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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 A review of published and unpublished studies showed that HIV seroprevalence among women attending women's health clinics was 0 to 2.6 percent, although the studies were difficult to compare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

1988. As the proportion of AIDS cases among homosexual and bisexual men decreases and the proportion of AIDS cases among intravenous drug users and their sexual partners increases, we expect the proportion of AIDS cases among women to increase.

Because of the lengthy average incubation period between infection and onset of symptoms, AIDS case reports do not necessarily reflect the current scope of human immunodeficiency virus, type 1 (HIV), infection or the recent patterns and trends of HIV transmission (*1*). Little is known about the seroprevalence of HIV infection among women in the United States (*2, 3*). Surveillance for HIV among women of reproductive age is needed in order to be able to describe current levels and future trends of infection, to project future health needs, and to formulate public health policy.

In 1987, CDC extensively reviewed both published and unpublished information on HIV seroprevalence among women in the United States (*4*). Seroprevalence studies that used a blinded survey design, which is serologic test results not linked to identifiable persons, indicated that women who attended family planning, abortion, and prenatal care clinics were at lower risk for HIV infection than those who attended sexually transmitted disease (STD) clinics or drug treatment centers. HIV seroprevalence rates among patients of family planning and abortion clinics ranged from 0.0 to 2.6 percent (*4, 5*), and from 0.0 to 1.5 percent in prenatal care clinics (*4, 6–9*). Differences in rates, however, are difficult to interpret because of differences in study methodologies.

CDC began a program of clinic-based HIV seroprevalence surveys in 1987 in collaboration with State and local health departments (*10*). The surveys, which now include 39 metropolitan areas, are complementary in design and conducted annually. The CDC family of seroprevalence surveys assesses HIV prevalence among persons attending STD clinics, tuberculosis clinics, drug treatment centers, women's health clinics in the sentinel cities, and, on a statewide basis, among women delivering infants. Metropolitan areas representing different geographic regions were selected for participation based on criteria that included the cumulative incidence of reported AIDS cases, and syphilis and gonorrhea case rates.

In the surveys, a special interest group is women of reproductive age who attend clinics offering family planning, abortion, and prenatal services, referred to here as women's health clinics. Women attending clinics offering family planning or abortion services, but not prenatal services, are unlikely to be included in the statewide survey of women delivering infants. Clinic-based survey results thus complement the statewide survey of women delivering infants.

'HIV seroprevalence surveys of women of reproductive age can help in determining the spread of HIV to heterosexual populations and in defining characteristics associated with perinatal HIV transmission.'

Survey Objectives

The objectives of the HIV seroprevalence surveys of women's health clinics are

- to determine the prevalence of HIV infection by race, ethnicity, age, and geographic location of patients attending clinics which serve women of reproductive age,
- to monitor trends in HIV seroprevalence over a period of time in the clinics, and
- to assess risk factors associated with HIV infection.

Survey Methods

Selection of clinics. Women's health clinics located in different neighborhoods in various metropolitan areas were selected for participation in the surveys according to

- the racial and ethnic diversity of the clinic populations served,
- the existence of procedures for routine medical assessment on all new clients, including the collection of venous blood,
- the willingness of clinic staff members to collaborate with the local health department and CDC and to adhere to standardized protocols, and
- the diversity of the type of clinic.

The women's health clinics which were eligible for inclusion in the surveys were those offering family planning, prenatal care, and abortion services. Such clinics serve a diverse range of women, but typically provide services to those who are young with low incomes. Although we attempted to include family planning, abortion, and prenatal care clinics in each sentinel metropolitan area, not all areas have surveys in each type of clinic.

Family planning clinics offer information on contraceptive services to women of reproductive age. Additional services may include testing and treatment for STDs, pregnancy testing, and comprehensive gynecologic care. The clinics may be run by State or

Information Requested in Nonblinded Risk Assessment Questionnaire

Demographic: Project area and site; age; race; ethnicity; date of visit; State, county, and zip code of residence; place of birth; age when client moved to the United States; marital status; and years of formal education.

Drug use: History of intravenous (IV) drug use since 1978 and in the past 12 months, primary IV drug used, frequency of IV drug use, and non-IV drug use.

Sexual history and activities: History of sex with men who were bisexual, hemophiliac, IV drug users, or had a history of AIDS or HIV infection; number of sexual partners since 1978 and in the past 12 months; history of exchange of drugs or money for sex; history and frequency of condom use in past 12 months; and self-reported change in sexual behavior to lower risk of being infected with HIV.

Medical history: History of blood transfusions, history and frequency of STDs, use and type of birth control used since 1978 and in the past 12 months, and current pregnancy status.

Test results: Serologic tests for syphilis, hepatitis B antigen/antibody, and Papanicolaou (Pap) smear.

local health departments, or by private agencies, such as those affiliated with the Planned Parenthood Federation of America.

Prenatal care clinics provide routine or specialized prenatal care services for pregnant women. Prenatal care clinics participating in HIV seroprevalence surveys are usually run by State or local health departments and may principally serve low income women.

Abortion clinics provide educational, counseling, and abortion services. Such clinics do not receive Federal funds, although some may receive State funds. They are usually privately owned and generally provide services to women of diverse ethnic and socioeconomic backgrounds.

General demographic information, such as the age, race, and ethnicity of clients attending each clinic, is reviewed each year to monitor whether clinic populations are changing.

Eligibility criteria for clients. Women attending clinics for routine services are eligible for inclusion in the surveys once during each survey period. Women not eligible include those attending the clinic solely for HIV testing and counseling.

Blinded surveys. Blinded surveys are conducted to obtain estimates of HIV seroprevalence in the clinic populations, unbiased by self-selection. In the surveys, HIV antibody tests are performed on the unused portion of serum collected for routine purposes, such as syphilis serology or hematocrit. After the routine testing is completed, general demographic information, including age, race, ethnicity, and zip code of residence, is recorded for each client. Personal identifiers, such as the client's name, address, and clinic chart number, are removed. Information is recorded on CDC survey forms and assigned a precoded study number. Serum identified with the same precoded number is sent to be tested for antibodies to HIV. Data forms and HIV test results are sent to a designated metropolitan survey coordinator, where the data are entered into computer data bases using a computer software package developed at CDC. Test results and demographic data are then linked. Only summary data, without individual test results, are returned to the clinic.

Nonblinded surveys. Some clinics conduct only nonblinded surveys (in which clients voluntarily agree to participate), while some conduct nonblinded surveys concurrently with blinded surveys. Clinics are chosen for nonblinded surveys because of a documented or suspected elevated HIV seroprevalence among their clients and a willingness of the staff members to participate and adhere to the standard protocols. Each metropolitan area must receive approval by a local institutional review board before beginning nonblinded surveys.

Women 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 women are therefore a self-selected subgroup of those included in blinded surveys. All women who participate in nonblinded surveys receive pretest 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 31 questions regarding drug use history, sexual history and behavior, and medical history, as well as demographic information, outlined in the accompanying box. (A copy of the women's health clinic risk assessment questionnaire may be obtained from the authors.)

Geographic (State and county of residence) and demographic (age, race, and ethnicity) information are obtained for all eligible clients, whether or not they participate in the survey, which allows calculation of participation rates and characterization of nonparticipants. The risk assessment questionnaire is completed for clients who have consented to participate in the survey. In addition to risk information, interviewers obtain selected laboratory test results 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. Separate data management systems, supported by computer software developed at

Estimated seroprevalence rates (percent positive), by observed seroprevalence and sample size of survey (95 percent confidence intervals)

Observed rate	Sample size						
	100	200	300	500	1,000	2,000	4,000
0.0	0 – 3	0 – 1.5	0 – 1	0 – 0.6	0 – 0.4	0 – 0.2	0 – 0.1
0.3	0 – 3.9	0 – 2.5	0.01– 1.8	0.02– 1.3	0.1 – 0.9	0.11– 0.6	0.15– 0.5
0.6	0 – 4.9	0.02– 3.0	0.07– 2.2	0.12– 1.7	0.22– 1.3	0.31– 1.0	0.38– 0.9
1.0	0.02– 5.5	0.1 – 3.6	0.2 – 2.9	0.3 – 2	0.5 – 1.8	0.6 – 1.5	0.7 – 1.4
2.0	0.2 – 7	0.6 – 5	0.7 – 4.3	1 – 3.6	1.2 – 3.1	1.4 – 2.7	1.6 – 2.5
5.0	2 –11	2 – 9	3 – 8	3 – 7	3.7 – 6.5	4 – 6	4.3 – 5.7
10.0	5 –18	6 –15	7 –14	8 –13	8.2 –12	8.7 –11.4	9.1 –11

CDC, are used for blinded and nonblinded seroprevalence studies.

Confidentiality provisions, counseling, and posttest services, such as partner notification, are provided according to CDC recommendations and in keeping with local policies.

Sample size. The required minimum sample size for both blinded and nonblinded surveys is based on considerations that include the expected HIV seroprevalence for each clinic and the desired precision of the seroprevalence estimate within certain bounds (95 percent confidence intervals). The survey period depends on the number of eligible women served per week in each clinic.

HIV seroprevalence for most women's health clinics can be expected to be zero to 1 percent. Given this expected rate, we recommended a minimum annual sample size of 1,000. The table lists intervals around an observed seroprevalence at a significance level of 5 percent (*11, 12*). These intervals have been calculated for seropositivity rates for surveys with various sample sizes. For example, if the survey sample size is 1,000 and the observed seroprevalence rate in the sample is 1 percent, we can be 95 percent certain that the true seroprevalence rate for the participating clinic is 0.5 to 1.8 percent.

Sample selection. To minimize selection bias, specimens from eligible women are sequentially collected in the surveys until the predetermined sample size is achieved. In some clinics the total number of specimens that can be collected in a year may be less than the recommended sample size; however, in these settings all specimens from eligible clients will be enrolled during a 12-month period. Surveys in subsequent years will be conducted during the same months to minimize the impact of any seasonality of either HIV infection or the reproduction-related reasons for clinic visits.

Laboratory methods. Specimens will be tested for antibodies to HIV according to manufacturer's recommendations at designated laboratories by an HIV enzyme immunoassay (EIA) licensed by the Food and Drug Administration (FDA). Serums that are repeatedly reactive must be tested by an FDA-licensed Western blot assay. The presence or the absence of each virus-specific band is reported to CDC. Participating laboratories are required to take part in the CDC program of quality assurance.

Use and Interpretation of Data

HIV seroprevalence surveys of women of reproductive age can help in determining the spread of HIV to heterosexual populations and in defining characteristics associated with perinatal HIV transmission. At each clinic, surveillance of HIV infection may suggest the need to augment AIDS prevention services. Among such services are

- providing AIDS educational and HIV risk-reduction information materials,
- instituting anonymous self-administered questionnaires that review behaviors that may be associated with HIV infection,
- instituting routine individual risk assessment of behaviors associated with HIV infection,
- offering routine HIV testing with pretest and posttest counseling,
- providing specialized services to HIV-positive women and women at high risk, and
- developing special outreach efforts for HIV-positive and high-risk women.

The data also may be used to direct age-specific and culturally appropriate programs to women at high risk for HIV infection. Annual surveys should reflect HIV transmission patterns in populations served by the clinics and may assist in evaluating AIDS prevention efforts.

The seroprevalence data from the surveys will provide important information on HIV infection among women of reproductive age. Nonetheless, there are

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important limitations to consider in the proper interpretation of the data. Because clinics were not chosen by a probabilistic sampling scheme, the data should not be used to estimate HIV seroprevalence among all women in the metropolitan area attending women's health clinics. Women seeking services in participating clinics do not represent all women of reproductive age or women receiving similar services from nonparticipating clinics or in other settings, such as physicians' offices or hospitals.

In addition, many family planning clinics do not routinely obtain venous blood specimens from clients during a clinic visit and therefore are not eligible for inclusion in the survey. Family planning clinics that do routinely collect venous blood may not be representative of all such clinics. In particular, clinics that routinely collect blood to screen for conditions such as syphilis, which may be associated with HIV infection, may be those that serve women at increased risk for sexually transmitted diseases, including HIV.

Some prenatal care clinics participating in the surveys may routinely refer high-risk obstetric clients, such as intravenous drug users, to hospitals or tertiary care institutions. Since these women are at increased risk for HIV infection, their exclusion may lead to an underestimate of HIV seroprevalence in a clinic population.

While these biases restrict generalization of clinic data to an entire metropolitan area, repeating the surveys annually will maintain clinic-specific biases constant over a period of time. The resulting trends will reflect HIV seroprevalence in the population served by the clinic.

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