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Issues - Needle Exchange Programs - Montreal

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MONTREAL

Bruneau J, Lamothe F, Franco E et al. 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 1997; 146, No.12: 994-1002.

Montreal researchers began recruiting a cohort of IDUs in 1988 with follow-up through Jan. 1995 to study risk behaviors, HIV seroprevalence and HIV seroincidence. Mean follow-up period was 21.7 months. 1599 subjects enrolled at baseline had an HIV seroprevalence of 10.7%. There were 89 new HIV infections. The cumulative probability of HIV seroconversion for NEP users was 33%; for non-NEP users, the same probability was 13%. In general, NEP attenders reported higher frequencies of risk behaviors related to drug injection, such as involvement in prostitution activities, sharing and borrowing equipment, use of shooting galleries, higher frequencies of injection, and were less likely to have been in treatment.

- In this study, NEPs alone did not have the protective effect to limit the spread of HIV in the IDU population that it served. NEPs are only one component of a broader HIV prevention strategy necessary to address populations whose risk behaviors place them at high risk for HIV.

- Montreal NEP users were at higher risk for HIV at baseline due to risky behaviors than those IDUs not using NEPs. They injected more frequently, they re-used other syringes more frequently, injecting in shooting galleries and often participating in commercial sex work.

- In the setting of this very high risk group, the established NEP had restrictions placed on the number of syringes that could be exchanged at any one time. The intent of this deliberate restriction was to encourage multiple visits and bind participants to the needle exchange program. The researchers indicated that the number of needles distributed may have been less than the actual number needed by this high risk population.

- Hence, the NEP was insufficient to meet the demand for adequate syringe replacement among this high risk population, or to address the multiple transmission risks among this group.

- Since no one single strategy is likely to be effective in reaching the at-risk population, communities should create multiple opportunities for IDUs to reduce their risk of HIV infection, with the goal of eliminating drug abuse through effective treatment for drug abuse.

March 25, 1998

NOTE TO SARAH HOLEWINSKI AND BRAD AUSTIN FROM PETER HARTSOCK

Re: Montreal

Attached is the 1997 *American Journal of Epidemiology* article on needle exchange in Montreal which was cited in the March 23, 1998 *New York Times* article.

I have also attached the section from 1995 National Academy of Sciences report which also dealt with the Montreal work.

Note especially the sections which I have starred and underlined in both documents. The National Academy of Sciences and the Montreal people admit that their *research cannot be used to evaluate needle exchange*. None-the-less, this work keeps getting inappropriately cited as such an evaluation.

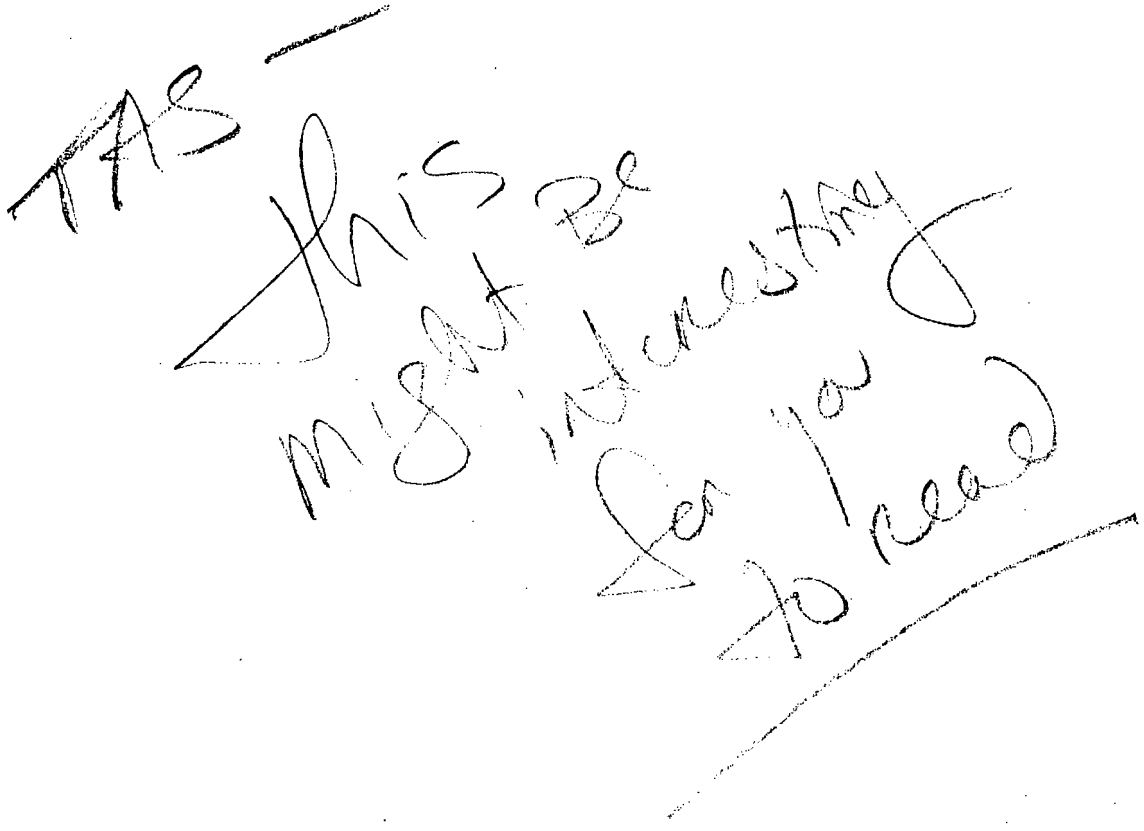

TABLE 5. Odds ratios (ORs) of becoming seropositive to the human immunodeficiency virus during follow-up among injection drug users associated with overall history of participation in a needle exchange program in Montreal, Quebec, Canada, 1988–1995*

Needle exchange program	No.	OR1†	95% CI	OR2‡	95% CI	OR3§	95% CI
All subjects	408						
Nonusers	129	1.0	Referent	1.0	Referent	1.0	Referent
Users <50% of time	110	1.3	0.5–3.2	0.9	0.3–2.7	0.7	0.7–2.5
Users ≥50% of time	104	3.9	1.7–8.7	2.6	1.0–6.7	2.2	0.6–5.7
Consistent users	65	22.9	8.4–62.3	10.2	3.3–31.5	13.1	2.7–41.0
Males only	367						
Nonusers	116	1.0	Referent	1.0	Referent	1.0	Referent
Users <50% of time	95	1.4	0.5–3.8	0.9	0.3–2.8	0.7	0.2–2.3
Users ≥50% of time	93	4.0	1.7–9.6	2.7	1.0–7.4	2.9	0.6–6.5
Consistent users	63	21.8	7.7–61.5	10.2	3.1–33.1	19.1	2.6–50.1

* Results from the nested case-control analysis by conditional logistic regression.
† From analysis conditioned on age, gender, year of admission, and language.
‡ Adjusted for intravenous (IV) drug use since last visit, number of times IV drugs were used in previous month, borrowed IV equipment since last visit, number of times new IV equipment was used in previous month, and practice of disinfection.
§ Adjusted for variables above and additionally for drug of choice, drug use alone in last 3 months, drug use with regular partners in last 3 months, drug use during occasional encounters in last 3 months, drug use with friends in last 3 months, number of partners from whom IV equipment was borrowed in last month, borrowed IV equipment from HIV-positive person since last visit, number of acquaintances known to be HIV positive, practiced booting in last 3 months, drug use while in prison, and living status.

estimates of effect for the NEP-risk association. All plausible sociodemographic, behavioral, and drug consumption variables available were examined as potential confounders.

Because of the low threshold for selecting empirical confounders, the regression models included an extensive list of covariates. This may have decreased the precision of the estimates of effect for NEP attendance, further adding an element of conservatism to our strategy. The fact that the association between NEP attendance and HIV infection risk persisted after being scrutinized with such a conservative analytical approach bolsters our conclusion that it is internally valid and merits further attention.

Before we address the possible implications of our study, it is important to consider its limitations. Our study is observational and was not specifically designed to evaluate the efficacy of NEP in preventing HIV infection. We cannot generalize its findings to other IDU populations in Montreal or elsewhere because of the type of recruitment and of the differences between participants and those lost to follow-up. It is also possible that despite the exhaustive data-driven process to identify confounders, some had been left unaccounted for in the analysis because they were absent from the list of variables derived from the interviews. However, this is unlikely, at least for individual variables, because our questionnaires probed repeatedly for detailed information on risk behaviors and other HIV determinants. Any irrelevant variable with respect to HIV risk that could be linked to NEP attendance would be unlikely to confound the association because confounding ensues only if a factor is associated with the outcome as well as with the exposure.

Misclassification bias could explain our results if we assume that at least one of the following conditions occurred: 1) HIV-positive attenders falsely reported NEP participation, or 2) HIV-negative NEP attenders underreported participation. These are unlikely to have occurred, however, because subjects were unaware of their serologic status before the follow-up interviews.

Substantial misclassification of confounder variables would also lead to a decreased ability to control for their effects in the regression analysis. The extent of the impact of such a misclassification is difficult to predict.

Apart from the statistical issues described above, what are the possible explanations for our results? In our cohort, subject recruitment has relied mostly on self-selection based on informal word-of-mouth advertisement about the existence of our investigation. One possibility is that this method may have led to oversampling of high risk (HIV infection-prone) individuals among NEP attenders in the cohort, affecting the external validity of our study. Even if subjects lost to follow-up did not differ on NEP attendance, differential attrition might have occurred. However, it is reassuring that an independent study among IDUs recruited at CACTUS-Montreal has found seroprevalence and seroincidence rates comparable with those in our study despite use of a different methodology (23).

Differences in baseline prevalence between groups of IDUs have already been pointed out as a predictor for seroconversion in a study of HIV incidence in different cities of the United States (24). This study may have targeted a subpopulation of IDUs attending NEP who are at particularly high risk for the propagation of HIV.

NEPs are often developed within a global organization of prevention and care for drug users. In Montreal, NEPs have been implemented in an environment where needles and syringes are readily available through pharmacies and where policies encouraging pharmacists to sell intravenous equipment to IDUs were introduced in 1988, a year before the first NEP (25). Among opiate users from Manchester in the United Kingdom, the access to sterile equipment through local pharmacies was thought to have reduced the effects of a NEP on sharing habits (26).

It is also conceivable that through a combination of factors, the dynamics in Montreal might have favored HIV acquisition among NEP attenders. NEPs were developed as multifaceted prevention programs offering additional services such as primary health care, support, and counseling. To achieve these goals, the exchange of needles and syringes in the various programs was deliberately limited in an effort to encourage multiple visits and binding to the program. CACTUS, the largest NEP in Montreal, has a needle and syringe exchange policy based on a ratio of one for one, with a maximum of 15 syringes exchanged per person per night. In view of the high risk population attending NEPs, the number of needles distributed may have been less than the actual number needed. Because of availability of clean equipment through pharmacies, which are often conveniently located in the neighborhood, NEPs might have attracted existing core groups of marginalized, high risk individuals. More importantly, NEP implementation, through new socialization among IDUs, also may have facilitated formation of new sharing networks, with the programs becoming gathering places for isolated IDUs. Nonuniform needle sharing among core group members of NEP attenders also may have contributed to the risk differentials seen in our study. The trends toward a decrease of the association over time in our study might be related to changes in the social dynamics around NEPs as well as to long-term effects of such programs.

In view of the higher baseline prevalence for NEP attenders, the risk of HIV acquisition per sharing episode with another NEP attender may be higher than for nonattenders. With a greater incidence around NEPs, sharing during the seroconversion phase may contribute further to HIV transmissibility because of the high viral load in the donor blood during that period (27–29). The predominance of closely related and possibly more infectious HIV strains among NEP attenders is also another hypothesis to consider (30).

In summary, Montreal NEP users appear to have higher HIV seroconversion rates than NEP nonusers. This study also indicates that at least in Montreal, HIV infection is associated with NEP attendance. These findings cannot be explained solely on the basis of the concentration around NEPs of a higher risk IDU population with a greater baseline HIV prevalence. Since NEPs have been viewed as a credible preventive intervention for drug users who continue to inject (1, 2), we believe that caution is warranted before accepting NEPs as uniformly beneficial in any setting. Our investigation was not designed to address a possible causal relation between NEP attendance and HIV infection; its conclusions were derived purely from an observational rather than an experimental study design. NEP implementation involves complex dynamics of individual and collective behaviors that may have different and possibly deleterious effects on HIV transmission. The impact of NEPs may be much more context sensitive and locally dependent than previously realized. It is also possible that the apparent impact of a NEP might diminish over time (31). In Amsterdam, a comparison of the injecting behavior of drug users who seroconverted for HIV with a control group that did not seroconvert yielded no evidence overall of a protective effect, except possibly in the early stages of the program (32). It may be possible also that impact of a NEP may have a longer latency period.

Public health authorities have been informed of our findings, and measures have already been implemented at CACTUS since January 1995—notably, removal of the individual quota on syringe distribution. Our work firmly suggests that NEP programs should be fine-tuned to local needs. More studies are needed to elucidate the mechanisms implicated on the transmission of HIV around NEPs in Montreal or elsewhere and to further assess the potential advantages of this intervention. Such expanded studies should include viral load measures, molecular epidemiology analyses of HIV strains, and qualitative investigations of risk behaviors and networking around NEPs.

ACKNOWLEDGMENTS

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means of a random bar code identifier to individual demographic and risk behaviors (in the previous 7 days) that were collected at each visit on a questionnaire on service delivery and behavior. Overall, 25 percent of the individuals approached agreed to provide a specimen; the 75 percent of program participants who declined indicated they were in a hurry. Yearly HIV prevalence estimates for the period of January 1990 through January 1993 are presented in Table A.1.

Seroincidence

Repeat test results on the same individuals using the random bar code identifiers were used to identify seroconversions and to estimate seroincidence for the same 3-year period (January 1990 through January 1993). The date of seroconversion was estimated as the midpoint between the last negative and first positive result. Hankins et al. (1993, 1994) reported that during that 3-year period a total of 13 of the 136 repeat participants seroconverted, for an overall incidence rate of 12.9 per 100 person years of observation (95 percent CI: 6.9 to 22.0).

Separate incidence estimates per year are provided in Table A.2. Participants who reported having borrowed or loaned needles in the previous 7 days were found to be substantially more at risk of seroconverting. Seroconversion was not found to be associated with age, sex, cocaine use, condom use, or the sexual orientation of males.

Data from Correctional Institutions

In a separate investigation undertaken to assess the degree of needle exchange program participant awareness, use, and satisfaction, Hankins et al. (1992) recruited injection drug users from three medium-security correctional institutions (n = 319) and one drop-in detoxification clinic (n = 173) for a brief structured interview (5 to 10 minutes). The sample of incarcerated injection drug users was originally recruited as part of an ongoing

TABLE A.1 HIV Prevalence Among Montréal Needle Exchange Participants

Year	Seropositive	Total	Proportion (%)	95% CI
1990	49	442	11.1	8.4 to 14.4
1991	51	345	14.8	11.3 to 19.0
1992	45	270	16.7	12.4 to 21.7

SOURCE: Adapted from Evaluating Montréal's Needle Exchange CACTUS-Montréal (Hankins et al., 1994:86).

TABLE A.2 HIV Incidence Rate Among the 25 Percent of Needle Exchange Participants Followed (Repeaters)

	1990	1991	1992	Total
Seroconversion	6/111	7/85	0/19	13/136
Percent	(5.4)	(8.2)	(0)	(9.6)
Person days	16,510	16,707	3,588	36,805
Incidence*	13.3	15.3	0	12.9
95 percent CI	(4.9 to 28.9)	(6.1 to 31.5)	—	(6.9 to 22.0)

*Per 100 person years.

SOURCE: Adapted from Evaluating Montréal's Needle Exchange CACTUS-Montréal (Hankins et al., 1994:89).

research project on risk factors for HIV infection among inmates in medium-security correctional institutions and included HIV antibody testing (Hankins et al., 1994). Results indicate that 73 percent of those interviewed had heard of the needle exchange program; 55 percent of this number had participated and 76 percent of them had used the program more than five times. Attenders expressed a very high level of satisfaction with the personnel (88 percent liked the staff), and 98 percent indicated that they had received the services they had requested.

An analysis of the serology test results shows that the overall HIV prevalence rate among incarcerated injection drug users was 10 percent (29/293). When needle exchange attenders were compared with nonattenders, program participants were found to be twice as likely to be HIV positive (14 and 7 percent, respectively). When the data are stratified by sex, this sizable disparity in HIV prevalence rates was not observed for female inmates; however, the rate was substantially higher for men (Table A.3).

Finally, Hankins and colleagues (1993) have reported meaningful reductions in risk behaviors among needle exchange participants. After the program opened, lending needles declined from 31 to 20 percent, and 62 percent of those who injected with used needles were doing so after having cleaned them with bleach compared with 30 percent in the first 2 months of operation.

Review

As with the San Francisco study, one of the panel's primary concerns with this research is the potential for severe bias in the prevalence and incidence estimates among needle exchange program users and nonusers. Given the nature of the samples studied and the shortfalls in the study

TABLE A.3 HIV Seroprevalence Rates (%) Among Incarcerated Injection Drug Users by Needle Exchange Participation

	Attenders	Non-Attenders	Total
Men	8/39 (20.5)	6/124 (4.8)	14/163 (8.6)
Women	8/69 (11.6)	7/61 (11.5)	15/130 (11.5)
Total	16/108 (14.8)	13/185 (7.0)	29/293 (10.0)

SOURCE: Adapted from Evaluating Montréal's Needle Exchange CACTUS-Montréal (Hankins et al., 1994:90).

design, it would be difficult for researchers to disentangle the potential causal effects of needle exchange programs on the outcome measures studied.

The seroprevalence base rates among needle exchange users reported by Hankins et al. (1994) are based on a 25 percent study participation rate. Clearly, this low participation rate raises concerns about the representativeness of the estimates and their accuracy in reflecting the HIV prevalence of the needle exchange user population. Moreover, the authors state that needle exchange participation stabilized at approximately 1,200 visits per week after the first year of operation. By assuming that a standard recruitment strategy was adopted over the 3 years of data collection, the number of recruited study participants—on which prevalence rates are based—dropped steadily over those 3 years and precipitously during the third year following the program opening (Table A.1). This latter observation further jeopardizes the representativeness of the derived prevalence estimates.

The same potential bias issues are relevant for the incidence rates reported in Table A.2. These are based on even smaller subgroups of those initial study participants who agreed to be tested more than once in a given year. Furthermore, the proportion of the initial base rate groups that were followed up in a given year also dropped substantially in the third year. Of the original 442 study participants in 1990, 25 percent were repeaters (111 of 442); this proportion remained stable in 1991 and dropped to 7 percent (19 of 270) in 1992.

To assess the potential effect of needle exchange participation on HIV prevalence, the investigators relied on data collected from a sample of incarcerated injection drug users who were part of an ongoing research project with another objective: identifying risk factors for HIV infection among inmates. The substantially higher prevalence rate observed among needle exchange program users compared with nonusers (especially for men) is disconcerting. Hankins et al. (1994) also report that incarcerated needle exchange program users were engaging in many more high-risk behaviors—e.g., using needles previously used by an HIV-positive person, receiving income from prostitution—than inmates who did not use the needle exchange program. Because this study examines only seroprevalence rates, neither the timing of the infections nor the temporal link needed to establish the viability of a causal effect for the observed relationship between serostatus and needle exchange program participation (i.e., seroconversion before attending needle exchange) can be determined.

The population sampled also precludes generalizing these findings to the needle exchange user population or to the total population of injection drug users in Montréal. Specific idiosyncrasies of the studied samples directly impact the magnitude of the observed relationships (i.e., properties of the distribution of the variables studied). Although the magnitude of the observed associations (as assessed by odds ratios) is not affected by the shapes of the conditional distributions, their shapes (as assessed by the sample studied) are nonetheless assumed to be representative of the population distributions to which the estimated associations are being generalized.

Given the severe selection bias issues associated with the reported HIV seroprevalence and seroincidence rates among program participants and with the seroprevalence rates among the sampled incarcerated population, the panel concludes that this evaluation study cannot provide valid estimates of program effects on HIV prevalence and incidence.

Epidemiologic Study

Researchers at St.-Luc Hospital in Montréal (Lamothe et al., 1995; Bruneau et al., 1995) initiated a prospective epidemiologic study of HIV infection among injection drug users in September 1988. Active injection drug users who had injected drugs in the past 6 months were recruited from the street (with offers of free HIV testing and precounseling) and from drug treatment programs. The proportion of study participants recruited from treatment programs represents approximately 10 to 15 percent of the total cohort (Bruneau, 1995). Study participants were followed at 6-month intervals and were paid $10 at each visit to complete a structured interview including information on sociodemographic, sexual, and drug-related behaviors and to provide a blood sample for HIV antibody testing. Bruneau et al. (1995) reported on the association between needle exchange attendance (as assessed by one questionnaire item) and HIV infection status among injection drug users by conducting three series of analyses to identify: (1) baseline determinants of HIV seroprevalence, (2) entry determinants of HIV seroincidence, and (3) follow-up determinants immediately preceding HIV seroconversion.

Seroprevalence

By September 1994, the open cohort had an enrollment of 1,506 participants. At entry, 11.1 percent (167/1,506) were HIV positive. The odds

ratio of HIV positivity at entry for needle exchange program attenders (i.e., those who had attended at least once in the last 6 months) versus nonattenders was 3.4 (95 percent CI: 2.4 to 3.9). The final solution of the logistic regression model revealed that the adjusted odds ratio for HIV positivity at entry and needle exchange program attenders versus nonattenders was 2.7 (95 percent CI: 1.8 to 4.1). Adjustments were made for study entry, gender, language, age, and several other sociodemographic and sexual and drug-use risk behaviors. In addition to needle exchange program participation, variables found to be associated with seropositivity at entry included: education, income level, and the number of sex partners in the last 6 months. Furthermore, several drug-use risk behaviors were found to be associated with HIV positivity at entry, including: drug of choice; number of times injected drugs in the last month; participated in the needle exchange during the last 6 months; injected drugs in shooting galleries during last 6 months; injected drugs while in prison; ever shared injection equipment; acquaintances known to be HIV positive; and ever shared injection equipment with HIV-positive person.

Seroincidence

Of the 1,339 study participants who were not seropositive at entry, 75 had no follow-up data due to their recent enrollment date and 354 (25 percent) were lost to follow-up. Of the remaining 910 participants followed up (median follow-up was 15.3 months), 77 seroconverted, for an overall incidence of 5.0 per 100 person years (95 percent CI: 3.9 to 6.2). An upward trend in incidence rates was found when these rates were examined over three consecutive 18-month periods: for the period of September 1988 through February 1990, an estimated incidence rate of 4.5 percent was observed. This was followed by an incidence rate of 7.5 percent during the second 18-month period and a 9.8 percent rate during the 18 months after September 1991. At entry, the odds ratio of becoming HIV positive based on needle exchange participation (attenders versus nonattenders) was 2.5 (95 percent CI: 1.6 to 4.0).

To further explore the association between needle exchange participation at enrollment and subsequent seroconversion, a proportional hazards model was used with adjustments for the following variables: age; entry period; number of times used drugs in previous month; number of partners sharing injection equipment in previous month; number of acquaintances known to be HIV positive; participation in drug abuse treatment; other sources of injection equipment; and drug of choice. Although noteworthy, the resulting hazards ratio for needle exchange program attendance did not reach statistical significance.

Finally, to try to identify potential determinants immediately preceding HIV seroconversion, a logistic regression model was fit to a nested case-control design, with the 77 seroconverters as cases and 279 matched controls (matched on gender, language, year of enrollment, and age). This analysis used information on sociodemographic variables, sexual behaviors, and drug-use risk behaviors collected during the last follow-up interview session preceding seroconversion. For the purpose of this analysis, a needle exchange program use variable was derived based on the sources of needles available to the participants, and cases were categorized as the participant: (1) had never used the needle exchange program as a source of needles, (2) had used the needle exchange program as the exclusive source of needles, and (3) had used the needle exchange program as one of several sources for obtaining needles. After controlling for multiple covariates in the logistic model (number of partners sharing equipment in previous month; number of times having used new injection equipment; number of acquaintances known to be HIV positive; booting; practicing disinfection; and drug of choice), the odds ratio (OR) associated with participants having used the needle exchange program as their exclusive source of needles in the last 6 months prior to seroconversion was found to be 5.19 (95 percent CI: 1.9 to 14.5). Those who did not make exclusive use of the needle exchange program as their source of needles were found to be 16.78 times more likely to seroconvert than needle exchange nonusers (i.e., OR = 16.78; 95 percent CI: 2.7 to 06.0).

Review

As with the other research discussed above, biases in parameter estimates due to the use of limited sampling strategies pose serious concerns for the generalizability of these findings either to the population of injection drug users or to the population of needle exchange program users in Montréal. One of the panel's concerns with this study is that the authors use causal language to describe the purpose of their analysis. In their abstract, Bruneau et al. (1995) state that they performed a series of analyses to assess the baseline determinants of HIV prevalence, entry determinants of HIV seroincidence, and follow-up determinants immediately preceding HIV seroconversion. The use of the term *determinants* would seem to indicate that these researchers are attempting to assess the causal effect of needle exchange participation on HIV prevalence and incidence. However, given the limitations of the study design and the analytical methods used, this study is incapable of sorting out the independent causal effects of each predictor on the outcome variables. It should be noted that, during a briefing session with the panel (Bruneau, 1995), the authors clearly communicated to us that they did not attempt to assess the causal effect of needle

exchange on seroprevalence or seroincidence. They consider their study to be purely descriptive in nature and not evaluative.

One difficulty associated with trying to assess needle exchange program effects on seroprevalence and seroincidence with these data relates to properly identifying and measuring confounding factors. The choice of variables for control is not well specified. This makes it extremely difficult to know whether the list of controls is relevant or complete enough to address the selectivity processes that might distinguish attenders from nonattenders. The measurement level of most variables is weak, consisting mostly of dichotomized or trichotomized variables, and this can significantly limit the capacity of the statistical adjustment process to adjust fully for the potential influence of those variables. Moreover, no attempt to assess the influence of interactions was discussed.

The key variable used in this study to assesses needle exchange program participation is limited, consisting of a single item asking respondents if they have used the needle exchange program at least once in the last 6 months. The use of a single item to categorize individuals as having participated in the needle exchange program raises concerns about measurement errors—mainly systematic errors in this case—in the variable being measured, which can produce serious biasing effects. *Systematic measurement error* refers to measurement validity. This type of error occurs when the true variable of interest has not been measured (e.g., time at risk while exposed to the needle exchange) and some other variable or proxy is used in its place (e.g., use of program at least once in last 6 months). When more than one covariate is used in the analysis, the effects of random and systematic errors become quite unpredictable and may overestimate or underestimate the regression coefficients.

Another noteworthy consideration is that injection drug users who do not use the needle exchange program in Montréal have access to sterile injection equipment through pharmacies (there is a pharmacy a block away from the exchange program that sells syringes and is open 24 hours a day). Furthermore, although the seroprevalence and seroincidence among needle exchange participants are higher than among nonparticipants, both groups have high rates of infection, although the nonexclusive needle exchange users were found to be at substantially higher risk than the exclusive users of the program.

Having access to sterile needles in Montréal through sources other than needle exchange is not problematic. It is clear that some selectivity processes are at work. Something is attracting high-risk injectors to the exchange program. Without a more detailed understanding of the characteristics that distinguish nonusers from users, we cannot ascribe the differences in the seroprevalence and seroincidence rates to the needle exchange program. Again, we note that the authors themselves do not attribute the observed differences to the program.

CHICAGO

Investigators in Chicago have recently reported in two unpublished manuscripts the results of an investigation of the relationship among access to free needles through needle exchange program participation, drug-use behaviors (injection frequency, needle use, needle exchange use), other HIV risk behaviors, and HIV incidence to disentangle the causal effect of the Chicago needle exchange on these critical variables.

Demand for Free Needles and Their Effect on Injecting Frequency and Needle Use

In their first paper, O'Brien et al. (1995a) attempt to examine the causal effect of needle exchange use on individual needle and drug use. The Chicago needle exchange program was initiated in 1992. Before the program was initiated, these investigators had been monitoring trends in risk behaviors and HIV incidence among out-of-treatment injection drug users in an effort to assess the impact of an extensive outreach HIV intervention program (discussed in detail in Chapter 6). This study's participants are part of three distinct cohorts that were recruited from three different inner-city neighborhoods: the South Side (mostly African American), North Side (ethnically mixed), and Northwest Side (largely Puerto Rican). The three cohorts were recruited from these three neighborhoods by outreach workers in local community settings, such as street corners, copping areas, and shooting galleries.

The first cohort (1988 cohort) was assembled as part of a longitudinal outreach HIV prevention study and consisted of 850 injection drug users, of which 25 percent were found to be HIV positive at baseline. An additional cohort of 244 injection drug users (baseline HIV prevalence was 32 percent) not exposed to the outreach HIV prevention program was recruited in 1992 (1992 cohort) to supplement the original cohort. Finally, a third cohort of 323 injection drug users, also not exposed to the outreach HIV prevention program, was recruited in 1994 (1994 cohort) and found to have a 24 percent baseline HIV prevalence rate. Results of the analyses presented in this manuscript are based on demographic characteristics, drug-use risk behaviors, sexual risk behaviors, and HIV serology test results collected in 1994 as part of the baseline assessment for the 1994 cohort and as part of a 1994 follow-up assessment for the 1988 and 1992 cohorts for members that were still injecting (n = 728) at the time. They are also based on interview data (demographic characteristics and risk behaviors) and se-

TAB - FYI - DCM

race/ethnicity, gender bias, and the socioeconomic, and political status of women. PANWHA's 15 members include organizations representing behavioral science, public health, civil rights, minority health, and clinical care.

A white paper summarizing the key issues raised in the briefing is currently being developed. For copies, send an e-mail request to hffields@astho.org or fax a request to Helen Fox Fields at (202) 371-9797. The policy brief should be available by the end of January.

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10) Study Shows Higher HIV Transmission Rates Among Needle Exchange Clients

On December 15, a study was published in the "American Journal of Epidemiology" which concludes that participants in a needle exchange program in Montreal appear to have greater HIV sero-conversion than non-participants. Canadian researcher Julie Bruneau led a team that studied approximately 1600 participants for over 20 months. The study says that the probability of seroconversion among needle exchange participants was 33% while it was 13% for non-participants, and that the adjusted odd ratio for HIV seroprevalence among injection drug users who report recent needle exchange use was 2.2.

In the same issue, Dr. Peter Lurie of the University of Michigan writes that the study's efforts were observational and that the study was not designed to evaluate needle exchange programs. Dr. Lurie writes that the study is subject to selection bias, and that a possible solution would be to conduct a randomized, control trial such as one being conducted in Alaska by the National Institutes on Drug Abuse (NIDA). However, randomized, controlled studies involving needle exchange have been criticized as unethical. Both the Montreal study – which has been discussed since early 1995 when unpublished data was available – and the Alaska study have been focus points for the contentious debate surrounding the current federal ban on needle exchange funding.

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11) Study in Africa Demonstrates Effectiveness of STD Treatment in HIV Prevention

In December, an article was published in the journal "Lancet" which concludes that treatment of STDs in six communities in Mwanza, Tanzania reduced HIV prevalence and averted HIV infections at the cost of $217.62 per HIV infection averted. Researchers compared the intervention in the six treatment communities with six matched communities. During two years of follow-up, the incidence of HIV infection was 1.16% in the treatment communities and 1.86% in the control group communities. Researchers argued that the cost of the intervention compares favorably to other intervention programs such as childhood immunizations. Furthermore, they conclude that cost effectiveness could be even higher if the intervention is expanded.

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12) FDA Approves New Formulation of First Protease Inhibitor

On November 7, the FDA approved a new formulation of Invirase, the first FDA-approved protease inhibitor. The new drug, called Fortovase, comes in a soft gel capsule, and delivers

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