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NEEDLE EXCHANGE PROGRAMS RESEARCH DATA THAT ADDRESS THE CRITERIA FOR LIFTING THE FEDERAL BAN

CRITERIA 1: Section 505(1) The Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV ... (PL 105-78)

Findings from 12 published studies of Needle Exchange provide data on the following endpoints/outcomes:

- **HIV and other blood borne infection rates among IDUs**
- **Expert reports**

CRITERIA 2: Section 506(1) The Secretary of Health and Human Services determines that exchange projects ... do not encourage the use of illegal drugs (PL 105-78)

Findings from 16 published studies of Needle Exchange provide data on the following endpoints/outcomes:

- **Initiation of drug injection by non-IDUs**
- **Frequency of injection drug use**
- **Linking IDUs to drug treatment**

Contents

CRITERIA 1

Section 505(1) The Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV ... (PL 105-78)

Table 1.1: HIV Infection Rates (11 studies: 5 found significant reductions in HIV seroincidence, 2 found increases in HIV incidence, 3 found stable seroprevalence, and 2 found reductions in seroprevalence)

[illegible]	[illegible]	[illegible]	[illegible]
Heimer et al., 1992 To assess the prevalence rates of HIV in needles/syringes used by New Have IDU.	1,860 randomly selected needles distributed and returned to the needle exchange Prospective open cohort	HIV seroprevalence rates ▸ Pre-NEP: prevalence at 68% ▸ NEP in 1st 2 months: prevalence at 64% ▸ NEP after 4 months: prevalence stable at 43% (reflecting a 33% decrease)	Independent reviews of model support conclusions about HIV infections averted by NEP.
Kaplan & O'Keefe. 1993; Kaplan, 1994 Estimate change in seroincidence rate among IDUs following their enrollment in New Haven NEP	Randomly selected syringes Mathematical models using unique Syringe Tracking and Testing System	HIV seroincidence: ▸ *33% reduction* among program participants ▸ *0.7 to 1.6 infections prevented per 100 person years*	
Kaplan & Heimer, 1994, 1995 Provide more accurate estimates (Maximum likelihood model) of change HIV incidence rates among IDUs who use NEP.	2,813 tested needles that were distributed and returned between November 1990 and June 1992 Maximum likelihood change point model applied to empirical data gathered in Syringe Tracking and Testing System	HIV seroincidence ▸ Incidence rate of 1.63 per 100 person years among program participants which was found not to differ from zero which means that the best estimate of new infection among needle exchange participant is zero	

Table 1.1 continues on next 3 pages.

Table 1.1: HIV Infection Rates (Continued)

Study Purpose	Sample Design	Results/Findings	Comments
Watters, 1994 To examine change in HIV risk behaviors and prevalence among IDUs between 1986 & 1992.	5,956 IDUs recruited from street settings and detoxification clinics Ecological study with 13 semiannual cross-sectional surveys over 6.5 years, 1986-1992	HIV seroprevalence rates • Needle exchange was implemented in 1988 • HIV prevalence rate doubled between 1986 and 1987 and remained stable between 1987 and 1992 (12%)	Cross-sectional data
Des Jarlais et al., 1994 Examine trends HIV risk behaviors & HIV prevalence among IDUs between 1984 & 1992.	1,115 IDUs admitted to drug detoxification program Ecological study with 2 randomly selected cross-sections, 1984 and 1992	HIV seroprevalence rates • Stable HIV prevalence at slightly more than 50%	Cross-sectional data
*Hurley, Jolley, & Kaldor, 1997. 349:1797-1800. Compare changes over time in HIV seroprevalence among IDUs for cities with and without NEPs.	Ecological study of 81 cities across Europe, Asia, and North America	Seroprevalence among increased by 5.9% per yr in the 52 cities without NEPs, and decreased by 5.8% per yr in cities with NEPs. The average prevalence rate was 11% lower in cities with NEPs.	Cities in Europe, Asia, and the US with NEPs report seroprevalence decrease. Due to the study design, no causal link between the presence of NEP and HIV prevalence reductions can be made.

Des Jarlais et al., 1996 Compare HIV incidence among IDUs who use NEPs with that among IDUs who do not participate.	2,630 IDUs from ▸ Syringe Exchange Evaluation (SEE) ▸ Vaccine Preparedness Initiative (VPI) ▸ National AIDS Demonstration Research (NADR) Meta-analytic technique combining HIV incident data across 3 studies	HIV seroincidence ▸ SEE: among continuing NEP users, incidence was 1.58 per 100 person years at risk (pyar) ▸ VPI: among continuing NEP users, incidence was 1.38 per 100 pyar; among non-NEP users, incidence was 5.26 per 100 pyar ▸ NADR: among non-NEP users, incidence was 6.23 per 100 pyar ▸ Pooled 3-study data indicate that non-NEP use was associated with a 3.35 greater risk of HIV infection	Causal link can not be made between NEP use and seroincidence. Data does show that NEP participation is protective of HIV seroconversion Dose response relationship between NEP participation and HIV infections averted.
*Strathdee, et al., 1997, AIDS, 11:F59-F65. Describe HIV prevalence and Incidence among prospective cohort of IDUs	1,006 IDUs were recruited through street outreach. Prospective cohort study with baseline, semi-annual data collection.	Predictors of HIV + status were: - low education, unstable housing, commercial sex, borrowing needles, injecting with others, and frequent NEP attendance. - 23 of the 24 HIV Seroconverters reported NEP as their most frequent source of needles and only 5 reported having difficulty accessing sterile syringes.	▸ Despite availability of NEPs, high incidence was reported ▸ NEP user most frequently report cocaine use ▸ Comprehensive services such as counseling & testing, drug treatment appear not to have been &/or insufficient to prevent HIV ▸ Study is epidemiologic in nature, was not intended to evaluate NEP (92% of study participant attended NEP) ▸ Can not establish causal relationship between NEP use and HIV infection. ▸ Comprehensive services such as counseling & testing, drug tx appear not to be available or insufficient to prevent HIV infection.

*Bruneau et al., 1997, Am J of Epidemiol, 146:994-1002. Assess the association between risk behaviors and HIV seroprevalence and incidence among IDUs in Montreal.	1,599 IDUs were recruited to participate in this open prospective cohort study. Data analyses included: - Cross-sectional analyses of baseline data to assess association of NEP use and serostaus, - Cohort analyses of NEP use at baseline as predictor of conversion, - Nested case-control analysis of NEP use during follow-up as predictor of conversion.	- NEP user were 2.2 times more likely to be positive at baseline. - The cohort analysis showed that the cummulative probability of HIV conversion was found to be 33% for NEP users versus 13% for Nonusers. - Nested case-control study revealed that consistent NEP users was associated with seroconversion (odds ratio = 10.5).	NEP users were at higher risk at baseline than non-NEP users. Study was not designed or intended to evaluate NEP. Epidemiologic study. No causal link between NEP participation and HIV infection can be made.
*Singer et al.,1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	3,050 randomly selected needles r Prospective open cohort with pretest and posttest measures returned to NEP	HIV seroprevalence rates: • Baseline NEP: prevalence at 58% • NEP after 2.5 years; prevalence relatively stable at <40%	

Table 1.3: Expert reports (2 studies: 2 found significant reductions)

Author, Date, Purpose	Sample Design	Results	Comments
GAO, 1993 To assess the effectiveness of NEP in reducing HIV infection rates.	Reviewed all publications on the topic.	The report stated the following, based on a thorough review of the only study at the time that reported HIV incidence findings (Kaplan and O'Keefe, 1993) : "Based on our expert consultant review, we found the model to be technically sound, its assumptions and data values reasonable and the estimated 33% reduction in new infections defensible."	
NRC/IOM To evaluate the effectiveness of NEP programs.	Reviewed all published and unpublished studies of NEPs.	The report states: "For the participants in a needle exchange program, the fraction of needles in circulation that are contaminated is lowered by this increased availability. This amounts to a reduction in an important risk factor for HIV transmission. The lower the fraction of needles in circulation that are contaminated, the lower the risk of new HIV infections."	

CRITERIA 2

Section 506(1) The Secretary of Health and Human Services determines that exchange projects ... do not encourage the use of illegal drugs (PL 105-78)

Table 2.1: Increases in Mean Age of NEP Users Indicate NEP Did Not Encourage New IDUs (2 studies: 1 found significant increase, 1 had some significant increase)

Author, Purpose	Study Design	Results	Comments
Watters et al., 1994 To evaluate a syringe exchange in San Francisco.	5,644 IDUs recruited from street settings and detoxification clinics Ecological cross-sectional study using 11 semiannual cross-sectional surveys over 5.5 years (12/86-6/92)	1987: Mean age of IDUs was 38.5 years 1992: Mean age of IDUs was 41.6 years The mean age of youngest NEP participants did not significantly over the 5.5 year study	
Guydish et al., 1993 To evaluate potential negative effects of the San Francisco NEP	35,460 drug treatment admissions: 24,120 IDUs 11,340 non-IDUs Ecological cross-section study. Data on records 2 years preceding NEP (1987-1988) and 2 years following NEP.	IDUs • Mean age at admission increased steadily over time • Mean age at first injection remained stable over time Non-IDUs • Pre-NEP, 31.6% switched to injection by time of 2nd treatment admission • Post-NEP, 35.4% switched to injection by time of 2nd treatment admission (not significant)	

Table 2.2: Reductions in Injection Frequency (9 studies: 5 had significant reductions, 2 had some significant reductions, 2 not significant)

Authors/Number/Objective	Sample/Design	Results/Findings	Comments
Watters et al., 1994 To evaluate a syringe exchange in San Francisco.	5,644 IDUs recruited from street settings and detoxification clinics Ecological cross-sectional study using 11 semiannual cross-sectional surveys over 5.5 years (12/86-6/92)	Median daily frequency of injection declined: • from 1.9 to 0.7 injections per day	
Paone et al., 1994 To evaluate NYC lower East side NEP.	1,752 IDUs, randomly selected needle exchange participants Multiple random cross-sections of NEP participants with recapture feature using retrospective data collection over 8 month (10/92-6/93)	Mean monthly frequency of injections declined: • from 95.2 to 85.6 times per month.	
Oliver et al., 1994 Evaluate NEP in Portland, OR.	• 83 participants attending NEP> 4 times • 32 participants attending > 4 times Prospective cohort study with pre-post measures	Mean monthly frequency of injection • Frequent NEP attenders: Baseline 28.7 reduced to Follow-up 8.9 • Infrequent NEP attenders: Baseline 33.0 reduced to Follow-up 30.7	
*Singer et al., 1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	233 NEP participants Prospective cohort study with pretest and posttest measures	Mean monthly frequency of injection • IDU injecting < 5 times/day at baseline: increase of 57 injections at posttest • IDU injecting >5 times/day at baseline: decrease of 90 injections at posttest	

Table 2.2 continues on next 2 pages.

Table 2.2: Reductions in Injection Frequency (Continued)

Author/Purpose	Sample/Design	Results/Findings	Comments
Guydish et al., 1993 To evaluate potential negative effects of the San Francisco NEP	35, 460 drug treatment admissions of which 24,120 were IDUs Ecological cross-sectional study. Data on records 2 years preceding NEP (1987-1988) and 2 years following NEP implementation.	**Decrease significant and stable not significant:** Proportion (%) of IDUs in various categories of frequency of injection in last 30 days • Decrease % of IDU injecting 2-3 times a day (before NEP 41% vs after NEP 28%) • Stable % of IDUs injecting once a day or less (before NEP 17% vs after NEP 17%) • Increase % of IDUs more than 3 times a day (before NEP 40.7% vs after 55.4%)	
Des Jarlais et al., 1994 Examine trends HIV risk behaviors & HIV prevalence among IDUs between 1984 & 1992.	1,115 IDUs admitted to drug detoxification program Ecological study with 2 randomly selected cross-sectional samples. 1984 and 1992	**Decrease significant and stable not significant:** Mean Frequency of injection per month • Decrease cocaine injections per month (55 vs 43) • Stable heroin injections per month (46 vs 44) • Stable speedball injections per month (43 vs 41)	
Hagan et al., 1993 To assess the potential effectiveness of the Tacoma NEP	204 needle exchange participants Retrospective cohort study (pre-post measure)	**Decrease not significant:** Mean monthly injection frequency • Stable injections at 155 a month prior to first use of NEP and 152 a month while participating in NEP	

Hagan et al.. 1994 To update the evaluation of Tacoma NEP.	426 needle exchange participants Retrospective cohort study	**Decreases not significant** (OR=.83, p>.05) Proportion of IDUs who inject < 37 times per month and injectors who inject ≥ 37 times per month Pre-exchange Post-exchange < 37 per month 42.2% 46.9% ≥37 per month 57.8% 53.1%	
Schoenbaum, Hartel, and Gourevitch, 1996, AIDS, 10:1729-1734. To compare prospectively injection behaviors of IDUs in methadone Tx who did and did not use local NEP.	904 IDUs who injected between 1985 and 1993 and attended a methadone treatment program in the Bronx were recruited. Bronx NEP opened in 1989. Prospective study.	Among active IDUs, there were declines in the proportion of IDUs who injected 30 or more times per month. That proportion decreased for NEP participants from 72.% in 1989 to 49% in 1993 compared with reductions of 70% to 45% among nonusers of NEP.	Study documents more substantial reductions in injection frequency and sharing among methadone Tx participants who also used NEP compared to IDUs in Tx who did not use NEP while in Tx.. Ongoing injection drug use while in methadone treatment is documented in this study and others in the literature. NEP and TX are compatible interventions.
*Vlahov et al..1997 To determine whether enrollment in NEP was associated with short-term reduction in risk behaviors.	221 IDUs in NEP Prospective study, baseline and 2 follow-ups (at 2 weeks and at 6 months)	Significant reductions were reported in the mean number of injections per syringe and mean number of injections per day at follow-up (from 5.9 to 4.9 per day).	

Table 2.3: Entry into Drug Treatment (4 studies: 4 found significant effects)

Author, Objective	Sample, Design	Results	Comments
Hagan et al., 1993 To assess the potential effectiveness of the Tacoma NEP	530 patients admitted to methadone treatment Ecological, all drug treatment admissions during 17-month period	Health Dept. methadone referral source for all patients during study period • NEP was the largest referrals source (43%) followed by self-referrals (38%), other outreach (8%), and other source (13%)	
Heimer & Lopes, 1994 To report on the increase in drug treatment associated with opening of NEP	1,512 IDUs using New Haven's NEP Prospective open cohort, compared treatment entry during first 7.5 mths (1990) to 11 mths experience 2-3 yrs later.	Number of monthly drug treatment entries • Drug treatment entries doubled (14.4 to 28.8 persons per month	
*Singer et al., 1997 To assess the effect of environmental changes on HIV risk behaviors and prevalence among IDUs.	315 needle exchange participants Prospective open cohort with pretest and posttest measures	After using NEP for more than 6 months, 58% report having enrolled in detox or drug treatment	
*Vlahov et al., 1997 To determine whether enrollment in NEP was associated with short-term reduction in risk behaviors.	221 IDUs in NEP Prospective study, baseline and 2 follow-ups (at 2 weeks and at 6 months)	Drug treatment participation tripled between baseline (5% of NEP users in treatment) and 6-month followup (15% of NEP users in treatment)	

Table 2.4: Expert reports (2 studies: 2 found significant reductions)

[redacted]	[redacted]	[redacted]	[redacted]
GAO, 1993 To assess the effectiveness of NEP in reducing HIV infection rates.	Reviewed all publications on the topic.	The report states: "One concern surrounding needle exchange programs is whetherthey lead to increased injection drug use. Seven of the nine projects looked at this issue, and five had strong evidence for us to report on outcomes. All five found that drug use did not increase among users; four reported no increase in frequency of injection and one found no increase in the prevalence of use."	
NRC/IOM To evaluate the effectiveness of NEP programs.	Reviewed all published and unpublished studies of NEPs.	The report states: "There is no credible evidence to date that drug use increased among participants as a result of programs that provide legal access to sterile equipment. The available scientific literature provides evidence based on self-reports that needle exchange programs do not increase the frequency of injection among program participants and do not increase the number of new initiates to drug use."	

References

1. Bruneau, J., Lamothe, F., Franco, E. et al. (1997). High rates of HIV infection among injection drug users participating in needle exchange programs in Montreal: results of a cohort study. *American Journal of Epidemiology, 146:994-1002.*

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

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

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

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

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

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

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

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

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

11. Heimer, R., & Lopes, M. (1994). Needle exchange hastens entry into drug treatment [letter]. *Journal of the American*

Medical Association, 271 (23):1825-1826.

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

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

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

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

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

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

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

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

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

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

MMWR, 46:565-568.

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

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

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

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

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

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

NEEDLE EXCHANGE PROGRAMS IN AMERICA: REVIEW AND EVALUATION OF SCIENTIFIC RESEARCH

Introduction

In September 1996, the Committee on Appropriations for the Departments of Labor, Health and Human Services, Education and Related Agencies requested the Secretary of the Department of Health and Human Services to provide a review of the scientific research on needle exchange programs. In response to that request, the Department provided a report to Congress in February 1997 with an overview of the status of scientific research on needle exchange programs, including a compilation of relevant studies and abstracts pertinent to the efficacy of needle exchange programs in reducing HIV transmission and their effect on utilization of injection drugs.

The February 1997 report included two extensive summaries (National Academy of Science/Institute of Medicine 1995, and University of California at Berkeley/San Francisco 1993) evaluating the research literature on the effectiveness of needle exchange programs for the prevention of HIV transmission among injection drug users and their effect on utilization of illegal drugs. An earlier report by the General Accounting Office (1993) reviewed the results of studies addressing the effectiveness of needle exchange programs in the United States and abroad, with an assessment of the credibility of a forecasting model developed at Yale University that estimates the impact of a needle exchange program on the rate of new HIV infections. The conclusion provided in the February 1997 report stated that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood borne infectious diseases in communities that choose to include them, and that needle exchange programs can have an impact on bringing difficult to reach populations into systems of care that offer drug dependency services, mental health, medical and support services.

Since the completion of the February 1997 report to Congress, a number of researchers have published data in peer-reviewed journals or presented research findings at national conferences. The National Institutes of Health also published an NIH Consensus Development Statement, Interventions to Prevent HIV Risk Behaviors, in March 1997. That document summarized the proceedings of an NIH Consensus Development Conference, which evaluated the available scientific information regarding the effectiveness of interventions designed to prevent HIV transmission, including needle exchange programs.

Consistent with the February 1997 report to the Congress, this report is limited to those studies conducted in the United States, with the exception of the inclusion of Canadian research data from Vancouver and Montreal. The National Academy of Sciences/Institute of Medicine previously reviewed the unpublished data from Montreal, now published in final form. Other international studies are not reviewed here, as drug use patterns are highly context sensitive in terms of both social, cultural and economic factors and findings could not be generalized to the U.S. population.

This report builds upon the February 1997 report to Congress, expanding on that summary to include newly available data and the implications for policy.

HIV Transmission Through Injection Drug Use

The consequences of injection drug use have become the driving force in the HIV epidemic in the United States. Half of all new infections are caused by the sharing of injection equipment contaminated with HIV, either due to injection drug use or through unprotected sex with an injection drug user or birth to a mother who herself, or whose partner, was infected with HIV through drug use. The proportion of AIDS cases and new HIV infections attributable to injection drug use has been rising steadily. Over 75% of new HIV infections in children result from injection drug use by a parent. The impact has been most devastating in communities of color, which accounted for 65% of newly reported AIDS cases between July 1996 - June 1997.

The primary goal of needle exchange programs is to reduce the transmission of HIV and other blood borne infections, such as hepatitis B (HBV) and hepatitis C (HCV), associated with drug injection by providing sterile needles in exchange for potentially contaminated ones. Researchers from Yale University empirically demonstrated that provision of sterile syringes results in removing from circulation contaminated syringes that could potentially be re-used, thereby decreasing the transmission risk associated with sharing contaminated equipment. In addition to exchanging syringes, needle exchange programs are effective access points for populations with multiple high risk behaviors for HIV infection to receive other services. Many needle exchange programs provide an array of other services including referrals to drug treatment and counseling, HIV testing and counseling, and screening for sexually transmitted diseases and tuberculosis. There are more than 100 needle exchange programs now operating in 71 cities and 28 states and one territory in the United States.

Summary of Research Findings on Needle Exchange Programs

This section summarizes in brief the primary research findings regarding needle exchange programs. A more extensive review of the studies included in the February 1997 DHHS Report to the Appropriations Committee can be found at Appendix A; an analysis of those studies completed since February 1997 is provided at Appendix B. A summary table of needle exchange research studies examining specific outcomes of interest is provided at Appendix C. A subset of this table identifying those studies reporting on the two criteria established in the Public Law 105-78 Appropriations legislation is provided at Appendix D.

Empirical Studies in the United States Needle exchange programs have been implemented in low, moderate and high HIV prevalence sites in an attempt to reduce the spread of HIV and other blood borne infectious diseases among injection drug users. A discussion of some of the methodological issues pertinent to studies on needle exchange is provided later in this document.

In brief, findings from a comprehensive review of the literature indicate that needle exchange programs: increase the availability of sterile injection equipment and reduce the proportion of contaminated needles in circulation (Kaplan and Heimer 1992, Kaplan 1994, and Heimer et al. 1993); reduce drug-related risk behaviors such as multi-person re-use of syringes (Hagan et al. 1991 and 1993, Guydish et al. 1993, Oliver et al. 1994, Paone et al. 1994, DesJarlais et al 1994, Watters et al. 1994, Singer et al. 1997, and Vlahov et al. 1997); increase drug treatment referrals (Heimer 1994) and entry into drug treatment (Hagan et al. 1993, Singer et al. 1997, and Vlahov et al. 1997); have successfully referred participants to drug treatment with resulting high drug treatment retention rates and reduced HIV risks (Brooner and Vlahov 1997); have shown small improvements in reducing sexual risk behaviors among needle exchange participants (Watters et al. 1994, DesJarlais et al. 1994, and Paone et al. 1994); have maintained low prevalence of blood borne HBV and HCV infections (Heimer et al. 1993, DesJarlais et al. 1995, Hagan et al. 1994, and Paone et al. 1994); have reduced HIV seroprevalence rates in certain cities (Hurley, Jolley and Kaldor 1997); and have reduced the rate of new blood borne infections like HIV and HBV among program participants (Hagan et al. 1991 and 1995, and DesJarlais et al. 1996). Additional information on the study design and findings of the studies listed above can be found in the summary documents at Appendices C and D.

Empirical Studies in Canada Two recent observational studies from Vancouver (Strathdee et al. 1997) and Montreal (Bruneau et al. 1997) reported a higher incidence of HIV among injection drug users participating in needle exchange than non-exchange participants. In Vancouver, HIV seroprevalence was estimated to be stable at 1%-2% among the injection drug using population from 1988, when the needle exchange program was established, through 1993. In 1994, a rapid expansion of the HIV epidemic took place, with a baseline seroprevalence of 23.2% observed in a prospective cohort study of injection drug users. Preliminary analysis from this cohort study found an HIV incidence rate of 18.6 per 100 person years. This study reported on a number of behavioral and social risk factors associated with HIV seropositive status, including a high level of injectable cocaine use, prostitution and longer histories of injection drug use. The presence of multiple behavioral risk factors confounded the ability to isolate participation in needle exchange as a predominant or predictive factor for HIV infection. Subsequent 1997 data from this cohort have showed a decline in HIV incidence to 4.4 per 100 person years.

An observational cohort study of injection drug users was conducted in Montreal. In a baseline assessment of HIV seroprevalence, individuals who attended a needle exchange program reported higher frequencies of risk behaviors associated with drug injection and more frequent involvement in prostitution activities. In a prospective HIV seroincidence analysis, HIV incidence among persons attending the needle exchange program was 7.9 per 100 person years, compared to 3.1 per 100 person years among non-attenders. As in the Vancouver study, demographic, behavioral and social factors were identified that in aggregate defined the high risk profile of those persons also attending needle exchange programs. A more complete review and analysis of these two studies is provided at Appendix B.

Synthesis Reports

Institute of Medicine

In 1995, the National Academy of Sciences/Institute of Medicine published a report, Preventing HIV Transmission: The Role of Sterile Needles and Bleach, reviewing the cumulative body of scientific literature available at that time. A summary of the conclusions of the NAS/IOM panel on the scientific assessment of needle exchange program effectiveness is provided as follows:

"On the basis of its review of the scientific evidence, the panel concludes:

o needle exchange programs increase the availability of sterile injection equipment. For the participants in a needle exchange program, the fraction of needles in circulation that are contaminated is lowered by this increased availability. This amounts to a reduction in an important risk factor for HIV transmission.

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

o There is no credible evidence to date that drug use is increased among participants as a result of programs that provide legal access to sterile equipment.

o The available scientific literature provides evidence based on self-reports that needle exchange programs do not increase the frequency of injection among program participants and do not increase the number of new initiates to injection drug use.

o The available scientific literature provides evidence that needle exchange programs have public support, depending on locality, and that public support tends to increase over time." p.4

The IOM concluded that " needle exchange programs should be regarded as an effective component of a comprehensive strategy to prevent infectious disease." (p.4)

NIH Consensus Development Statement

In March 1997, the National Institutes of Health published the Consensus Development Statement on Interventions to Prevent HIV Risk Behaviors, summarizing the proceedings of a Consensus Development Conference. A panel of non-Federal experts evaluated the available scientific information regarding behavioral interventions to reduce risk for HIV/AIDS. Presentations of scientific data were made to the panel by distinguished researchers, including ongoing evaluation studies of needle exchange programs. Specific behaviors and community contexts that produce elevated risks for HIV infection were reviewed, as well as the spectrum of available interventions to reduce behavioral risks. After reviewing the data on needle exchange programs, the panel concluded that these programs have beneficial effects on reducing behaviors

such as multi-person re-use of syringes. They reported that "studies show a reduction in risk behaviors as high as 80% in injecting drug users, with estimates of a 30% or greater reduction of HIV." (p.11) The panel also concluded that the preponderance of evidence shows either a decrease in injection drug use among participants or no changes in their current levels of use.

University of California at Berkeley and San Francisco Study for the CDC

In 1993 the University of California published a review and analysis of the literature on needle exchange programs to answer a number of research questions, including the effect of needle exchange programs on HIV infection rates and HIV risk behaviors. Study findings reported included the following: needle exchange programs served as a bridge to other health services, particularly drug abuse treatment; needle exchange programs generally reached a group of injecting drug users with long histories of drug injection and limited exposure to drug abuse treatment; there was no evidence that needle exchange programs increased the amount of drug use in participants or changes in overall community levels of drug use; needle exchange programs did not result in an increase in the number of discarded syringes in public places; the rates of HIV drug risk behaviors were reduced in needle exchange participants; needle exchange programs were associated with reductions in hepatitis B among injection drug users; and, the data were too limited at that time to draw conclusions about needle exchange programs and reductions in HIV infection rates.

Summary of New Research Findings

Since completion of the Department of Health and Human Services' February 1997 report to the Congress on needle exchange programs, several scientific studies have added new data on the effects of needle exchange programs, corroborating and expanding knowledge about the role needle exchange programs play in reducing HIV transmission. In addition, these new data continue to demonstrate that needle exchange programs do not encourage drug use, and in fact will increase referrals into drug treatment for hard-to-reach populations. A more complete description of these studies is provided at Appendix B.

In a study by Vlahov et al. (1997), reductions in high risk drug use behaviors and an increase in enrollment in drug treatment were observed in a cohort participating in the needle exchange program. In a study by Brooner et al (in press), a high rate of acceptance of substance abuse treatment and retention in treatment was demonstrated among injection drug users referred from needle exchange programs, despite greater severity of drug use and high risk behaviors for HIV and psychosocial problems in this group. Hurley et al (1997) identified decreased HIV seroprevalence among 29 cities with needle exchange programs compared to 52 cities without these programs, with cities selected according to the availability of HIV prevalence data for their injection drug using population for 2 or more years. Two studies from Canada reported increased HIV incidence among injection drug users also using needle programs, but the design of these studies and the behavioral characteristics of the study populations limit the

generalizability of the findings to the United States populations. Subsequent data from one Canadian study (Vancouver) has shown a significant decrease in HIV incidence since publication of the first study.

Methodological Considerations

In reviewing the scientific data on needle exchange, it is relevant to note the wide range of methodologic approaches utilized and the impact of these study design choices on the conclusions drawn. As was noted in the 1995 report by the National Academy of Sciences/Institute of Medicine, some of the studies that examine needle exchange and bleach distribution programs have various limitations including inadequate sample size, improper controls and problematic measures including self-reporting instruments. In behavioral research, these study designs and instruments are the best available tools to describe complex behaviors. In addition, multiple behavioral risk factors, including drug choices such as cocaine, confound the ability to isolate cause and effect relationships for HIV transmission among injection drug users. This whole body of research is burdened by these constraints.

Nevertheless, as the NAS/IOM report states "... the limitations of individual studies do not necessarily preclude us from being able to reach scientifically valid conclusions based on the entire body of literature available. The situation resembles the exploration of the relationship between cigarette smoking and lung cancer; virtually every individual study was vulnerable to some particular objection, yet collectively those studies justified a compelling conclusion. It was essential for the panel first to distinguish between studies of high quality and those of lesser quality, and then to weigh the credibility of the findings, according to their completeness and soundness. Using this approach, the panel based its conclusions on the pattern of evidence provided by a set of high-quality studies, rather than relying on the preponderance of evidence across less scientifically sound studies." p. 3-4

Maximizing the Public Health Benefits of Needle Exchange Programs

In assessing the public health benefits gained from needle exchange programs, certain characteristics have consistently emerged from the research data that confirms the unique role that needle exchange programs can play as part of the public health response to an epidemic driven by injection drug use. To ensure that federal dollars are maximized in this effort, a careful consideration of those factors most predictive of public health benefit must be heeded. To this end, it is critical that no reduction in drug treatment capability occur, as substance abuse treatment remains the long term strategy for reducing injection drug use and the associated risk of HIV transmission. Needle exchange programs are appropriately supported as an HIV prevention activity in those communities that choose to develop them. Other important factors include local support of health department leaders and affected communities for needle exchange as a necessary component of a broader, comprehensive HIV prevention plan. Those programs which consistently provide referral to medical and drug treatment afford the greatest opportunity

to reduce HIV infection and decrease injection drug use. Concerns among communities have highlighted the need for appropriate disposal of hazardous wastes. Where collection and disposal of used syringes has been implemented, and syringes are provided on a replacement basis only, community support has been achieved. Those programs that operate in accordance with state and local laws, or which are granted waivers from applicable laws, have shown the greatest success in linking together the range of medical and drug treatment services needed by their clients. Finally, there is an important role for ongoing evaluation of needle exchange programs to maximize their effectiveness in reaching high risk populations and providing the means for injection drug users to eliminate or reduce both their risks for HIV and injection drug use.

Public Health Implications

The scientific data now available have established the utility of needle exchange programs in reducing new HIV infections with no evidence of increasing injection drug use. The data supports the unique role needle exchange programs can play in creating an access point into social services, drug treatment and medical care for the population most responsible for new HIV seroconversions. This role as a conduit into care is amplified in that needle exchange programs offer, at multiple points in time, repeated opportunities for prevention intervention as well as an ongoing opportunity to develop trusting relationships between professional staff and the injection drug-using population. This is often the most significant social connection in an active drug user's life and creats a foundation with which future interventions may depend. In addition to the immediate replacement of a contaminated needle with a clean one, we see the efficacy of a needle exchange program as dependent on its relationship to a constellation of services that are directed at identifying high risk populations and creating formal conduits into care.

The public health need to target high risk populations most responsible for driving HIV seroconversion rates is evident. Our understanding of how HIV moves through communities must be structured into responses to epidemiologic surveillance data that describe modes of transmission. This includes allowing States and localities to coordinate their resources and target them to those population groups that cannot stop participating in high risk behaviors. However, federal funding is only appropriate for those programs that provide the critical linkages with drug treatment and health care services and incorporate the spectrum of prevention services that have proven effective HIV prevention tools.

We remain committed to exploring through research those factors that affect the demonstrated utility of needle exchange programs in curtailing transmission of HIV in communities and the relative effects on drug use and entry into drug treatment.

Attachments
Appendix A: 1997 Report to Congress
Appendix B: Analysis of Recent Data
Appendix C: Summary Tables of Research Studies
Appendix D: Summary of Data by Statutory Criterion