

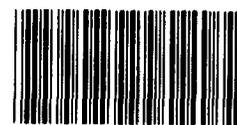
GAO

Report to the Chairman, Select
Committee on Narcotics Abuse and
Control, House of Representatives

March 1993

NEEDLE EXCHANGE PROGRAMS

Research Suggests Promise as an AIDS Prevention Strategy



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Human Resources Division

B-247447

March 23, 1993

The Honorable Charles B. Rangel
Chairman, Select Committee on
Narcotics Abuse and Control
House of Representatives

Dear Mr. Chairman:

AIDS or the acquired immune deficiency syndrome is an epidemic that is disproportionately affecting the nation's young, poor, and women in minority communities. Injection drug use is considered a major risk behavior that is helping to spread the human immunodeficiency virus (HIV), the virus that causes AIDS, among these groups. Injection drug users are at greatest risk for AIDS when they share HIV-infected needles and other injecting equipment.

One strategy to reduce the spread of HIV among drug users who cannot stop taking drugs or get treatment is needle exchange. Needle exchange programs typically involve the exchange of new, sterile syringes for used ones that may be infected with HIV. Programs can take a variety of forms: some are legally sanctioned, others are not; some operate on street corners, others operate out of mobile vans; some are funded by a public health agency, others by AIDS advocacy groups; and some have a much wider range of services, such as testing for HIV and tuberculosis (TB), than others.

In July 1991, the National Commission on AIDS, an independent body created to advise the President and Congress, put forth five recommendations to reduce the spread of HIV infection among drug users. These recommendations reflect an array of strategies, including the removal of legal barriers to the purchase and possession of injection equipment.¹ The Commission reported that legal barriers—such as state drug paraphernalia laws—limit the availability of new and clean injection equipment and, therefore, encourage sharing of injection equipment and the increased possibility of HIV transmission. In presenting their recommendation to remove legal barriers, the Commission cited the value

¹Others are: (1) expanding drug abuse treatment and continually working to improve the quality and effectiveness of this treatment, (2) federal leadership in developing and maintaining programs to prevent HIV transmission related to licit and illicit drug use, (3) expanding and funding research and epidemiological studies on the relationship between licit and illicit drug use and HIV transmission, (4) mobilizing public and private sectors to mount a serious and sustained attack on the social problems that promote illicit drug use. National Commission on AIDS, The Twin Epidemics of Substance Use and HIV, July 1991.

of programs such as needle exchange in reducing the risk of HIV infection among those who continue to inject drugs.

This letter responds to your concern over whether there is evidence to show that needle exchange programs reduce the spread of HIV. Specifically, you requested that we (1) review the results of studies addressing the effectiveness of needle exchange programs in the United States and abroad, (2) assess 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, and (3) determine whether federal funds can be used in support of studies and demonstrations of needle exchange programs.

Background

In June 1986, the U.S. Public Health Service (PHS), within the Department of Health and Human Services (HHS), projected that of the estimated 1 to 1.5 million Americans infected with HIV, 200,000 to 450,000 could develop AIDS by 1991. In 1989, AIDS was the second leading cause of death for men and sixth leading cause for women between the ages of 25 and 44 years. As of September 1992, 242,000 people were diagnosed as having AIDS and 160,000 deaths had been attributed to the disease.

Approximately 32 percent of adult/adolescent AIDS cases are related to injection drug use. Injecting drugs in and of itself does not pose an AIDS risk, but sharing needles does. Some drug users may share their needles without sterilizing them between use, thereby enabling the transmission of HIV. Furthermore, HIV-infected drug users can spread AIDS to nondrug using populations. Pregnant drug users, for example, can transmit the virus to their unborn children. In September 1992, the Centers for Disease Control and Prevention (CDC) reported that among children (those under 13 years old), 40 percent of those with AIDS were born to women who contracted HIV through injection drug use and 17 percent were born to women who contracted HIV through sex with an injection drug user.

Needle exchange programs emerged as a strategy to reach dependent drug users unable or unwilling to stop using drugs in order to minimize the health risks associated with such practice. These programs aim at encouraging injection drug users to exchange used needles and syringes for new, sterile ones and at discouraging sharing injection equipment with others in order to reduce the spread of HIV. The goal of the programs is to, if not eliminate needle sharing, at least moderate sharing to reduce the transmission of AIDS and other blood-borne diseases. Some programs also

provide other services to participants, including referral to drug treatment and health care services.

Needle exchange programs were originally begun in the Netherlands to reduce the spread of hepatitis B among the hard-to-reach injection drug users. Later, programs were developed to reduce the spread of HIV in Australia, Sweden, the United Kingdom, Canada and other countries. Such programs are not widespread in the United States and they are also controversial. First, many states have statutes that directly restrict access to sterile drug-injection equipment. These include (1) drug paraphernalia statutes that ban the manufacture, sale, distribution, or possession of devices that may be used to introduce illicit substances into the body and (2) statutes that criminalize the sales of needles and syringes without a medical prescription.² Second, program opponents contend that providing needles gives the appearance that public officials condone illegal drug use. In addition, opponents are concerned that providing needles may not only perpetuate but increase drug use.

As of December 1992, 32 known needle exchange programs were in operation in 27 different United States cities or counties. Beginning with the Tacoma, Washington, program, all of these programs came into existence since 1988. Only 15 of the 32 programs are legally sanctioned.³

Results in Brief

Measuring changes in needle sharing behaviors is an indicator often used to assess the impact of needle exchange programs on HIV transmission. We identified nine needle exchange projects that had published results. Only three of these reported findings that were based on strong evidence. Two of these three reported a reduction in needle sharing while a third reported an increase.

One concern surrounding needle exchange programs is whether they 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

²Gostin, Larry, J.D., "The Needle-Borne HIV Epidemic: Causes and Public Health Responses," *Behavioral Sciences and the Law* (1991), Vol. 9, pp. 287-304.

³Despite state drug paraphernalia and/or syringe prescription laws, some needle exchange programs have obtained legal status. For example, while retaining their state drug paraphernalia laws, the Hawaiian and Connecticut state legislatures enacted laws in 1990 authorizing the establishment of these programs for the purpose of reducing the transmission of HIV among injection drug users; in the state of Washington, legal status was approved by the courts for needle exchange programs administered by local health authorities; and, in New York, the state health commissioner recently exempted individuals connected with authorized pilot needle exchange programs in New York City from prosecution for possession of needles without prescriptions.

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. None of the studies that addressed the question of whether or not the needle exchange programs contributed to injection drug use by those not previously injecting drugs had findings that met our criteria of strong evidence. Our review of the projects also found that seven reported success in reaching out to injection drug users and referring them to drug treatment and other health services.

We also found the forecasting model developed at Yale University to be credible. This model estimated a 33 percent reduction in new HIV infections among New Haven, Connecticut, needle exchange program participants over 1 year. Based on our expert consultant review, we found the model to be technically sound, its assumptions and data values reasonable, and the estimated 33 percent reduction in new HIV infections defensible. This reduction stems from the program's ability to lessen the opportunity for needles to become infected, to be shared, and to infect an uninfected drug user. To gather data in assessing program impact for use in the New Haven model, the researcher developed a new system for tracking and testing for HIV in returned needles.

While these findings suggest that needle exchange programs may hold some promise as an AIDS prevention strategy, HHS is currently restricted from using certain funds to directly support the funding of needle exchange programs. Under the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, block grant funds authorized by title XIX of the PHS Act may not be used to carry out any needle exchange program unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. However, HHS does have the authority to conduct demonstration and research projects that could involve the provision of needles.

Scope and Methodology

Our work consisted of an examination of published evaluation studies on needle exchange programs and site visits to programs located in Tacoma, Washington, and New Haven, Connecticut. To review the forecasting model developed at Yale University, we contracted with outside experts. We also analyzed the legal authority applicable to federal support of research and services related to needle exchange.

To identify the studies for review, we conducted a literature search of medical and social science computerized bibliographic files; obtained the

research materials used by the National Commission on AIDS; reviewed the abstracts from and presentations given at several international conferences on AIDS; and relied upon information referrals from outside experts in the fields of drug abuse research and AIDS. These efforts identified over 800 citations related to needle exchange programs. After eliminating duplicate citations and documents that were not evaluations of exchange programs, we examined 20 published studies and 21 abstracts and/or presentations on evaluations of needle exchange programs in the United States and five foreign countries.⁴ To avoid any duplication of the study findings, we grouped those published studies, abstracts, and presentations that represented the same study effort into projects.⁵ A total of nine separate projects were identified.⁶ Only one of the evaluation projects was on a needle exchange program in the United States.

For each project we sought to identify study findings on the following outcomes: (1) rate of needle sharing, (2) prevalence of injection drug use, (3) frequency of injection, (4) rate of new HIV infections, (5) rate of new entrants to injection drug use, (6) incidence rate of other blood-borne infections, (7) rate of other HIV risk behaviors, and (8) risks to the public's health. We also reviewed the methodologies used in developing the findings.

For these eight outcomes, we present only those project findings that met our criteria for strong evidence. We considered evidence to be strong if:

1. supporting data were published in a scientific journal or a government research monograph,
2. a statistical significance test was done, when appropriate, and the statistical significance level was 0.05, and
3. the author did not attribute the effect to anything other than the needle exchange program.

⁴The studies included in our analysis cover needle exchange programs in Sydney, Australia (3 studies and 3 abstracts/presentations); Vancouver, Canada (1 study); Amsterdam, the Netherlands (4 studies and 4 abstracts/presentations); Lund, Sweden (1 study and 4 abstracts/presentations); the United Kingdom (10 studies and 7 abstracts/presentations); and Tacoma, Washington (1 study and 3 abstracts/presentations).

⁵These projects include studies conducted on the same needle exchange program and by the same team of researchers. Many of the studies were published at different points in time as new study data were developed.

⁶See bibliography for studies that make up the different projects and for other relevant abstracts/presentations reviewed in preparing this report.

As a result, we found strong evidence for only the first three outcomes (rate of needle sharing, prevalence of injection drug use, and frequency of injection). For the next five outcomes, either the study project did not address the outcome or the findings did not meet our criteria for strong evidence.

For three other outcomes, which represent the ability of needle exchange programs to reach out to injection drug users and refer them to drug treatment and other health services, we present only those project findings that reported evidence that these services were offered and also reported the number of injection drug users who received them.

For information on the project designs and methodologies see appendix I. Appendix II provides more details on the needle exchange programs by location for the nine projects we examined as well as for the New Haven program.

To review the New Haven model, we contracted with expert consultants with backgrounds in operations research-based modeling techniques and HIV transmission among injection drug users. Issues reviewed were: the technical adequacy of the model's mathematical specifications, reasonableness of the underlying assumptions used, quality of the data and sources relied upon, and the conclusiveness of the model's 33 percent estimate. See appendix III for more information on our review of the New Haven model.

Our work was conducted from January 1992 to November 1992 in accordance with generally accepted government auditing standards.

Some Research Suggests Programs May Reduce AIDS-Related Risk Behavior

Six of the nine projects we reviewed provide strong evidence on one or more of three AIDS-related risk behavior outcomes: (1) rate of needle sharing, (2) prevalence of injection drug use, and (3) frequency of injection. Table 1 presents the results of our analysis.

Table 1: Results of Needle Exchange Program Study Projects

Project number, by country	HIV transmission	Injection drug use	
	Rate of needle sharing	Prevalence of use	Frequency of injection
Australia			
1	a	No increase	b
Canada			
2	b	b	b
Netherlands			
3	a	a	No increase
4	Lower	b	No increase
Sweden			
5	a	a	a
United Kingdom			
6	a	a	a
7	a	b	Less often
8	Increased	b	b
United States (Tacoma, WA)			
9	Lower	b	No increase

^aStudy project addressed outcome but results did not meet our criteria of strong evidence.

^bStudy project did not address outcome measure.

Two of Nine Study Projects Associate Reduced Needle Sharing With Programs

The risk of becoming HIV infected or transmitting the virus to others is diminished if needle sharing is reduced. All but one of the projects we reviewed examined needle sharing behaviors, but only three of the projects reported findings that meet our criteria of strong evidence.

Two of these projects found that needle exchange programs are associated with reduced needle sharing among participants. A project that studied a needle exchange program in Amsterdam, the Netherlands, found that needle exchange participants reported significantly less needle sharing than a sample of injection drug users who were not participants, both at the outset of the project in 1987 and a year later.⁷ A second project, which studied a Tacoma, Washington exchange program, found that exchange participants reported borrowing and lending used needles less often

⁷Project 4: The Netherlands. Hartgers, Christina, et al., "The Impact of the Needle and Syringe-Exchange Programme in Amsterdam on Injecting Risk Behavior," *AIDS* (1989), Vol. 3, pp. 571-76.

during the time they participated in the exchange than they did before participating.⁸

A third study found that those using an exchange program in Manchester, England, on a regular basis were more likely to lend injection equipment to others than a sample of injection drug users not using the exchange program regularly. The authors noted that some needle exchange program participants reported that they were the focus of pressure to supply injecting equipment to others once it was known that they were getting regular supplies themselves. Program participants also reported giving away unused sterile equipment at times. However, the authors also concluded that those participants who were in long-term drug treatment were less likely to pass on their equipment than those who either were in drug treatment of shorter duration or not in treatment at all.⁹

Most Projects Suggest That Programs Do Not Increase Injection Drug Use

Some policymakers have been concerned that needle exchange programs will increase injection drug use by increasing the availability of needles. As table 1 shows, of the seven projects that examined injection drug use, whether by measuring either the prevalence of drug use or the frequency of injection, five reported findings that meet our criteria of strong evidence. These projects used data based on self-reported behavior or urine specimen tests. Four of the five projects presented strong findings that drug use did not increase and one reported that injection drug users injected less often once they began participating in a program.

For example, results of an Amsterdam project showed that injection drug users reported no increase in the frequency with which they injected drugs for a 2-year period during which there was an exchange program in that city.¹⁰ The Tacoma project reported a similar finding.¹¹

In a second Amsterdam project, 72 percent of needle exchange participants reported that they injected as often or less than they did 6

⁸Project 9: Tacoma, Washington. Hagan, Holly, et al., "The Tacoma Syringe Exchange," Journal of Addictive Diseases (1991), Vol. 10, No. 4, pp. 81-88.

⁹Project 8: United Kingdom. Klee, Hilary, et al., "The Sharing of Injecting Equipment Among Drug Users Attending Prescribing Clinics and Those Using Needle-Exchanges," British Journal of Addiction (1991), Vol. 86, pp. 217-23.

¹⁰Project 3: The Netherlands. Van den Hoe, Johanna A.R., et al., "Risk Reduction Among Intravenous Drug Users in Amsterdam Under the Influence of AIDS," American Journal of Public Health (1989), Vol. 79, No. 10, pp. 1355-57.

¹¹Project 9: Tacoma, Washington. Hagan, Holly, et al., "The Tacoma Syringe Exchange," Journal of Addictive Diseases (1991).

months previously as compared to 49 percent of injection drug users in the study who did not participate in the exchange program.¹² This study reported that this difference between exchange participants and nonparticipants remained the same at follow-up which occurred 10 to 20 months later. A United Kingdom project found that participants reported injecting less often in the third month after entry than before they entered the program.¹³ In addition to these four projects, which used data based on self-reported behavior, a fifth project used what is considered more objective evidence—the results of urine testing. An Australian project reported no difference in the prevalence of injection drug use among methadone clients in a clinic near a needle exchange program and clients in a clinic 25 kilometers from that exchange program over a 3-month period.¹⁴

Projects Show That Programs Reach Out to Addicts and Provide a Link to Drug Treatment and Other Health Services

As table 2 shows, data from several projects support the view that needle exchange programs are reaching injection drug users and referring them to drug treatment or other health services.

¹²Project 4: The Netherlands. Hartgers, Christina, et al., "The Impact of the Needle and Syringe-Exchange Programme in Amsterdam on Injecting Risk Behaviour," *AIDS* (1989).

¹³Project 7: United Kingdom. Hart, Graham J., et al., "Evaluation of Needle Exchange in Central London: Behavior Change and Anti-HIV Status Over One Year," *AIDS* (1989), Vol. 3, pp. 261-65.

¹⁴Project 1: Australia. Wolk, Jael, et al., "The Effect of a Needle and Syringe Exchange on a Methadone Maintenance Unit," *British Journal of Addiction* (1990), Vol. 85, pp. 1445-50.

Table 2: Needle Exchange Program Outcomes Measured and Reported

Project number, by country	Attracted IDUs ^a not in treatment	Referred IDUs to drug treatment	Referred IDUs to other health services
Australia			
1	b	b	b
Canada			
2	b	Yes	Yes
Netherlands			
3	b	b	b
4	Yes	b	b
Sweden			
5	Yes	b	Yes
United Kingdom			
6	Yes	b	b
7	Yes	Yes	Yes
8	b	b	b
United States (Tacoma, WA)			
9	Yes	Yes	b

^aInjection drug users.

^bNot measured or reported.

Five of the nine projects reported that many of the injection drug users who were participating in an exchange program were not receiving drug treatment services. Projects in the Netherlands, Sweden, the United Kingdom and Tacoma, Washington reported that between 24 and 74 percent of these exchange participants were not receiving drug treatment.¹⁵

¹⁵Project 4: The Netherlands. Hartgers, Christina, et al., "The Impact of the Needle and Syringe-Exchange Programme in Amsterdam on Injecting Risk Behaviour," *AIDS* (1989).

Project 6: United Kingdom. Stimson, Gerry V., et al., *Injecting Equipment Schemes Final Report*, University of London: Goldsmiths' College, 1988.

Project 5: Sweden. Ljungberg, Bengt, et al., "HIV Prevention Among Injecting Drug Users: Three Years of Experience from a Syringe Exchange Program in Sweden," *Journal of Acquired Immune Deficiency Syndromes* (1991), Vol. 4, pp. 890-95.

Project 7: United Kingdom. Carvell, Andrea M. and Graham J. Hart. "Help-seeking and Referrals in a Needle Exchange: A Comprehensive Service to Injecting Drug Users," *British Journal of Addiction* (1990), Vol. 85, pp. 295-40.

Project 9: Tacoma, Washington. Hagan, Holly, et al., "The Tacoma Syringe Exchange," *Journal of Addictive Diseases* (1991), Vol. 10, No. 4, pp. 81-88.

Once injection drug users are enrolled, needle exchange programs can play the role of linking them with drug treatment and other health services. The Tacoma project reported that the exchange referred more than 150 active injection drug users to drug treatment.¹⁶ The Swedish project documented that in each of the 3 years following the establishment of an exchange program in a clinic for infectious diseases, the number of HIV tests performed by that clinic increased at least seven-fold. The researchers claim that more than 90 percent of these tests were performed in connection with the needle exchange program.¹⁷ In two other projects, needle exchange programs played a dual role in linking injection drug users with both drug treatment and health services. For example, the Vancouver project provides data showing that the exchange program made over 600 referrals to drug treatment, HIV testing and other health services.^{18, 19}

Although needle exchange programs are able to refer injection drug users to drug treatment, not all drug users are able to obtain treatment. For example, Tacoma needle exchange program officials told us that publicly-funded treatment slots for specific types of drug treatment are not always available when addicts are referred for treatment. Consequently, many of the drug users referred from the needle exchange program are placed on waiting lists. We also learned of a similar problem facing the New Haven needle exchange program. Local public health officials administering the program there told us that many of New Haven's injection drug users are polydrug users (for example, they inject heroin combined with amphetamines), but the primary public treatment available is methadone maintenance for heroin addicts. They added that they also do not have a sufficient number of public treatment programs designed to treat the needs of women, particularly pregnant women.

¹⁶Project 9: Tacoma, Washington. Hagan, Holly, et al., "The Tacoma Syringe Exchange," Journal of Addictive Diseases (1991).

¹⁷Project 5: Sweden. Ljungberg, Bengt, et al., "HIV Prevention Among Injecting Drug Users: Three Years of Experience from a Syringe Exchange Program in Sweden," Journal of Acquired Immune Deficiency Syndromes (1991).

¹⁸Project 2: Canada. Bardsley, John, et al., "Vancouver's Needle Exchange Program," Canadian Journal of Public Health (1990), Vol. 81, pp. 39-45.

¹⁹A pilot needle exchange program tested in New York City (November 1988 through February 1990) not included in our review also presented data on enrollment of program participants in drug treatment programs. Based on the first 12 months of operation, the program was able to refer 80 percent of 290 program participants, half of whom were confirmed to have entered a treatment program.

Forecasting Model Estimates Reduction in HIV Transmission

A model developed by a Yale University researcher to estimate the impact of a needle exchange program on HIV transmission among program participants in New Haven, Connecticut, suggests that such programs are effective.²⁰ The model predicts a 33 percent reduction in new HIV infections over 1 year among program participants. Based on our expert consultant review, we found the model to be credible. Our experts found that the model is technically sound, its assumptions and data values are reasonable, and the estimated 33 percent reduction in new HIV infections defensible.²¹ (For more details on our review of the model, see appendix III.)

The estimated 33 percent reduction stems from the needle exchange program's ability—by gathering used needles in return for unused ones—to decrease the amount of time that needles are in use. Thus, the opportunity for needles to become infected, to be shared, and to infect an uninfected drug user is lessened.

In order to measure the program's impact, the researcher developed a data collection system. This system, syringe tracking and testing (STT), collects data on needles distributed and returned, including to and from whom they were given or returned as well as when and where they were distributed or returned. The needles are monitored by assigning sequential tracking numbers to each needle and anonymous code names to each program participant. In addition, tests are conducted on a sample of returned needles to detect the presence of HIV from the residual blood remaining in the syringe. These tests use the polymerase chain reaction (PCR) procedure, a technique capable of detecting HIV in extremely small amounts of blood.

Legislation Limits Funding of Needle Exchange Programs but Allows Research

The Congress, on several occasions, has specifically prohibited or restricted the use of appropriated funds by HHS to support needle exchange programs.²² More recently, the ADAMHA Reorganization Act of 1992 generally precludes the use of block grant funds (authorized by title XIX of the PHS Act) for needle exchange programs. Existing statutory

²⁰Intervention strategies for social programs often require longitudinal studies to measure their results conclusively. In the interim, researchers sometimes use proxies, such as forecasting models.

²¹As a result of the New Haven model, the Connecticut state legislature enacted legislation that expanded legal authorization to needle exchange programs in other cities. In addition, the legislature modified existing laws to allow for the purchase and possession of up to 10 needles without a prescription effective as of July 1, 1992.

²²Appendix IV provides a detailed review of congressional action on needle exchange programs.

authority does, however, in our opinion, permit use of federal funds for studies or demonstrations of needle exchanges, which might involve the provision of needles.

Our position on this issue is supported by the 1993 HHS appropriations act, which states:

“... no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles for the hypodermic injection of any illegal drug unless the Surgeon General of the United States determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, except that such funds may be used for such purposes in furtherance of demonstrations or studies authorized in the ADAMHA Reorganization Act (P.L. 102-321).”

Demonstration projects are typically used to explore new areas and conduct research where a sound body of knowledge does not exist. In such projects, the delivery of services is often coupled with an evaluation methodology to build a strong base of knowledge about the impact of the services provided. At present, HHS has not conducted demonstrations of needle exchange programs.²³

As requested, we did not obtain written agency comments on this report. However, we met with officials from PHS on the subject of HHS's authority to fund research and demonstrations on needle exchange programs. In addition, we discussed our findings on the New Haven model with the principal researcher. Where appropriate, we incorporated their comments into the report.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 7 days after its issue date. At that time, we will send copies to other interested congressional committees; the Secretary of Health and Human Services; the Director, Office of Management and Budget; and other interested parties. We will also make copies available to others on request.

²³However, there are HHS research activities that do not involve the provision of services. These include: a 1992 research award through the National Institute on Drug Abuse (NIDA), now part of the National Institutes of Health, for refinement of the New Haven model; two other NIDA awards for studies of programs in San Francisco, California and Seattle, Washington; and a study contracted by the CDC to review existing data on needle exchange programs, conduct site visits to programs, and to obtain unpublished program data.

Should you have any questions concerning this report, please call me at (202) 512-7119. Other major contributors are listed in appendix V.

Sincerely yours,



Mark V. Nadel
Associate Director, National and
Public Health Issues

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Abbreviations

ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
AIDS	acquired immune deficiency syndrome
CDC	Centers for Disease Control and Prevention
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
IDU	injection drug use
IDUs	injection drug users
NIDA	National Institute on Drug Abuse
PCR	polymerase chain reaction
PHS	U.S. Public Health Service
STD	sexually transmitted diseases
STT	syringe tracking and testing
TB	tuberculosis

Study Project Designs and Methodologies

Project and location	Study designs	Study methodologies	
		Data collection method	Sample designs
Australia			
1	Longitudinal—cohort ^a with comparison group	Urine testing for drugs, administrative files of client demographic data	Universe
	Longitudinal—trend ^b	HIV testing of needles, self-administered questionnaire	"Selected arbitrarily"
Canada			
2	Longitudinal—trend	Administrative files	Universe
Netherlands			
3	Longitudinal—panel ^c	Structured interview and HIV testing for incidence	Self-selected
	Longitudinal—trend	HIV testing for prevalence, administrative files—hepatitis B surveillance data	Self-selected
4	Cross-sectional ^d and Longitudinal—panel with comparison group	Structured interview	Self-selected
Sweden			
5	Longitudinal—trend	Interview, HIV testing of exchange clients, self-administered questionnaires, administrative files—HIV surveillance data	Convenience
United Kingdom			
6	Longitudinal—trend	Structured interview	Snowball ^e
	Longitudinal—panel with comparison group	Administrative files, structured interview	Not specified
7	Longitudinal—panel	HIV testing of exchange clients (saliva test), interview, administrative files—client demographic data	Not specified
	Cross-sectional	Self-administered questionnaire—HIV testing of exchange clients (saliva test)	Self-selected
8	Cross-sectional with comparison group	Semi-structured interview	Not specified
United States (Tacoma, WA)			
9	Cross-sectional with comparison group	Structured interview, HIV testing of exchange clients, administrative files—hepatitis B surveillance data	Systematic, self-selected, snowball

^aDesigned to permit observations over an extended period of time, so that specific subpopulations (cohorts) drawn from general populations can be examined as they change over time.

^bObservations made at many times of samples drawn from general populations.

^cObservations made at many points in time of the same sample of people each time.

^dBased on observations made at one point in time.

^eMethod of developing an ever-increasing set of sample participants.

Appendix I
Study Project Designs and Methodologies

Needle Exchange Programs: IDU Population and Program Characteristics

Location	Program start date	Estimated IDU population size	Estimated HIV infection levels among IDUs
Australia (Sydney)	11/86	10,000 - 14,000 ^a	5.2% (1989)
Canada (Vancouver)	03/89	10,400-13,000	Not available
Netherlands (Amsterdam)	Summer 1984	2,800	34% (1989)
Sweden (Lund)	11/86	1,000	1% (1990)
United Kingdom ^b	04/87	60,000 - 100,000	Varies ^c
United States (New Haven, CT)	11/90	2,300	60% (1991) ^d
(Tacoma, WA)	08/88	3,000	1-2% (1990) ^e

**Appendix II
Needle Exchange Programs: IDU Population
and Program Characteristics**

Exchange protocol	Hours and mode of operation	Services offered
Needles exchanged on a 1-for-1 basis.	Days and hours vary by site. Mobile bus visits areas of prostitution and IDU and fixed sites at drug abuse clinics and pharmacy.	Information on HIV risk associated with needle sharing and unsafe sexual practices. Counseling and referrals to drug treatment and AIDS assistance. Also provides condoms, swabs, spoons, sterile water and cotton.
Needles exchanged on a 1-for-1 basis. Maximum of 2 provided per exchange.	Hours/days of operation not reported. Mobile van and walking tours of minority neighborhoods. Fixed sites at a youth center and a shopping mall opened to the general public.	Educational materials and advice on HIV risks, safe sex and safe injection techniques. Referrals to drug treatment and medical services (e.g., HIV testing and counseling, sexually transmitted diseases (STDs), and IDU-related illnesses). Also provides condoms.
Needle exchanged on a 1-for-1 basis. Limit on the number of needles that can be exchanged.	Daily. Mobile buses that also dispense methadone, visit 6 IDU areas, and fixed sites at drug agencies and STD clinics.	Information on safe drug use and safe sex. General health education and referrals to methadone and drug-free clinics. Also provides condoms, first aid, and counseling.
Not reported.	Open during office hours. Fixed site at a hospital outpatient clinic.	Information on HIV and STD risks as well as the availability of HIV testing and referral to drug treatment services. Also provides condoms.
Needles exchanged on a 1-for-1 basis. An average of 9 needles issued per exchange.	15 programs with various hours and days. Fixed sites at hospitals or health centers and drug advice agencies.	Counseling and advice on drug problems, HIV transmission, safe sex, and HIV testing. Also, in many cases, a broader range of social and medical care for clients.
Needles exchanged on a 1-for-1 basis. Maximum of 5 provided per exchange.	4 days/week, 6 hrs./day. Mobile van visits 5 IDU areas.	Risk-reduction education, drug treatment referral, counseling and advocacy. Information on HIV and other health risks (e.g., TB, STDs, hepatitis B) and available medical services. Also provides condoms and bleach kits.
Needles exchanged on a 1-for-1 basis.	5 days/week, 5-8 hrs./day. Mobile van visits 2 IDU areas and delivers clean needles to requesting IDUs. Fixed site at health department's pharmacy.	Risk-reduction education, counseling, HIV testing, and referral to drug treatment and other medical or social services. Also provides condoms, bleach, and alcohol pads for cleaning needles as well as TB and STD screening.

^aEstimate is for New South Wales, in which Sydney is located.

^bEngland and Scotland only.

^cEstimate for England ranged from 0 to 10 percent (1987); and in Scotland 4.5 percent for Glasgow (1985) and between 38 and 65 percent for Edinburgh (1985-86).

^dCDC estimated at 35.6 percent in 1990.

^eEstimate is for Pierce County, in which Tacoma is located.

Review of the New Haven Model

Our review of the study of the New Haven needle exchange program entailed an in-depth assessment of its forecasting model. This model predicts that the needle exchange program results in a 33 percent reduction over a 1 year period in the rate of new HIV infections among injection drug users participating in the program. The prediction is based on the theory that the program may be able to reduce the length of time that needles are in circulation by exchanging used needles in return for unused ones. This reduces the opportunity for needles to become infected, to be shared, and to transmit HIV to an uninfected drug user.

To assess the reasonableness of the model's estimate, we (1) analyzed relevant published and unpublished materials describing the model's specifications, assumptions and data sources; (2) visited the New Haven needle exchange program and interviewed the principal researcher who developed the model, Dr. Edward H. Kaplan, Associate Professor of Policy Modeling and Public Management, Operations Research and Medicine, Yale University, to obtain clarifications on the approach used and the rationale for incorporating certain assumptions and data values; and (3) obtained expert review from two outside consultants, Dr. Margaret L. Brandeau, Stanford University, and Dr. N. Scott Cardell, Washington State University.¹

Our review and expert inquiry explored the technical adequacy of the model's mathematical specifications, reasonableness of the underlying assumptions used, quality of the data and sources relied upon, and the conclusiveness of the model's 33 percent estimate. We also explored with our experts the impact on the model's outcome if various other assumptions or data values had been adopted. The results of our assessment are summarized below.

Technical Adequacy of Model's Mathematical Specifications

The New Haven model incorporates two simultaneous nonlinear differential equations that express the level of HIV infection among injection drug users and needles in circulation over time.² This modeling approach is based on the concept of a dynamic epidemic model

¹We selected these two experts after considering several potential candidates recommended by others in the fields of drug abuse and epidemiologic modeling. Our selection criteria were twofold: (1) The expert possesses advanced knowledge in operations research-based modeling techniques for HIV transmission as well as issues related to HIV transmission among injection drug users and (2) The expert provides assurances of objectivity and no professional conflicts of interest.

²The concept of needles in circulation was also introduced in this study. This concept provides a basis for estimating the effect of a needle exchange program on the number of new HIV infections among injection drug users. The effect is estimated by measuring the impact of a reduction in needle circulation time with the program.

traditionally used and validated by epidemiologists studying many infectious diseases, including HIV infection. Both our experts found that the mathematical specifications used in both equations appropriately express the dynamic process of HIV transmission among injection drug users via infected needles. They agreed in their assessment that the model is technically sound and incorporates all key parameters.

Reasonableness of Model's Underlying Assumptions

The model assumes that the needle exchange program impacts only on the length of time needles are available to be shared, and that it does not produce changes in addict behaviors. That is, the rate at which injection drug users share their needles, the frequency of their injection practices, and the frequency of their bleaching practices were assumed as not affected by the exchange program. By adopting an assumption that the program did not have any positive effects on drug users' injection practices,³ our experts found that Dr. Kaplan's model works to produce a conservative estimate of the program's impact. If the model had assumed any positive behavioral changes, the estimated number of infections averted due to the New Haven program would have been greater than the 33 percent estimate.

Our experts agreed that Dr. Kaplan's assumptions serve to underestimate the impact of the New Haven program on the rate of new HIV infections. The expert reviewers strongly believe that 33 percent understates the true percentage reduction in new infections attributable to the program. Other assumptions incorporated into the model that also serve to understate the potential impact of the needle exchange program include: no change in the size of the injection drug using population,⁴ high level of needle sharing behaviors, and HIV-infected injection drug users would continue to inject drugs until development of AIDS.

³For example, positive changes would include some combination of reducing the level of needle sharing, decreasing the frequency of injection, and increasing the rate of bleaching practices.

⁴The model ignores any reductions in the size of the injection drug using population and consequent reduction in new HIV infections attributable to the placement of participants in drug treatment. During the first 7-1/2 months of New Haven's needle exchange program, about one out of every seven participants were placed in drug treatment.

Quality of Model's Data Sources and Values

The data used in the model were primarily obtained from three sources: (1) data developed from the program's syringe tracking and testing system,⁵ (2) self-reports from injection drug users participating in the program, and (3) data developed from other AIDS research studies. Our experts noted that the data values used from these sources are reasonable and produce a conservative estimate of the program's impact on the rate of new HIV transmissions. For example, Dr. Kaplan chose to use an estimate of the sharing rate he developed based on the STT system because it was higher than the sharing rate based on self-reports of program participants (31.5 versus 8.4 percent). If the lower estimate was used, the model's outcome would be significantly greater than the estimated 33 percent reduction in new HIV infections.

In addition to choosing conservative values for use in the model, Dr. Kaplan conducted a sensitivity analysis using several different values for the parameter reflecting the probability that drug users disinfect their needles using bleach. This analysis showed that, even if the actual probability of disinfecting was much lower than the probability based on self-reported data used in the model (0.84), the estimated decline in new HIV infections attributable to the needle exchange program remains significant.

Model's 33 Percent Estimate Defensible

The model's estimate that the New Haven needle exchange program results in a reduction of new HIV infections among participants over 1 year is defensible as a minimal estimate of the program's impact. The 33 percent difference is strictly attributable to the reduction in levels of infection in needles due to the shorter length of time that needles are in use (or needle circulation time).

⁵STT data provide estimates on the level of needle sharing and the level of HIV infection in needles. The estimate for needle sharing (31.5 percent) is obtained by tracking those needles returned by someone other than the person to whom the needle was given to. An estimate for the prevalence of HIV infection (60 percent) is obtained based on testing a sample of returned needles using the polymerase chain reaction testing procedure to detect the presence of the virus.

Legal Barriers to Federal Funding of Needle Exchange Programs

Since 1988, Congress has passed at least six laws (in addition to the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992) that contain provisions prohibiting or restricting use of federal funding for needle exchange programs and activities. These provisions are contained in:

- the Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988;
- the Health Omnibus Programs Extension of 1988;
- the Ryan White Comprehensive AIDS Resources Emergency Act of 1990; and
- the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts of 1990, 1991, and 1993 (the Appropriations Act of 1992 did not contain such a provision).

The Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988 required states, as a condition for receiving ADAMHA block grant funds under title XIX of the PHS Act, to agree that funds would not be used

“to carry out any programs of distributing sterile needles for the hypodermic injection of any illegal drug or distributing bleach for the purpose of cleansing needles for such hypodermic injection . . .”

This provision was repealed by the ADAMHA Reorganization Act (1992).

The Health Omnibus Programs Extension of 1988 authorizes funds and programs aimed at combatting the AIDS epidemic and preventing its transmission. Among other things, the act authorizes grants and contracts through the Director of the National Institute of Allergy and Infectious Diseases to assist public and nonprofit private entities in conducting research and training in advanced diagnostic, prevention, and treatment methods for AIDS. These grants may be used to operate demonstration projects in long-term monitoring and outpatient treatment of HIV-infected individuals. The act also authorizes funds for AIDS education. Additionally, the Director of the National Institutes of Health is to establish projects to promote cooperation among public health agencies and with private entities in research concerned with the diagnosis, prevention, and treatment of AIDS. The act provides further:

“None of the funds provided under this Act or an amendment made by this Act shall be used to provide individuals with hypodermic needles or syringes so that such individuals

Appendix IV
Legal Barriers to Federal Funding of Needle
Exchange Programs

may use illegal drugs, unless the Surgeon General of the Public Health Service determines that a demonstration needle exchange program would be effective in reducing drug abuse and the risk that the public will become infected with the etiologic agent for acquired immune deficiency syndrome."

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (42 U.S.C. § 300ff et seq.) authorizes grants to localities disproportionately affected by the HIV epidemic. The act prohibits use of

"funds made available under this Act, or an amendment made by this Act . . . to provide individuals with hypodermic needles or syringes so that such individuals may use illegal drugs."

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts of 1990 and 1991 contained identical prohibitions regarding needle exchange programs (section 520 of P.L. 101-166 and section 512 of P.L. 101-517). The provision stated:

"None of the funds appropriated under this Act shall be used to carry out any program of distributing sterile needles for the hypodermic injection of any illegal drug unless the President of the United States certifies that such programs are effective in stopping the spread of HIV and do not encourage the use of illegal drugs."

In contrast, the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Act of 1993, states in section 514 of the "General Provisions":

"Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles for the hypodermic injection of any illegal drug unless the Surgeon General of the United States determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, except that such funds may be used for such purposes in furtherance of demonstrations or studies authorized in the ADAMHA Reorganization Act (P.L. 102-321)."

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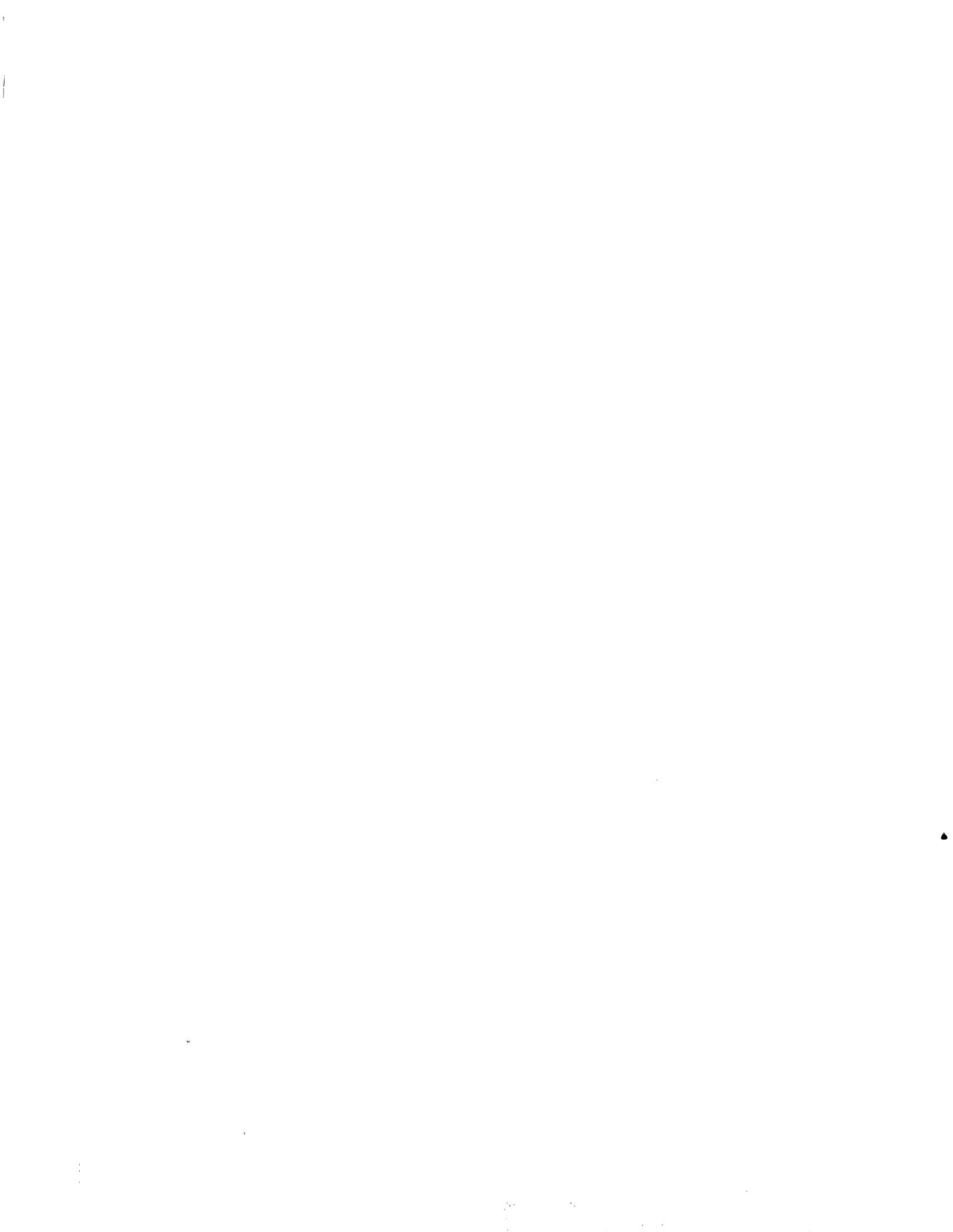
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