Monitoring the Levels and Trends of HIV Infection: the Public Health Service's HIV Surveillance Program

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Synopsis

A comprehensive, multifaceted approach to HIV surveillance is needed to provide the information necessary for public health management and policy. Because HIV infection is not readily or uniformly ascertained, survey methods and sentinel surveillance approaches must be used. At least some of the surveys must be blinded, that is, anonymous and unlinked to identifiable persons, to avoid the uninterpretable impact of self-selection bias that could lead to both significant underestimates and occasional overestimates of HIV prevalence. Other surveys must be nonblinded, with careful interviews of volunteer participants to evaluate risk factors for HIV infection. These various surveys must continue over time to evaluate trends in infection.

A comprehensive family of complementary HIV surveys and studies and a national household-based HIV seroprevalence survey have been undertaken by the Public Health Service in collaboration with other Federal agencies, State and local health departments, blood collection agencies, and medical research institutions. These projects focus on accessible segments of the general population, childbearing women, persons at high risk for HIV, and persons in special settings such as prisons and colleges. This comprehensive surveillance approach will help monitor the levels and trends of HIV infection in the United States and help prioritize, target, and evaluate HIV prevention activities.

THE PREVALENCE OF HIV INFECTION varies widely by geographic area and by demographic and behavioral subgroup (*1*). It is essential at the State and local levels that HIV prevention activities be targeted to those geographic areas and population groups currently affected by HIV and to those into which the virus may be spreading. The impact of prevention activities is reflected in the prevalence and trends of infection over time. At regional and national levels, knowledge of the current patterns of HIV infection and estimates of the total number of infected persons are important for anticipating future health needs and setting public policy.

To serve these various public health functions, health officials need information concerning the levels and trends of HIV in (*a*) groups recognized to be at increased risk, including homosexual men and intravenous (IV) drug abusers, (*b*) groups at lower but potential risk, particularly childbearing women and heterosexually active persons, (*c*) the general population—which comprises persons at various levels of risk, (*d*) different geographic areas, (*e*) various demographic subgroups (by age, sex, and race-ethnicity), and (*f*) special settings that require specialized public health approaches, such as prisons, colleges, tuberculosis clinics, and hospital emergency rooms.

Two specific examples illustrate the kinds of public health-related information needed:

- For IV drug abusers, the prevalence of infection ranges from 50 to 60 percent in the New York City vicinity to 5 percent or less in most cities surveyed outside the east coast area (*1*). These data indicate a great but generally underrecognized potential for a rapid increase in infection in many areas. Because of the lengthy incubation period between infection with HIV and expression of AIDS, a silent explosion of infection among IV drug abusers could occur long before a rise in IV drug-associated AIDS cases became evident. (Note: Such a rapid spread of infection in IV drug abusers has occurred in New York City, San Francisco, Edinburgh, Scotland, and in Italy and Spain.) Health departments must assess and moni-

tor the level of infection among local drug abusers to ensure that appropriate priority is given to preventing HIV infection in drug abusers and their sex partners and babies.

- Infected childbearing women are the only source for perinatal HIV transmission. The level of risk for perinatal transmission varies with the prevalence of HIV infection in women. Limited data indicate that this prevalence varies from essentially 0 (*1*) to well over 3 percent (according to personal communication with Lloyd Novick and Rachel Stricof, New York State Department of Health, March 1988). To assess whether perinatal HIV prevention programs are needed in specific localities and to evaluate the effectiveness of such programs, surveys of HIV infection prevalence in childbearing-aged women are essential.

No one surveillance activity yields the myriad information that is needed concerning HIV. Rather, complementary approaches must be taken. This report is a review of the elements and applicability of the comprehensive HIV surveillance program undertaken by the Public Health Service.

It is important in this discussion to distinguish epidemiologic surveillance from public health interventions. Surveillance entails (*a*) gathering high-quality interpretable data on the occurrence of diseases or infections, and (*b*) analyzing and using those data to target and evaluate public health interventions, such as health education, HIV-antibody testing, and counseling. Failure to distinguish surveillance activities from the prevention efforts that the surveillance activities serve can lead to confusion about objectives and methods.

Preexisting Data Sources

Several sources of information have HIV surveillance implications.

AIDS case reporting. Since 1981, AIDS cases have been voluntarily reported to the Centers for Disease Control (CDC) by State and local health departments. Completeness of case reporting reached 90 percent in 1985–86 (*2,3*). Analyses of reports on AIDS cases have permitted identification of the geographic areas most affected and the demographic and behavioral subgroups at greatest risk. Although the surveillance of AIDS cases serves as an essential index of the spread of HIV by tracking the severe clinical consequences of HIV, it has a key limitation: because of the long incubation period between infection and disease, AIDS cases reflect previous HIV transmission patterns and will not quantitatively indicate recent changes in transmission until years after the fact. For example, one benefit of prevention efforts not yet apparent from surveillance of AIDS cases is the major reduction in HIV transmission from blood transfusions and clotting-factor concentrates since screening of blood donors, testing for antibodies to HIV, and heat treatment of factor concentrates became widespread in early 1985. Thus, AIDS case surveillance remains essential, but it does not meet many of the public health data needs.

Counseling and testing programs. Beginning in 1985, with the licensure of the enzyme immunoessay (EIA) to detect antibodies to HIV, counseling and testing programs were established throughout the country and now constitute a key component of the AIDS prevention activities. Data on the prevalence of infection among persons who seek testing are available. However, persons who seek testing represent neither the entire community nor specific definable subgroups. Further, the likelihood of one's seeking testing varies from place to place and over time in accordance with prevailing attitudes about AIDS and the test. HIV prevalence and trend data from these programs are not readily interpretable and probably do not reflect HIV prevalence or trends in the community. It is important to evaluate data from counseling and testing programs for program management purposes (for example, acceptance of services, percent of the community reached), but the value of those data as they relate to HIV surveillance is limited.

Reporting of HIV infection. Currently, 11 States require the reporting of all detected HIV infections: Alabama, Arizona, Colorado, Idaho, Minnesota, Missouri, North Dakota, Oklahoma, South Carolina, Texas, and Wisconsin. Such reporting, if it provides personal identifiers, permits health departments to ensure counseling and clinical evaluation of infected persons and, in some areas, of their sexual and needle-sharing partners as well. The impact of a reporting policy on the likelihood of infected persons seeking or permitting serologic testing has been debated. Detection of HIV infection, however, results from a chance mixture of screening of blood donors, military applicants and active-duty military personnel, counseling and testing activities, diagnostic evaluations, and other

testing. The completeness of detecting and reporting infection is highly variable. In Colorado, 4.7 HIV infections were reported for every AIDS case (R. E. Hoffman, Colorado Department of Health, personal communication, March 1988); in Maricopa County, AZ, the ratio of reported HIV infections plus AIDS-related complex to AIDS is 1.4 to 1 (C. W. Juels, Maricopa County Health Department, personal communication, March 1988). Nationally, an estimated 20–30 persons have been infected for each reported case of AIDS. Although reporting of HIV infection can be valuable for public health followup of infected persons and their intimate contacts, such reporting cannot effectively evaluate levels, trends, or risk factors for HIV infection in the community, except where virtually universal screening is practiced.

Current surveys and studies. Several large groups are screened for HIV: blood donors, military applicants and active-duty personnel, and Job Corps entrants. The data from these screening programs are applicable to surveillance as outlined subsequently. A variety of surveys and studies in high- and low-risk populations have been conducted throughout the country (*1*). This report provides a description of a more systematic approach to conducting HIV surveys in sentinel areas and groups throughout the country that is a component of the Public Health Service's HIV surveillance program.

Need for Blinded Testing

In blinded surveys, blood specimens collected for other purposes are permanently stripped of personal identifiers, then serologically tested for HIV. Such an approach is needed for technical, ethical, and practical reasons. To be interpretable, data on levels and trends of HIV infection must be as free from bias as possible. Self-selection bias—the impact of persons who are at risk or know they are infected being either more or less likely to be tested than persons who are otherwise similar but without recognized risk—poses a methodological problem because of its quantitatively unpredictable impact on the data.

Self-selection bias. Self-selection substantially raises the observed seroprevalence in groups seeking counseling and testing or undergoing diagnostic evaluations. In contrast, the impact of persons at risk declining to participate in voluntary surveys or to volunteer for activities in which screening for antibodies to HIV is routinely performed (for example, donating blood, serving in the military) lowers the observed prevalence. Recently, among patients with sexually transmitted diseases (STD) in Albuquerque, NM, the HIV seroprevalence in the 82 percent of patients who agreed to participate in a nonblinded survey was less than one-fifth as high as in the 18 percent of patients who declined to participate but were tested anonymously in a blinded survey. The observed prevalence in the nonblinded survey was 1.0 percent whereas the true prevalence was at least 1.8 percent; for homosexual men, the observed prevalence was 7.0 percent compared with the true prevalence of at least 14.3 percent. (C. J. Bettinger, H. F. Hull, New Mexico Health and Environment Department, personal communication March 1988). Similarly, a voluntary HIV study of pregnant women in New York City missed more than 85 percent of HIV infections (*4*).

Ethical issues in blinded surveys. Ethically, a study of HIV infection in identifiable persons must be done with informed consent and must permit refusal to participate, a process that introduces self-selection bias. Since blinded surveys avoid self-selection bias, they are increasingly recognized as the method of choice for determining prevalence (*5*). Blinded surveys are consistent with ethical norms because no participants are placed at risk of identification (*5–8*). Such surveys are also considerably simpler, faster, and less expensive to conduct than nonblinded surveys and do not require special measures to ensure confidentiality.

The unavoidable limitation of blinded surveys is the inability to identify and counsel infected persons. However, a blinded survey does not preclude encouraging persons at risk to seek counseling and testing as usual. Indeed, data from a blinded survey that indicate appreciable levels of infection will help target the health education and counseling and testing resources to areas with greatest need. The surveillance activity, in this case an HIV prevalence survey, must not be confused with the public health intervention for which the survey may indicate a need. A survey in which specimens from only a sample of those present were tested would be an inefficient way to reach persons at risk for infection. Moreover, having all the infrastructure in place for the intervention—counselors, rapid availability of test results, confidentiality systems—should not be a prerequisite to assessing whether the intervention is necessary.

The ethics and policies related to HIV testing will no doubt change when treatment or chemo-

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prophylactic methods that benefit the otherwise healthy HIV-infected person become available. However, blinded surveys will remain an important public health tool for evaluating the size and location of populations in need of, as well as reached by, this intervention.

Sentinel Surveillance

For monitoring the levels and trends of a condition such as HIV infection, which is not routinely or completely ascertained, quality information collected under standardized conditions in a limited number of places is preferable to information collected haphazardly everywhere. The places, including selected clinics, hospitals, and blood collection centers, serve as examples and thus can be considered sentinels. Persons at sentinel sites are unlikely to truly represent all persons in the community, but if well selected, the sentinel populations should reflect the levels, and particularly the trends, of infection prevalent in the community.

Prevalence and Incidence

Surveillance activities produce two principal statistics: prevalence and incidence. *Prevalence* is the level of infection in a given population at the particular time. It is usually expressed as a rate, such as percent of the population infected or number of infected persons per 1,000 or 10,000 persons in the population. This statistic requires only that the number of infected and noninfected persons be determined in a given population, or an appropriate sample of that population, on one occasion. *Incidence* is the rate of new infection occurring in a given population during a given period and is typically expressed as the percent of susceptibles becoming infected per year or the number of new infections per 1,000 or 10,000 persons per year. Incidence is difficult to measure; it requires that the same persons be tested on more than one occasion, which is logistically complex and introduces potentially serious self-selection bias. Incidence can also be inferred statistically by comparing surveys conducted at two or more points in time on appropriate samples drawn from the same population. All the surveys and studies outlined subsequently produce prevalence data, and since most are repeated over time using the same methods, they also indicate trends in prevalence over time. Only a few surveys directly measure incidence of new infection, although some permit incidence to be inferred from prevalence data developed at different points in time.

The Program of HIV Surveys and Studies

The surveys and studies outlined will continue indefinitely as long as the HIV epidemic remains dynamic. These projects complement one another, and each highlights a different facet of the epidemic with somewhat different public health applications. Some of the activities have been under way since 1985. Others are scheduled for implementation during 1988.

To facilitate rapid and consistent implementation of those surveys that are based in clinical settings, CDC established cooperative agreements to provide technical and funding support to 30 major metropolitan areas throughout the country. Surveillance based on six groups is included in this implementation phase: newborns and selected patients at STD clinics, drug treatment centers, women's health clinics, tuberculosis clinics, and sentinel hospitals. Over 400 clinics and hospitals in the 30 cities will participate. The other surveys and studies are more national in scope and are not focused in particular health jurisdictions.

Segments of the general population.

Blood donors. Since licensure of the EIA in early 1985, approximately 12 million blood donations made by 8 million donors have been screened routinely each year. Donor populations largely exclude homosexual and bisexual men, IV drug abusers, and persons with hemophilia, as well as persons who are known to be HIV-infected. Prevalence is observed in first-time donors; prevalence and incidence of new infection are measured in repeat donors; and trends in mode of transmis-

sion are monitored in 20 blood collection regions throughout the country through followup interviews to assess risk in seropositive donors.

Civilian applicants for military service. Since October 1985, approximately 600,000 military applicants have been serologically screened each year for HIV infection. Applicants underrepresent homosexual and bisexual men, IV drug abusers, and persons with hemophilia. Prevalence and trends in prevalence in this young segment of the population are observed directly, and trends in mode of transmission are monitored through followup interview programs that are being established. The surveillance implications of monitoring military applicants is analogous to blood donor monitoring, although the populations that are assessed differ somewhat in demographic composition.

Active duty military personnel. The Department of Defense requires periodic HIV screening of its personnel. This activity provides the opportunity to directly measure the annual incidence of new HIV infection in this relatively low-risk population.

Job Corps entrants. HIV-antibody screening is conducted on entrants to residential programs of the Job Corps, about 60,000 persons per year. This group comprises disadvantaged youths ages 16–21 years, with heavy representation of minorities and inner-city and rural poor. There is no restriction based on sexual orientation or hemophilia, but active drug addicts are underrepresented. This survey is important for assessing trends in HIV infection in young persons from inner-city minority groups.

Sentinel hospitals. To avoid the self-selection bias associated with volunteer groups that restrict entrance based on behavior and HIV infection and to provide data on persons of all ages, blinded surveys are also conducted of selected patients at sentinel hospitals. Approximately 40 hospitals throughout the country will participate in this network, each testing 300 specimens per month on a sampling system that overrepresents young adults and children. The HIV data from the sentinel hospital population should reflect prevalence and particularly trends of HIV infection in these communities over time.

Clinical specimens. Blinded surveys based on blood specimens from patients of a national consortium of family practitioners and from a major laboratory that receives diagnostic specimens from primary health care practitioners are underway. These surveys are analagous to the sentinel hospital survey and will provide similar prevalence and trend data without self-selection bias. However, the population surveyed through the clinical specimens is more rural than that accessible at the sentinel hospitals.

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Surveys of women of reproductive age.

Screening of newborns. Newborn infants throughout the country are routinely screened for treatable metabolic disorders by filter-paper blood specimens collected shortly after birth by heel-stick puncture. These specimens can also be tested serologically (*9*) to detect HIV antibody that was passively transferred from the mother and thus represents infection in the mother (but not necessarily in the infant). Blinded surveys of blood specimens from newborn infants are being undertaken in at least 25 States. These surveys will indicate local areas and populations needing perinatal HIV prevention programs. The surveys also will help evaluate the impact of such programs on perinatal HIV transmission. In addition, this survey approach will indicate the prevalence of infection among women of reproductive age.

Women's health clinics. Surveys are under way in a variety of family planning, prenatal, abortion, and similar clinics to assess levels and trends of HIV infection in reproductive-aged women. These surveys can indicate the level of infection among women not bearing children and can identify clinic populations needing HIV prevention programs. Approximately 1,000 women per clinic per year are surveyed and most of the surveys are blinded.

Surveys in populations at increased risk.

STD clinics. Homosexually and heterosexually active persons with STDs are serologically surveyed

in blinded surveys to measure HIV prevalence and in nonblinded surveys to assess sexual, drug, and other risk behaviors. Over time, these surveys will indicate trends in the spread of HIV among homosexual men and heterosexual males and females. A projected 1,200 persons will be surveyed per clinic per year, including 200 homosexual and bisexual men, 500 heterosexual men, and 500 women.

Drug treatment centers. Surveys of IV drug abusers entering treatment assess the current level of HIV infection in drug abusers in the community. Blinded surveys measure the prevalence of infection, while nonblinded surveys permit evaluation of specific risk behaviors. (Voluntary counseling and testing for all IV drug abusers, an important public health intervention, have been strongly recommended by the Public Health Service.) Typically, a target of 500 persons entering treatment will be surveyed per clinic per year. Some clinics may also initially survey patients currently in treatment. In the future, evaluation of HIV infection levels in drug abusers not in treatment will be necessary through an outreach approach.

Surveys in special populations. Four special populations that present unique approaches and opportunities for HIV prevention are assessed through focused ongoing surveys.

College students. In collaboration with the American College Health Association, surveys are being developed on approximately 15 college campuses throughout the country. To avoid self-selection bias, seroprevalence is assessed through blinded testing of blood specimens drawn for routine diagnostic purposes at college clinics.

Prisoners. In collaboration with the National Institute of Justice, blinded surveys have been undertaken for entrants in 10 State prison systems. Each system will sample 1,000 entrants per year. This systematic approach complements the various prisoner surveys and routine screening programs already being conducted (*1*).

Tuberculosis patients. Clinical tuberculosis (TB) can occur as an opportunistic disease in persons with HIV infection who are also infected with the tubercle bacillus. Therefore, HIV-infected persons may increasingly be found in clinics treating TB patients. CDC is supporting State and local health departments in rapidly expanding serologic surveys in TB clinics to assess the local prevalence of HIV among TB patients and the consequent need for public health interventions.

Hospital emergency rooms. Emergency rooms have the potential to be one of the sites with high risks for occupational exposure of health care workers to HIV-infected blood and body fluids. Emergency patients (particularly trauma victims, such as those suffering from drug-related gunshot and knife wounds) are at greater likelihood of infection (*10*), exposure of health care workers to patients' blood occurs frequently, and it is virtually impossible to prescreen patients for HIV. CDC is developing collaborative studies to assess the prevalence of HIV infection among emergency room patients and the risk of HIV exposure to health care workers in this setting.

Monitoring results of HIV-related studies. Included in the comprehensive surveillance of HIV infection is the monitoring of findings of a variety of ongoing specialized surveys and studies related to HIV.

Cohorts of persons at risk. Twelve recruited cohorts of homosexual and bisexual men and two cohorts of IV drug abusers are evaluated periodically for new HIV infection by investigators at several health departments, medical research institutions, the National Institutes of Health, and CDC. These studies permit direct measurement of incidence of new infection and detailed evaluation of infection risk associated with specific behaviors.

NHIS. The National Health Interview Survey (NHIS) is conducted by the National Center for Health Statistics (NCHS), CDC. NHIS is an ongoing survey of a random sample of U.S. households in which standardized health interviews are conducted. The survey now includes questions on knowlege of, attitudes toward, and selected behaviors related to HIV and will include questions on the frequency of (*a*) use of hospitals and various types of clinics, (*b*) childbirth, and (*c*) other health-related activities in which persons might be tested for HIV in a blinded or nonblinded survey. This information, combined with seroprevalence rates observed in such settings, will help investigators estimate the overall U.S. seroprevalence.

NHANES III. The third National Health and

Applications of the HIV surveillance activities in meeting public health information needs

Information needed	*Survey-study approach*
1. Incidence of new HIV infection General population In males and females By race-ethnicity By area of the country	Inference from prevalence trends in sentinel hospitals and clinical specimens, military applicants, blood donors, Job Corps entrants Direct measurement of HIV seroconversion in repeatedly tested blood donors and active-duty military personnel
In childbearing women and newborns	Inference from prevalence trends in newborn screening (filter paper, passive maternal antibody detected); youngest-age segment of sentinel hospital patients and clinical specimens; and women's health clinics
In persons at risk	Seroconversion in cohorts of persons with high-risk behavior; by inference from prevalence trends at STD clinics and IV drug treatment centers
2. Prevalence (level) of current HIV infection and trends in prevalence; detailed data needed to assess risk at national and local levels for targeting and evaluating prevention programs	
General population By sex, age, race-ethnicity, and geographic area	Sentinel hospitals and clinical specimens, military applicants, blood donors, Job Corps entrants, newborn screening (filter paper), NHANES–III, national HIV survey
In persons at risk	STD clinics, drug treatment centers
Perinatal transmission	Newborn screening (filter paper), women's health clinics, youngest-age segment in sentinel hospitals and clinical specimens
In settings with special control implications	TB clinics, prisons, colleges, hospitals emergency rooms
3. Estimated number of HIV infections overall in the United States. This estimate is needed for policy planning, anticipation of future health care needs, and so forth. A precise number is not possible from any of the approaches, only a range of values; inherent biases and methodologic limitations with all the approaches require that several approaches be used to converge on the "best estimate"	Empirical estimate from size of subpopulations at risk multiplied by average of seroprevalence for those subpopulations; prevalence data from the surveys mentioned earlier Mathematical model approach using AIDS case data and data on disease progression from cohort studies; prevalence trend and incidence data used to evaluate reality of the various hypothetical projection curves National household-based HIV survey (if pilot studies indicate feasibility and likely absence of serious bias from selective underparticipation) supplemented by empirical estimates for HIV-infected groups not fully reachable by household survey (for example, IV drug abusers, prisoners)
4. Monitoring HIV spread to groups of special interest	
Spread among heterosexuals	STD clinics (nonblinded studies with interview); blood donors and military applicants (followup interview of seropositives)
Spread in minority groups	Sentinel hospitals and clinical specimens; military applicants; blood donors; Job Corps entrants; newborn screening (filter paper); women's health clinics; STD clinics; drug treatment centers
Spread among adolescents	Sentinel hospitals and clinical specimens; Job Corps entrants; military applicants; youngest segment of mothers in newborn screening and women's health clinics
Spread to health care workers	Surveys of health care workers in emergency rooms; military active-duty personnel testing (which includes military health care workers); blood donors (followup interview of seropositives may detect infected health care workers)
5. Emergence of new modes of HIV transmission	AIDS case surveillance: evaluation of persons with no identified risk; blood donors (followup interview of seropositive donors); military applicants (followup interview of seropositive applicants)

Nutrition Examination Survey (NHANES III), a broad-based national sample survey of the U.S. population, will be conducted by NCHS, CDC, beginning in 1988. Pilot studies for the survey began in 1987. Under the present plan, blinded HIV-antibody testing will be conducted on an estimated 18,000 blood specimens collected during the 6-year project. Data from the first phase will be available in 1991.

National Household Seroprevalence Survey. A nationwide household-based survey to determine the number of persons infected with HIV in the United States is scheduled to begin in mid-1988. The survey will be conducted in two phases under the coordination of NCHS, CDC. The first phase will consist of pilot studies and presurveys in selected metropolitan areas to examine factors affecting study validity, such as participation rates, response bias, and procedural and logistical approaches. This phase will require approximately 1 year to complete. Based on the outcome of the pilot phase, the second phase—the nationwide survey—will begin in 1989 and require about 2 years to complete and analyze.

Role of Surveys and HIV Data Needs

These surveys and studies reveal different aspects of the HIV epidemic. Each survey has its own particular strengths and limitations. Trends apparent in one survey must be evaluated in terms of those observed in others. Individually and in combination, these surveillance activities help meet the information needs for sound public health management and policy planning. Some of the applications of the HIV surveillance data are listed in the table.

Conclusion

A comprehensive, multifaceted HIV surveillance approach is needed to provide the HIV information necessary for public health management and policy. Because HIV infection is not readily or uniformly ascertained, survey methods and sentinel surveillance approaches must be used. At least some of the surveys must be blinded, with the use of blood specimens already available, to avoid the uninterpretable impact of self-selection bias. Other surveys must be nonblinded, with careful interviews of volunteer participants to evaluate risk factors for HIV transmission. The surveys must continue over time to evaluate trends in infection. The family of complementary surveys and studies outlined in this report represents the collaborative HIV surveillance program undertaken by the Public Health Service to monitor the levels and trends of HIV infection in the United States and to help prioritize, target, and evaluate HIV prevention activities.

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