Estimating HIV Levels and Trends Among Patients of Tuberculosis Clinics

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Synopsis

Symptomatic tuberculosis (TB) can occur as an opportunistic disease in immunosuppressed persons who are infected with human immunodeficiency virus (HIV) and who have been previously infected with Mycobacterium tuberculosis. *Increases in TB cases have occurred in areas which have reported large numbers of cases of the acquired immunodeficiency syndrome (AIDS), and a high proportion of these TB cases have been HIV seropositive. Therefore, increasing numbers of HIV-infected persons may be found in TB clinics and hospitals.*

HIV serologic surveys in TB clinics and hospitals providing clinical services to TB patients are needed to assess the local prevalence of HIV infection in TB patients and the consequent need for public health intervention to prevent further spread of HIV and TB infection. The Centers for Disease Control (CDC), in collaboration with State and local health departments, has initiated HIV surveillance of patients with confirmed and suspected TB in TB clinics and hospitals in the United States. Blinded (serologic test results not linked to identifiable persons) HIV seroprevalence surveys are conducted in sentinel TB clinics and hospitals that provide TB clinical services each year to obtain estimates of the level of HIV infection in TB patients and to follow trends in infection over time. Nonblinded (voluntary) surveys will also be conducted to evaluate behaviors that have placed TB patients at risk for or protected them against HIV infection. Data from these surveys will be used to target education and prevention and control programs for TB and HIV infection and to monitor changes in behavior in response to such programs.

FROM 1963 THROUGH 1985, the incidence rate of tuberculosis (TB) in the United States declined an average of 5.9 percent annually (*1*); from 1984 to 1985, however, the decrease was only 0.2 percent (*2*). By contrast, in 1986, there was a 2.6 percent increase in indigenous TB morbidity (*3*). Data from 1987 show a 1.1 percent decline and for 1988 show a 0.4 percent decline in TB morbidity in the United States (*4*). It has been suggested that infection with human immunodeficiency virus (HIV) may be partially responsible for this changing pattern in TB morbidity.

Several studies of TB patients have shown a high prevalence HIV infection. In Dade County, FL, 31 percent of TB patients (22 of 71) consecutively tested by the health department over a 6-month period in 1985–86 were HIV seropositive (*5*). In New York City, 53 percent (31 of 58) of male TB patients ages 25–44 who were admitted to selected municipal hospitals were seropositive for HIV (New York City Department of Health, unpublished data). In the New York State Department of Correctional Services System, 53 percent of tested TB patients in 1985 and 56 percent in 1986 had HIV infection (*6*).

Matching of TB and acquired immunodeficiency syndrome (AIDS) registries in 24 States and four localities revealed that 4.2 percent (645 of 15,181) of patients with AIDS also were known to have had TB (*7*). Available data suggest that the number of patients known to have both TB and AIDS may represent only a small proportion of HIV-infected persons with TB (*5*). When acquired by patients with latent TB infection, HIV infection allows the progression to overt clinical TB by impairing the immune system (*8*). Preliminary evidence suggests that TB patients with HIV infection require a modification of the standard anti-TB therapy, since they may have a higher incidence of adverse drug reactions (*9*) and a higher treatment failure rate during therapy (*10, 11*) than patients without HIV infection. The relapse rate of HIV-infected TB patients after completion of therapy is unknown but may be higher than that

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of nonimmunocompromised patients. Therefore, the CDC and the American Thoracic Society have recommended a more aggressive approach to the treatment of TB in HIV-infected patients (*12, 13*). Furthermore, HIV-infected patients who have TB should be monitored frequently and carefully for adverse drug effects during therapy and should be evaluated periodically for signs of relapse after therapy is completed.

Information on the levels and trends of HIV infection in TB patients is needed to develop, target, and evaluate intervention strategies for preventing and controlling TB in HIV-infected persons and their contacts and for preventing the transmission of HIV infection by HIV-infected TB patients. Realizing the need for this information at both the national and the local levels, CDC, in collaboration with State and local health departments and medical research institutions, has initiated HIV surveys in groups of patients with confirmed and suspected TB in clinics and hospitals providing TB clinical services in the United States. This paper describes the survey design and discusses potential uses and limitations of data from the survey.

Objectives

Seroprevalence surveys in TB clinics and hospitals are a component of the comprehensive CDC HIV family of surveys program (*14*). The objectives of the TB clinic surveys are (*a*) to determine the prevalence of HIV antibodies in persons with confirmed or suspected TB, (*b*) to assess risk behaviors associated with HIV seropositivity, (*c*) to monitor trends in infection levels and risk behaviors, (*d*) to help prevent and control TB in HIV-infected persons, and (*e*) to help target and evaluate HIV prevention programs. A standardized protocol is needed to facilitate comparison of data over time and among different TB clinics and hospitals.

Survey Methods

Selection of clinics. In each of the 39 metropolitan areas included in the family of surveys program, all facilities that provide medical care for TB patients (including those in settings other than the health department) and that agree to follow the CDC standardized protocol are eligible to participate. Priority is given to clinics whose primary function is to provide TB services and whose populations have varied sociodemographic characteristics (race and ethnicity, country of origin, and likelihood of acquiring HIV infection, especially through intravenous (IV) drug use).

Hospitals are considered the optimal setting for assessing HIV status of TB patients in area where a significant proportion of patients whose cases of TB has been recently diagnosed and the patients hospitalized, or who are unlikely to be followed up in a TB clinic. Most TB clinics participating in the surveys are supported by State and local health departments.

Eligibility criteria for patients. Persons tested in the survey include patients who have been recently diagnosed with TB based on a positive culture of *Mycobacterium tuberculosis* (a case) or persons in whom TB is suspected (TB suspect). A case of TB is confirmed if the case definition recommended by CDC (*15*) is met. A patient is considered a TB suspect if clinical signs, symptoms, and preliminary evaluation (tuberculin skin test, acid fast bacillus (AFB) smear, chest X-ray) are sufficiently suggestive of TB to warrant initiating anti-TB drug therapy with two or more drugs.

Patients who have TB infection alone (positive skin test without clinically active disease) and patients who come only for HIV testing are not included in the survey. To minimize selection bias, eligible patients are sequentially enrolled in the surveys during the survey period for that clinic.

Blinded surveys. Blinded surveys (serologic test results not linked to identifiable persons) are conducted to estimate the level of HIV infection in TB clinic and hospital patients. Blood specimens, routinely collected for other purposes (for example, liver function tests to monitor toxicity of anti-TB drugs) from all newly enrolled patients with confirmed or suspected TB are permanently stripped of personal identifiers (name, address, clinic or chart number) and tested for antibodies to HIV. Some or all of the following information obtained as part of the routine clinical evaluation is abstracted from the clinic record and recorded on a CDC data collection form: (*a*) State, county, and zip code of residence; (*b*) quarter of and year of visit; (*c*) age range (under 20 years, 5-year groups, 60 and over); (*d*) sex; (*e*) race and ethnicity; (*f*) country of origin; (*g*) clinical status (TB case or suspect) and anatomic site (pulmonary, extrapulmonary, both, or unknown) of TB; (*h*) culture results; and (*i*) risk

Information Requested in the Nonblinded Risk Assessment Questionnaire for Tuberculosis Clinics

Category	Information requested
Demographic data	Month and year of visit; State, county, and zip code of residence; sex; age in years; race and ethnicity; country of birth and age when moved to the United States; marital status; education
Medical history	Past history and frequency of sexually transmitted diseases, receipt of blood and blood products.
Drug use	History of IV and non-IV drug use, frequency and type of drug used, history of sharing "works" (for example, needles and syringes)
Sexual history	History of sexual contact with persons at risk for HIV infection, type and number of sexual partners, use of rubber or condom, exchange of drugs or money for sex
Test results	Tuberculin skin test, anatomic site of disease, serologic test for syphilis, TB culture results

NOTE: Copies of the TB clinic risk assessment questionnaire may be obtained from the Division of HIV/AIDS, HIV Seroepidemiology Branch, Clinic and Special Surveys Section, Centers for Disease Control.

Table 1. Observed seroprevalence rates and 95 percent confidence interval by sample size of survey

	Sample size rate						
Observed rate	*100*	*200*	*300*	*500*	*1,000*	*2,000*	*4,000*
0	0 – 3	0 – 1.5	0 – 1	0 – .6	0 – .4	0 – .2	0 – .1
1	.02– 5.5	.1– 3.6	.2– 2.9	.3– 2.3	.5– 1.8	.6– 1.5	.7– 1.4
2	.2 – 7	.6– 5	.7– 4.3	1 – 3.6	1.2– 3.1	1.4– 2.7	1.6– 2.5
5	2 –11	2 – 9	3 – 8	3 – 7	3.7– 6.5	4 – 6	4.3– 5.7
10	5 –18	6 – 15	7 – 14	8 – 13	8.2– 12	8.7– 11.4	9.1– 11
20	13 –29	15 – 26	16 – 25	17 – 24	17.6– 22.6	18.3– 21.8	18.8– 21.3
50	40 –60	43 – 57	44 – 56	46 – 54	46.9– 53.2	47.8– 52.2	48.4– 51.6

EXAMPLE: If 300 serums are tested and none are positive, one can be 95 percent confident that the true seroprevalence is 0 percent to 1 percent. If 3 of the 300 (1 percent) specimens are positive, one can be 95 percent confident that the true seroprevalence is 0.2 percent to 2.9 percent. The size of the interval can be narrowed by increasing sample size. For example, if 600 specimens are collected and none are positive, one can be 95 percent confident that the true seroprevalence is 0 percent to 0.5 percent; if 6 are positive (1 percent), the true seroprevalence falls within 0.4 percent to 2.2 percent.

exposures. Each CDC data collection form has a coded survey number that is also used to identify the serum specimen to be tested for HIV. No patient identifying information (name, clinic record number, address) is linked to the survey number.

Nonblinded (voluntary) surveys. Since persons infected with both TB and HIV are at risk for severe clinical TB, all patients with TB should be counseled routinely and tested for HIV antibody (*12, 16*). In TB clinics and hospitals providing these services, patients who consent to HIV testing and counseling and who are eligible for the nonblinded survey are administered a risk assessment questionnaire. TB clinics and hospitals not providing routine HIV counseling and testing services recruit eligible patients for the nonblinded survey, obtain informed consent, and test for HIV. Consenting patients are assigned a code number, interviewed using a standard risk assessment instrument (box, this page), and given pretest HIV counseling and an appointment to return for test results and posttest counseling. The assigned code number is placed on the risk assessment instrument and on the tube containing the blood specimen to be tested for HIV.

In areas where TB clinic population sizes are so small that maintaining confidentiality in a blinded survey would be extremely difficult, only a nonblinded survey is done. As recommended by CDC (*16*), confidentiality provisions, HIV counseling, and posttest services (for example, partner notification, contact tracing, and referral for other clinical services) that are consistent with local standards and regulations are provided.

The risk assessment questionnaire, consisting of 24 questions used to assess behavior practices that may increase or decrease the risk of exposure to HIV, is administered by a trained counselor or interviewer (this page). If the patient's clinic records are available, the

Table 2. Tuberculosis cases and case rates, 1988 from cities participating in the family of HIV seroprevalence surveys

Metropolitan area	TB cases	Case rate per population	Rank according to rate
Region I:			
Boston, MA	131	24.8	8
New Haven, CT	18	14.1	23
Providence, RI	22	14.0	24
Region II:			
Newark, NJ	154	49.0	2
New York City	2,317	32.8	5
Rochester, NY	37	15.7	21
San Juan, PR	73	16.4	18
Region III:			
Baltimore, MD	172	22.9	9
Richmond, VA	31	14.4	22
Washington, DC	177	28.7	6
Wilmington, DE	7	1.0	39
Philadelphia, PA	260	15.8	20
Region IV:			
Atlanta, GA	196	43.2	3
Jacksonville, FL	75	11.1	28
Memphis, TN	85	13.0	27
Miami, FL	203	55.0	1
Birmingham, AL	49	17.2	15
Region V:			
Chicago, IL	682	22.8	10
Cleveland, OH	88	16.4	17
Detroit, MI	237	21.8	11
Minneapolis, MN	25	7.0	35
Indianapolis, IN	59	8.1	33
Milwaukee, WI	34	5.6	37
Region VI:			
Albuquerque, N.M.	17	3.5	38
Dallas, TX	188	17.9	14
Houston, TX	549	27.6	7
New Orleans, LA	73	13.4	26
Little Rock, AR	32	16.5	16
Oklahoma City, OK	41	10.1	29
Region VII:			
Kansas City, MO	44	10.0	30
St. Louis, MO	34	8.1	34
Region VIII:			
Denver, CO	44	8.6	32
Salt Lake City, UT	11	7.0	36
Region IX:			
Honolulu, HA	81	21.3	12
Los Angeles, CA	664	19.6	13
Phoenix, AZ	80	8.6	31
San Francisco, CA	313	42.3	4
Region X:			
Portland, OR	59	13.7	25
Seattle, WA	80	16.1	19
TOTAL	7,442	...	...

SOURCE: Centers for Disease Control, Center for Prevention Services, Division of Tuberculosis Control, Atlanta, GA (unpublished data).

interviewer records results of the TB skin test and TB culture, and the serologic tests for syphilis and indicates the anatomic site of TB. Demographic information is collected on all patients eligible for the nonblinded survey so that participation rates for clinics can be calculated and the characteristic of patients who agree to participate can be compared with those who refuse.

Sample size and study period. The minimum sample size is based on the expected HIV servoprevalence in each clinic and the desired precision of the seroprevalence estimate within certain bounds (95 percent confidence interval). The survey period depends on the number of eligible TB patients served per week in each facility and the time required to collect the target number of samples. For example, if the survey sample size is 300 and observed seroprevalence is 10 percent, one is 95 percent confident that the true seroprevalence would be within the bounds of 7 percent to 14 percent (table 1) (*17*). Larger sample sizes will allow more precise estimates of seroprevalence.

The number of new TB cases reported by the 39 cities participating in the surveys to CDC in 1988 ranges from 7 to 2,317 (median, 75 cases; mean, 188 cases) (table 2). Because of the small number of new TB cases identified in most facilities, blood specimens for all newly diagnosed TB patients in each area are tested in the blinded survey when feasible. Similarly, all eligible TB patients are invited to participate in the nonblinded survey.

The duration of blinded and nonblinded surveys in most TB clinics and hospitals is year-round because of the limited number of expected new TB patients. The same criteria for patient and serum selection will be required to permit valid comparison of data. In subsequent years, surveys should be conducted at the same time of year, if less than the full 12 months is used for sampling, to minimize the impact of seasonality of either TB or HIV.

Laboratory methods. At designated local laboratories, blood specimens are tested for antibodies to HIV–1 by an enzyme immunoassay (EIA) licensed by the Food and Drug Administration (FDA). Serums repeatedly reactive by EIA are tested by an FDA-licensed Western blot assay. The presence or the absence of each virus-specific band is reported to CDC. The selected laboratories are required to participate in a quality assurance program provided by CDC (*18*).

Interpretation of Data

Data from HIV seroprevalence surveys in TB clinics and hospitals will provide estimates of and trends in HIV seroprevalence and associated characteristics of patients. Thus, the data will be valuable for planning

and evaluating TB and HIV prevention and control activities. They will indicate the degree of need for ongoing HIV testing, counseling, and contact tracing activities with the TB clinics. Likewise, they will indicate the degree of need for TB prevention activities within clinics that diagnose and manage HIV-infected persons. Following trends will be one way of evaluating the success of TB and HIV prevention programs. Assessing which risk behaviors are locally associated with HIV in TB patients can help guide intervention. For example, IV drug users are at risk for HIV infection and may be at increased risk for TB; therefore, this group should be targeted for HIV and TB prevention activities and counseling to prevent further transmission of HIV and TB infection to the contacts of these patients.

TB clinics and hospitals participating in the CDC HIV family of surveys were chosen by health departments to illustrate the various likely patterns of HIV and TB infection in their communities. Although illustrative, they were not chosen by a probabilistic sampling scheme and thus may not be representative of TB facilities throughout the United States or other TB facilities in the same metropolitan area.

Data from seroprevalence surveys in TB clinics and hospitals cannot be used to estimate the level of HIV infection in TB patients who receive services in other settings, such as physicians' offices or hospitals. Additionally, specific situations may occur in a given metropolitan area or a TB clinic or hospital that bias estimates of seroprevalence rates; some of these biases may be unavoidable even by strict adherence to protocols. For example, policies for routine blood tests, and therefore the availability of blood for blinded sampling, differ among TB facilities. Although CDC recommends that baseline liver function tests be performed on all adults treated for TB, some facilities perform tests only on patients more than 35 years of age or with known underlying liver disease, IV drug use, or alcoholism.

In some metropolitan areas, a large proportion of new TB patients are diagnosed and initially treated in the hospital. Some of the TB patients may be IV drug users who will not attend the TB clinic for followup and may not be accessible to the survey. Surveys of patients attending only the TB clinics will probably underestimate HIV seroprevalence rates in newly diagnosed TB patients. Thus, inclusion of hospitals serving TB patients as survey sites has been strongly recommended.

In the TB clinic survey, a patient is considered a TB suspect if clinical signs, symptoms, and preliminary laboratory work are sufficiently suggestive of TB to warrant initiating anti-TB drug therapy with two or more drugs. However, in some areas, two-drug therapy is used to treat persons who have TB infection only (positive skin test in the absence of clinically active disease), who have a history of alcoholism or IV drug use, or who may not comply with therapy. Blood specimens may be collected on these patients for routine diagnostic testing but should not be included in the blinded survey. A patient who is considered a TB suspect is usually started on anti-TB therapy when AFB are seen on AFB smears. Infection with the *Mycobacterium avium* complex, which is commonly associated with clinical AIDS (but is relatively uncommon in persons without compromised immune systems), is indistinguishable from *M. tuberculosis* on AFB smears. Inclusion of patients infected with *M. avium* complex may increase observed HIV seroprevalence rates since this would enrich the sample with AIDS patients.

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Methods of Surveillance for HIV Infection at U.S. Sentinel Hospitals

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Synopsis

The U.S. sentinel hospital surveillance system for human immunodeficiency virus (HIV) infection includes approximately 40 short-stay hospitals located in 31 metropolitan areas in the United States and Puerto Rico. Several hospitals began testing in late 1986, and additional sentinel hospitals have since been recruited. At each sentinel hospital, anonymous, unlinked testing for antibody to HIV is conducted monthly on 300 blood specimens, selected systematically and stratified by age of the patient. Specimens are excluded from patients whose reason for hospital visit on that occasion was for a medical condition associated with HIV infection or with risk factors for HIV infection, in order to limit the expected overrepresentation of HIV-infected persons among hospital patients compared with the general catchment population of the hospital.

The incidence of acquired immunodeficiency syndrome (AIDS) in metropolitan areas with sentinel hospitals has been approximately twice the incidence of AIDS in the entire United States. However, while absolute levels of HIV seroprevalence should therefore be interpreted with caution, trends in the age-, sex-, and race-specific HIV seroprevalence at sentinel hospitals likely reflect trends in the communities served by the hospitals.

Although concentrated in areas disproportionately affected by AIDS, sentinel hospitals will contribute seroprevalence data over time that reflect the impact of HIV infection across all age and behavioral risk groups. Sentinel hospitals will also constitute a key surveillance system to help integrate the age group-specific and risk group-specific findings from other activities in the CDC family of seroprevalence surveys.

THE SENTINEL HOSPITAL surveillance system for human immunodeficiency virus (HIV) infection is one of a family of ongoing, sentinel serologic surveillance projects of the Public Health Service (*1*, *2*). The first sentinel hospital began sampling in late 1986, and additional hospitals have been recruited since that time. By September 1989, a total of 40 acute care hospitals were participating in the sentinel hospital network. This report reviews the objectives, survey design issues, and the methods of sentinel hospital surveillance and discusses briefly how these methods influence the interpretation of findings.

Objectives

Trend analysis. The principal objectives of the sentinel hospital surveillance system are to (*a*) establish a stable, systematic mechanism for sampling HIV seroprevalence in the catchment populations of a group of acute care (short-stay) hospitals, and (*b*) follow trends over time in