seroconversion was assessed using univariate and multivariate Cox proportional hazards regression. All current IDUs participating in the Saint-Luc cohort as of January 1995 were included in the analysis. Results: The post-1995 cohort included 981 seronegative subjects, 797 men and 184 women. Mean age was 34.5, and 42% reported NEP attendance in the past 3-6 months. 83% and 34% used cocaine and heroin respectively in the past 3-6 months. 42.3% reported unstable housing. From January 1995 to September 1998, 68 seroconverted for a global incidence of 4.3 per 100 person-years (CI 95%: 3.4-5.5 : 4.2 per 100 person years (CI 95%: 2.8-6.1) among NEP attenders, and 4.4 per 100 person-years (CI 95%: 3.1-5.9) among non-attenders. (HR: 0.97 [0.60 - 1.58]). In a Cox proportional hazards model, factors independently associated with HIV seroconversion were:

<u>Factors</u>	<u>Hazard Ratio</u>	<u>95% CL</u>
Drug Injected (ref: other)		
Cocaine IV (3-6 months)	2.20	0.5-9.9
Heroin IV (3-6 months)	0.33	0.2-0.7
Nb injections last month (ref: 0)		
1-30	2.18	0.9-5.5
30-100	2.22	0.8-6.1
>100	3.81	1.4-10.4
Booting 3-6 months	2.04	1.0-4.1
Inject alone 3-6 months	1.91	0.9-3.9
Sharing with HIV+	2.29	1.3-3.9
Gender (ref: female)	2.70	1.0-7.6

Conclusion: After 1995, no association was found between NEP attendance and HIV seroconversion among current IDUs followed in the Saint-Luc cohort. This situation is different from what was observed from 1988 - 1995, and coincided with modifications of needle exchange programs in Montreal.

COMMENT Remis, Bruneau and Hankins published a related paper titled "Enough Sterile Syringes to Prevent HIV Transmission Among Injection Drug Users in Montreal?", in the Journal of Acquired Immunodeficiency Syndrome and Human Retrovirology; Vol 18, Suppl.I, July 1998. The study compared the estimated number of syringes required by injection drug users in 1994 with the number of syringes distributed through needle exchange programs. Syringes distributed through NEPs addressed less than 5% of the estimated demand for syringes by IDUs in Montreal in 1994. The authors advanced the hypothesis that unless the disparity between unmet need and available syringes was reduced, it is unlikely that sufficient syringes would be available to prevent HIV transmission. The observation in this study that NEP use and HIV seroconversion were not associated since 1995 in the Montreal cohort is coincident with modifications of the NEP program and differs from pre-1995 data.

Robles R, Colon H, Matos T, Finlinson H, Munoz A, Marrero C, Garcial M, Reyes J. Syringe and Needle Exchange as HIV/AIDS Prevention for Injection Drug Users in Puerto Rico. Health Policy, 1998; Vol. 45: 209-220.

ABSTRACT This study evaluated the effectiveness of the first needle exchange program (NEP) established in Puerto Rico. The data for this study were collected during the first months of the NEP from July 1995 to March 1996 in 13 communities of the San Juan metropolitan area. Subjects were the participants of two modalities of the NEP: a mobile team and a community-based drug treatment program. During the 3-week evaluation period, 2401 injection drug users (IDUs) were recruited, resulting in a total of 19,195 exchange contacts and 146,323 syringes exchanged. No significant change in drug injection was observed. However, the program was effective in reducing sharing of syringes and cookers. The study suggests that the NEP did help in reducing needle sharing in Puerto Rico. However, the HIV seropositivity in returned syringes suggests the need to continue aggressive prevention programs to arrest the epidemic among IDUs. However, factors related to the socio-cultural environment as well as cultural norms and traditions need to be considered when planning and expanding NEPs.

COMMENT In this study, 40% of a sample of 1075 syringes returned to the NEP and studied showed a 27% seropositivity rate for HIV. A significant increase in the number of returned syringes was observed over the evaluation period (12.4% rising to 32.5% at 8 months). The importance of decreasing needle circulation time as an HIV prevention intervention is particularly acute in this setting with high rates of HIV seropositivity in contaminated syringes. Entry into substance abuse treatment among study participants increased over time, with 28% of the NEP participants reporting treatment entry by the seventh month after the NEP began. Both short term and long term harm reduction goals among IDUs were advanced by the NEP.

Des Jarlais DC, Perlis T, Friedman SR, Deren S et al. Declining Seroprevalence in a Very Large HIV Epidemic: Injecting Drug Users in New York City, 1991 to 1996. Am J Public Health, 88(12): 1801-1806, 1998.

ABSTRACT Objective: This study assessed recent trends in HIV seroprevalence among injecting drug users in New York City. Methods: We analyzed temporal trends in HIV seroprevalence from 1991 to 1996 in 5 studies of injecting drug users recruited from a detoxification program, a methadone maintenance program, research storefronts in the Lower East Side and Harlem areas, and a citywide network of sexually transmitted disease clinics. A total of 11,334 serum samples were tested. Results: From 1991 through 1996, HIV seroprevalence declined substantially among subjects in all 5 studies: from 53% to 36% in the detoxification program, from 45% to 29% in the methadone program, from 44% to 22% at the Lower East Side storefront, from 48% to 21% at the Harlem storefront, and from 30% to 21% in the STD clinics (all $p < .002$ by chi square tests for trends). Conclusions: The reductions in HIV seroprevalence seen among injecting drug users in New York City from 1991 through 1996 indicate a new phase in this large HIV epidemic. Potential explanatory factors include the loss of HIV seropositive individuals through disability and death and lower rates of risk behavior leading to low HIV incidence.

COMMENT This article is included here as a snapshot of HIV prevalence among IDUs in a major city with the largest AIDS epidemic among IDUs in the world. Risk reduction programs including needle exchange programs, street outreach, and detoxification programs were components of the public health response to the epidemic during the years studied. An overall reduction in HIV seroprevalence among IDUs was found, in the setting of a stable number of IDUs. Declines in HIV transmission-related behavior, such as reusing contaminated injection equipment and lending it to others, were reported from several sites. Many factors might contribute to the decline in HIV seroprevalence. The presence of a broad-based prevention effort focused on IDUs, which has included NEPs, has been associated with lower infection rates among the IDU population.

Hagan H, McGough JP et al. Volunteer Bias in Non-Randomized Evaluations of the Efficacy of Needle Exchange Programs. Journal of Urban Health (Accepted for publication)

ABSTRACT Objective: Nonrandomized comparisons of the incidence of HIV and hepatitis between injection drug users (IDUs) who do and do not attend voluntary needle exchange programs may be subject to bias. To explore possible sources of bias, we examined characteristics associated with voluntarily beginning or ceasing to participate in the Seattle needle exchange. Methods: In a cohort of 2879 IDUs, a standardized questionnaire measured characteristics present at enrollment. We examined the relation of these characteristics to the proportion of IDUs who began to use the program during the ensuing 12-month follow-up period, and to the proportion of current exchangers who dropped out during that period of time. Results: Thirty-two percent of the 494 never-exchangers at baseline attended the program during follow-up: those who reported sharing syringes or who were homeless at enrollment were more likely to become new exchanger users (adjusted risk ratio for becoming an exchange user (ARR) = 1.8 for those who shared syringes, and ARR = 2.2 for those who were homeless). Sixteen percent of 1274 current exchangers stopped using the exchange during follow-up, with daily injectors (ARR = 0.6) and those who reported backloading (ARR = 0.6) being relatively less likely to drop out of the exchange. Conclusions: The analysis suggests that IDUs participating in needle exchange programs at a given point in time may include a particularly high proportion of those injectors whose pattern of drug use puts them at elevated risk of blood-borne viral infections.

COMMENT This study of participants in SEP programs shows that individuals who were homeless and those sharing needles were the most likely to utilize an SEP, and persons who stopped attending the SEP were less likely to be injecting daily or using risky injection techniques. This SEP is attracting and retaining those persons with greatest risk factors for bloodborne disease transmission.

Cost-Effectiveness of Needle Exchange Programs

Holtgrave DR, Pinkerton SD, Jones TS, Lurie P, Vlahov D. (1998). Cost and cost- effectiveness of increasing access to sterile syringes and needles as an HIV prevention intervention in the United States. J Acquir Immune Defic Syndr Hum Retrovirol 1998;18 Suppl 1:S133-8.

ABSTRACT Summary: We determined the cost of increasing access of injection drug users (IDUs) to sterile syringes and needles as an HIV prevention intervention in the United States and the cost per HIV infection averted by such a program. We considered a hypothetical cohort of 1 million active IDUs in the United States. Standard methods were used to estimate the cost and cost-effectiveness of policies to increase access to sterile syringes and syringe disposal at various levels of coverage (e.g. a 100% coverage level would ensure access to a sterile syringe for each injection given current levels of illicit drug injection in the United States; a 50% coverage level would ensure access to one half of the required syringes). A mathematical model of HIV transmission was employed to link programmatic coverage levels with estimates of numbers of HIV infections averted. A policy of funding syringe exchange programs, pharmacy sales, and syringe disposal to cover all illicit drug injections would cost just over \$423 million (U.S.) for 1 year. One third of these costs would be paid for as out-of-pocket expenditures by IDUs purchasing syringes in pharmacies. Compared with the status quo, this policy would cost an estimated \$34,278 (U.S.) per HIV infection averted, a figure well under the estimated lifetime costs of medical care for a person with HIV infection. At very high levels of coverage (>88%), the marginal cost-effectiveness of increased program coverage becomes less favorable. Although the total costs of funding large-scale IDU access to sterile syringes and disposal seem high, the economic benefits are substantial. Even at high levels of coverage, such funding would save society money. As part of a comprehensive program of HIV prevention, policies to increase IDUs access to sterile syringes urgently need further consideration by public health decision makers.

COMMENT The estimates provided in this study should be considered in the context of an estimated \$108,469 lifetime medical cost of treating an individual with HIV infection, which is three fold greater than estimates of preventing one HIV infection.

Kahn J. Economic Evaluation of Primary HIV Prevention in Injection Drug Users. In Holtgrave D., edit: **Handbook of Economic Evaluation HIV Prevention Programs.** Plenum Press, New York: 1998.

NO PUBLISHED ABSTRACT In this paper, the author implemented the Yale Circulation Model using empirical data obtained from 4 NEP programs in 4 Cities to assess the cost-effectiveness of such an HIV prevention intervention. The Yale Circulation Model is a mathematical model used to estimate the change in the number of new HIV infections based on lowering the HIV prevalence in used needles as a result of reducing the circulation time of contaminated syringes. The author applied a simplified Yale Needle Circulation Model to 4 hypothetical needle exchange programs in areas with differing HIV prevalence and incidence rates. The researcher reports that reductions in HIV incidence rates varied across cities from 17% to 70% across the 4 hypothetical settings. Higher reductions were associated with more needles per client-year. Greater efficiency was associated with low cost per needle exchanged. The estimated cost savings per HIV infection averted ranged from \$12,000 to \$98,000. Greater efficiency was associated with low cost per needle exchanged. The author suggests that for a fixed number of needles, the absolute impact is higher when the needles are spread out among a greater number of clients.

COMMENT This study shows that variations in the cost-effectiveness of syringe exchange programs will occur, depending on the type and structure of the program, and the HIV prevalence and incidence in the geographic area to be served.

Risk Associated with Closing a Needle Exchange Program

Broadhead R, Van Hulst Y, and Heckathorn D. (In Press). Termination of an established needle exchange: A study of claims and their impact. Social Problems, 1999; Vol. 46, No. 1: 48-66.

NO PUBLISHED ABSTRACT This study assessed the impact of the Windham CT needle exchange program closure on risk behaviors, and discarded syringes. The project conducted 330 initial and 173 follow-up risk assessment interviews of NEP participants between 1994 and 1997 while the NEP was in operation. Following the closure of the NEP in 1997, researchers conducted 111 interviews at 11 months post closure and 78 interviews 3 months later. In addition, starting 7 months prior to the closure of the NEP and for a period of 1 and ½ years following the NEP closure the research team surveyed public outdoor areas for discarded syringes where high levels of drug use occurred. Findings indicate that while the NEP was in operation, 14% of the sample reported obtaining syringes from unsafe sources compared with 36% following the closure of the NEP. Prior to the closure of the NEP, the mean number of times a syringe was re-used before disposal was 3.52 compared with a high of 8.18 times following the NEP closure. The closure of the NEP was also found to increase self-reported syringe sharing. Sixteen percent of NEP participants reported sharing a syringe within the last 30 days while the NEP was in operation compared with 34% of participants after the NEP closed. Finally, no difference in the number of discarded syringes in public places was detected, suggesting that the closure of the NEP had no effect on the number of discarded syringes in the area.

COMMENT This study documented the experience of IDUs in one community following closure of a NEP. Risk behaviors increased among IDUs when they no longer had access to the services of the needle exchange program, increasing the likelihood of HIV transmission resulting from multiperson reuse of syringes.

Related Article by Same Authors: Broadhead RS, van Hulst Y, Heckathorn, DD. The Impact of a Needle Exchange's Closure. Public Health Reports 1999; 114: 439-447.

Needle Exchange Related Issues

Junge B, Vlahov D, Riley E, Huettner S, Brown M, Beilenson P. Pharmacy access to sterile syringes for injection drug users: attitudes of participants in a syringe exchange program. J Am Pharm Assoc (Wash) 1999 Jan-Feb;39(1):17-22.

ABSTRACT Objective: To examine attitudes of participants of a van-based syringe exchange program (SEP) toward the hypothetical prospect of pharmacy-based syringe access. Design: One-time, cross-sectional survey. Setting: Baltimore, Maryland. Participants: 206 injection drug users who participate in the Baltimore SEP. Interventions: Face-to-face interviews. Main Outcome Measures: Location preferred for obtaining syringes, drug and syringe use, past experience with pharmacies, and willingness to pay. Results: The sample was 67% men, 95% African American, and 95% unemployed; mean age was 39.8 years. A total of 19% of respondents had bought syringes at a pharmacy during the prior six months. Some 37% reported having been turned down when asking for syringes at a pharmacy, most commonly due to lack of identification to prove diabetic status (50%). If legal restrictions were lifted, 92% of respondents would obtain syringes from pharmacies, and would be willing to pay a mean price of \$0.80 (median = \$1.00) per syringe. Women were more likely than men to report the intention to switch from van-based SEP to pharmacy (57% versus 38%, $p = 0.045$). Conclusion: If current legal restrictions were lifted, pharmacies would be a viable syringe source appealing particularly to women, suggesting gender-specific access issues that should be addressed. The per syringe price that study participants would be willing to pay exceeds typical retail prices, suggesting that pharmacists could charge enough per syringe to recoup operational costs.

COMMENT This study reflects a willingness and effort to obtain sterile injection equipment at pharmacies by a substantial percentage of IDUs currently using a van-based syringe exchange program. It highlights the impact of legal restrictions on syringe availability through pharmacies for the IDU population. The study notes that pharmacies provide an alternative controlled distribution mechanism of sterile injection equipment and are widely available in most communities.

Paone D, Cooper H, Alperen J et al. HIV Risk Behaviors of Current Sex Workers Attending Syringe Exchange: The Experiences of Women in five US Cities. AIDS CARE 1999; 11 (3): 269-280.

ABSTRACT Existing research indicates that sex workers who inject drugs are vulnerable to HIV infection through both risky sexual and drug use practices. This study is the first attempt to learn whether this increased risk persists among current sex workers who participate in syringe exchange programmes (SEPs). With data from interviews with randomly selected participants in five US cities, we compared the demographic characteristics, sexual risk behaviours, drug use practices, emotional and physical health, and SEP utilization patterns of currently active female sex workers who attend SEPs with female SEP participants who do not engage in sex work. Data indicate that women enrolled in SEPs who were currently trading sex typically reported greater HIV risk than women non-sex workers. Current sex workers reported higher levels of risk for every drug risk variable examined in bivariate analysis. They were more likely than other women to inject with a syringe previously used by someone else, to inject daily and to attend shooting galleries; they were less likely to use a condom with their primary partners and to report higher levels of psychological distress than their counterparts. The relationship between sex work status and risky injection practices persisted when potential confounders were controlled for in multivariate analysis. SEPs

can serve a pivotal role in providing sex workers with services and referrals which would help them reduce risk behaviours.

COMMENT This study documents that women who attend SEPs and engage in sex work typically report greater HIV risk than women non-sex workers attending SEPs, reinforcing the importance of this variable. In this study, current sex workers engaged in heavier drug use than other women; reported using a greater variety of injection and non-injection drugs; injected substantially more frequently than both sexually active and non-sexually active women, with sex workers injecting on average 124 times a month while other women injected approximately 82 times a month ($p < 0.0005$); were more likely to inject daily and smoke crack daily than their counterparts; and were more likely to be at risk of bloodborne infection through risky injection practices such as renting, buying or borrowing used syringes for injection and visiting a shooting gallery more often than other women.

Riley E, Beilenson P, Vlahov D, Smith L, Koenig M et al. Operation Red Box: a pilot project of needle and syringe drop boxes for injection drug users in East Baltimore. J Acquir Immune Defic Syndr Hum Retrovirol 1998;18 Suppl 1:S120-5.

ABSTRACT Summary: We assessed the acceptability and the use of a community-based needle and syringe disposal project designed to serve injection drug users. In June 1996, three surplus U.S. mail collection boxes were painted red and used as syringe and needle drop boxes in locations with high drug use in East Baltimore. Acceptance of the drop boxes was measured by focus groups of residents, drug users, and police, held before and after project implementation. Use was measured by weekly counts of needles recovered from the red boxes. A sample of all deposited needles was randomly chosen for needle washing and subsequent HIV antibody testing. Community impact was measured by systematic surveys of needles discarded on public sidewalks, in areas with and areas without drop boxes. Before implementation, members of focus groups expressed concerns that drop boxes could convey mixed messages to youth (e.g. seeming to condone drug use), might result in increased loitering, and could further community stigmatization. After project implementation, all focus groups expressed support of project expansion. In the first 10 months, 2971 needles were collected. Of 156 needles tested, 10.9% were positive for HIV antibody. Needle counts on the street showed no significant change in red box areas compared with control areas. In this pilot project, red boxes were accepted by the community and drug users. Police officers also used the boxes to dispose of confiscated needles. Although limited in the number of drop boxes and follow-up time, this pilot project shows promise as a community-based method of safe needle disposal.

COMMENT This paper addresses the important issue of safe disposal of used injection equipment. While the study design is not directly linked with a syringe exchange program, the issues of access to, and safe disposal of, used syringes are important to consider as components of an overall public health and safety effort. The drop boxes were placed in high drug use areas of Baltimore, which has existing NEPs. The 11% HIV antibody positivity rate in discarded syringes

highlights the role that safe disposal mechanisms can play in reducing the circulation time of infected needles, regardless of the presence or absence of a syringe exchange program.

Needle Exchange and Hepatitis B and C Viruses

Hagan H, McGough JP, Thiede H, Weiss N, Hopkins S, Russell A. (1999). Syringe exchange and risk of infection with hepatitis B and C viruses. *American Journal of Epidemiology*, 149, 203-213.

ABSTRACT The authors utilized a cohort study among Seattle injection drug users (IDUs) to assess whether participation in a syringe exchange program was associated with incidence of hepatitis B virus (HBV) and hepatitis C virus (HCV) infection. Susceptible IDU subjects (187 seronegative for antibody to HCV, and 460 seronegative for core antibody to HBV) were identified in drug treatment, corrections, and social service agencies from June 1994 to January 1996, and followed for seroconversion one year later. The subjects included in the analysis were Seattle-King county (Washington State) area IDUs enrolled in a larger multipurpose cohort study, the Risk Activity Variables, Epidemiology, and Network Study (RAVEN Study). There were 39 HCV infections (20.9/100/year) and 46 HBV infections (10.0/100/year). There was no apparent protective effect of syringe exchange against HBV (former exchange users, relative risk (RR) = 0.68, 95% confidence interval (CI) 0.2-2.5; sporadic exchange users, RR = 2.4, 95% CI 0.9-6.5; regular users, RR = 1.81, 95% CI 0.7-4.8; vs. RR = 1.0 for nonusers of the exchange; adjusted for daily drug injection). Neither did the exchange protect against HCV infection (sporadic users, RR = 2.6, 95% CI 0.8-8.5; regular users, RR = 1.3, 95% CI 0.8-2.2; vs. RR = 1.0 for nonusers; adjusted for recent onset of injection and syringe sharing prior to enrollment). While it is possible that uncontrolled confounding or other bias obscured a true beneficial impact of exchange use, these data suggest that no such benefit occurred during the period of the study.

COMMENT: Seattle is an area with a high HCV prevalence (70%-80%) and low HIV prevalence (5%) among the IDU population. The probability that an IDU was an HCV carrier was greater than 70%; and given the efficiency of HCV transmission, any syringe sharing or sharing of other injection equipment (e.g., cooker, rinse water, cotton) increases the risk for HCV infection. During the period in which HBV/HCV was studied in this cohort, the incidence of HIV infection was quite low, with only 4 seroconversions (0.2%) among 1651 study participants. A high incidence of viral hepatitis can occur in the presence of low HIV incidence, presumably related to higher prevalence of HCV/HBV carriers as well as the greater infectiousness and higher per-contact risk of acquiring HBV than HIV.

Needle Exchange Programs in Vancouver: An Update on Needle Exchange Programs and HIV Incidence

Schechter M, Strathdee S, Cornelisse PGA et al. Do needle exchange programs increase the spread of HIV among injection drug users: An investigation of the Vancouver outbreak. AIDS 1999 Apr 16;13(6):F45-51.

ABSTRACT Objective: An association between needle exchange attendance and higher HIV prevalence rates among injecting drug users (IDU) in Vancouver has been interpreted by some to suggest that needle exchange programmes (NEP) may exacerbate HIV spread. We investigated this observed association to determine whether needle exchange was causally associated with the spread of HIV. Design and Method: Prospective cohort study of 694 IDU recruited in the downtown eastside of Vancouver. Subjects were HIV-negative at the time of recruitment and had injected illicit drugs within the previous month. Results: Of 694 subjects, the 15-month cumulative HIV incidence was significantly elevated in frequent NEP attendees (11.8 + 1.7 versus 6.2 + 1.5%; log-rank $P = 0.012$). Frequent attendees (one or more visits per week) were younger and were more likely to report: unstable housing and hotel living, the downtown eastside as their primary injecting site, frequent cocaine injection, sex trade involvement, injecting in 'shooting galleries', and incarceration within the previous 6 months. The Cox regression model predicted 48 seroconversions among frequent attendees; 47 were observed. Although significant proportions of subjects reported obtaining needles, swabs, water and bleach from the NEP, only five (0.7%) reported meeting new friends or people there. When asked where subjects had met their new sharing partners, only one out of 498 respondents cited the needle exchange. Paired analysis of risk variables at baseline and the first follow-up visit did not reveal any increase in risk behaviours among frequent attendees, regardless of whether they had initiated drug injection after establishment of the NEP. Conclusions: We found no evidence that this NEP is causally associated with HIV transmission. The observed association should not be cited as evidence that NEPs may promote the spread of HIV. By attracting higher risk users, NEPs may furnish a valuable opportunity to provide additional preventive/support services to these difficult-to-reach individuals.

COMMENT This report from the Vancouver Injection Drug User Study documents the severity of drug use, high risk behaviors and lifestyle characteristics of frequent attenders of the Vancouver needle exchange program compared with infrequent attenders of the program. There was no evidence that the NEP promoted new needle sharing network formation, and no evidence of increased risk behaviors related to injection practices. Significant variables distinguishing the frequent attenders from infrequent attenders (at $p < 0.001$ level) included unstable housing, living in a hotel, injecting in shooting galleries, frequency of heroin and cocaine use, incarceration in the past 6 months, involvement in the sex trade, and other sources of illegal income. The impact of these differences must be noted, and two statistical models were used to assess the impact of these higher risk characteristics on expected new HIV seroconversions. A multivariate Cox regression model containing these variables yielded a good fit with the actual observation of new seroconversions in both frequent attenders (48 predicted, 47 observed) and among infrequent

attenders (18 seroconversions predicted, 17 observed). A second analysis was conducted using a logistic regression model, with predicted seroconversion rates of 45 among frequent attenders and 19 among infrequent attenders - fairly close to the 47 observed in frequent attenders and 17 observed in infrequent attenders, respectively. This suggests that these risk factors themselves are more predictive of HIV seroconversion than patterns of SEP attendance. A more comprehensive approach to addressing the needs of the IDU may be required, in addition to the availability of sterile injection equipment, to achieve effective HIV prevention in this highest risk population.

SUMMARY POINTS From Updated Syringe Exchange Literature

- ▶ Laboratory studies show prolonged viability of HIV in used needles (> 4 weeks), providing strong biologic rationale for removal of used drug injection equipment from circulation.
- ▶ Syringe exchange programs (SEPs) consistently attract persons with highest risk profiles for HIV infection and severe drug use, and are successful in referring SEP clients into detoxification and substance abuse treatment programs.
- ▶ SEP-referred clients have similar rates of retention in substance abuse treatment as individuals from standard referral sources, despite more severe baseline drug use and high-risk lifestyles.
- ▶ Clients participating in SEPs have decreased reuse of contaminated syringes and reduced sharing of injection equipment
- ▶ The data indicate that the presence of a syringe exchange program does not increase the use of illegal drugs among participants, and in many cases, a decrease in injection frequency has been observed among those attending these programs.
- ▶ Provision of sterile injection equipment through SEPs and pharmacy access is cost-effective; one HIV infection can be prevented for one third the cost of medical care for an infected person.
- ▶ The scientific evidence accumulated to date provides a basis on which municipalities that are heavily affected by an HIV epidemic driven by injection drug use should consider syringe exchange programs as a tool for the identification, referral and retention of active users of injection drugs into these services, as part of a comprehensive HIV prevention plan.



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 17 2000

The Honorable Nancy Pelosi
House of Representatives
Washington, DC 20515

Dear Ms. Pelosi:

Thank you for your letter of inquiry regarding the state of scientific knowledge of the public health effects of syringe exchange programs. As you know, HIV transmission related to injection drug use remains a serious public health concern, since many new HIV infections result from behaviors associated with injection drug use.

In response to your inquiry, I asked the Assistant Secretary for Health and Surgeon General, Dr. David Satcher, to provide me with an update on the scientific research regarding the effects of syringe exchange programs. I am attaching his response, which includes the Department's updated review of the published scientific literature on the public health effects of syringe exchange programs.

Thank you for your interest and commitment to the issue of slowing the HIV/AIDS epidemic in our country. I look forward to working together with you on this common goal.

Sincerely,

A handwritten signature in black ink, appearing to read "Donna E. Shalala", is written over the word "Sincerely,". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Donna E. Shalala

Enclosure

EVIDENCE-BASED FINDINGS ON THE EFFICACY OF SYRINGE EXCHANGE PROGRAMS: AN ANALYSIS FROM THE ASSISTANT SECRETARY FOR HEALTH AND SURGEON GENERAL OF THE SCIENTIFIC RESEARCH COMPLETED SINCE APRIL 1998

Introduction

The issues of substance abuse addiction and HIV transmission related to injection drug use remain serious public health challenges, and the need to define and implement effective public health interventions remain urgent. The scientific research continues to define the unique role that syringe exchange programs can play in curtailing the expansion of the HIV epidemic in vulnerable communities affected by substance abuse, as part of a well designed and implemented comprehensive HIV prevention strategy.

This paper provides a review of recently published peer-reviewed research on syringe exchange programs completed by senior scientists and public health experts within the Department of Health and Human Services. An overview of the research studies is followed by an annotated bibliography providing the published abstracts, directly quoted, and relevant commentary. In summary, the new studies contribute substantially to the strength of the data showing the following effects of effective syringe exchange programs: a decrease in new HIV seroconversions; an increase in the numbers of injection drug users referred to and retained in substance abuse treatment; and well documented opportunities for multiple prevention services and referral and entry into medical care. The data indicate that the presence of a syringe exchange program does not increase the use of illegal drugs among participants in syringe exchange programs, and in many cases, a decrease in injection frequency has been observed among those attending these programs.

Throughout the literature, the terms syringe exchange programs and needle exchange programs have been used interchangeably in characterizing programs providing sterile injection equipment to injection drug users. This paper will use the term syringe exchange program, except where a published abstract has specified needle exchange program.

Overview

Numerous studies have shown that syringe exchange programs reach and serve the most disenfranchised populations at high risk for HIV infection. In this regard, syringe exchange programs play a unique role in facilitating the engagement of these populations in meaningful prevention interventions and treatment opportunities, when implemented as part of a comprehensive HIV prevention and substance abuse strategy. The scientific evidence accumulated to date provides a basis on which municipalities that are heavily affected by an HIV epidemic driven by injection drug use should consider syringe exchange programs as a tool

for the identification, referral and retention of active users of injection drugs into these services, as part of a comprehensive HIV prevention plan.

Serious discussions about syringe exchange programs must be placed in the context of the HIV epidemic in this country. The urgency to address the consequences of substance abuse is clear, as injection drug use continues to fuel the HIV epidemic in the United States. As many as half of new HIV infections are caused by the sharing of injection equipment contaminated with HIV, either directly due to injection drug use, through unprotected sex with someone who acquired HIV infection through injection drug use, or birth to a mother who acquired HIV infection through these means (CDC, 1999). Women of color and their children continue to be disproportionately affected by HIV/AIDS due to injection drug use. An estimated three out of four AIDS cases among women are due to injection drug use or heterosexual contact with someone infected with HIV through injection drug use, and over 75% of new infections in children result from the consequences of injection drug use in a parent (CDC, 1999). All too often women are unaware of their risk, due to a distant history of drug use in a partner. The ability to halt this devastating epidemic, particularly among minority women and children, requires a three part strategy: (i) preventing substance abuse ; (ii) facilitating entry of those with addictions into substance abuse treatment; and (iii) establishing effective outreach to engage active and former drug users in HIV prevention strategies that will protect them, their partners and families from exposure to HIV, and bring them into substance abuse treatment and medical care. HIV prevention and treatment programs targeting HIV-infected injection drug users and their partners, and similar programs within criminal justice institutions, are also important components in preventing the transmission of HIV.

In the Department's prior reviews of the literature on syringe exchange programs in 1997 and 1998, there was discussion of the methodological issues and constraints present across most published studies in this area. These include self-reported measures and difficulty in establishing proper control groups. However, the Department's senior scientists continue to concur with the conclusion of the Institute of Medicine that the pattern of evidence is sufficiently strong to support scientifically clear conclusions regarding the utility of syringe exchange programs, in communities that choose to adopt them, as part of a comprehensive HIV prevention strategy.

A recent national survey of syringe exchange programs (Paone et al, 1999) found that a growing number of local communities have chosen to implement a syringe exchange program to reach injecting drug users who are not in substance abuse treatment, in order to reduce the transmission of HIV through reduction in drug use behaviors and unsafe injection practices. This survey also documented that, in addition to exchanging sterile syringes for contaminated ones, 97% of syringe exchange programs provide a range of other services including referral to substance abuse treatment, prevention education for sexually transmitted diseases, HIV counseling and testing, tuberculosis screening, and primary health care. These trends also were found in a 1997 national survey (CDC, 1998).

The biological rationale for removing contaminated injection equipment from circulation has been demonstrated in a new study by Abdala et al (1999), confirming empirical observations of previous studies. This study showed that HIV-1 can survive over 4 weeks in a contaminated syringe, remaining infectious to individuals who reuse that syringe over this prolonged period. Riley et al (1998) found that 10.9% of used syringes discarded in needle boxes at community locations tested positive for the HIV antibody, while Robles et al (1998) reported that 27% of contaminated syringes returned to a new needle exchange program were positive for HIV. The longevity of the HIV-1 virus, combined with its prevalence in used equipment in some communities, is basic to the public health rationale for removal of used syringes from the community environment.

Knowledge of the effectiveness of syringe exchange programs in reducing the sharing of injection equipment and reuse of contaminated syringes among injection drug users has recently been reinforced by a number of new studies (Heimer et al, 1998; Robles et al, 1998; Bluthenthal et al, 1998). Conversely, the closing of an established syringe exchange program in Connecticut was associated with an increase in reuse and sharing of contaminated equipment among injection drug users, exposing these individuals and their partners and families to an increased risk of preventable bloodborne diseases (Broadhead et al, 1999).

Recent research studies document the role that effective syringe exchange programs serve as mechanisms to engage very high risk and hard to reach individuals in substance abuse treatment services. Brooner et al (1998) found that half of syringe exchange program clients referred for substance abuse treatment actually entered treatment, with 76% completing the first 13 weeks of treatment. These results were achieved despite the fact that these clients had more severe drug use, more HIV risk behaviors, less employment and greater engagement in illegal activities than clients referred to substance abuse treatment from traditional sources. Hagan et al (In Press) reported reduced frequency of injection drug use among current and former users of a needle exchange program, and entry into methadone treatment programs among former, current and new users of a syringe exchange program. Strathdee et al showed that attendance at a syringe exchange program was positively associated with individuals entering detoxification services independent of other variables, again representing an important bridge that facilitates entry into substance abuse treatment.

Concerns about elevated HIV seroconversion rates linked to the use of syringe exchange programs remain scientifically unfounded, as the data primarily reflect the impact of multiple high-risk factors among individuals who participate in these programs – a population at extremely high risk that is not engaged in appropriate interventions through traditional mechanisms of outreach and treatment referral. Studies of HIV incidence among two study cohorts in Canada, and some recent data on the incidence of hepatitis B and hepatitis C in Seattle, are relevant as these relate to syringe exchange programs. In the Department's internal review of these data in 1998, careful attention was given to the study data on these Canadian cohorts, with the conclusion that syringe exchange programs were not associated with an increase in HIV seroconversions. Subsequent data from the

Montreal cohort (Bruneau et al, 1999) have confirmed this lack of association between HIV seroconversion and attendance at a syringe exchange program, with longer follow-up of the study participants and appropriate availability of sterile injection supplies. Efforts to identify any grounds for a causal relationship continue to show negative results (Schechter et al, 1999), when controlling for risk factors in the statistical model.

Public health scientists have long known about the incidence of hepatitis B (HBV) and hepatitis C (HCV) among injection drug users. These are highly infectious bloodborne diseases that are endemic among some drug-using populations. In Seattle, where there is a high prevalence of hepatitis C among injection drug users (70%-80%), participation in the syringe exchange program did not appear to be protective against new HCV or HBV infection (Hagan et al, 1999). Because of the high background prevalence of HCV in this population, a single exposure to a syringe used by an injection drug user carries a high level of risk that it will be contaminated with HCV. Although syringe exchange programs can greatly reduce the reuse of contaminated syringes, maximal prevention of HCV transmission among this population would require distribution of a sufficient volume of sterile syringes to preclude any reuse of injecting equipment. In contrast to this scenario, since HIV seroprevalence is yet low in this population, the empirical data support the potential of a protective effect for HIV among individuals seeking clean injection equipment at the syringe exchange program.

In summary, injection drug use is a driving force for new HIV infections, disproportionately affecting minority populations. Yet, HIV transmission via injection drug use is preventable. Efforts to halt the HIV epidemic are in part dependent on effective prevention interventions targeted to this population. Prevention will require successfully engaging injection drug users and bringing them into systems of care that offer substance abuse treatment, mental health, medical, and social support services. The availability of medical, social and preventive services alone are often not enough to engage the highest risk populations of active injection drug users, absent effective methods of outreach to this population. The scientific research has shown that well designed and implemented syringe exchange programs have demonstrated efficacy in engaging populations at severe risk for HIV and reducing the further spread of HIV among injection drug users, their sexual partners and children. Furthermore, these programs have not been shown to encourage the use of illegal drugs, and fit well into comprehensive substance abuse treatment strategies.

After reviewing all of the research to date, the senior scientists of the Department and I have unanimously agreed that there is conclusive scientific evidence that syringe exchange programs, as part of a comprehensive HIV prevention strategy, are an effective public health intervention that reduces the transmission of HIV and does not encourage the use of illegal drugs. In many cases, a decrease in injection frequency has been observed among those attending these programs. In addition, when properly structured, syringe exchange programs provide a unique opportunity for communities to reach out to the active drug injecting population and provide for the referral and retention of individuals in local substance abuse treatment and counseling programs and other important health services. The scientific evidence accumulated to date provides a basis on which

municipalities that are heavily affected by an HIV epidemic driven by injection drug use should consider syringe exchange programs as a tool for the identification, referral and retention of active users of injection drugs into these services, as part of a comprehensive HIV prevention plan.

ANNOTATED BIBLIOGRAPHY: SCIENTIFIC RESEARCH ON SYRINGE EXCHANGE PROGRAMS PUBLISHED SINCE APRIL 1998

Needle Exchange in the U.S. - National Surveys

Paone D, Clark J, Shi Q, Purchase D, Des Jarlais DC. Syringe exchange in the United States, 1996: A national profile. Am J Public Health 1999 Jan; 89(1):43-6.

ABSTRACT Objectives: This paper provides 1996 information on the status of US syringe exchange programs and compares these findings with data from our 1994 survey. Methods: In November 1996, questionnaires were mailed to 101 syringe exchange programs. Program directors were contacted to conduct telephone interviews based on the mailed questionnaires. Data collected included number of syringes exchanged, syringe exchange program operations, legal status, and services offered. Results: Eighty-seven programs participated in the survey. A total of 46 (53%) were legal, 20 (23%) were illegal but tolerated, and 21 (24%) were illegal-underground. Since 1994, there has been a 54% increase in the number of cities and a 38% increase in the number of states with syringe exchange programs. Eighty-four programs reported exchanging approximately 14 million syringes, a 75% increase from 1994. Syringe exchange programs also provided a variety of other services and supplies, and legal programs were more likely than illegal ones to provide these services. Conclusion: Despite continued lack of federal funding, syringe exchange programs expanded in terms of the number of syringes exchanged, the geographic distribution of programs, and the range of services offered.

COMMENT Many syringe exchange programs provide a range of preventive health services and health care, directly and through referrals. Of those programs surveyed, 97% provided referral to substance abuse treatment, 80% provided education to reduce risks of STDs, while many others provided HIV counseling and testing, primary health care, and tuberculosis screening in addition to exchanging sterile syringes for contaminated ones. The finding that legal programs are more likely to provide health services may reflect their ability to establish more regular hours and locations and to more formally refer clients to existing health, mental health and substance abuse treatment services. It has recently been estimated (Des Jarlais, 1999) that only 10% of injection drug users have access to needle exchange programs and their associated ancillary services, despite evidence that these programs are effective in reaching populations at very high risk for HIV and in need of substance abuse treatment services.

Centers for Disease Control and Prevention. Update: Syringe Exchange Programs – United States, 1997. Morbidity and Mortality Weekly Report, August 14, 1998, Vol 47 (31); 652-655.

(NO PUBLISHED ABSTRACT)

COMMENT This report provides an updated survey of the number and characteristics of syringe exchange programs (SEPs) in operation in the United States. The findings indicate continued expansion in the number, geographic coverage, and activity of SEPs in the United States. Of 113 SEPS contacted, 100 (89%) participated in the survey. These 100 SEPs reported operating in 80 cities in 30 States, the District of Columbia, and Puerto Rico. In 1997, 96 of the SEPs provided information about the number of syringes and reported exchanging approximately 17.5 million syringes (median; 57,343 syringes per SEP). The 10 largest volume SEPs (i.e. those that exchanged greater than or equal to 500,000 syringes) exchanged approximately 10.3 million (59%) of all syringes exchanged. Most of the 100 SEPs provided other public health and social services: 99% offered instruction to prevent sexual transmission of HIV and other sexually transmitted diseases; 96% provided IDUs with information about safer injection techniques and/or use of bleach to disinfect equipment; and 94% referred clients for substance abuse treatment programs. Health care services offered on site included HIV counseling and testing (64%), tuberculosis skin testing (20%), STD screening (20%), and primary health care (19%). The 100 SEPs operated in various settings, with 69% operating in multiple settings. SEPs reported receiving financial support from various sources including foundations, individuals, and state and local governments.

Risks Associated with Re-use of Syringes: A Laboratory study

Abdala N, Stephens PC, Griffith BP, Heimer R. (1999). Survival of HIV-1 in Syringes. J Acquir Immune Defic Syndr Hum Retrovirol 1999 Jan 1;20(1):73-80

ABSTRACT Summary: We performed a study to determine the duration of survival of HIV-1 in syringes typically used by injectors of illicit drugs (IDUs). We describe the effectiveness of a microculture assay in detecting viable virus in volumes of blood typical of those commonly found inside used syringes. Using this assay and modeling the worse-case situation for syringe sharing, we have recovered viable, proliferating HIV-1 from syringes that have been maintained at room temperature for periods in excess of 4 weeks. The percentage of syringes with viable virus varied with the volume of residual blood and the titer of HIV-1 in the blood. These experiments provide a scientific basis for needle exchange schemes, harm reduction, and other interventions among IDUs that support the nonsharing and removal of used syringes from circulation.

COMMENT Since the early years of the epidemic, researchers have documented that sharing of blood-contaminated equipment carries a substantial risk for transmission of HIV, and hepatitis B and C. These newly reported findings which document the long survival time of HIV-1 in syringes have implications for needle exchange program, in that the study confirms that a substantial

proportion of needles removed from circulation may have viable HIV and could transmit the infection. This data provides a scientific virologic rationale for the role syringe exchange programs play in reducing HIV transmission via used injection equipment, as these programs are organized to provide new, sterile injection equipment and remove from circulation potentially infectious needles and syringes.

Effectiveness of Needle Exchange Programs

Brooner R., Kidorf M., King V., Bielensohn P., Svikis D., Vlahov D. A Drug Abuse Treatment Success among Needle Exchange Participants. Public Health Reports, 113; Supplement 1: pp. 130-139, June 1998.

ABSTRACT Objective: Although lowering incidence rates of human immunodeficiency virus (HIV) transmission is the primary goal of needle exchange programs (NEPs), other desirable outcomes are possible. Referring exchange participants to more comprehensive drug abuse treatment programs has the potential to reduce or eliminate the use of drugs. This possibility was evaluated by comparing the treatment responses of new admissions with an outpatient opioid agonist treatment program in Baltimore, Maryland. Methods: New admissions (1994-1997) to an opioid agonist treatment program were first grouped by referral source (needle exchange, $n = 82$, vs. standard referrals, $n = 243$) and then compared on admission demographic and clinical variables and response to treatment during the first three months. Outcome measures included retention rates, self-reported drug use and injecting frequencies, self-reported illegal activities for profit, and results from weekly urinalysis testing for opioids and cocaine. Results: Patients from the NEP were significantly older and more likely to be male, African American, and unemployed than standard referral patients. Needle exchange patients also had a greater baseline severity of drug use than patients in the standard referral group. Despite these baseline differences, both groups achieved comparably good short-term treatment outcomes (including reduced drug use and criminal activity for profit); treatment retention was also good, although slightly better in the standard referral group (88% vs. 76%). Conclusion: These data demonstrate the feasibility and merits of creating strong linkages between NEPs and more comprehensive drug abuse treatment clinics.

COMMENT Two significant findings of this study are the ability of a NEP to successfully refer NEP clients to a substance abuse treatment program (51% of referrals were admitted to treatment) and the relatively high treatment retention rates for NEP-referred clients, despite greater severity of baseline drug use among this population compared to clients from standard referral sources. Establishing linkages between syringe/needle exchange programs and substance abuse treatment programs may lead to meaningful reductions in, or the elimination of, drug use among NEP clients in addition to the primary goal of reducing the risk of bloodborne infectious diseases in this population.

Hagan H, McGough JP et al. Reduced Injection Frequency and Increased Entry and Retention in Drug Treatment Associated with Needle Exchange Participation in Seattle Drug Injectors. In Press, Journal of Substance Abuse Treatment

ABSTRACT Objectives: The association between needle exchange, change in drug use frequency and enrollment and retention in methadone drug treatment was studied in a cohort of Seattle injection drug users (IDUs). Methods: Participants included IDUs classified according to whether they had used a needle exchange by study enrollment and during the 12-month follow-up period. The relative risk (RR) and the adjusted RR (ARR) were estimated as measures of the association. Results: IDUs who had formerly been exchange users were more likely than never exchangers to report a substantial ($\geq 75\%$) reduction in injection (ARR=2.85, 95% CL 1.47-5.51, to stop injecting altogether (ARR=3.5, 95% CL 2.1-5.9), and to remain in drug treatment. New users of the exchange were five times more likely to enter drug treatment than never-exchangers. Conclusions: Reduced drug use and increased drug treatment enrollment associated with needle exchange participation may have many public health benefits, including prevention of blood-borne viral transmission.

COMMENT The frequency of drug injection among active IDUs using a needle exchange program decreased during the time of this study. Both current users and new users of the needle exchange program were more likely to enter methadone treatment programs than IDUs who did not use the needle exchange program. Retention in methadone treatment at 12-month follow-up was 68% for former users of the NEP, 60% of current users of the exchange, and 45% of new users of the NEP. These findings support the role NEPs can play as a conduit into sustainable substance abuse treatment among heroin injectors.

Strathdee S, Celentano D et al. Needle Exchange Attendance and Health Care Utilization Promote Entry into Detoxification. In Press, Journal of Urban Health

ABSTRACT This study was undertaken to identify factors associated with entry into detoxification among injection drug users (IDUs), and to assess the role of needle exchange programs (NEPs) as a bridge to treatment. IDUs undergoing semi-annual human immunodeficiency virus (HIV) tests and interviews were prospectively studied between 1994 and 1998, during which time a NEP was introduced in Baltimore. Logistic regression was used to identify independent predictors of entry into detoxification, stratifying by HIV serostatus. Of 1490 IDUs, similar proportions of HIV-infected and uninfected IDUs entered detoxification (25% vs. 23%, respectively). After accounting for recent drug use, hospital admission was associated with four-fold increased odds of entering detoxification for HIV-seronegative subjects. Among HIV-infected subjects, hospital admission, outpatient medical care and having health insurance independently increased the odds of entering detoxification. After accounting for these and other variables, needle exchange attendance also was independently associated with entering detoxification for both HIV-infected (adjusted odds ratio [AOR]=3.2) and uninfected IDUs (AOR=1.4). However, among HIV-infected subjects, the increased odds of detoxification associated with needle exchange diminished significantly over time, concomitant with statewide

reductions in detoxification admissions. These findings indicate that health care providers and NEPs represent an important bridge to drug abuse treatment for HIV-infected and uninfected IDUs. Creating and sustaining these linkages may facilitate entry into drug abuse treatment and serve the important public health goal of increasing the number of drug users in treatment.

COMMENT This study provides a quantitative measure of the association between NEP attendance and subsequent entry into drug abuse treatment in an out-of-treatment population. NEP attendance was independently associated with entry into detoxification programs for both HIV-negative and HIV-infected clients. The researchers noted that the decreased strength of the association over time was likely due to external factors, such as the increased difficulty in obtaining admission for detoxification in Maryland and third party reimbursement barriers that differentially affected HIV-infected IDUs previously eligible for social security benefits. The research supports previous observations that NEPs can be a conduit to drug abuse treatment for very high risk populations.

Heimer R, Khoshnood K, Bigg D, Guydish J, Junge B. Syringe Use and Reuse: Syringe Exchange Programs in Four Cities. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 1998; 18(Suppl 1): S37-S44.

ABSTRACT Summary: We determined the effect of syringe exchange programs (SEPs) on syringe reuse patterns. Five methods were employed to estimate injections per syringe made by exchange clients in four cities. In San Francisco, Chicago, and Baltimore, self-reported data on the number of injections per syringe were obtained. In New Haven, self-reported injection frequencies were combined with syringe tracking data to derive two methods for estimating the mean injections per syringe. The average number of injections per syringe declined by at least half after establishment of SEPs in New Haven, Baltimore, and Chicago, all cities where such an analysis could be made. There were significant increases in the percentages of exchangers reporting once-only use of their syringes in San Francisco, Baltimore and Chicago, all cities where the data were amenable to this form of analysis. Self-report and syringe tracking estimates were in agreement that SEP participation was associated with decreases in syringe reuse by drug injectors. SEP participation was associated with increases in the once-only use of syringes. These findings add to earlier studies supporting the role of SEPs in reducing the transmission of syringe-borne infections such as HIV and hepatitis.

COMMENT This study uses several methods to assess syringe reuse among participants of syringe exchange programs, including syringe tracking data to minimize potential response bias associated with self-reported data. The decreased reuse of contaminated syringes observed over time in these study cohorts is significant in light of the previous study by Abdala et al, irrespective of the absence of a control group of non-SEP clients.

Bluthenthal RN, Kral AH, Erringer EA, and Edlin BR. Use of an Illegal Syringe Exchange and Injection-Related Risk Behaviors among Street-Recruited Injection Drug Users in Oakland, California, 1992-1995. *Journal of AIDS and Human Retrovirology*, 1998.

ABSTRACT Objective: To determine factors associated with syringe and injection supply sharing among injection drug users (IDUs) in a community with an illegal underground syringe exchange program. Methods: From 1992-1995, semi-annual cross-sectional samples of IDUs were recruited in Oakland, CA. To account for multiple observations from the same individual, we used general estimating equations with logit transformations to determine factors associated with sharing syringes and other injection works. Results: 1304 IDUs were interviewed; 684 (53%) returned for more than one interview. 2830 interviews were available for analysis. SEP use increased and syringe and supply sharing declined from 1992 to 1995 among study participants. In multivariate analysis, SEP users were less likely to share syringes than non-SEP users (adjusted odds ratio [AOR] = 0.57; 95% confidence interval [CI] = 0.46-0.72). SEP use was not significantly associated with the sharing of injection supplies (AOR = 0.85; 95% CI = 0.68 - 1.07). Syringe sharing and injection supply sharing were significantly less likely to occur among African American and HIV-positive IDUs. Conclusions: These data suggest that illegal SEPs can be effective HIV prevention programs. Lower rates of syringe-based risk factors among African American and HIV-positive IDUs are encouraging.

COMMENT The researchers re-examined seven semi-annual waves of interviews from both the baseline and follow-up assessments of IDUs who lived in a community with an illegal SEP. Variables that previous research has suggested would have an impact on syringe sharing, such as substance abuse treatment, marital status, gender, and income were included in the models to control for potential confounding factors, as well as control for the potential effects of temporal trends in use of NEPs and syringe sharing. Substantial declines in syringe sharing were observed over the interview periods among users of the SEP compared to non-SEP users. Use of the SEP increased from 5% in 1992 to 36% in 1995 despite arrests of program volunteers during the study period. The study adds to the literature in that it shows a decrease in syringe reuse is also associated with an illegal SEP, whereas most other reported studies come from legal or community-tolerated SEPs.

Bruneau J, Lachance N et al. Changes in HIV Seroconversion Rates of IDUs Attending Needle Exchange Programs in Montreal: The Saint-Luc Cohort. *Canadian Journal of Infectious Diseases*, [Supplement] May 1999.

ABSTRACT Objectives: From 1988 to 1995, we observed a positive association between NEP attendance and HIV seroconversion. Since 1995, modifications have been implemented in needle exchange programs (NEPs) in Montreal, including the opening of new distribution sites and the lifting of the syringe quota. The objective is to examine the association between NEPs and HIV seroconversion in the Saint-Luc Cohort after January 1995. Methods: Recent injection drug users (IDUs) were recruited by word-of-mouth and through substance abuse treatment agencies.

Information was collected and HIV status was assessed at each visit. The association between factors on demographics, drug and sexual behaviours and HIV seroconversion was assessed using univariate and multivariate Cox proportional hazards regression. All current IDUs participating in the Saint-Luc cohort as of January 1995 were included in the analysis. Results: The post-1995 cohort included 981 seronegative subjects, 797 men and 184 women. Mean age was 34.5, and 42% reported NEP attendance in the past 3-6 months. 83% and 34% used cocaine and heroin respectively in the past 3-6 months. 42.3% reported unstable housing. From January 1995 to September 1998, 68 seroconverted for a global incidence of 4.3 per 100 person-years (CI 95%: 3.4-5.5 : 4.2 per 100 person years (CI 95%: 2.8-6.1) among NEP attenders, and 4.4 per 100 person-years (CI 95%: 3.1-5.9) among non-attenders. (HR: 0.97 [0.60 - 1.58]). In a Cox proportional hazards model, factors independently associated with HIV seroconversion were:

<u>Factors</u>	<u>Hazard Ratio</u>	<u>95% CL</u>
Drug Injected (ref: other)		
Cocaine IV (3-6 months)	2.20	0.5-9.9
Heroin IV (3-6 months)	0.33	0.2-0.7
Nb injections last month (ref: 0)		
1-30	2.18	0.9-5.5
30-100	2.22	0.8-6.1
>100	3.81	1.4-10.4
Booting 3-6 months	2.04	1.0-4.1
Inject alone 3-6 months	1.91	0.9-3.9
Sharing with HIV+	2.29	1.3-3.9
Gender (ref: female)	2.70	1.0-7.6

Conclusion: After 1995, no association was found between NEP attendance and HIV seroconversion among current IDUs followed in the Saint-Luc cohort. This situation is different from what was observed from 1988 - 1995, and coincided with modifications of needle exchange programs in Montreal.

COMMENT Remis, Bruneau and Hankins published a related paper titled "Enough Sterile Syringes to Prevent HIV Transmission Among Injection Drug Users in Montreal?", in the Journal of Acquired Immunodeficiency Syndrome and Human Retrovirology; Vol 18, Suppl.I, July 1998. The study compared the estimated number of syringes required by injection drug users in 1994 with the number of syringes distributed through needle exchange programs. Syringes distributed through NEPs addressed less than 5% of the estimated demand for syringes by IDUs in Montreal in 1994. The authors advanced the hypothesis that unless the disparity between unmet need and available syringes was reduced, it is unlikely that sufficient syringes would be available to prevent HIV transmission. The observation in this study that NEP use and HIV seroconversion were not associated since 1995 in the Montreal cohort is coincident with modifications of the NEP program and differs from pre-1995 data.

Robles R, Colon H, Matos T, Finlinson H, Munoz A, Marrero C, Garcial M, Reyes J. Syringe and Needle Exchange as HIV/AIDS Prevention for Injection Drug Users in Puerto Rico. Health Policy, 1998; Vol. 45: 209-220.

ABSTRACT This study evaluated the effectiveness of the first needle exchange program (NEP) established in Puerto Rico. The data for this study were collected during the first months of the NEP from July 1995 to March 1996 in 13 communities of the San Juan metropolitan area. Subjects were the participants of two modalities of the NEP: a mobile team and a community-based drug treatment program. During the 3-week evaluation period, 2401 injection drug users (IDUs) were recruited, resulting in a total of 19,195 exchange contacts and 146,323 syringes exchanged. No significant change in drug injection was observed. However, the program was effective in reducing sharing of syringes and cookers. The study suggests that the NEP did help in reducing needle sharing in Puerto Rico. However, the HIV seropositivity in returned syringes suggests the need to continue aggressive prevention programs to arrest the epidemic among IDUs. However, factors related to the socio-cultural environment as well as cultural norms and traditions need to be considered when planning and expanding NEPs.

COMMENT In this study, 40% of a sample of 1075 syringes returned to the NEP and studied showed a 27% seropositivity rate for HIV. A significant increase in the number of returned syringes was observed over the evaluation period (12.4% rising to 32.5% at 8 months). The importance of decreasing needle circulation time as an HIV prevention intervention is particularly acute in this setting with high rates of HIV seropositivity in contaminated syringes. Entry into substance abuse treatment among study participants increased over time, with 28% of the NEP participants reporting treatment entry by the seventh month after the NEP began. Both short term and long term harm reduction goals among IDUs were advanced by the NEP.

Des Jarlais DC, Perlis T, Friedman SR, Deren S et al. Declining Seroprevalence in a Very Large HIV Epidemic: Injecting Drug Users in New York City, 1991 to 1996. Am J Public Health, 88(12): 1801-1806, 1998.

ABSTRACT Objective: This study assessed recent trends in HIV seroprevalence among injecting drug users in New York City. Methods: We analyzed temporal trends in HIV seroprevalence from 1991 to 1996 in 5 studies of injecting drug users recruited from a detoxification program, a methadone maintenance program, research storefronts in the Lower East Side and Harlem areas, and a citywide network of sexually transmitted disease clinics. A total of 11,334 serum samples were tested. Results: From 1991 through 1996, HIV seroprevalence declined substantially among subjects in all 5 studies: from 53% to 36% in the detoxification program, from 45% to 29% in the methadone program, from 44% to 22% at the Lower East Side storefront, from 48% to 21% at the Harlem storefront, and from 30% to 21% in the STD clinics (all $p < .002$ by chi square tests for trends). Conclusions: The reductions in HIV seroprevalence seen among injecting drug users in New York City from 1991 through 1996 indicate a new phase in this large HIV epidemic. Potential explanatory factors include the loss of HIV seropositive individuals through disability and death and lower rates of risk behavior leading to low HIV incidence.

COMMENT This article is included here as a snapshot of HIV prevalence among IDUs in a major city with the largest AIDS epidemic among IDUs in the world. Risk reduction programs including needle exchange programs, street outreach, and detoxification programs were components of the public health response to the epidemic during the years studied. An overall reduction in HIV seroprevalence among IDUs was found, in the setting of a stable number of IDUs. Declines in HIV transmission-related behavior, such as reusing contaminated injection equipment and lending it to others, were reported from several sites. Many factors might contribute to the decline in HIV seroprevalence. The presence of a broad-based prevention effort focused on IDUs, which has included NEPs, has been associated with lower infection rates among the IDU population.

Hagan H, McGough JP et al. Volunteer Bias in Non-Randomized Evaluations of the Efficacy of Needle Exchange Programs. Journal of Urban Health (Accepted for publication)

ABSTRACT Objective: Nonrandomized comparisons of the incidence of HIV and hepatitis between injection drug users (IDUs) who do and do not attend voluntary needle exchange programs may be subject to bias. To explore possible sources of bias, we examined characteristics associated with voluntarily beginning or ceasing to participate in the Seattle needle exchange. Methods: In a cohort of 2879 IDUs, a standardized questionnaire measured characteristics present at enrollment. We examined the relation of these characteristics to the proportion of IDUs who began to use the program during the ensuing 12-month follow-up period, and to the proportion of current exchangers who dropped out during that period of time. Results: Thirty-two percent of the 494 never-exchangers at baseline attended the program during follow-up: those who reported sharing syringes or who were homeless at enrollment were more likely to become new exchanger users (adjusted risk ratio for becoming an exchange user (ARR) = 1.8 for those who shared syringes, and ARR = 2.2 for those who were homeless). Sixteen percent of 1274 current exchangers stopped using the exchange during follow-up, with daily injectors (ARR = 0.6) and those who reported backloading (ARR = 0.6) being relatively less likely to drop out of the exchange. Conclusions: The analysis suggests that IDUs participating in needle exchange programs at a given point in time may include a particularly high proportion of those injectors whose pattern of drug use puts them at elevated risk of blood-borne viral infections.

COMMENT This study of participants in SEP programs shows that individuals who were homeless and those sharing needles were the most likely to utilize an SEP, and persons who stopped attending the SEP were less likely to be injecting daily or using risky injection techniques. This SEP is attracting and retaining those persons with greatest risk factors for bloodborne disease transmission.

Cost-Effectiveness of Needle Exchange Programs

Holtgrave DR, Pinkerton SD, Jones TS, Lurie P, Vlahov D. (1998). Cost and cost-effectiveness of increasing access to sterile syringes and needles as an HIV prevention intervention in the United States. J Acquir Immune Defic Syndr Hum Retrovirol 1998;18 Suppl 1:S133-8.

ABSTRACT Summary: We determined the cost of increasing access of injection drug users (IDUs) to sterile syringes and needles as an HIV prevention intervention in the United States and the cost per HIV infection averted by such a program. We considered a hypothetical cohort of 1 million active IDUs in the United States. Standard methods were used to estimate the cost and cost-effectiveness of policies to increase access to sterile syringes and syringe disposal at various levels of coverage (e.g. a 100% coverage level would ensure access to a sterile syringe for each injection given current levels of illicit drug injection in the United States; a 50% coverage level would ensure access to one half of the required syringes). A mathematical model of HIV transmission was employed to link programmatic coverage levels with estimates of numbers of HIV infections averted. A policy of funding syringe exchange programs, pharmacy sales, and syringe disposal to cover all illicit drug injections would cost just over \$423 million (U.S.) for 1 year. One third of these costs would be paid for as out-of-pocket expenditures by IDUs purchasing syringes in pharmacies. Compared with the status quo, this policy would cost an estimated \$34,278 (U.S.) per HIV infection averted, a figure well under the estimated lifetime costs of medical care for a person with HIV infection. At very high levels of coverage (>88%), the marginal cost-effectiveness of increased program coverage becomes less favorable. Although the total costs of funding large-scale IDU access to sterile syringes and disposal seem high, the economic benefits are substantial. Even at high levels of coverage, such funding would save society money. As part of a comprehensive program of HIV prevention, policies to increase IDUs access to sterile syringes urgently need further consideration by public health decision makers.

COMMENT The estimates provided in this study should be considered in the context of an estimated \$108,469 lifetime medical cost of treating an individual with HIV infection, which is three fold greater than estimates of preventing one HIV infection.

Kahn J. Economic Evaluation of Primary HIV Prevention in Injection Drug Users. In Holtgrave D., edit: Handbook of Economic Evaluation HIV Prevention Programs. Plenum Press, New York: 1998.

NO PUBLISHED ABSTRACT In this paper, the author implemented the Yale Circulation Model using empirical data obtained from 4 NEP programs in 4 Cities to assess the cost-effectiveness of such an HIV prevention intervention. The Yale Circulation Model is a mathematical model used to estimate the change in the number of new HIV infections based on lowering the HIV prevalence in used needles as a result of reducing the circulation time of contaminated syringes. The author applied a simplified Yale Needle Circulation Model to 4 hypothetical needle exchange programs in areas with differing HIV prevalence and incidence rates. The researcher reports that reductions in HIV incidence rates varied across cities from 17% to 70% across the 4 hypothetical settings. Higher reductions were associated with more needles per client-year. Greater efficiency was associated with low cost per needle exchanged. The estimated cost savings per HIV infection averted ranged from \$12,000 to \$98,000. Greater efficiency was associated with low cost per needle exchanged. The author suggests that for a fixed number of needles, the absolute impact is higher when the needles are spread out among a greater number of clients.

COMMENT This study shows that variations in the cost-effectiveness of syringe exchange programs will occur, depending on the type and structure of the program, and the HIV prevalence and incidence in the geographic area to be served.

Risk Associated with Closing a Needle Exchange Program

Broadhead R, Van Hulst Y, and Heckathorn D. (In Press). Termination of an established needle exchange: A study of claims and their impact. Social Problems, 1999; Vol. 46, No. 1: 48-66.

NO PUBLISHED ABSTRACT This study assessed the impact of the Windham CT needle exchange program closure on risk behaviors, and discarded syringes. The project conducted 330 initial and 173 follow-up risk assessment interviews of NEP participants between 1994 and 1997 while the NEP was in operation. Following the closure of the NEP in 1997, researchers conducted 111 interviews at 11 months post closure and 78 interviews 3 months later. In addition, starting 7 months prior to the closure of the NEP and for a period of 1 and ½ years following the NEP closure the research team surveyed public outdoor areas for discarded syringes where high levels of drug use occurred. Findings indicate that while the NEP was in operation, 14% of the sample reported obtaining syringes from unsafe sources compared with 36% following the closure of the NEP. Prior to the closure of the NEP, the mean number of times a syringe was re-used before disposal was 3.52 compared with a high of 8.18 times following the NEP closure. The closure of the NEP was also found to increase self-reported syringe sharing. Sixteen percent of NEP participants reported sharing a syringe within the last 30 days while the NEP was in operation compared with 34% of participants after the NEP closed. Finally, no difference in the number of discarded syringes in public places was detected, suggesting that the closure of the NEP had no effect on the number of discarded syringes in the area.

COMMENT This study documented the experience of IDUs in one community following closure of a NEP. Risk behaviors increased among IDUs when they no longer had access to the services of the needle exchange program, increasing the likelihood of HIV transmission resulting from multiperson reuse of syringes.

Related Article by Same Authors: Broadhead RS, van Hulst Y, Heckathorn, DD. The Impact of a Needle Exchange's Closure. Public Health Reports 1999; 114: 439-447.

Needle Exchange Related Issues

Junge B, Vlahov D, Riley E, Huettner S, Brown M, Beilenson P. Pharmacy access to sterile syringes for injection drug users: attitudes of participants in a syringe exchange program. J Am Pharm Assoc (Wash) 1999 Jan-Feb;39(1):17-22.

ABSTRACT Objective: To examine attitudes of participants of a van-based syringe exchange program (SEP) toward the hypothetical prospect of pharmacy-based syringe access. Design: One-time, cross-sectional survey. Setting: Baltimore, Maryland. Participants: 206 injection drug users who participate in the Baltimore SEP. Interventions: Face-to-face interviews. Main Outcome Measures: Location preferred for obtaining syringes, drug and syringe use, past experience with pharmacies, and willingness to pay. Results: The sample was 67% men, 95% African American, and 95% unemployed; mean age was 39.8 years. A total of 19% of respondents had bought syringes at a pharmacy during the prior six months. Some 37% reported having been turned down when asking for syringes at a pharmacy, most commonly due to lack of identification to prove diabetic status (50%). If legal restrictions were lifted, 92% of respondents would obtain syringes from pharmacies, and would be willing to pay a mean price of \$0.80 (median = \$1.00) per syringe. Women were more likely than men to report the intention to switch from van-based SEP to pharmacy (57% versus 38%, $p = 0.045$). Conclusion: If current legal restrictions were lifted, pharmacies would be a viable syringe source appealing particularly to women, suggesting gender-specific access issues that should be addressed. The per syringe price that study participants would be willing to pay exceeds typical retail prices, suggesting that pharmacists could charge enough per syringe to recoup operational costs.

COMMENT This study reflects a willingness and effort to obtain sterile injection equipment at pharmacies by a substantial percentage of IDUs currently using a van-based syringe exchange program. It highlights the impact of legal restrictions on syringe availability through pharmacies for the IDU population. The study notes that pharmacies provide an alternative controlled distribution mechanism of sterile injection equipment and are widely available in most communities.

Paone D, Cooper H, Alperen J et al. HIV Risk Behaviors of Current Sex Workers Attending Syringe Exchange: The Experiences of Women in five US Cities. AIDS CARE 1999; 11 (3): 269-280.

ABSTRACT Existing research indicates that sex workers who inject drugs are vulnerable to HIV infection through both risky sexual and drug use practices. This study is the first attempt to learn whether this increased risk persists among current sex workers who participate in syringe exchange programmes (SEPs). With data from interviews with randomly selected participants in five US cities, we compared the demographic characteristics, sexual risk behaviours, drug use practices, emotional and physical health, and SEP utilization patterns of currently active female sex workers who attend SEPs with female SEP participants who do not engage in sex work. Data indicate that women enrolled in SEPs who were currently trading sex typically reported greater HIV risk than women non-sex workers. Current sex workers reported higher levels of risk for every drug risk variable examined in bivariate analysis. They were more likely than other women to inject with a syringe previously used by someone else, to inject daily and to attend shooting galleries; they were less likely to use a condom with their primary partners and to report higher levels of psychological distress than their counterparts. The relationship between sex work status and risky injection practices persisted when potential confounders were controlled for in multivariate analysis. SEPs

can serve a pivotal role in providing sex workers with services and referrals which would help them reduce risk behaviours.

COMMENT This study documents that women who attend SEPs and engage in sex work typically report greater HIV risk than women non-sex workers attending SEPs, reinforcing the importance of this variable. In this study, current sex workers engaged in heavier drug use than other women; reported using a greater variety of injection and non-injection drugs; injected substantially more frequently than both sexually active and non-sexually active women, with sex workers injecting on average 124 times a month while other women injected approximately 82 times a month ($p < 0.0005$); were more likely to inject daily and smoke crack daily than their counterparts; and were more likely to be at risk of bloodborne infection through risky injection practices such as renting, buying or borrowing used syringes for injection and visiting a shooting gallery more often than other women.

Riley E, Beilenson P, Vlahov D, Smith L, Koenig M et al. Operation Red Box: a pilot project of needle and syringe drop boxes for injection drug users in East Baltimore. J Acquir Immune Defic Syndr Hum Retrovirol 1998;18 Suppl 1:S120-5.

ABSTRACT Summary: We assessed the acceptability and the use of a community-based needle and syringe disposal project designed to serve injection drug users. In June 1996, three surplus U.S. mail collection boxes were painted red and used as syringe and needle drop boxes in locations with high drug use in East Baltimore. Acceptance of the drop boxes was measured by focus groups of residents, drug users, and police, held before and after project implementation. Use was measured by weekly counts of needles recovered from the red boxes. A sample of all deposited needles was randomly chosen for needle washing and subsequent HIV antibody testing. Community impact was measured by systematic surveys of needles discarded on public sidewalks, in areas with and areas without drop boxes. Before implementation, members of focus groups expressed concerns that drop boxes could convey mixed messages to youth (e.g. seeming to condone drug use), might result in increased loitering, and could further community stigmatization. After project implementation, all focus groups expressed support of project expansion. In the first 10 months, 2971 needles were collected. Of 156 needles tested, 10.9% were positive for HIV antibody. Needle counts on the street showed no significant change in red box areas compared with control areas. In this pilot project, red boxes were accepted by the community and drug users. Police officers also used the boxes to dispose of confiscated needles. Although limited in the number of drop boxes and follow-up time, this pilot project shows promise as a community-based method of safe needle disposal.

COMMENT This paper addresses the important issue of safe disposal of used injection equipment. While the study design is not directly linked with a syringe exchange program, the issues of access to, and safe disposal of, used syringes are important to consider as components of an overall public health and safety effort. The drop boxes were placed in high drug use areas of Baltimore, which has existing NEPs. The 11% HIV antibody positivity rate in discarded syringes

highlights the role that safe disposal mechanisms can play in reducing the circulation time of infected needles, regardless of the presence or absence of a syringe exchange program.

Needle Exchange and Hepatitis B and C Viruses

Hagan H, McGough JP, Thiede H, Weiss N, Hopkins S, Russell A. (1999). Syringe exchange and risk of infection with hepatitis B and C viruses. *American Journal of Epidemiology*, 149, 203-213.

ABSTRACT The authors utilized a cohort study among Seattle injection drug users (IDUs) to assess whether participation in a syringe exchange program was associated with incidence of hepatitis B virus (HBV) and hepatitis C virus (HCV) infection. Susceptible IDU subjects (187 seronegative for antibody to HCV, and 460 seronegative for core antibody to HBV) were identified in drug treatment, corrections, and social service agencies from June 1994 to January 1996, and followed for seroconversion one year later. The subjects included in the analysis were Seattle-King county (Washington State) area IDUs enrolled in a larger multipurpose cohort study, the Risk Activity Variables, Epidemiology, and Network Study (RAVEN Study). There were 39 HCV infections (20.9/100/year) and 46 HBV infections (10.0/100/year). There was no apparent protective effect of syringe exchange against HBV (former exchange users, relative risk (RR) = 0.68, 95% confidence interval (CI) 0.2-2.5; sporadic exchange users, RR = 2.4, 95% CI 0.9-6.5; regular users, RR = 1.81, 95% CI 0.7-4.8; vs. RR = 1.0 for nonusers of the exchange; adjusted for daily drug injection). Neither did the exchange protect against HCV infection (sporadic users, RR = 2.6, 95% CI 0.8-8.5; regular users, RR = 1.3, 95% CI 0.8-2.2; vs. RR = 1.0 for nonusers; adjusted for recent onset of injection and syringe sharing prior to enrollment). While it is possible that uncontrolled confounding or other bias obscured a true beneficial impact of exchange use, these data suggest that no such benefit occurred during the period of the study.

COMMENT: Seattle is an area with a high HCV prevalence (70%-80%) and low HIV prevalence (5%) among the IDU population. The probability that an IDU was an HCV carrier was greater than 70%; and given the efficiency of HCV transmission, any syringe sharing or sharing of other injection equipment (e.g., cooker, rinse water, cotton) increases the risk for HCV infection. During the period in which HBV/HCV was studied in this cohort, the incidence of HIV infection was quite low, with only 4 seroconversions (0.2%) among 1651 study participants. A high incidence of viral hepatitis can occur in the presence of low HIV incidence, presumably related to higher prevalence of HCV/HBV carriers as well as the greater infectiousness and higher per-contact risk of acquiring HBV than HIV.

Needle Exchange Programs in Vancouver: An Update on Needle Exchange Programs and HIV Incidence

Schechter M, Strathdee S, Cornelisse PGA et al. Do needle exchange programs increase the spread of HIV among injection drug users: An investigation of the Vancouver outbreak. AIDS 1999 Apr 16;13(6):F45-51.

ABSTRACT Objective: An association between needle exchange attendance and higher HIV prevalence rates among injecting drug users (IDU) in Vancouver has been interpreted by some to suggest that needle exchange programmes (NEP) may exacerbate HIV spread. We investigated this observed association to determine whether needle exchange was causally associated with the spread of HIV. Design and Method: Prospective cohort study of 694 IDU recruited in the downtown eastside of Vancouver. Subjects were HIV-negative at the time of recruitment and had injected illicit drugs within the previous month. Results: Of 694 subjects, the 15-month cumulative HIV incidence was significantly elevated in frequent NEP attendees (11.8 + 1.7 versus 6.2 + 1.5%; log-rank $P = 0.012$). Frequent attendees (one or more visits per week) were younger and were more likely to report: unstable housing and hotel living, the downtown eastside as their primary injecting site, frequent cocaine injection, sex trade involvement, injecting in 'shooting galleries', and incarceration within the previous 6 months. The Cox regression model predicted 48 seroconversions among frequent attendees; 47 were observed. Although significant proportions of subjects reported obtaining needles, swabs, water and bleach from the NEP, only five (0.7%) reported meeting new friends or people there. When asked where subjects had met their new sharing partners, only one out of 498 respondents cited the needle exchange. Paired analysis of risk variables at baseline and the first follow-up visit did not reveal any increase in risk behaviours among frequent attendees, regardless of whether they had initiated drug injection after establishment of the NEP. Conclusions: We found no evidence that this NEP is causally associated with HIV transmission. The observed association should not be cited as evidence that NEPs may promote the spread of HIV. By attracting higher risk users, NEPs may furnish a valuable opportunity to provide additional preventive/support services to these difficult-to-reach individuals.

COMMENT This report from the Vancouver Injection Drug User Study documents the severity of drug use, high risk behaviors and lifestyle characteristics of frequent attenders of the Vancouver needle exchange program compared with infrequent attenders of the program. There was no evidence that the NEP promoted new needle sharing network formation, and no evidence of increased risk behaviors related to injection practices. Significant variables distinguishing the frequent attenders from infrequent attenders (at $p < 0.001$ level) included unstable housing, living in a hotel, injecting in shooting galleries, frequency of heroin and cocaine use, incarceration in the past 6 months, involvement in the sex trade, and other sources of illegal income. The impact of these differences must be noted, and two statistical models were used to assess the impact of these higher risk characteristics on expected new HIV seroconversions. A multivariate Cox regression model containing these variables yielded a good fit with the actual observation of new seroconversions in both frequent attenders (48 predicted, 47 observed) and among infrequent

attenders (18 seroconversions predicted, 17 observed). A second analysis was conducted using a logistic regression model, with predicted seroconversion rates of 45 among frequent attenders and 19 among infrequent attenders - fairly close to the 47 observed in frequent attenders and 17 observed in infrequent attenders, respectively. This suggests that these risk factors themselves are more predictive of HIV seroconversion than patterns of SEP attendance. A more comprehensive approach to addressing the needs of the IDU may be required, in addition to the availability of sterile injection equipment, to achieve effective HIV prevention in this highest risk population.

SUMMARY POINTS From Updated Syringe Exchange Literature

- ▶ Laboratory studies show prolonged viability of HIV in used needles (> 4 weeks), providing strong biologic rationale for removal of used drug injection equipment from circulation.
- ▶ Syringe exchange programs (SEPs) consistently attract persons with highest risk profiles for HIV infection and severe drug use, and are successful in referring SEP clients into detoxification and substance abuse treatment programs.
- ▶ SEP-referred clients have similar rates of retention in substance abuse treatment as individuals from standard referral sources, despite more severe baseline drug use and high-risk lifestyles.
- ▶ Clients participating in SEPs have decreased reuse of contaminated syringes and reduced sharing of injection equipment
- ▶ The data indicate that the presence of a syringe exchange program does not increase the use of illegal drugs among participants, and in many cases, a decrease in injection frequency has been observed among those attending these programs.
- ▶ Provision of sterile injection equipment through SEPs and pharmacy access is cost-effective; one HIV infection can be prevented for one third the cost of medical care for an infected person.
- ▶ The scientific evidence accumulated to date provides a basis on which municipalities that are heavily affected by an HIV epidemic driven by injection drug use should consider syringe exchange programs as a tool for the identification, referral and retention of active users of injection drugs into these services, as part of a comprehensive HIV prevention plan.