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Let The Needles Do The Talking!

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- United States National Institute on Drug Abuse Grant #R01–DA07676–01 ("A Syringe Tracking and Testing System for IVDU Epidemics")
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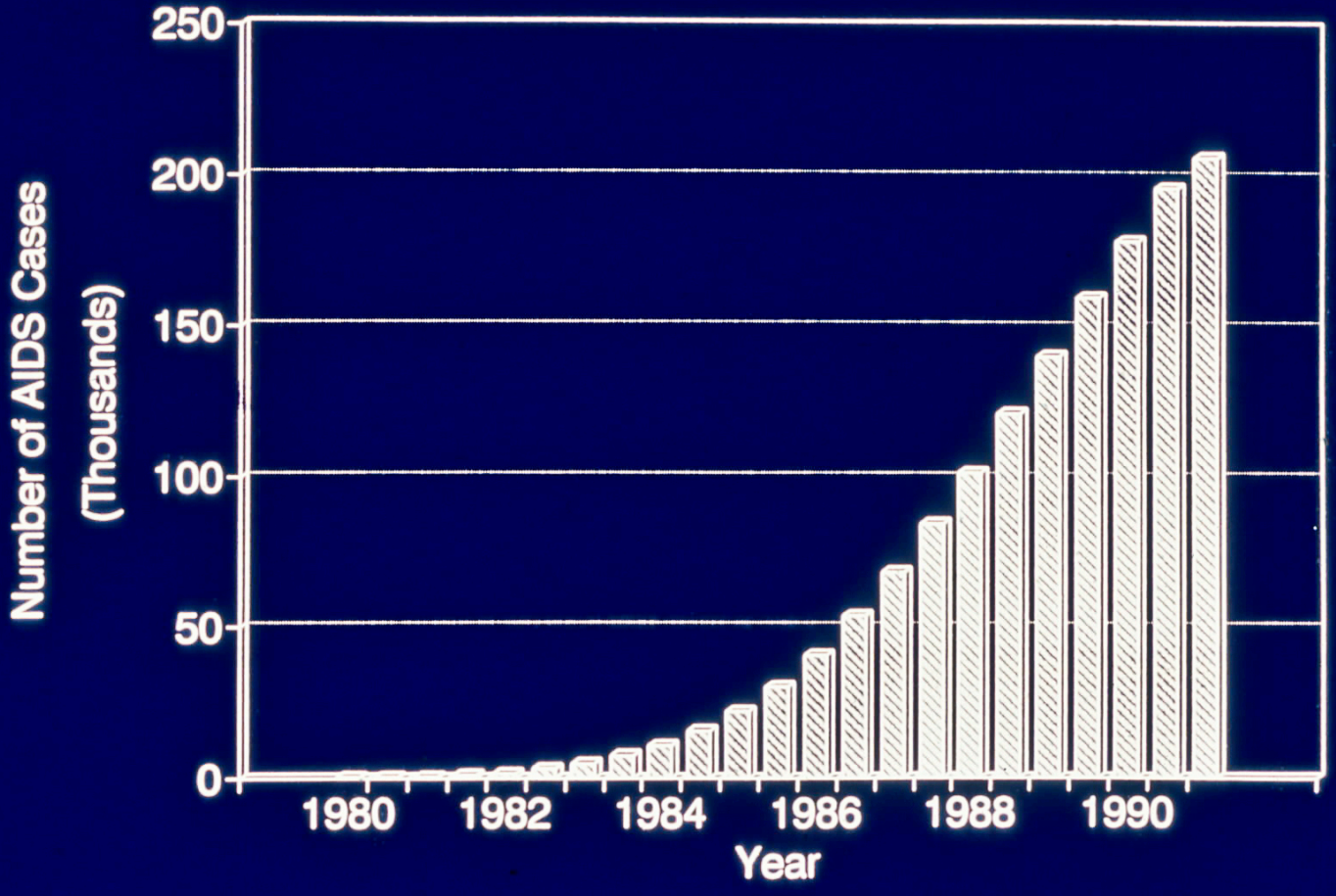
Epidemiology and Public Health)

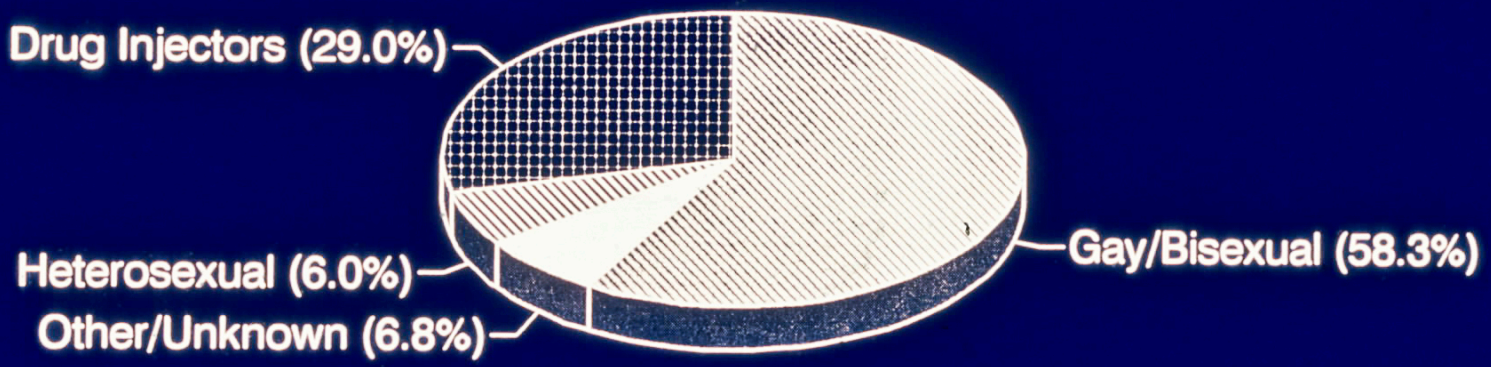
Outreach staff of New Haven Needle Exchange

Cumulative Reported U.S. AIDS Cases

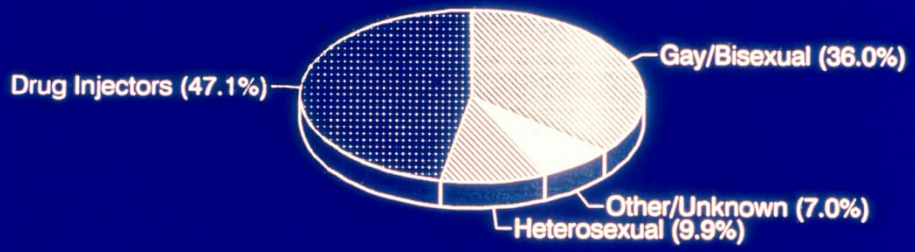
(Source: Centers for Disease Control)



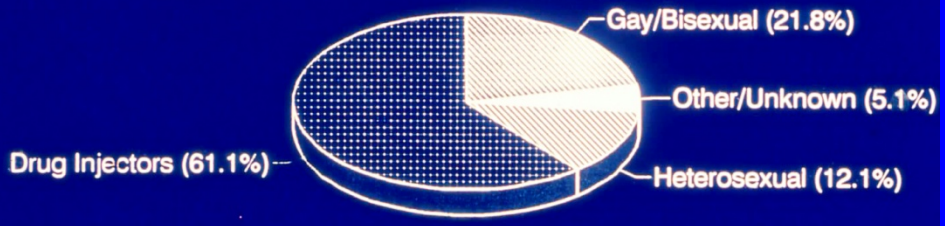
Cumulative Reported U.S. AIDS Cases
(Source: Centers for Disease Control)



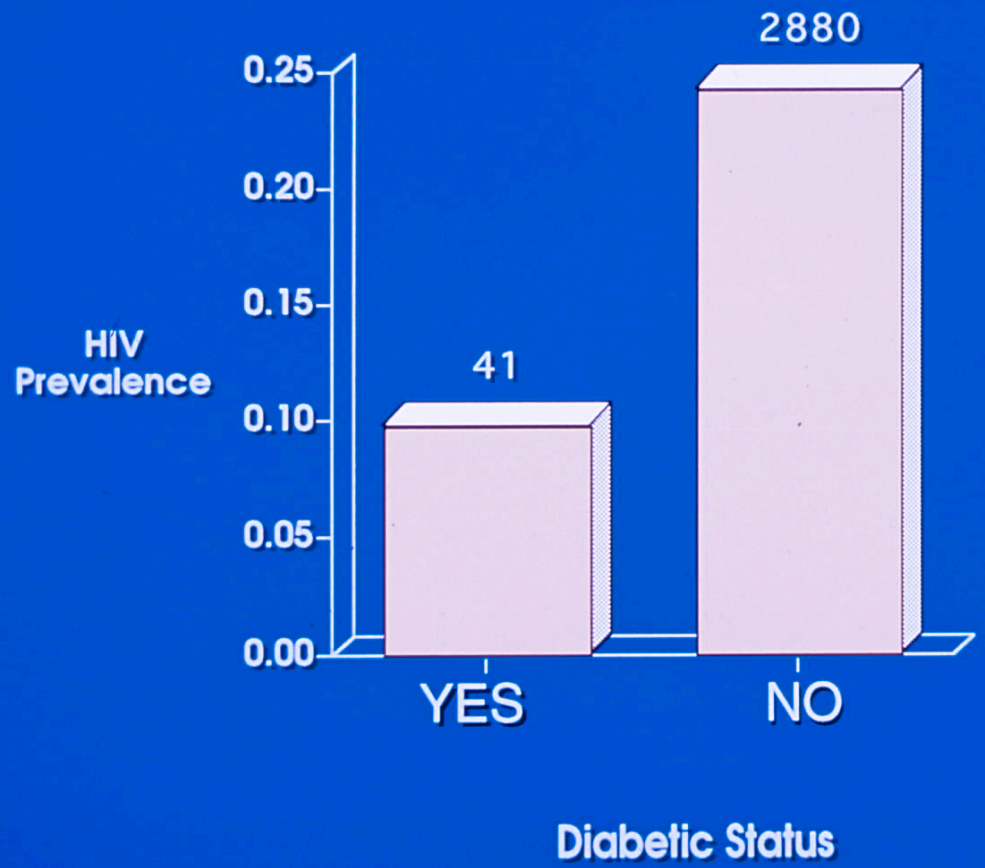
Cumulative Connecticut AIDS Cases
(Source: Connecticut State Health Dept)



Cumulative New Haven AIDS Cases
(Source: Connecticut State Health Dept)



HIV AMONG DIABETICS: ACCESS TO CLEAN SYRINGES LOWERS PREVALENCE



ALIVE Study
Baltimore, MD
Nelson et al.

NEEDLE EXCHANGE

- OBJECTIVE: Reduce the spread of human immunodeficiency virus (HIV) infection.
- METHOD: Provide drug injectors with clean needles in exchange for used ones.

BACKGROUND TO NEEDLE EXCHANGE

- 1987: New Haven Mayor's Task Force on AIDS lobbies for street outreach to drug addicts
- 1987-1990: Lobbying plus community organizing efforts produce bill legalizing needle exchange in New Haven
- May 1990: Needle exchange bill passes Connecticut House (99-36) and Conncecticut Senate (26-10)
- June 1990: Governor O'Neill signs the bill into law

BACKGROUND TO NEEDLE EXCHANGE

- Summer 1990: New Haven Health Department forms protocol committee to operationalize the program
- EVALUATION DESIGN IS BUILT INTO THE PROTOCOL
- November 13, 1990: First day of NEP operations (18 clients received 45 syringes/ needles; 2 are returned the same day)
- February 28, 1991: 389 persons have joined the program, 3007 syringes have been distributed, and 2717 syringes have been turned in to the program

NEP OPERATIONS

- Program operates out of a mobile van
- Exchange conducted by outreach workers
- Clients receive fictitious ID's that provide immunity from arrest for syringe possession
- All ID's are UNIQUE, enabling their use for client (and syringe) tracking
- Clients NEVER reveal their true identities to the program

NEEDLE EXCHANGE PROGRAM PARTICIPANT
NEW HAVEN HEALTH DEPARTMENT

I.D. Sample only

Telephone
787-8709

540 Ella Grasso Blvd.
New Haven, CT 06511

NEP OPERATIONS

- Clients may deposit any number of syringes (including non-program syringes)
- Exchange is one-for-one to a maximum of 5
- On intake, a client with no needles receives a single syringe
- Clients are counseled regarding safer sex and drug injection practices, drug treatment programs, anonymous HIV testing, etc.
- Bleach and condoms are distributed


NEW HAVEN HEALTH DEPARTMENT
787-8709
No Drugs On Board
OUTREACH WORKERS HAVE NO CASH


No Drugs On Board
OUTREACH WORKERS HAVE NO CASH


E3
GD


Don't Open This.


ABA
ABA


2000 EACH
EASE
x 34 60 SHEETS
50 SHEETS

NEEDLE EXCHANGE RESEARCH AND POLICY THROUGH 1990

- A number of published studies suggested the efficacy of needle exchange programs.
- Policy makers in the United States, with few exceptions, failed to find them convincing.

ISSUES IN EVALUATING NEEDLE EXCHANGE

Common Criticisms of Past Work

- Many programs have been "self-evaluated" (Akin to students grading their own exams)
- Almost all studies rely primarily on data self-reported by drug injectors regarding risky behavior (The program says "Don't share! Don't share!" Then clients are asked "How often do you share?")
- What is the link between behavior change and the incidence of HIV infection?
- What is the link between needle exchange program operations and the incidence of HIV infection?

DATA SOURCES FOR EVALUATION
SYRINGE TRACKING AND TESTING SYSTEM

- Every client in the program receives a unique code name
- All program syringes distributed are coded
- Date and location of distribution are recorded
- Code name of client receiving needles is recorded
- Date and location of syringe return are recorded
- Code name of client returning needles is recorded
- Samples of returned needles are tested for HIV using polymerase chain reaction (PCR)

Circulation Theory

Needle exchange does not change the number of needles in circulation (conservation law)

Needle exchange increases the turnaround of needles (i.e. increases needle removal rate)

Increasing the turnaround reduces needle circulation times

Reducing circulation times reduces the number of users per needle (i.e. needles share fewer people)

This lowers the fraction of needles in circulation that are infected

The Theory Leads to Testable Conjectures

Law of conservation of needles

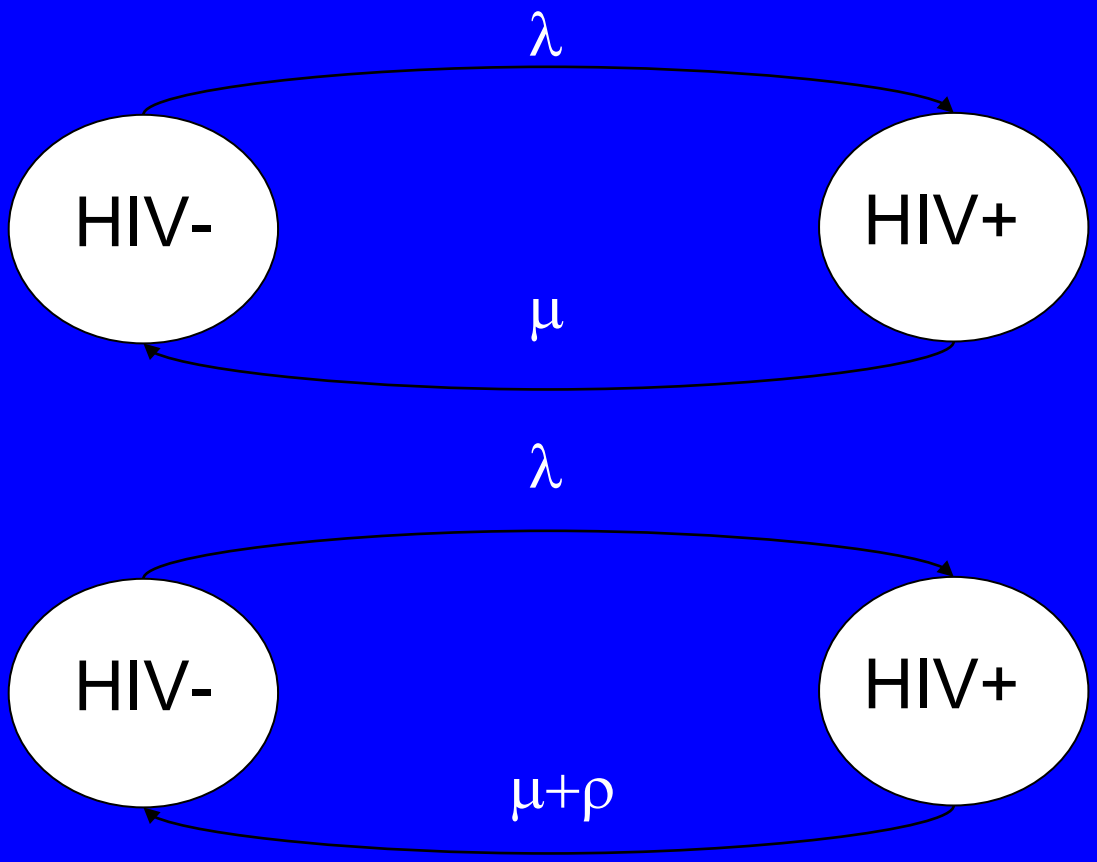
Drop in circulation times

Needle exchange increases removal rates

Fraction of needles infected falls

Should be able to "backcast" the level of infection in pre-program needles

Think Of The Needles



$$\Pr\{\text{HIV}^+\} = \frac{\lambda}{\lambda+\mu}$$

$$\Pr\{\text{HIV}^+\} = \frac{\lambda}{\lambda+\mu+\rho}$$

Figure 1

Client Participation and Visitation

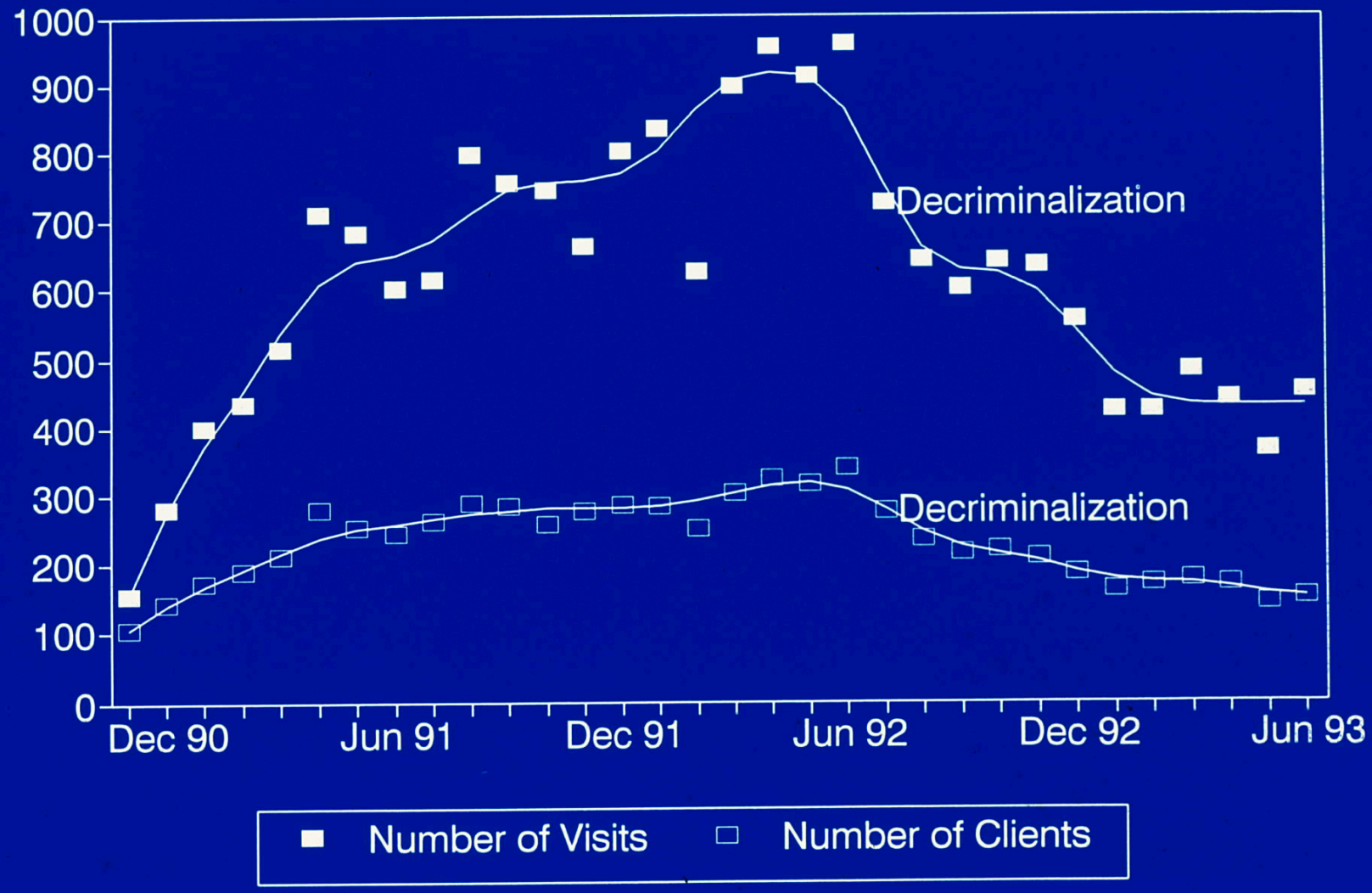


Figure 2

Volume of Needle Exchange

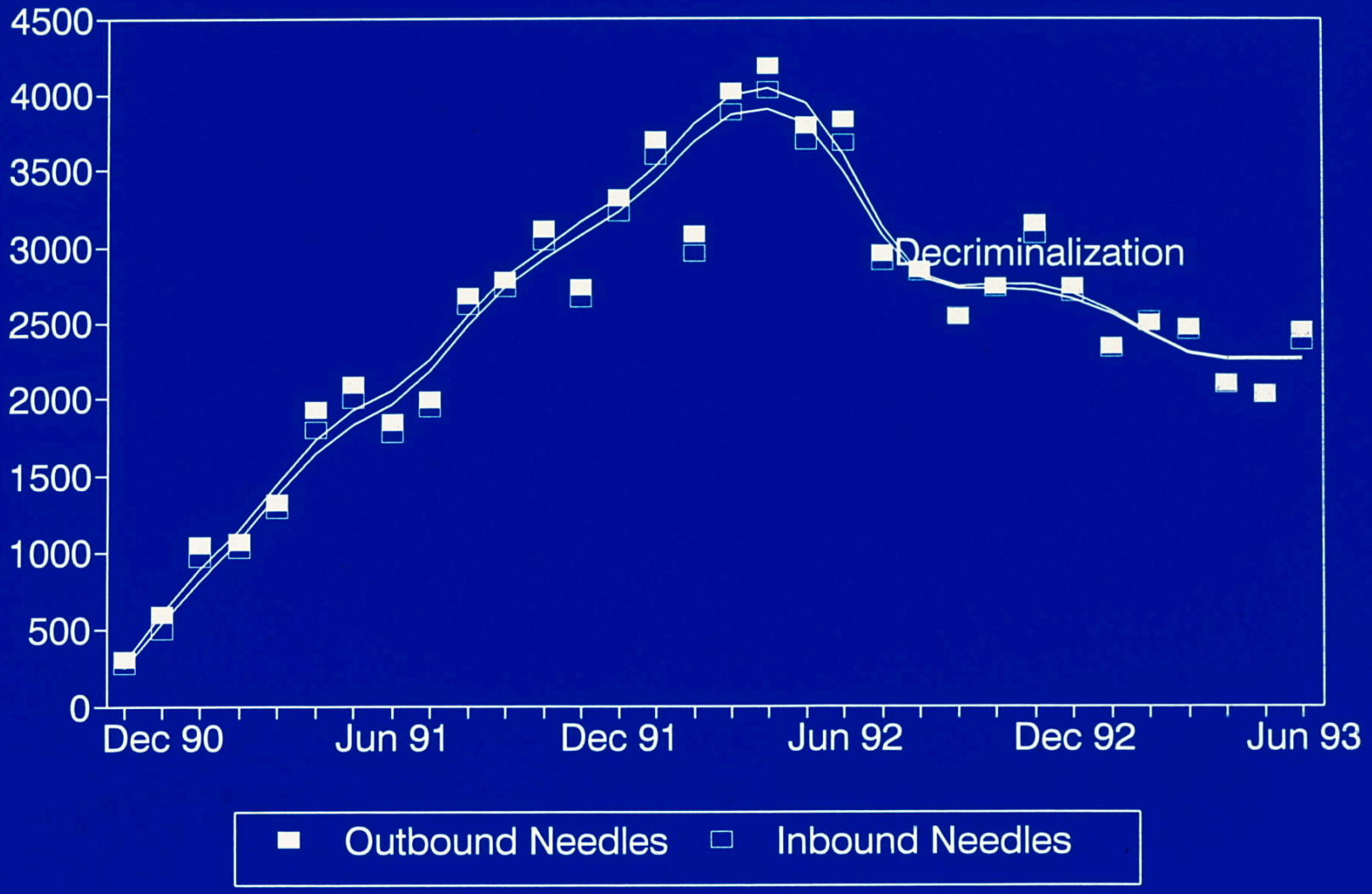


Figure 4

Needle Exchange and Removal Rates

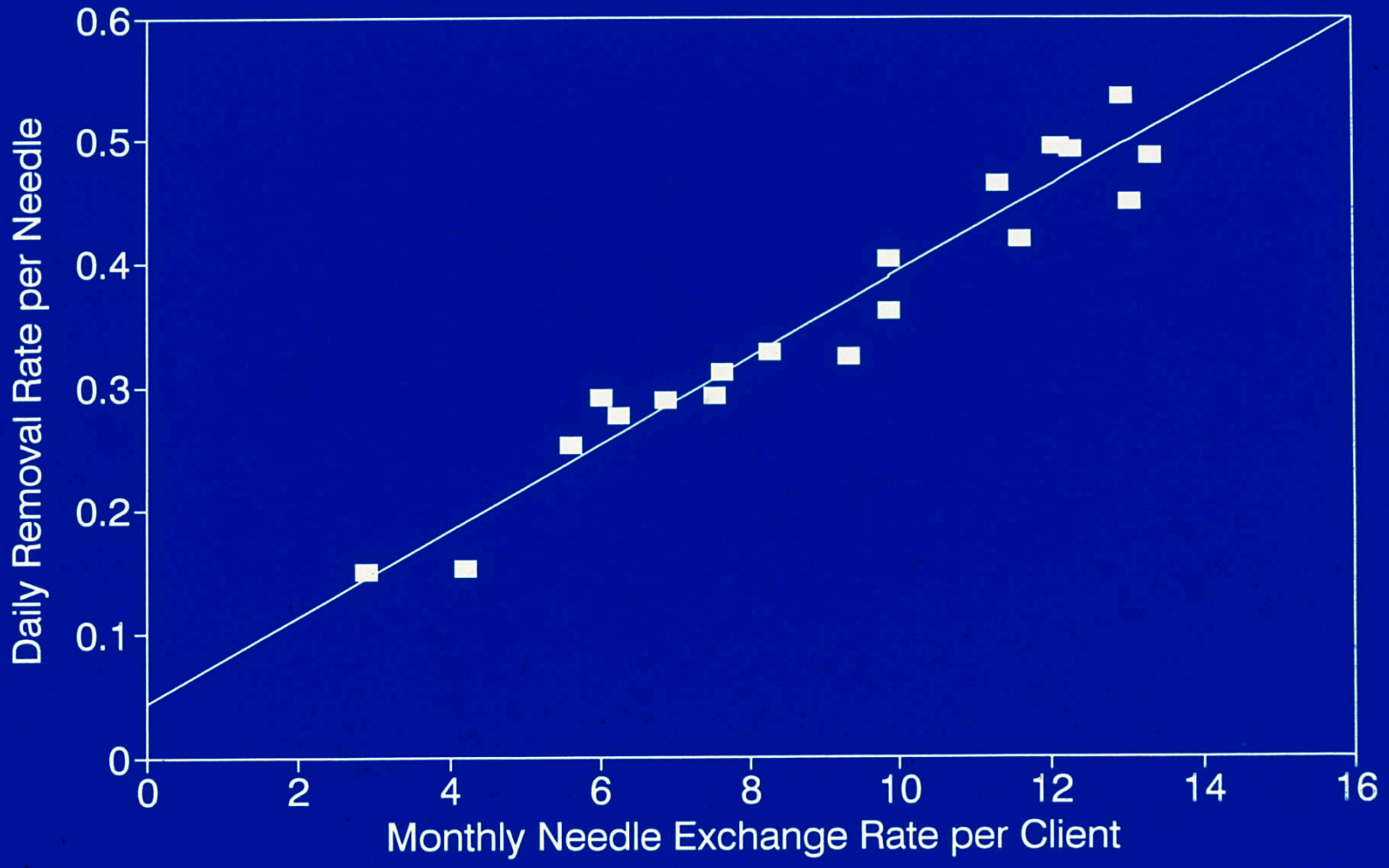
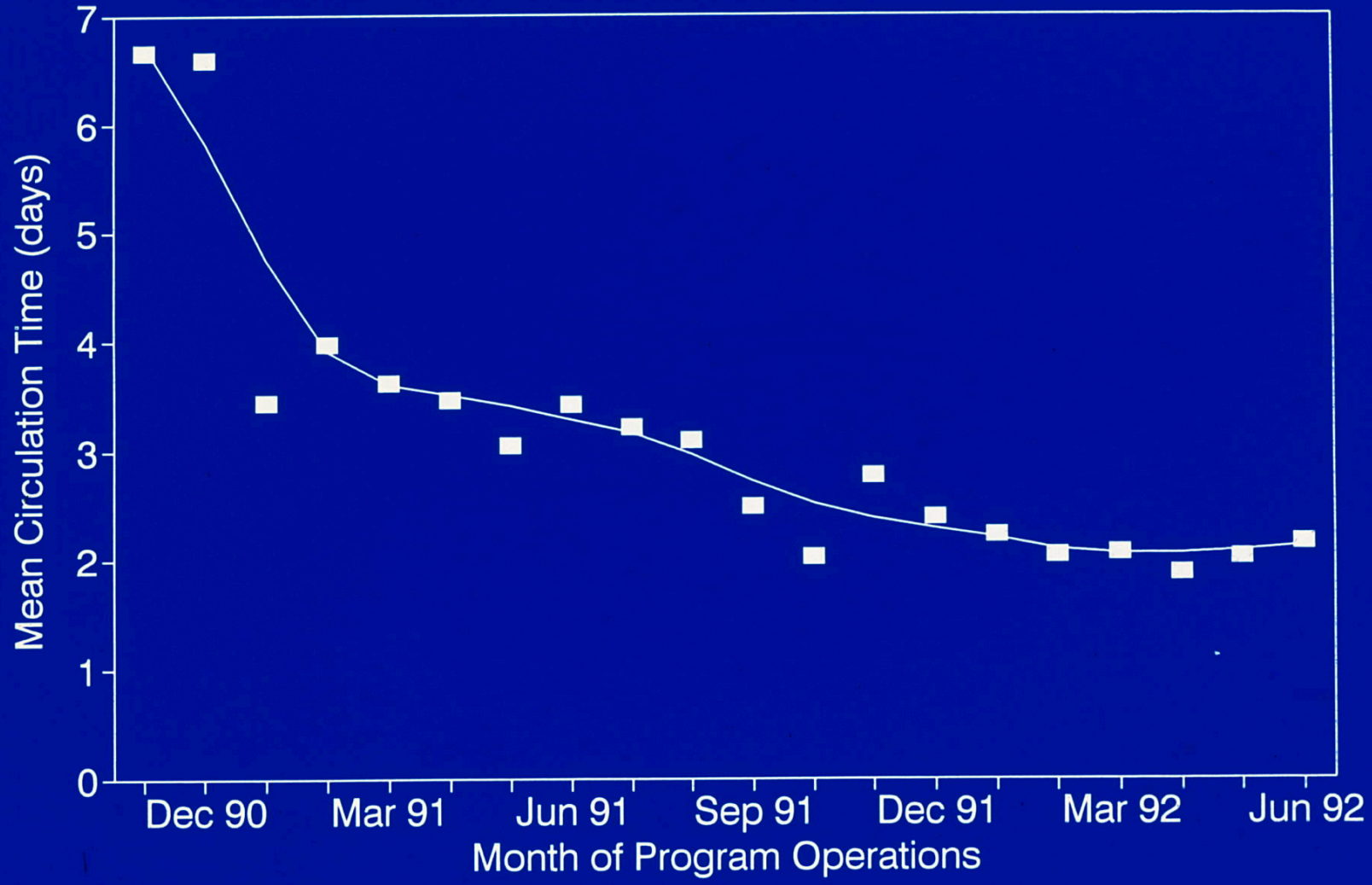


Figure 3

Mean Needle Circulation Time

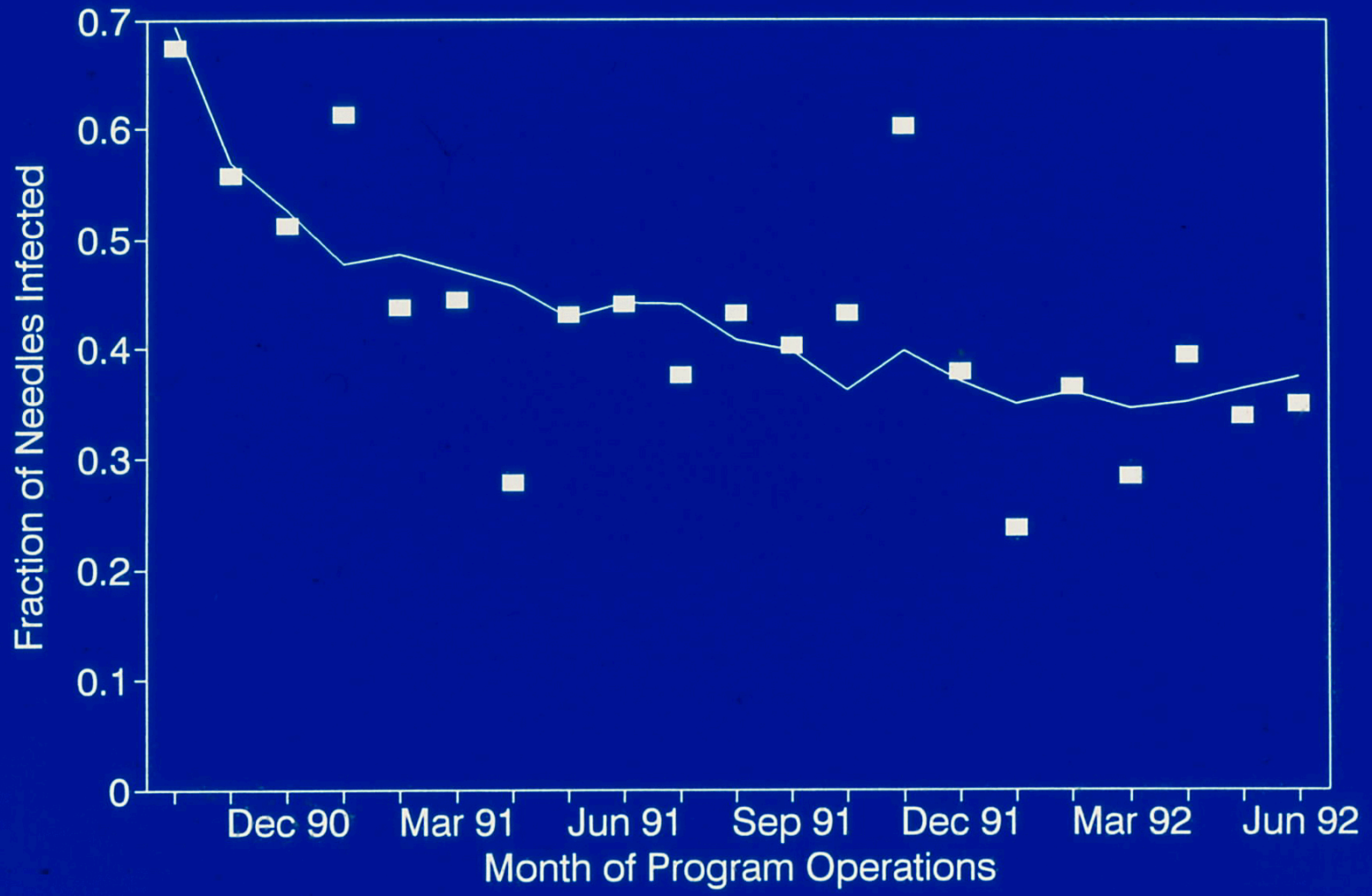


Circulation Theory Needle Testing
(New Haven Needle Exchange Program)

- 49,405 needles distributed from November 1990 through June 1992
- 2,813 (or 5.7%) tested for HIV via PCR
- 1,163 (or 41.3%) tested HIV+

Modeled HIV Prevalence in Needles

(New Haven Needle Exchange Program)



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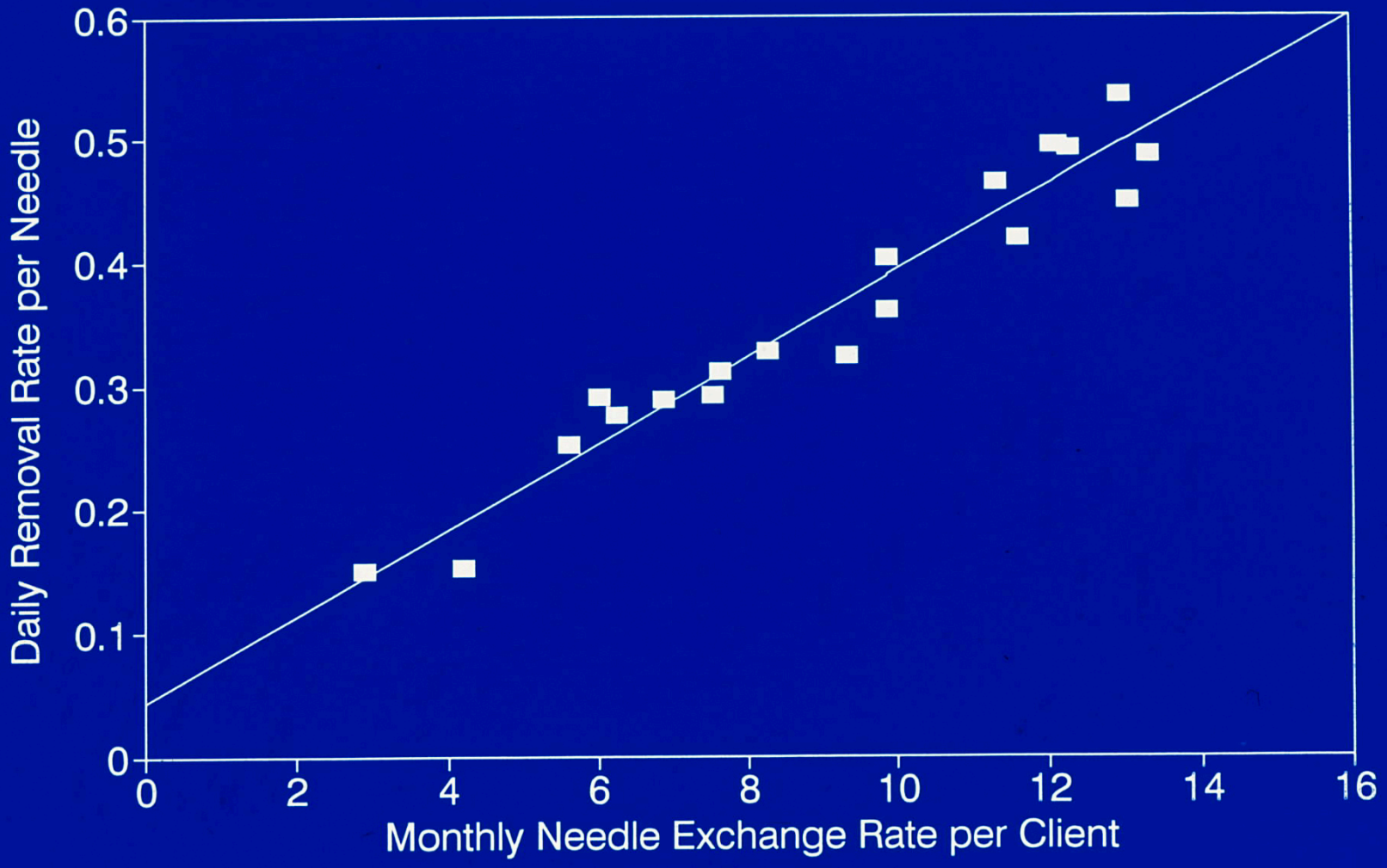

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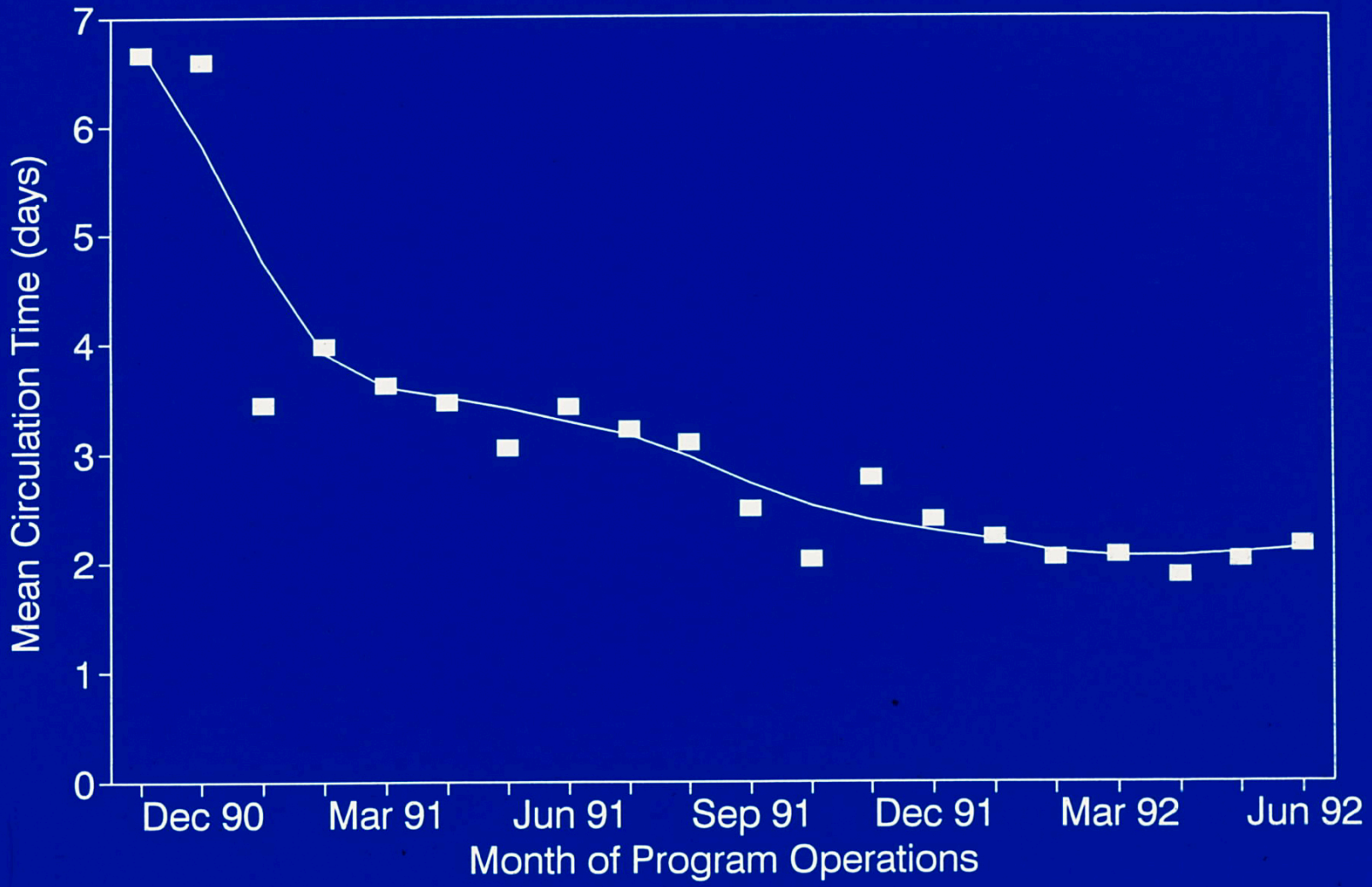
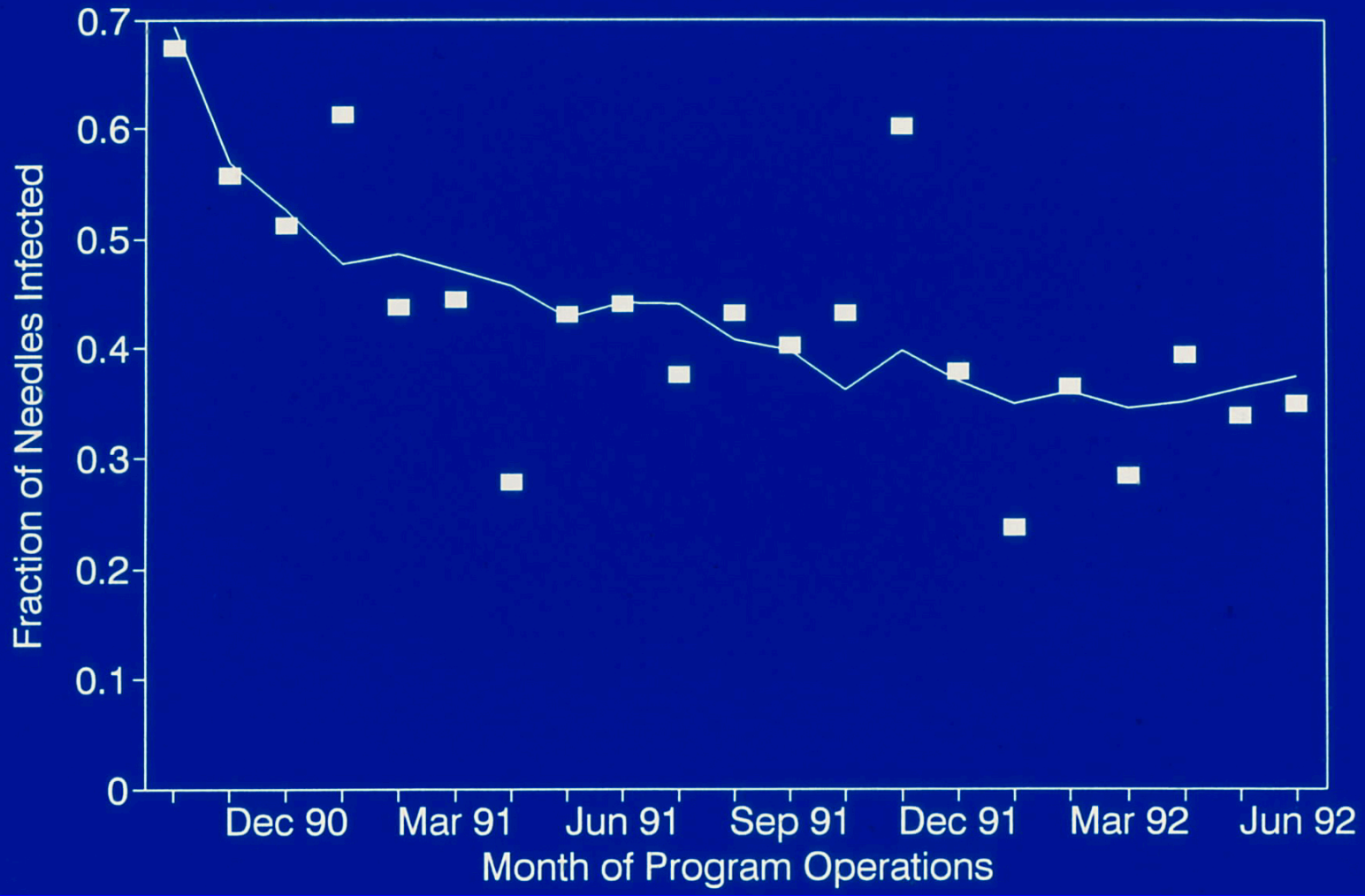
Mean Needle Circulation Time



Modeled HIV Prevalence in Needles

(New Haven Needle Exchange Program)



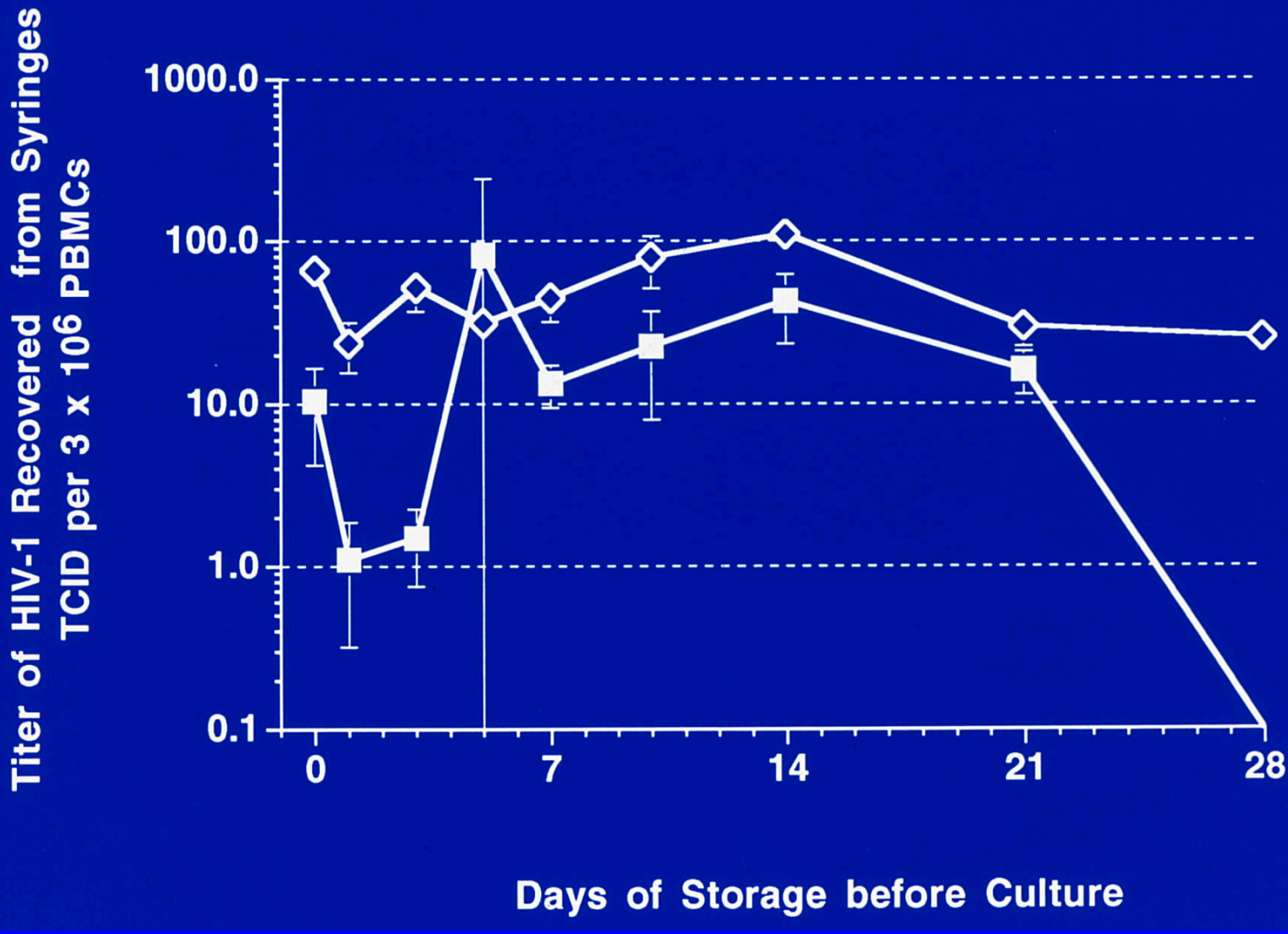
Estimated Absolute Incidence Reduction

"Steady state" approach: HIV prevalence between 30% and 70%; progression rate of 0.10/yr; % infections that are sexually acquired between 30% and 40%; relative reduction of 33%; absolute reduction between 0.6 and 1.6 infections per 100 IDUs per year

"Backcalculation" approach: estimate 160 annual infections among all IDUs in New Haven; # IDUs between 2,000 and 7,000; % infections sexually acquired between 30% and 40%; relative reduction of 33%; absolute reduction of 0.45 to 1.85 per 100 IDUs per year

Kaplan's Needle Exchange Program

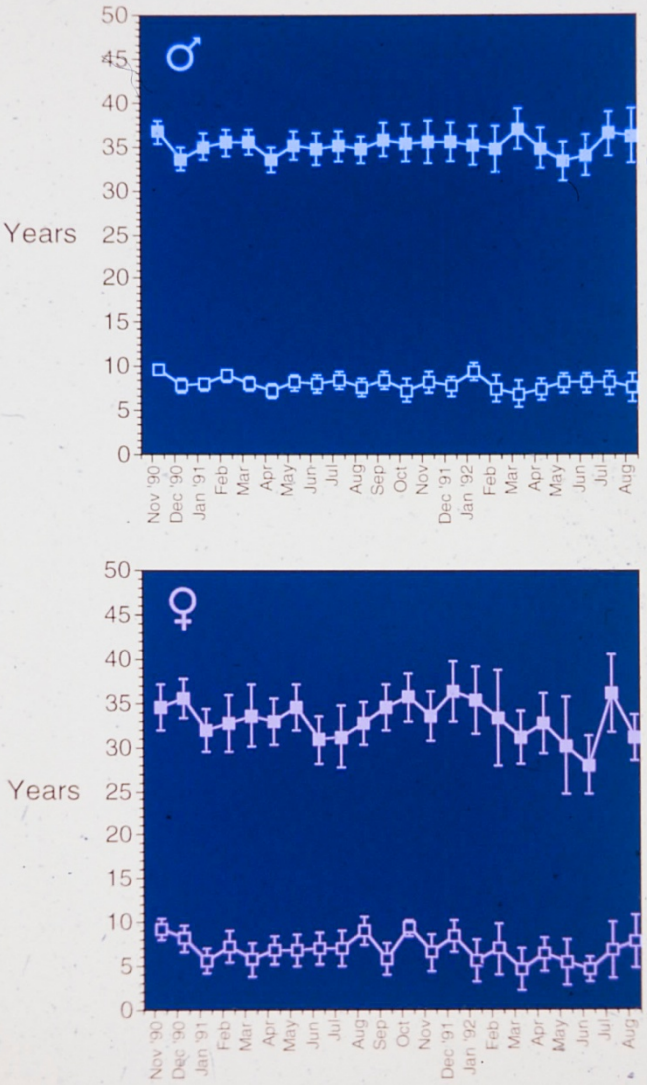
Prolonged Survival of HIV-1 in Syringes



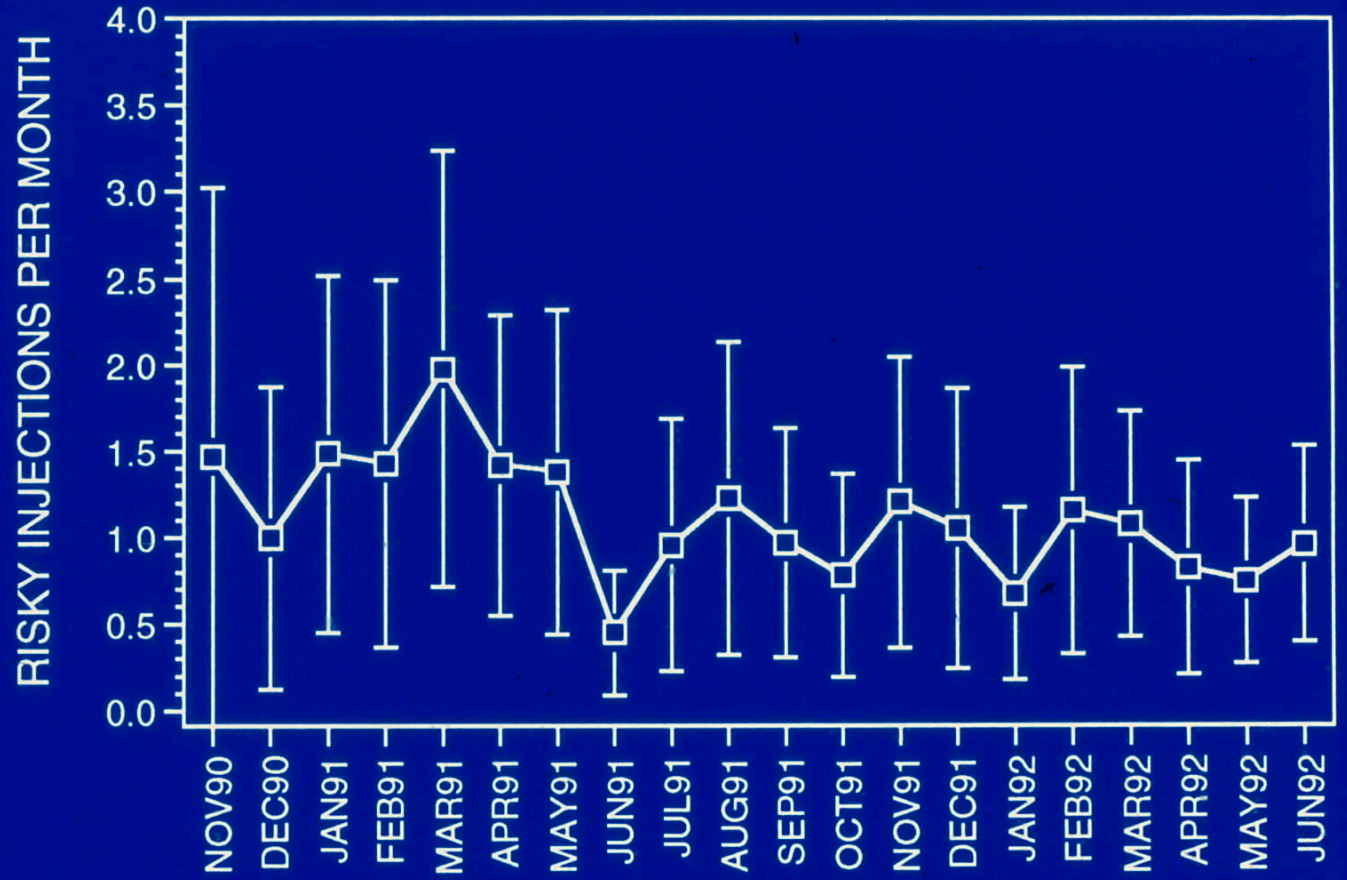
DATA SOURCES FOR EVALUATION
CLIENT SURVEYS

- Information collected from clients at intake
- Data relate to demographics (age, sex, ethnicity) and risk behaviors (duration of drug use, injection frequency, sharing level, cleansing rate)
- All client survey data are self-reported

Average Age & Duration of Drug Use Among Needle Exchange Clients



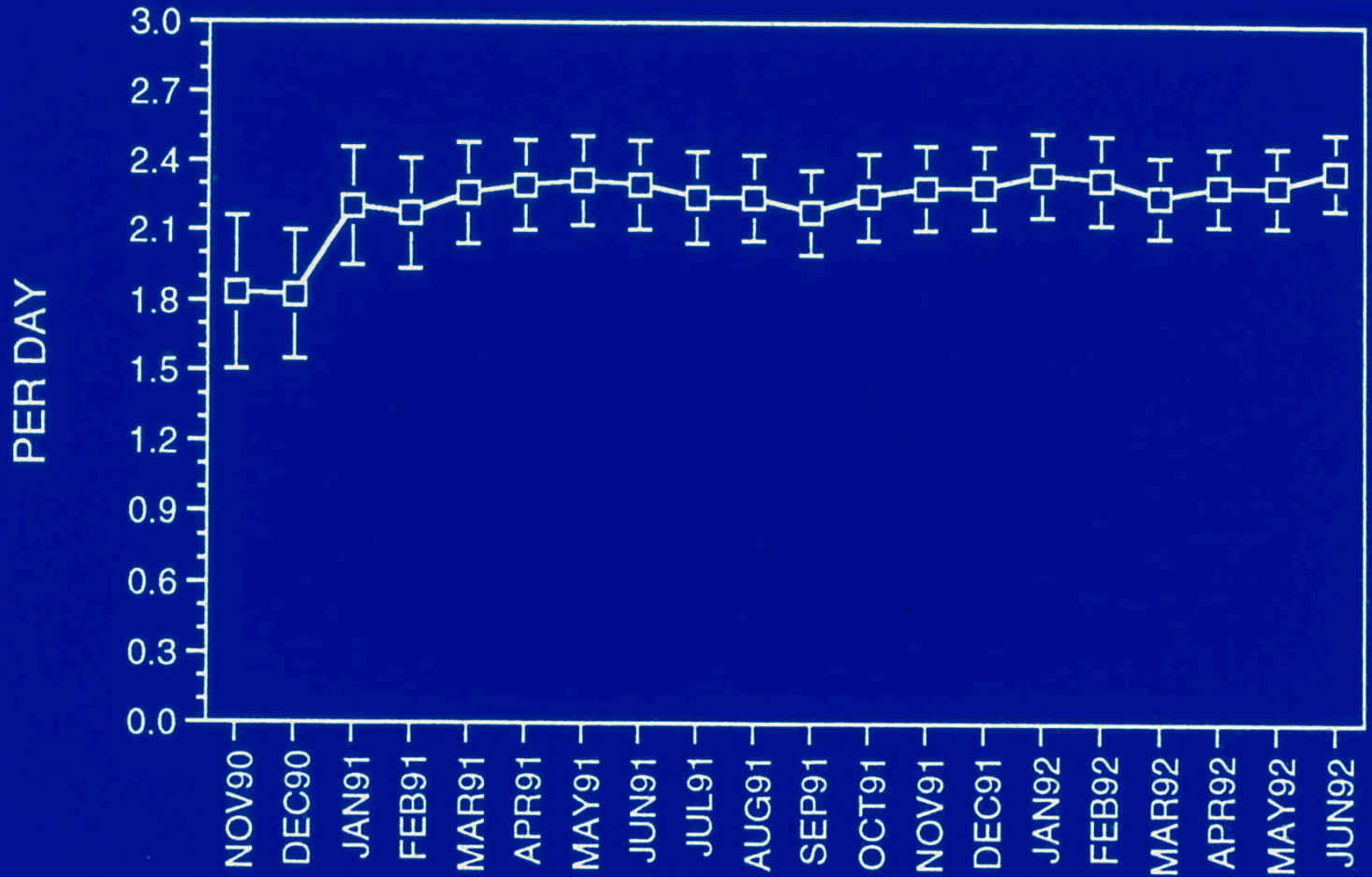
"RISKY INJECTIONS" AMONG ACTIVE NEP CLIENTS



NOTES:

1) RISKY INJECTION = FREQ. INJECT. X FRAC. SHARED X (1-FRAC. CLEANED) X 30.
2) 95% C.I. AROUND MEANS ARE SHOWN

FREQUENCY OF INJECTION AMONG ACTIVE NEP CLIENTS



NOTE: 95% C.I. AROUND MEANS ARE SHOWN

THE LINK TO DRUG TREATMENT

- 1 in 4 clients request entry into drug treatment programs
- 1 in 7 clients have actually been placed in drug treatment programs
- While over 60% of those found in New Haven area drug treatment programs are white, over 60% of the needle exchange clients placed in treatment are non-white
- The needle exchange has successfully removed some of the barriers preventing minorities from entering drug treatment

PRELIMINARY REPORT

CITY OF NEW HAVEN

NEEDLE EXCHANGE PROGRAM

MAYOR JOHN C. DANIELS

July 31, 1991

Prepared By:

Elaine O'Keefe, AIDS Division Director, New Haven Health Department

Edward Kaplan, Yale University, School of Organization and Management
School of Medicine, Principal Investigator

Kaveh Khoshnood, Yale University, School of Epidemiology and Public Health
Research Assistant

Yale Study Reports Clean Needle Project Reduces AIDS Cases

By MIREYA NAVARRO
Special to The New York Times

NEW HAVEN, July 31 — A program here to give intravenous drug users new needles for old ones is helping to curb the spread of the AIDS virus, a new study says.

The study, released today by Yale University researchers, estimates that the eight-month-old needle exchange program has reduced new infections with the HIV virus, which causes AIDS, by 33 percent among participants. The sharing of contaminated needles is the major way that the virus is transmitted in New Haven, New York City and other major urban areas.

The project used a novel method to measure new infections: it tested the needles for HIV virus contamination.

The results of the study seem likely to add heat to the debate over whether needle-exchange programs that are designed to prevent AIDS encourage another ill — drug use. This argument was made by the administration of Mayor David N. Dinkins when New York City scrapped a similar program last year.

While emphasizing that their study sample was small and the results preliminary, New Haven officials hailed the results as evidence that the programs work.

"This program is not a solution to AIDS or to drug addiction," Mayor

Continued on Page B2, Column 1

Yale study sways NYC on needles

By Laura Johannes
Register Staff

Inspired by evidence that New Haven's year-old needle exchange program has slowed the spread of the AIDS virus, New York City Mayor David Dinkins reversed his longstanding opposition to such programs Thursday.

A Yale study released this summer, which provided the nation's first hard data on needle exchange effectiveness, is "the clearest demonstration yet that such a program can reduce the risk of transmission," Dinkins wrote in a letter this week to New Haven Mayor John C. Daniels.

The Yale study estimated that swapping used needles for clean ones can reduce the spread of the AIDS virus, known as HIV, by 33 percent among intravenous drug users in New Haven. Researchers have cautioned, however, that more research is necessary to be certain those estimates are correct.

At a Manhattan press conference Thursday, Dinkins announced that New York City will provide technical support and monitoring to any community group willing to manage a privately funded needle exchange program.

*Turn to **Needles**, Page 14*

The Bridgeport Post *7 May 1992*

Experts praise needle program

Yale study shows exchange does not encourage drug use

By DEBBIE CARVALKO
Staff writer

A 33 percent, sustained decrease in the spread of AIDS among intravenous drug users is being attributed to a needle-exchange program in New Haven.

And Yale University researchers studying the program's effects say other findings are just as important.

Along with showing that such an approach can dramatically slow the spread of AIDS, their study proves that legally providing addicts with clean needles does not encourage other people to become drug abusers, said two scientists leading the research team.

"What's remarkable about this is that we've broken the state of equipoise" between proponents and opponents of providing clean needles, said Edward Kaplan, an associate professor at Yale who designed and initiated the research.

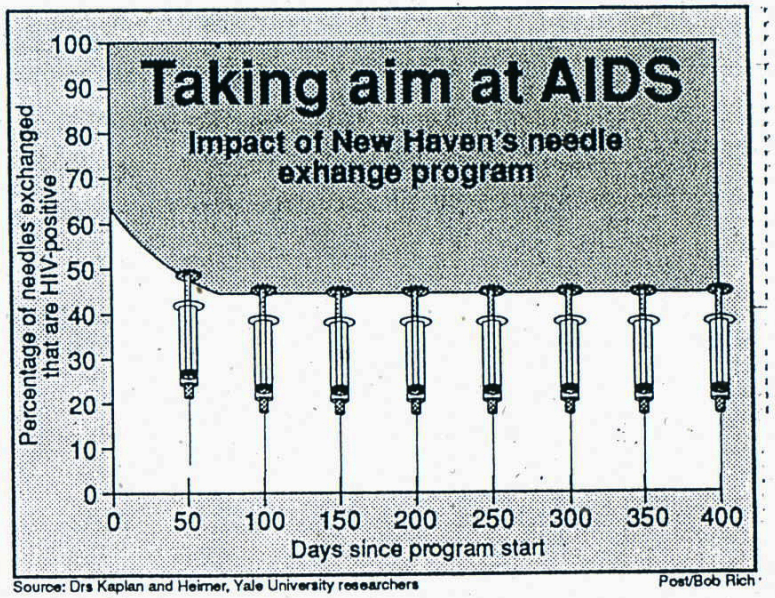
In the past, proponents have argued that programs trading clean needles for used ones are of great value because they slow the spread of disease facilitated by the sharing of needles when syringes are rare.

Opponents argued legally providing needles makes it appear that society condones drug abuse and makes the behavior more attractive to non-users.

Past research failed to tip the scales of evidence in either direction.

This city's program, run from a van staffed by New Haven Health Department outreach workers, apparently had an additional positive effect on some participants.

Since it began in 1990, New Haven's needle exchange program has helped get many HIV-infected needles off the streets.



Source: Drs Kaplan and Heimer, Yale University researchers Post/Bob Rich

"Another, larger social question we've answered is whether or not such (needle exchange) policies can in any way change the behavior of drug users," said Robert Heimer, an associate research scientist.

Of the 1,200 intravenous drug users who participated in the program since it began in November 1990, some 15 percent who met with health care workers later entered drug rehabilitation treatment.

San Francisco SENTINEL June 11, 1992

Life Saving Legislation Now Approved in Both Houses

State Senate Passes Needle Exchange Bill by 21-14 Vote

In the second victory for needle exchange legislation in the past few weeks, SB 1418 (Watson, D-LA) was approved with bipartisan support by the full Senate by a vote of 21-14 on June 5. The bill's identical companion measure, AB 2525 (Brown) was approved on May 18 in the Assembly by a vote of 43-33.

Co-sponsored by the San Francisco AIDS Foundation and the City and County of San Francisco, the legislation would allow communities to participate in a pilot needle exchange program as part of a comprehensive plan to reduce HIV transmission among injection drug users.

"The California State Legislature has shown that they are in sync with the growing nationwide movement toward legalized needle exchange," said Regina Aragon, state governmental affairs coordinator for the San Francisco AIDS Foundation. "It is urgent that we adopt this vital measure at a time when one-third of the nation's AIDS cases originate form injection drug use. Such an extraordinary public health emergency calls for an extraordinary public health response. SB 1418 is part of that response; it will prevent the spread of HIV and save lives. Not only is it an ethical and moral choice, but a logical fiscal response to the growing problem of HIV among injection drug users, their partners and children," Aragon concluded.

It is urgent that we adopt this vital measure at a time when one-third of the nation's AIDS cases originate form injection drug use.

According to the San Francisco Department of Public Health, an estimated sixteen percent of the 16,000 injection drug users in San Francisco are infected with HIV. The State Office of AIDS reports that injection drug use has recently emerged as one of the most prevalent risk factors for new AIDS cases in California. Nationally, 71 percent of all females with AIDS are linked directly or indirectly to injection drug use, as are 70 percent of all pediatric AIDS cases.

SB 1418 has gained widespread support from many of the most respected health policy groups in California, including the California Medical Association, the California Nurses Association, the California Association of County Drug Program Administrators and the California Conference of local Health Officers. ■

(h) Studies of injection drug users in New York, New York; San Francisco, California; Tacoma, Washington; Boulder, Colorado; Portland, Oregon; and other cities in the United States indicate that injection drug users are concerned about AIDS and do change their behavior when offered, in a nonjudgmental setting, reasonable strategies to protect themselves. A San Francisco study of injection drug users found that the percentage of drug users who reported using bleach to sterilize their equipment increased from 3 percent to 61 percent after a street outreach program was in operation for six months and to 86 percent after two years.

(i) A study by Yale University of a needle exchange program in New Haven, authorized by the Connecticut Legislature in 1990, estimates that in the first eight months of operation, the program reduced new HIV infections by 33 percent.

From the California Assembly bill AB 2525

New Haven Register

180TH YEAR, NO. 192; NEW HAVEN, CONN., FRIDAY, JULY 10, 1992; NEWSSTAND 50 CENTS ★★

Turn to Veteran, Page 8

Feds blast city's needle exchange

■ Yale study attacked:

Martinez disputes evidence of slower AIDS spread.

By Tamara Lytle
Register Washington Bureau

WASHINGTON — The federal government's drug czar launched a national attack Thursday on New Haven's needle exchange program and the Yale study that found the program effective in slowing the spread of AIDS.

Federal officials said they are concerned because the study, carrying the prestige of having been done by a Yale research team, is being used to promote needle exchange programs nationally.

"Needle exchange programs are a false promise — an act of desperation, a product of frustration," said Bob Martinez, head of the Office of National Drug Control Policy. "They squander our nation's hard-earned gains in the drug war, capitulating at a time when we should be making greater efforts to help drug users end their addiction, not perpetuate it."

Martinez's office released a bulletin Thursday criticizing the New Haven study and saying there is no evidence that needle exchanges reduce the spread of AIDS. The bulletin will be sent to doctors, mayors, lawmakers and law enforcement officials.

A study last year by Yale professor Edward Kaplan said the New Haven program slowed the spread of HIV infection among intravenous drug users by 33 percent. He could not be reached Thursday.

New York City recently restarted its needle exchange program based on the Yale study. Twelve states have needle exchange programs, and Connecticut recent-

Turn to Martinez, Page 8

Continued from Page 1

ly expanded programs from New Haven to Hartford and Bridgeport.

Elaine O'Keefe, director of the New Haven AIDS Division, said she gets calls every week from cities interested in the program and study. The Yale study tested needles for the AIDS-causing human immunodeficiency virus and monitored whether users returned the same needles they had received originally.

"It is one of the most rigorous evaluations of a needle exchange done," O'Keefe said. "It's shocking that federal leaders would not support a program as critical as needle exchanges."

HIV is spread by intravenous drug users who share needles, among other ways. Needle exchange programs give users clean, fresh needles in exchange for used ones, so that they don't have to share infected needles.

Khalid Lum, spokesman for New Haven Mayor John C. Daniels, said the city stands by the effectiveness of the needle exchange program and by the study.

"This is very probably a case of 'we don't want this to be the truth, and therefore we don't accept this as the truth,'" Lum said. "We suspect strongly this has more to do with politics than with science."

Ingrid Kolb, a member of Martinez' staff who is in charge of finding ways to reduce demand for drugs, said the New Haven study was flawed. She said the study had too few participants and used mostly addicts who were never sharing needles in the first place.

O'Keefe said the program has 600 participants. Twice that many have enrolled but some have dropped out, gotten treatment or been jailed.

"Needle exchange programs put the weapons of destruction into the hands of addicts who need treatment, not another fix," Martinez said. "Treatment is the real solution here, and it must be more widely available."

Kolb said a better alternative is outreach programs that send social workers to the streets to encourage addicts to seek treatment.

But Lum said the federal government has not done enough to fund treatment programs. Needle exchanges are needed until there is treatment available for all addicts, he said.

Kolb said the federal outreach plan has encouraged 31 percent of the participants to seek treatment, compared with 15 percent of those who went into treatment in New Haven after hooking up with the needle exchange program.

Kolb said the outreach workers teach addicts to cleanse needles with bleach if they refuse treatment. She said that is different than actually providing needles. "Every time you give them a needle, you are increasing the chance they are going to contract HIV or die of an overdose," Kolb said.

But O'Keefe said the federal support for bleach was inconsistent with the opposition to needle exchanges.

"Why is bleach OK and needles are not?" O'Keefe said.

Martinez: Exchange thwarts treatment effort

United States General Accounting Office

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

PREVENTING HIV Transmission

The Role of Sterile Needles and Bleach

NATIONAL RESEARCH COUNCIL • INSTITUTE OF MEDICINE

THE PUBLIC HEALTH IMPACT OF NEEDLE EXCHANGE PROGRAMS IN THE UNITED STATES AND ABROAD

Volume I

SCHOOL OF PUBLIC HEALTH,
UNIVERSITY OF CALIFORNIA, BERKELEY

INSTITUTE FOR HEALTH POLICY STUDIES,
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

PREPARED FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

September 1993

EMBARGOED
until 12:00 noon PST
Thursday, September 30, 1993

HEALTH

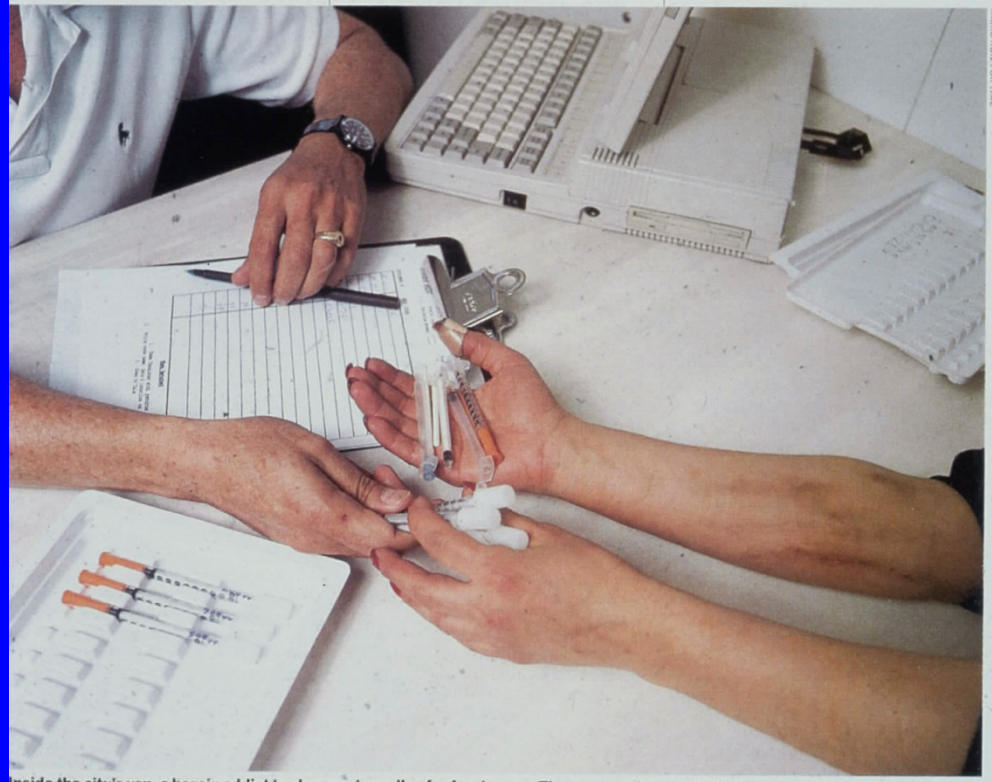
Getting the Point In New Haven

The city's clean-needle program has cut the spread of AIDS. Now other towns see the light.

By DICK THOMPSON NEW HAVEN

THE VAN, PAINTED WITH VIVID stripes and a rising sun, plies the drearier streets of New Haven, Conn., drawing eager throngs like some dark version of the Good Humor truck. Four times a week, the "dope fiends," as they call themselves, line up to enter the vehicle. They identify themselves to city workers by their code names ("Carol Burnett," "Streetcat," "Wizard") and, in exchange for used needles, receive survival kits: bottles of bleach, bottles of water, clean needles, and condoms. They do this because they are terrified of the epidemic that is raging through their city. "Just because I shoot drugs doesn't mean I don't care about AIDS. I care a lot," says a petite white woman, 45, who works as an executive assistant. That's right, says a dope dealer known as "Philip Morris": "Heroin don't make you retarded."

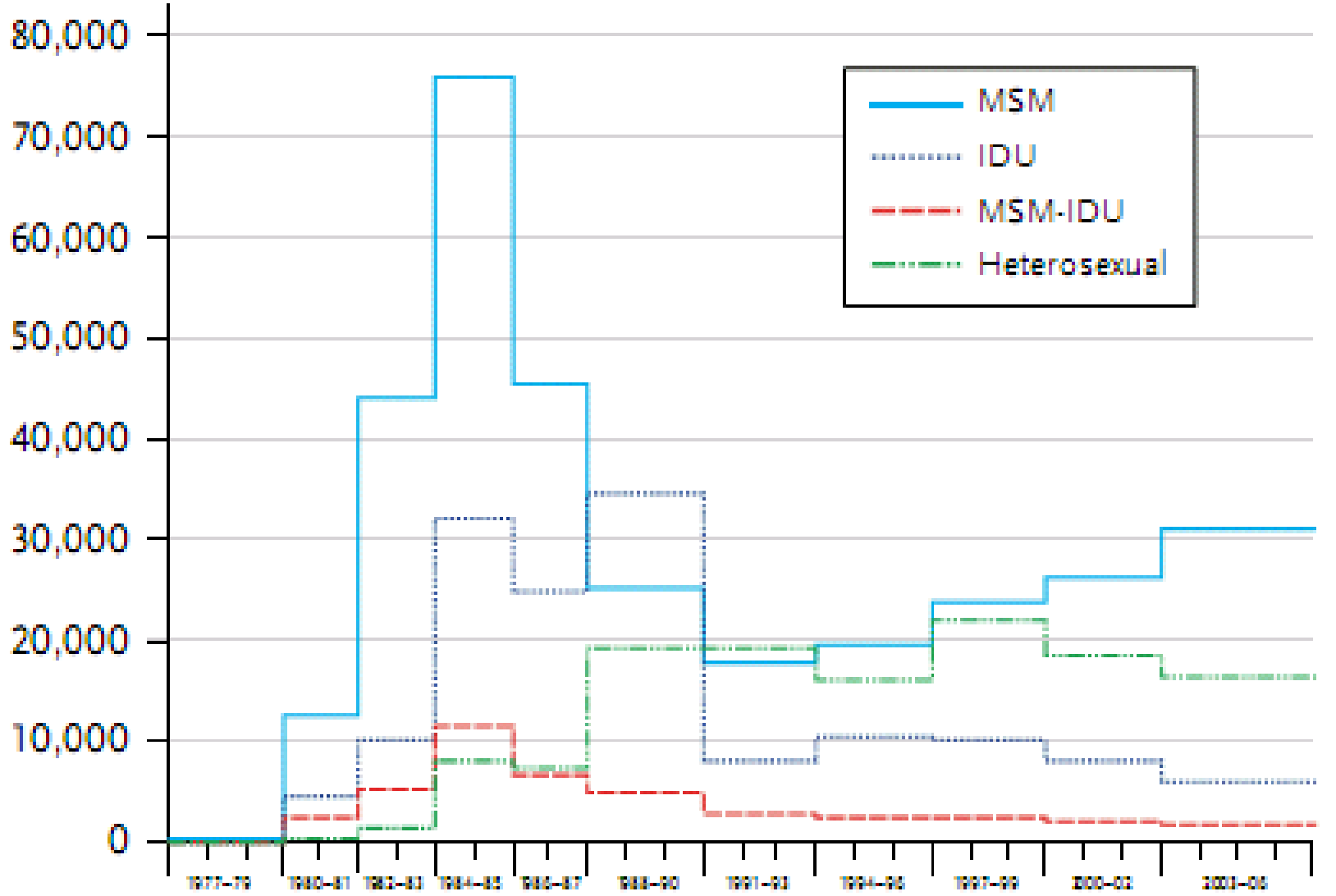
No, it doesn't, but for years the acrimonious debate over how to protect heroin users has impeded efforts by health authorities to control the spread of AIDS. Civic leaders have been caught up in moralistic arguments over whether providing clean needles to addicts would only accelerate inner-city drug abuse. In minority communities, opponents insisted that needle handouts were akin to genocide. Meanwhile, AIDS raced through intravenous-drug-using populations. Today one-third of the nation's AIDS cases originate from IV drug use. More specifically, 71% of all females with AIDS are linked directly or indirectly to IV drug use, as are 70% of all pedi-



MARIO RUIZ FOR TIME

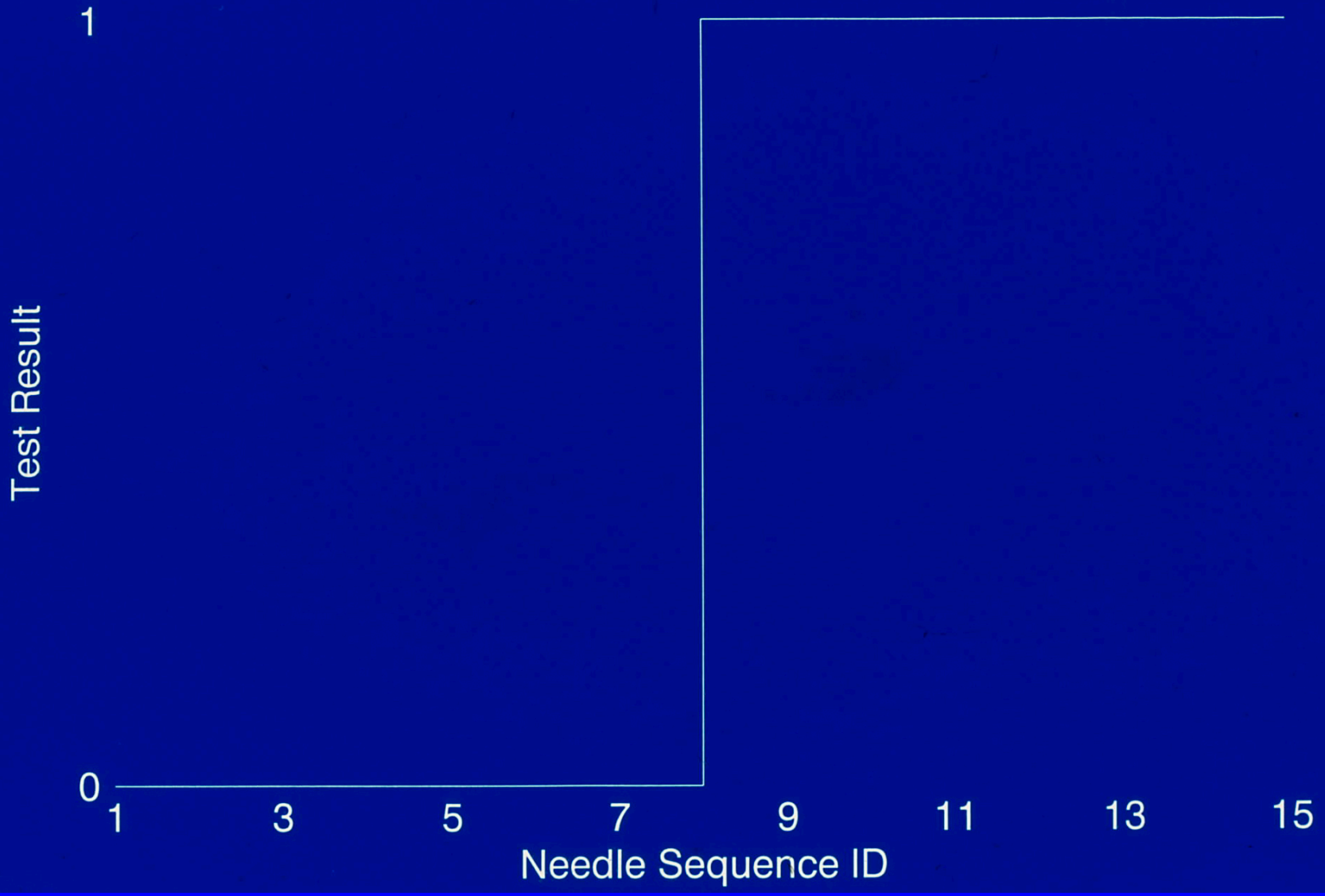
Inside the city's van, a heroin addict trades used needles for fresh ones. The program has not led to increased drug abuse.

Figure 2. Estimated Number of New HIV Infections, Extended Back-Calculation Model, 1977–2006, by Transmission Category

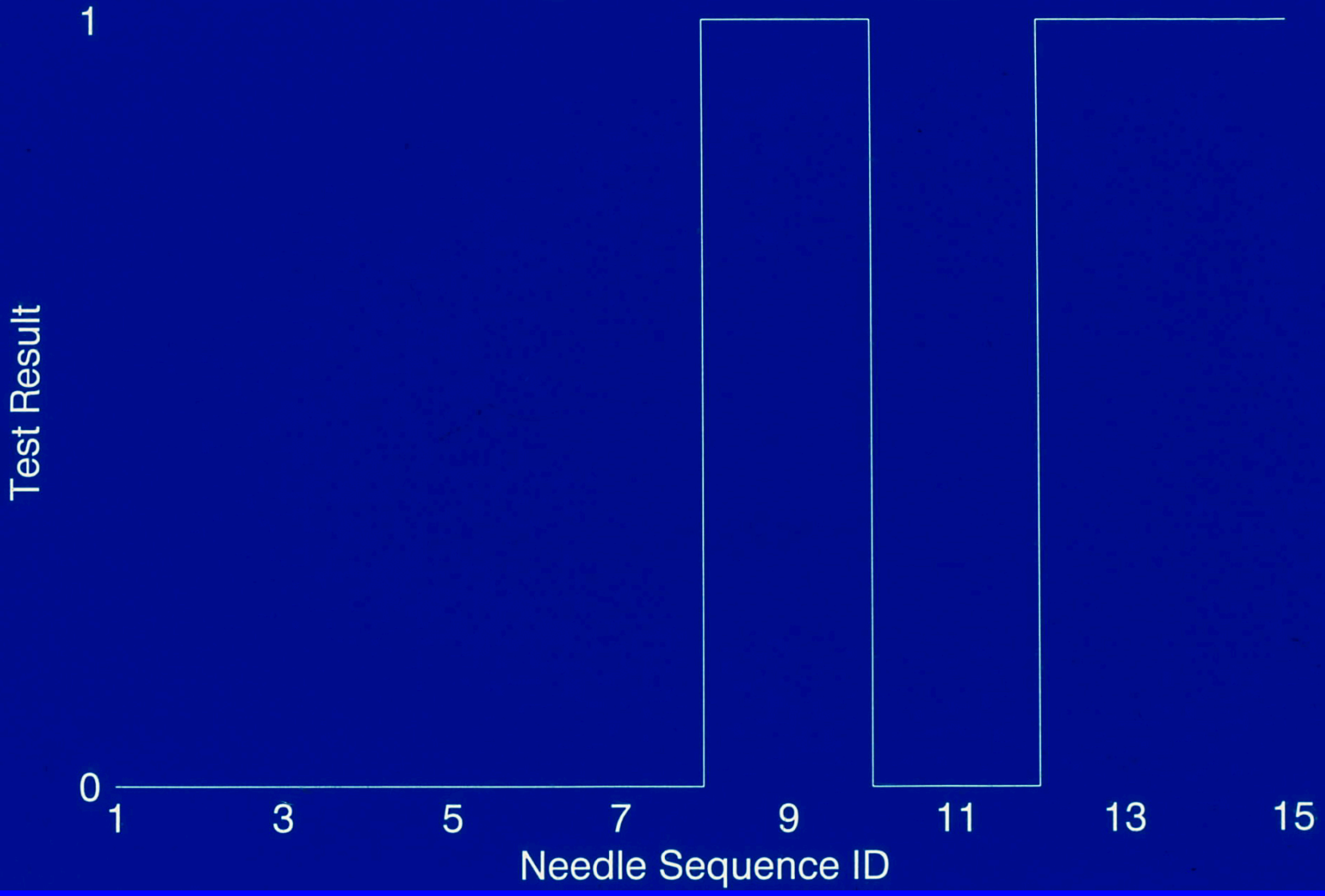


Note: Estimates are for 2-year intervals during 1980–1987, 3-year intervals during 1977–1979 and 1988–2002, and a 4-year interval for 2003–2006.

No Sharing/Perfect Testing

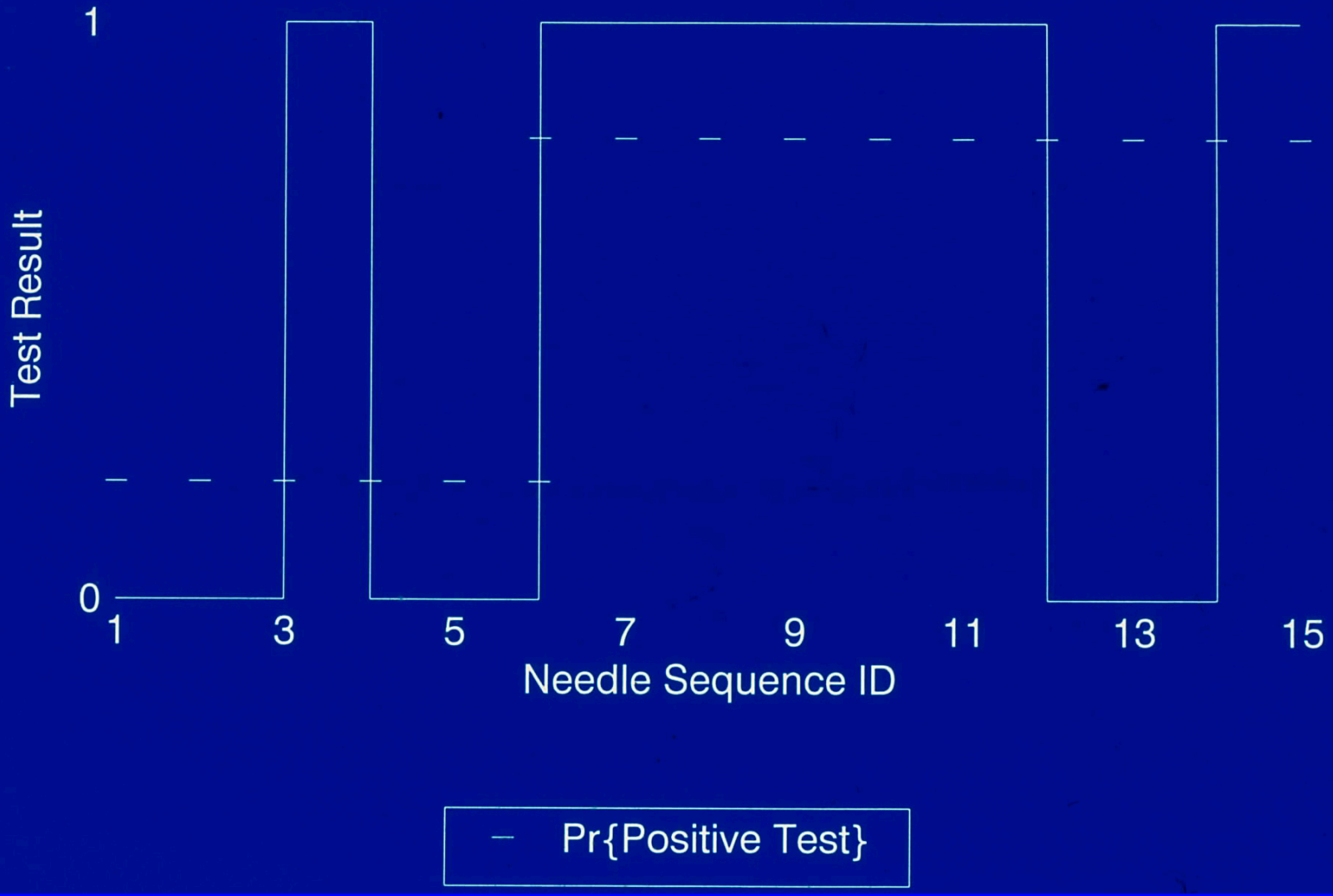


No Sharing/False Negatives



Sharing/Testing Errors

Proposed Split At Needle #6



A Maximum Likelihood Change Point Model

$$\mathcal{L} = \prod_{i=1}^{s} \pi(-)^{x_i} \left(1-\pi(-)\right)^{1-x_i} \prod_{i=s+1}^{n} \pi(+)^{x_i} \left(1-\pi(+)\right)^{1-x_i}.$$

CHANGE POINT MODEL

Let $\hat{\pi}(-)$, $\hat{\pi}(+)$,and $\hat{s}$ be the maximum likelihood estimates of $\pi(-)$, $\pi(+)$, and s.

Let $\mathcal{L}(\hat{\pi}(-), \hat{\pi}(+), \hat{s})$ be the maximized likelihood function.

Let $\mathcal{L}(\hat{\pi}) = \prod_{i=1}^{n} \hat{\pi}^{x_i}(1-\hat{\pi})^{1-x_i}$ where $\hat{\pi} = \sum_{i=1}^{n} x_i/n$.

Conclude infection occurred if

$$2 \log \frac{\mathcal{L}(\hat{\pi}(-), \hat{\pi}(+), \hat{s})}{\mathcal{L}(\hat{\pi})} \geq c.$$

An Idealized Incidence Study

Modeling the Probability of Infection

$$\Pr\{\text{Infection}\} = (1-\phi)\,(1-e^{-\rho\delta}) \approx (1-\phi)\,\rho\,\delta \equiv \theta\,\delta$$

The *A Priori* Probability of "Observing" a New Infection

$$r(\theta) = \theta\delta(1-\beta) + (1-\theta\delta)\alpha = \alpha + (1-\alpha-\beta)\theta\delta.$$

The Hypothesis of Zero Incidence

Suppose the true incidence rate equals zero. Then the probability of concluding that any given IDU became infected equals the significance level *alpha*. Thus, the number of IDUs *thought* to have become infected would follow a binomial distribution with *m* trials and "success" probability *alpha*. It is therefore a simple matter to determine the probability of observing the data under the null hypothesis of *no new infections.*

The Maximum Likelihood Incidence Rate Model

$$\mathcal{L}(\theta) = \prod_{i=1}^{m} r_i(\theta)^{y_i} \left(1 - r_i(\theta)\right)^{1-y_i}$$

Maximum Likelihood Incidence Rate

It is easy to prove that the maximum likelihood estimate of the HIV incidence rate equals zero if the significance level (alpha) exceeds a threshold

This threshold is given by the ratio of the person days of exposure for those thought to have become infected (i.e. y=1) to the total person days of exposure for all in the study

Otherwise...

The Maximum Likelihood Estimate is the Root of this Equation

$$\sum_{i=1}^{m} y_i \delta_i \,/\, r_i(\theta) = \sum_{i=1}^{m} (1-y_i)\delta_i / \left(1-r_i(\theta)\right)$$

New Haven Data
(November 1990 - May 1992)

Restricted to clients who had at least
5 returned needles tested

1,920 needles tested over 132 clients
for an average of 14.5 needles/client

34,903 exposure days in total

6 change point tests led to rejection
(i.e. *think* 6 IDUs became infected)

1389 exposure days among these 6 IDUs

Change point significance = 0.05
Change point power > 0.50

One Cannot Reject the Hypothesis of *No New Infections* In New Haven's NEP

$$\Pr\{\text{Number of Rejections} \geq 6\} = \sum_{i=6}^{132} \binom{132}{i} 0.05^{i}\ 0.95^{132-i} = 0.6512.$$

Maximum Likelihood Incidence = 0

1,389 exposure days among IDUs *thought* to become infected

34,903 exposure days in total

1,389/34,903 = 0.0398 < 0.05 = *alpha*

Thus, the maximum likelihood estimate for HIV incidence equals zero!