HIV Seroprevalence Surveys in Drug Treatment Centers

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Synopsis

Sharing of equipment used to inject illicit drugs intravenously is a risk factor for human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS). Systematic surveillance of HIV infection among intravenous drug users (IVDUs) in the United States is essential to monitor the HIV epidemic and to target and evaluate prevention programs for IVDUs and their partners.

The most accessible segment of the largely covert population of IVDUs are those in drug treatment programs. In collaboration with State and local health departments and drug abuse treatment agencies, the Centers for Disease Control is conducting blinded (serologic test results not linked to identifiable persons) and nonblinded (in which clients voluntarily agree to participate) surveys of IVDUs entering drug treatment in 39 U.S. metropolitan areas. The same protocol is used in all participating drug treatment centers. Blinded surveys will be carried out annually to determine HIV seroprevalence rates in eligible IVDUs entering drug treatment and to monitor trends over time. Each year, nonblinded surveys of IVDUs entering drug treatment will assess self-reported drug use and sexual behaviors to help design educational interventions and to detect changes in behavior over time. This sentinel surveillance system, using a standardized methodology, will provide the best national and regional data available on the seroprevalence of HIV among IVDUs and the relationships of drug use, sexual behaviors, and HIV serologic status of IVDUs.

In 1988, 10,747 CASES OF ACQUIRED immunodeficiency syndrome (AIDS) were reported among intravenous drug users (IVDUs), their sex partners, and children born to mothers who were IVDUs or sex partners of IVDUs (*1*). These IVDU-associated AIDS cases represented 33.4 percent of all AIDS cases reported in 1988. The risk exposure groups included in the IVDU-associated AIDS cases were 7,531 (70.1 percent) heterosexual male and female IVDUs, 2,055 (19.1 percent) homosexual-bisexual male IVDUs, 847 (8.3 percent) men and women with heterosexual contact with IVDUs, and 314 (2.9 percent) children born to mothers who were IVDUs or the sexual contacts of IVDUs. The primary mechanism through which IVDUs become infected and infect others with human immunodeficiency virus (HIV) is the sharing of drug injection equipment contaminated with HIV. In addition to direct transmission of HIV through drug use, IVDUs play important roles in heterosexually transmitted AIDS (47 percent of cases) and perinatally transmitted AIDS (72 percent of mothers are IVDUs or sex partners of IVDUs) (*2*).

The number of IVDUs in the United States is unknown, in part because such drug use is illegal. The National Institute on Drug Abuse (NIDA) has estimated that there are 1.1 to 1.3 million regular IVDUs in the United States (R. Battjes, NIDA, March 1988). IVDUs differ substantially in the drugs that they inject, frequency of injections, sharing of needles, and types and levels of sexual activity (*3*). While opiates (particularly heroin) have historically been the drugs most commonly injected, the injection of cocaine appears to be increasing (*4, 5*).

The number of IVDUs and other drug users in drug treatment programs is unknown. A 1987 survey provides some data on participants in drug treatment (*6*).

In 1987, the Centers for Disease Control (CDC) and NIDA reviewed published and unpublished studies of HIV seropositivity among IVDUs in the United States (*7, 8*). In the 91 studies examined, the geographic differences in HIV seroprevalence were marked. HIV seropositivity among IVDUs tested was highest in the Northeast (8 to 65 percent) and Puerto Rico (45 percent); lower in the metropolitan areas of Atlanta (10 percent), Detroit (8 to 12 percent), and San Francisco (7 to 13 percent); and 5 percent or less in cities in the West, Midwest, and South. The different study designs

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used for these surveys make comparisons between geographic areas difficult.

The rate of spread of HIV infection among IVDUs has varied. Rapid increases in HIV seropositivity among IVDUs have been reported from several European countries (*9–13*), the northeastern United States (*5*), and Thailand (H. Haverkos, NIDA, personal communication, January 1989). Recent studies suggest stable but high HIV seropositivity among IVDUs in New York City (*5, 14*) and R. Battjes, NIDA, personal communication, January 1989) and stable but low rates in Los Angeles (P. Kerndt, Los Angeles Health Department, February 1989). Again, the differences in methods used make it difficult to compare seropositivity rates from different periods.

Because of the key role of IV drug use in the HIV epidemic, implementation of effective prevention programs targeting IVDUs is an urgent priority. Standardized studies of IVDUs are needed to determine levels of seropositivity, to monitor changes in seropositivity, and to monitor changes in reported drug use and sexual behaviors over time.

A blinded (serologic test results not linked to identifiable persons) survey design, in which serums remaining after routine blood tests are tested for HIV antibody, is essential to obtaining seroprevalence levels with a minimum self-selection bias (*15*). IVDUs entering drug treatment centers are the most practical subgroup of the population of IVDUs for a blinded survey, because they can be reached in institutions where blood specimens are routinely obtained as part of the medical assessment upon admission to drug treatment. Moreover, in drug treatment centers, standardized cross-sectional surveys of IVDUs can be repeated yearly to compare the seropositivity and behaviors over time. Also, comprehensive HIV prevention services can be offered to them and be evaluated. Since most (80 to 90 percent) IVDUs are not in drug treatment, they cannot be easily reached and systematically included in an unbiased, blinded survey.

The drug treatment center survey is a component of the CDC family of HIV surveys, which includes surveys in sexually transmitted diseases (STD) clinics and in family planning, prenatal care, abortion, and tuberculosis clinics in 39 selected metropolitan areas. Surveys of childbearing women are also conducted through blinded testing of neonatal blood specimens obtained to screen for metabolic defects.

Objectives

The objectives of the HIV seroprevalence surveys of IVDUs are

1. to determine, through blinded surveys, the seroprevalence of antibodies to HIV, over time, in IVDUs entering drug treatment;
2. to evaluate, through nonblinded (in which clients voluntarily agree to participate) surveys, behavioral risk factors for HIV seropositivity in IVDUs entering drug treatment; and
3. to determine, through nonblinded surveys, the current self-reported drug use and sexual behaviors of IVDUs entering treatment, in order to monitor behavioral change in response to HIV infection and AIDS and to assess the effect of interventions intended to reduce HIV transmission.

Survey Methods

The surveys use blinded and nonblinded methods in annual cross-sectional studies of entrants to drug treatment centers.

Selection of treatment centers. The following criteria were used in selecting drug treatment centers for participation in the seroprevalence survey: (*a*) routine collection of blood specimens from all clients entering drug treatment; (*b*) large numbers of eligible IVDUs entering treatment; (*c*) willingness to participate in the survey, adhere to the standard protocol, and collaborate with local, State, and CDC investigators; and (*d*) willingness to establish voluntary HIV testing and counseling services for all clients. When a metropolitan area had several drug treatment centers meeting these criteria, centers were selected to include those using different drug treatment modalities, serving different neighborhoods and population subgroups, and treating clients who use various types of drugs.

Surveys have been started in agencies using the following types of drug treatment programs: methadone maintenance, methadone detoxification, residential drug-free, cocaine treatment, and outpatient drug-free. In addition, in five metropolitan areas, central medical

intake services are participating in the surveys. These central medical intake services are excellent sites for blinded surveys of IVDUs entering treatment because large numbers of IVDUs entering treatment in these metropolitan areas receive their initial medical evaluation (including blood tests) at such facilities.

Drug treatment centers already participating in nonblinded surveys sponsored by other agencies were eligible for the blinded surveys sponsored by CDC but not for nonblinded surveys. Centers that excluded persons known to be or suspected of being HIV seropositive were not eligible. Centers participating in blinded and nonblinded surveys must offer or refer all interested clients for voluntary HIV testing and counseling.

Eligibility criteria. Clients are eligible if they are being evaluated for admission to drug treatment, reported injecting drugs intravenously at least once in the past 12 months and, for nonblinded surveys, are legally able to consent to participate.

Client selection. For blinded surveys, eligible clients entering drug treatment are enrolled consecutively during the selected sampling period. For nonblinded surveys, all eligible clients are asked to participate. In centers where constraints (for example, limited space, limited number of interviewers, patient flow) make it impossible to invite all clients to participate in the nonblinded survey, a systematically selected subsample of eligible clients is asked to participate.

Blinded surveys. After personal identifying information is removed, the serum remaining from blood tests that are routinely performed on clients entering drug treatment centers is tested for HIV antibody. For example, Food and Drug Administration (FDA) regulations require that all clients entering drug treatment centers using methadone have a medical assessment, including a serologic test for syphilis.

Blinded surveys collect the following data: location and treatment modality of the drug treatment center; quarter and year of visit; State, county, and zip code of residence; sex, age group, race, and ethnic group; primary drug injected; other drug(s) injected; sexual orientation; and enzyme immunoassay (EIA) and Western blot results (including positive bands).

Demographic data and data on drugs injected, type of drug treatment, and, if available, sexual orientation are abstracted from the client's chart and entered on the data form of the CDC blinded drug treatment center survey. Each form has a unique printed survey code number and a laboratory report section in which HIV antibody test results are recorded. A sticker with the survey code number is attached to one of the blood collection tubes for routine serologic studies (for example, serologic test for syphilis, liver function tests, and hepatitis B serology). After the serum has been tested, leftover serum is transferred to a specimen container labeled only with the blinded survey code number. No personal identifiers (for example, name, address, clinic identification number) are placed on the specimen container or on the survey data form.

The labeled specimen container is sent to the laboratory performing the HIV serologic testing. Laboratory workers who perform the HIV testing must not be the same persons who handled the original blood specimens or transferred the blinded study code numbers. The results of the HIV antibody test are reported on the blinded survey laboratory report form.

Data management staff of the seroprevalence survey link the demographic data and HIV laboratory results by the blinded survey code number, using the CDC HIV family of surveys data management software. The data management staff have no information on the personal identifiers of the clients and no contact with them. Only summary data from the blinded survey that cannot be linked to individual persons are given to the staff of the participating clinics.

Nonblinded surveys. In addition to conducting blinded surveys, many clinics will conduct concurrent nonblinded, linked surveys. Each metropolitan area must receive local institutional review board approval before beginning nonblinded surveys.

All clients meeting the eligibility criteria for blinded surveys are asked to participate in the nonblinded survey. Eligible clients are included in nonblinded surveys once per survey period. Clients who agree to participate give written informed consent to be interviewed for an assessment of risk behaviors and for HIV testing. These persons are, therefore, a self-selected subgroup of those included in blinded surveys. All clients who participate in nonblinded surveys will receive pre- and post-HIV test counseling.

Trained interviewers administer a standardized questionnaire that reviews behaviors that may be associated with HIV infection. The questionnaire consists of 42 questions in four categories (see box): (*a*) demographic information, (*b*) drug use history, (*c*) sexual history and behavior, and (*d*) medical history. Geographic (State and county of residence) and demographic (age, race, and ethnicity) information are obtained on all eligible clients which allows the calculation of participation rates and description of the general characteristics of persons who refuse to participate. The remaining parts of the questionnaire are completed on clients who give informed consent to participate in the survey.

In addition to completing the risk assessment ques-

Information Requested in Nonblinded Risk Assessment Questionnaires at Drug Treatment Centers

Demographic: project area and site, age, race, ethnic origin, data of visit, State, county, and zip code of residence

General: place of birth, marital status, years of formal education

Drug use behaviors: history of enrollment in drug treatment, primary and secondary IV drugs used, frequency of IV drug use, needle cleaning, and needle sharing

Sexual history and activities: homosexual or bisexual activity, sexual contact with IVDUs since 1978 and in the last 12 months, sexual contact with someone who has AIDS or HIV infection, prostitution, frequency of condom use in past 12 months, self-reported change in sexual behavior to lower risk of HIV infection

Medical history: blood transfusions, frequency of sexually transmitted diseases

Test results: serological test for syphilis, hepatitis B antigen/antibody, tuberculin skin test

NOTE: Copies of the drug treatment center risk assessment questionnaire may be obtained from the Division of HIV/AIDS, Seroepidemiology Branch, Clinic-Based Survey Section, Centers for Disease Control.

tionnaire, interviewers obtain results of selected tests, including serologic tests for syphilis, hepatitis B antigen-antibody, and tuberculin skin test from the client's clinical record.

The completed questionnaire is sent to the metropolitan seroprevalence coordinator for data entry and linkage to HIV test results. The CDC HIV family of surveys computer software system is used for collecting and collating data from the blinded and the nonblinded surveys.

Sample Size Considerations

The estimated HIV seropositivity rates in the drug treatment centers conducting blinded surveys range from 1 to 50 percent. A nominal sample size of 500 clients per year at each survey site was chosen to provide sufficient participants to give 95 percent confidence intervals of 0.3 to 2 percent for a 1 percent seroprevalence level and 46 to 54 percent for a 50 percent level (*16*). In practice, most drug treatment centers have fewer than 500 eligible IVDUs entering drug treatment per year, requiring that specimens from all eligible clients be included in the blinded survey and that all eligible clients be asked to participate in the nonblinded survey. For centers that receive more than 500 eligible admissions per year (particularly, central medical intake services), larger numbers of clients (up to 1,500) can be included to give greater statistical power in estimating seropositivity rates for different demographic and behavioral subgroups.

Laboratory Methods

Blood specimens are tested for antibody to HIV by an EIA licensed by the FDA and performed according to the manufacturer's recommendations. Serums repeatedly reactive by EIA are tested with a Western blot assay licensed by FDA. The presence or the absence of each virus-specific band is reported. Laboratories performing the tests are required to participate in the laboratory quality assurance program provided by CDC (*17*).

Time Frame

The surveys will continue for at least 5 years to provide information on changes in seropositivity and behaviors. Because of the limited number of eligible entrants, most drug treatment centers will enroll both blinded and nonblinded clients continuously throughout the year. Centers enrolling the targeted number of clients in less than a year will start enrollment at the same time each year to minimize the possible effects of seasonal changes in seroprevalence and behaviors.

Special Considerations

Blood for routine laboratory tests cannot be obtained from 10 percent or more of the clients entering some drug treatment centers. Scarring of veins because of multiple injections is one of the major reasons for failure to obtain blood from IVDUs. Since difficulty in obtaining blood is likely to be related to the duration and intensity of IV drug use, HIV seroprevalence data from centers with many clients who cannot give blood by venipuncture are likely to lead to an underestimated seropositivity rate for persons entering drug treatment. In some centers, microvette tubes are used to collect capillary blood for routine laboratory tests (for example, serologic test for syphilis) from clients from whom blood cannot be obtained by venipuncture. Leftover serums from these capillary blood specimens can be used for the blinded survey.

This survey was designed to study IVDUs. Non-IV drug use, including subcutaneous injection of drugs (skin popping) and particularly the smoking of crack cocaine, may also be associated with HIV transmission through sexual contact. For example, increases in

reported cases of syphilis in 1987 and 1988 have been attributed to heterosexual spread of the disease among blacks and Hispanics, and may be associated with drug use (*18*). Plans are being developed to extend these surveys to non-IV drug users.

Uses of Data

These surveys establish a national sentinel surveillance system to monitor the HIV seropositivity (blinded surveys) and behaviors (nonblinded surveys) of IVDUs entering selected drug treatment centers. The surveys will yield data representative of the clients entering drug treatment at the centers that participate in the surveys. Although serving as indices of the levels and trends in HIV infection among IVDUs in the participating metropolitan areas, the data will not yield estimates of the seroprevalence of all IVDUs in the United States (*19*). The surveys in drug treatment centers are part of a wider program of sentinel surveillance of HIV infections in the United States (*20*).

Interpretation of Data

Caution should be used in extrapolating from the seroprevalence data obtained from clients of a particular drug treatment clinic to other populations of IVDUs. Interpreted conservatively, the blinded survey seroprevalence data represent only IVDUs from whom blood was tested for HIV antibody.

Because the participating drug treatment centers were selected according to the criteria already discussed rather than as a probability sample, the HIV seroprevalence data from the participating centers do not necessarily represent IVDUs in drug treatment in the community. Since the surveys are conducted in drug treatment centers, the seroprevalence data are not representative of IVDUs who are not in treatment for drug addiction. NIDA estimates that only 10 to 15 percent of IVDUs are in drug treatment at any time. If drug treatment capacity is substantially expanded, the characteristics of IVDUs entering treatment including the rates of HIV seropositivity may change.

Since only persons who have used drugs intravenously within the 12 months before admission are eligible for the survey, the results will not be representative of former IVDUs or non-IV drug users.

Data indicate that HIV seroprevalence differs by racial and ethnic group, drugs injected, sexual orientation, and geographic area (*7, 8*). Caution should be used in comparing overall seroprevalence data from clinics that differ in these variables. Many drug treatment centers admit considerably fewer IVDUs than the target sample of 500 clients a year. Smaller numbers of clients will limit the precision of overall point prevalence estimates, especially for demographic subgroups.

Conclusion

Better data on the epidemiology of HIV infection in IVDUs are urgently needed. In collaboration with State and local health departments and drug abuse agencies, CDC has started a sentinel surveillance system to monitor the HIV seroprevalence (through blinded surveys) and the drug use and sexual behaviors (through nonblinded surveys) of IVDUs entering drug treatment in selected treatment centers in 39 metropolitan areas in the United States. The use of a standardized protocol will facilitate comparisons between different geographic areas and types of drug treatment. Repeat surveys of the same clinics using the same protocol will allow monitoring of secular changes in seropositivity and risk behaviors in IVDUs entering drug treatment. These should be the best available national and regional data on HIV seroprevalence and the behaviors of IVDUs.

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Determining HIV Seroprevalence Among Women in Women's Health Clinics

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Synopsis

Human immunodeficiency virus, type 1 (HIV), seroprevalence studies are needed to determine the level and trends of HIV infection among women attending family planning, abortion, and prenatal care clinics in the United States. A review of published and unpublished studies showed that HIV seroprevalence among women attending women's health clinics was 0 to 2.6 percent, although the studies were difficult to compare because of differences in methodology.

The Centers for Disease Control, in association with State and local health departments, has developed a standardized protocol to determine HIV seroprevalence among women attending women's health clinics in selected metropolitan areas. Blinded HIV serosurveys (serologic test results not identified with a person) are being conducted annually in selected sentinel clinics in order to obtain estimates of HIV seroprevalence unbiased by self-selection, as well as to monitor trends in infection among clients attending these clinics. In areas with high HIV seroprevalence, nonblinded serosurveys (in which clients voluntarily agree to participate) will be used to assess behaviors that may place women at increased risk of exposure to HIV.

Data from the surveys can be used in developing age-specific and culturally appropriate AIDS educational materials, assessing the amount and type of counseling activities required, and evaluating acquired immunodeficiency syndrome (AIDS) prevention activities. The information will provide epidemiologic data to complement the results of other surveys in characterizing the scope of HIV infection among women of childbearing age in the United States.

CASES of acquired immunodeficiency syndrome (AIDS) among women, reported to the Centers for Disease Control (CDC) since 1981, totaled 10,611 as of December 31, 1989, amounting to 9.2 percent of all reported AIDS cases.

The proportion of AIDS cases among women increased from 6.4 percent in 1984 to 10.4 percent in 1988. The overall proportion of women among persons with AIDS, excluding homosexual and bisexual men, increased from 24.7 percent in 1984 to 28.3 percent in