

Estimates of HIV Incidence Among Persons Testing for HIV Using the Sensitive/Less Sensitive Enzyme Immunoassay, New York City, 2001

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Background: Estimates of the incidence of HIV infection among persons testing for HIV can be derived by applying a newly available serologic test to the diagnostic specimen of HIV-positive persons. Such estimates would enhance the targeting of HIV prevention resources and provide a sensitive outcome measure for prevention program evaluation. The goal of this investigation was to estimate the incidence of HIV infection among persons testing for HIV in New York City.

Methods: The study population consisted of persons testing for HIV in public settings in New York City during 2001 ($n = 114,703$). We applied a less sensitive enzyme immunoassay (LS-EIA) (Vironostika, BioMerieux, Durham, NC) to the diagnostic blood specimen of 1022 persons in whom HIV (non-AIDS) had been diagnosed for the first time in 2001. The distribution of transmission risk among HIV-negative persons—men who have sex with men (MSM), injection drug users (IDUs), heterosexuals—from a large telephone health survey was used to generate denominators for transmission risk groups.

Results: The 1022 persons tested by the LS-EIA represented 27% of all persons in whom HIV (non-AIDS) had been diagnosed in New York City during 2001. The incidence of HIV was estimated to be 0.29% per year (95% CI: 0.20–0.38), and was significantly higher for men than women (rate ratio 3.6, 95% CI: 2.6–5.1), and HIV incidence increased with age. Male IDU and MSM testers had the highest HIV incidence rates: 2.7% per year (95% CI: 2.3–3.1) and 2.5% per year (95% CI: 2.1–2.8), respectively.

Conclusions: Male IDUs and MSM may be good candidates for intensified targeting of HIV prevention resources in New York City.

Key Words: HIV, surveillance, less sensitive enzyme immunoassay, STARHS, HIV incidence

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Timely and accurate population-based surveillance data are critical tools for health departments to use in monitoring disease trends and allocating resources for interventions and treatment.^{1,2} This is particularly true for dynamic and ongoing infectious disease epidemics such as the HIV epidemic in New York City and other areas with large HIV epidemics. Many health departments conduct population-based surveillance for incident HIV diagnoses.^{3,4} Due to the long incubation period of HIV,⁵ however, incident HIV diagnoses represent a combination of both early (incident) and established (prevalent) HIV infections, leaving an unclear impression of trends in incidence of HIV infection. Evaluating progress toward reducing the number of new infections will require population-based estimates of HIV incidence at the state and local level.

HIV incidence rates have been estimated in high-risk cohorts and convenience samples using a less sensitive HIV enzyme immunoassay (LS-EIA) serologic test on a single serum specimen.^{6–15} When applied to the serum from a person with HIV antibodies detected by a sensitive EIA (S-EIA) and confirmed by Western blot, the LS-EIA can classify persons as having probable early HIV infection vs. established infection. This 2-stage testing algorithm, also known as the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS), exploits the fact that antibody levels are lower in early HIV infection than in established infection.¹⁶ Persons who are positive on the sensitive EIA but negative on the less sensitive EIA therefore are likely to represent persons in the early stages of HIV infection. This testing algorithm has been shown to have good performance characteristics for estimating HIV incidence at the aggregate level.^{16,17} Application of the S/LS-EIA to diagnostic HIV specimens has the potential to greatly enhance HIV/AIDS surveillance data by permitting population-based estimates of the incidence of HIV infection among persons testing for HIV.

In June of 2000, HIV infection became a reportable condition in New York State. The goals of this investigation were to estimate the annual incidence of HIV infection among persons testing for HIV in New York City and to characterize those groups who may have been at highest risk for incident HIV infection in New York City during 2001.

METHODS

Two laboratories, the New York City DOHMH Public Health Laboratories (NYCPHL) and the NYS Department of

Health Wadsworth Center Laboratories (NYSWCL) in Albany, NY, perform all HIV tests ordered at approximately 110 publicly funded HIV testing and counseling sites in New York City; these tests account for an estimated 30% of the total annual volume of HIV tests performed in New York City (personal communication, S. Beatrice, NYCPHL, 2002). These laboratories performed 136,992 HIV tests in 2001, 2959 (2.2%) of which were confirmed positive by both S-EIA and Western blot. HIV-positive specimens were archived at -70°C by each laboratory. We applied the LS-EIA to the diagnostic serum specimens of those persons in whom HIV was diagnosed for the first time during 2001 ($n = 6356$), as determined through epidemiologic and clinical information from the New York City HIV/AIDS surveillance registry as of December 31, 2002.²⁹

Case Definition for Incident HIV Diagnoses in the New York City HIV/AIDS Surveillance Registry

Diagnostic Events

For the purposes of identifying persons with incident HIV diagnoses, HIV diagnostic events were defined as: a positive Western blot; a provider report of a new HIV diagnosis; or documentation of an HIV diagnosis date in the patient medical record. Detectable viral load (VL) tests, while indicative of HIV infection, were not considered diagnostic events in this analysis. CD4 test results and reports of AIDS-defining opportunistic illnesses following HIV diagnosis were used to classify HIV-infected individuals according to the stage of HIV infection: HIV (non-AIDS) or AIDS (CD4 < 200 cells/ μL or opportunistic illness).

Incident HIV Diagnoses

Incident HIV diagnoses were attributed to the calendar year of an HIV-infected person's earliest known HIV diagnostic event. Persons with a detectable VL or CD4 test that preceded their earliest known diagnostic event were assumed to be prevalent cases of HIV in that year unless the VL or CD4 test occurred ≤ 60 days before the earliest diagnostic event. Persons in whom HIV was diagnosed in 2001 were classified based on all laboratory and clinical events reported to the HIV/AIDS surveillance registry through December 31, 2002. Additional data and definitions on persons in whom HIV was diagnosed in New York City during 2001 have been published previously.²⁹

Study Population

HIV-Positive Persons

Population-based HIV surveillance identified 6356 unique individuals who met the definition for incident HIV diagnoses in 2001. Of these, 1723 (27%) had been diagnosed through testing performed at the NYCPHL or NYSWCL. Diagnostic specimens were available for 90% (1544 of 1723) of these persons. Persons in whom HIV was diagnosed in 2001 who had developed AIDS as of December 31, 2002 ($n = 500$) were assumed to have established HIV infection and were excluded from incidence calculations. An additional 22 HIV-positive specimens were excluded because they were

confirmatory tests and did not represent the diagnostic HIV specimen. The remaining 1022 specimens were retrieved during 2003, aliquoted, anonymized, and tested by the LS-EIA under NYCDOHMH institutional review board-approved protocol #00-019.

HIV-Negative Tests

The NYCPHL and NYWCL tested 116,273 and 20,719 HIV-negative specimens, respectively (total $n = 136,992$) in 2001. After excluding HIV tests performed on patients who were not residents of New York City ($n = 10,813$), anonymous HIV tests ($n = 10,586$), known repeat negative HIV tests in the same individual ($n = 1454$), HIV tests for validation and confirmatory purposes for other laboratories and research projects ($n = 333$), and HIV tests performed as part of institutional review board-approved research studies that did not report results ($n = 125$), the volume of confidential HIV-negative tests performed at the PHL and Wadsworth Center and used in this analysis was 92,962 and 20,719, respectively (total negative tests = 113,681).

For the purposes of this analysis, the negative HIV tests ($n = 113,681$) were assumed to represent unique individuals. However, since names were not available for persons with negative HIV test results, and since some individuals could have had > 1 negative HIV test during the study period, negative tests performed by the 2 laboratories in 2001 actually represent a smaller number of unique individuals. We estimated the proportion of duplicate testers to be 10%–20% by generating a “unique identifier” key (sex, race/ethnicity, month and year of birth, and testing site).

The final study population included 114,703 persons with an HIV test in a public setting in 2001, of whom 1022 (0.89%) were diagnosed with HIV for the first time in 2001, and had no clinical or laboratory evidence of AIDS as of December 31, 2002.

Demographic Information

Information on sex, race/ethnicity, date of birth, zip code, and borough of residence at the time of HIV/AIDS diagnosis was collected for all 1022 HIV (non-AIDS) diagnoses. Race/ethnicity was classified as non-Hispanic black, non-Hispanic white, Hispanic, Asian/Pacific Islander (A/PI), Native American (NA), or other/unknown.

Transmission Risk Factor Information for HIV-Positive Persons

As part of routine HIV/AIDS surveillance investigation, information on the transmission mode is collected when available from the medical record or from the diagnosing facility and is classified according to Centers for Disease Control and Prevention (CDC) definitions¹⁸ into one of the following nonoverlapping groups: men who have sex with men (MSM), injecting drug user (IDU), heterosexual, or no reported risk factor.

Multiple Risks

Persons with multiple risks factors were categorized into one of the above groups based on the following hierarchy: parenteral (IDU, pre-1985 transfusion), perinatal, sexual

(MSM, heterosexual). Similar hierarchies have been used in HIV/AIDS surveillance settings by other investigators.^{19,20}

Transmission Risk Factor Information for HIV-Negative Persons

In June of 2000, the NYCPHL and NYSWCL stopped collecting HIV risk factor information on the laboratory requisition form for HIV testing. To determine the risk factor distribution among the 113,681 HIV-negative testers in 2001 and generate denominators for incidence calculations by risk group, we used data from the New York City Community Health Survey (CHS), a random digit dialing household telephone survey of a representative sample of 10,000 New Yorkers conducted in 2002.²¹ We analyzed risk behaviors reported by CHS respondents who stated they were tested for HIV during 2001 or 2002 at a public facility (defined as counseling and testing sites, tuberculosis clinics, sexually transmitted disease [STD] clinics, community health clinics, other health department sites and public clinics, or in prison). Risk behavior was assessed from questions regarding the number of sex partners, sex of sex partners, and a composite question on whether the respondent had a history of any of the following: use of IV drugs, recent STD treatment, exchange of sex for drugs, and unprotected anal sex.

Risk distributions of MSM, IDUs, and heterosexual testers were estimated from the CHS based on the following categorizations: 1) all men who said they had sex with only men, or with both men and women, were classified as MSM; 2) all non-MSM men and all women who had at least one male sex partner during the 12 months prior to the survey, and who did not report engaging in one of the behaviors in the composite high-risk question, were classified as heterosexual; 3) we classified 12% of non-MSM male respondents and all female respondents who reported engaging in at least one of the behaviors in the composite risk question as heterosexuals since approximately 5% of persons in the United States are diagnosed with an STD annually,²² and 7% of heterosexual persons report engaging in anal intercourse²³ (12% total). Remaining persons (88%) who answered "Yes" to the composite question were classified as IDUs. Persons who did not fall into any of the above categories were classified as having "other risk."

Laboratory Methods

LS-EIA testing was performed at the New York State Department of Health Wadsworth Center's HIV Testing Laboratory. Anonymized specimens were tested using a modified Vironostika EIA (bioMerieux, Durham, NC).¹⁷ To make the test less sensitive, a sample dilution of 1:20,000 was used, and sample and conjugate incubation times were reduced to 30 minutes, using an automated sample preparation and testing process. Substrate incubation time ranged from 10–13 minutes. Specimens that had a standard optical density (SOD) of <2.00 were retested twice to confirm the result (SOD = [sample OD – negative control OD]/positive control OD). Interpretation of the result was based on the median SOD of the 3 tests. Median SOD values <1.00 were considered LS-EIA nonreactive, and values ≥ 1.00 were considered LS-EIA reactive. HIV-positive persons who were nonreactive on the

LS-EIA were presumed to have seroconverted within the 170 days (95% CI: 162–183 days) prior to HIV diagnosis and were classified as being in the "early" stage of HIV infection at the time of the HIV diagnosis.¹⁷ HIV-positive persons who were reactive on the LS-EIA were considered to have "established" infections at the time of the HIV diagnosis. The performance characteristics of the Vironostika EIA have been recently evaluated and determined to be suitable for epidemiologic purposes (ie, incidence estimation).¹⁷

Statistical Analyses

Incidence Calculation

Estimates of annual incidence among testers were calculated using the formula and method developed by Janssen et al¹⁶: $I = (n/N) * (365.25/170) * (100\%)$, where I is the annual incidence rate (% per year), n is the number of new HIV diagnoses with a nonreactive LS-EIA result (early infections), and N is the number of people with a nonreactive result on the LS-EIA (early infections) plus the number who tested negative during 2001 ($n = 113,681$). Persons with a first HIV diagnosis in 2001 with no evidence of AIDS who were positive by the LS-EIA at HIV diagnosis were considered to have established HIV infection at HIV diagnosis and were excluded from incidence calculations. Incidence rate ratios (RRs) were calculated in subgroups using a referent category.

Standard errors for incidence rates and RRs were calculated assuming a Poisson distribution for the number of early HIV infections, using an adjustment for the uncertainty around the 170-day LS-EIA early infection window period (95% CI: 162–183 days).¹⁶ Poisson regression analysis was performed on the number of early infections adjusting for sex, age, race/ethnicity, and borough of residence. Transmission risk information could not be included in Poisson regression models because it was not available at the individual level for HIV-negative persons, and the distributions obtained from the CHS data were too imprecise upon stratification by the other variables to be used in the Poisson regression models.

To evaluate the extent to which persons with incident HIV (non-AIDS) diagnoses in 2001 whose diagnostic specimens were tested with the LS-EIA ($n = 1022$) were comparable to those persons diagnosed with HIV (non-AIDS) whose diagnostic specimens were not available for testing by the LS-EIA ($n = 2659$), demographic and risk categories were compared between those who received an LS-EIA test and those who did not, using a χ^2 test for independence.

All statistical analyses were carried out using Statistical Analysis Software Version 8 (SAS Institute, Cary, NC).

RESULTS

Of the 1022 persons in whom HIV (non-AIDS) was diagnosed for the first time in 2001, 14.8% (151/1022) were classified by the LS-EIA as being in the early stages of HIV infection (ie, SOD < 1) at the time of diagnosis. Those 871 who represented established HIV infections were excluded from incidence calculations, leaving a denominator of 113,832 persons. Table 1 shows the estimated incidence rates for the study population. Overall, incidence among persons testing for HIV was 0.29% per year (95% CI: 0.20–0.38) and was

TABLE 1. Annual HIV Incidence Rates (% per year) and Rate Ratios Among 113,832 Persons Tested for HIV in Public Settings, New York City, 2001

	Total				Males				Females			
	# With Early Infection	# Tested	Annual Incidence Rate* (95% CI)	RR (95% CI)	# With Early Infection	# Tested	Annual Incidence Rate* (95% CI)	RR (95% CI)	# With Early Infection	# Tested	Annual Incidence Rate* (95% CI)	RR (95% CI)
Total	151	113,832	0.29 (0.20–0.38)	—	96	35,453	0.58 (0.44–0.72)	—	55	75,583	0.16 (0.10–0.22)	—
Sex												
Male	96	35,453	0.58 (0.44–0.72)	3.6 (2.6–5.0)	96	35,453	0.58 (0.44–0.72)	—	NA	NA	NA	NA
Female	55	75,583	0.16 (0.10–0.22)	1.0 (ref)	NA	NA	NA	NA	55	75,583	0.16 (0.10–0.22)	—
Race/ethnicity												
White	13	7315	0.38 (0.28–0.49)	1.0 (ref)	12	3490	0.74 (0.58–0.90)	1.0 (ref)	1	3657	0.06 (0.03–0.10)	1.0 (ref)
Black	84	41,772	0.43 (0.32–0.54)	1.1 (0.6–2.0)	47	14,915	0.68 (0.53–0.83)	0.9 (0.5–1.7)	37	25,848	0.31 (0.22–0.40)	5.2 (0.71–37.66)
Hispanic	51	48,726	0.22 (0.15–0.30)	0.6 (0.2–1.9)	34	12,803	0.57 (0.44–0.70)	0.8 (0.4–1.5)	17	34,807	0.10 (0.05–0.15)	1.7 (0.22–12.52)
Asian/Pacific Islander/Native American	3	6064	0.11 (0.06–0.16)	0.3 (0.1–1)	3	1072	0.60 (0.46–0.74)	0.8 (0.2–2.9)	0	4824	0.00 (0.00–0.13)	—
Age at Diagnosis												
Under 20	8	16,499	0.10 (0.05–0.15)	0.6 (0.3–1.4)	5	3631	0.30 (0.21–0.39)	1.1 (0.3–3.4)	3	12,559	0.05 (0.02–0.08)	0.4 (0.10–1.42)
20–24	23	26,167	0.19 (0.12–0.26)	1.1 (0.6–2.1)	18	6636	0.58 (0.44–0.72)	2.1 (0.9–5.0)	5	19,030	0.06 (0.03–0.10)	0.5 (0.15–1.38)
25–29	16	20,585	0.17 (0.11–0.24)	1.0 (ref)	7	5386	0.28 (0.19–0.37)	1.0 (ref)	9	14,804	0.13 (0.08–0.19)	1.0 (ref)
30–34	30	16,504	0.39 (0.28–0.50)	2.3 (1.3–4.2)	17	5074	0.72 (0.56–0.87)	2.6 (1.1–6.2)	13	11,116	0.25 (0.17–0.33)	1.9 (0.82–4.50)
35–39	30	12,377	0.52 (0.39–0.65)	3.1 (1.7–5.6)	22	4637	1.0 (0.80–1.2)	3.6 (1.5–8.4)	8	7499	0.23 (0.15–0.31)	1.8 (0.68–4.59)
40–44	23	8072	0.61 (0.47–0.75)	3.6 (1.9–6.8)	12	3630	0.71 (0.55–0.86)	2.5 (1.0–6.4)	11	4287	0.55 (0.42–0.68)	4.2 (1.75–10.21)
45–49	13	4655	0.60 (0.46–0.74)	3.5 (1.7–7.3)	8	2285	0.75 (0.59–0.91)	2.7 (1.0–7.4)	5	2272	0.47 (0.35–0.59)	3.6 (1.21–10.79)
50+	8	8274	0.21 (0.14–0.28)	1.2 (0.5–2.9)	7	3878	0.39 (0.28–0.50)	1.4 (0.5–4.0)	1	3678	0.06 (0.03–0.10)	0.5 (0.06–3.64)
Under 25	31	42,666	0.16 (0.10–0.22)	1.0 (ref)	23	10,267	0.48 (0.36–0.60)	1.0 (ref)	8	31,589	0.05 (0.02–0.09)	1.0 (ref)
25+	120	70,467	0.37 (0.27–0.47)	2.3 (1.6–3.4)	73	24,890	0.63 (0.49–0.77)	1.3 (0.8–2.1)	47	43,656	0.23 (0.15–0.31)	4.6 (2.17–9.73)
Borough of Residence												
Manhattan	46	24,307	0.41 (0.30–0.52)	1.0 (ref)	32	9519	0.72 (0.56–0.87)	1.0 (ref)	14	14,231	0.21 (0.14–0.28)	1.0 (ref)
Bronx	35	36,486	0.21 (0.14–0.28)	0.5 (0.3–0.8)	22	9982	0.47 (0.35–0.59)	0.7 (0.4–1.1)	13	25,634	0.11 (0.06–0.16)	0.5 (0.25–1.11)
Brooklyn	44	28,779	0.33 (0.24–0.43)	0.8 (0.5–1.2)	24	9812	0.53 (0.40–0.66)	0.7 (0.4–1.2)	20	18,166	0.24 (0.16–0.32)	1.1 (0.58–2.26)
Queens	23	22,987	0.21 (0.14–0.29)	0.5 (0.3–0.8)	15	5425	0.59 (0.45–0.73)	0.8 (0.4–1.5)	8	17,019	0.10 (0.05–0.15)	0.5 (0.20–1.14)
Staten Island	0	1270	0.00 (0.00–0.51)	—	0	712	0.00 (0.00–0.90)	—	0	533	0.00 (0.00–1.20)	—
Transmission Risk†												
MSM	55	4750	2.5 (2.1–2.8)	20.8 (14–31)	55	4750	2.5 (2.1–2.8)	20.8 (11.4–38.1)	NA	NA	NA	NA
IDU history	21	5821	0.78 (0.61–0.94)	6.5 (3.9–11)	13	1017	2.7 (2.3–3.1)	22.5 (10.4–48.5)	8	4804	0.36 (0.26–0.46)	3.0 (1.4–6.5)
Heterosexual	43	77,983	0.12 (0.07–0.17)	1.0 (ref)	13	23,278	0.12 (0.07–0.17)	1.0 (ref)	30	54,705	0.12 (0.07–0.17)	1.0 (ref)
Unknown/other/under investigation	32	22,485	0.31 (0.22–0.40)	2.6 (1.6–4.1)	15	6411	0.50 (0.38–0.62)	4.2 (2.0–8.8)	17	16,074	0.23 (0.15–0.31)	1.9 (1.1–3.5)
Source												
STD clinics	38	20,683	0.39 (0.28–0.50)	1.0 (ref)	30	10,918	0.59 (0.45–0.73)	1.0 (ref)	8	9074	0.19 (0.12–0.26)	1.0 (ref)
Community based organizations	15	3569	0.90 (0.72–1.1)	2.3 (1.3–4.2)	11	1499	1.6 (1.3–1.9)	2.7 (1.4–5.4)	4	1949	0.44 (0.33–0.55)	2.3 (0.7–7.7)
NYC Health and Hospital Corporation	19	36,248	0.11 (0.06–0.16)	0.3 (0.2–0.5)	9	4303	0.45 (0.33–0.57)	0.8 (0.4–1.6)	10	31,153	0.07 (0.03–0.11)	0.4 (0.1–0.9)
Tuberculosis clinics	0	1306	0.00 (0.00–0.49)	—	0	702	0.00 (0.00–0.92)	—	0	556	0.00 (0.00–1.20)	—
Private MDs	40	22,834	0.38 (0.28–0.48)	1.0 (0.6–1.5)	27	7033	0.82 (0.65–0.99)	1.4 (0.8–2.3)	13	15,342	0.18 (0.11–0.25)	0.9 (0.4–2.3)
NYC corrections	11	3921	0.60 (0.46–0.74)	1.5 (0.8–3)	7	3073	0.49 (0.37–0.61)	0.8 (0.4–1.9)	4	783	1.10 (0.89–1.3)	5.8 (1.7–19.2)
Other	28	25,271	0.20 (0.10–0.30)	0.5 (0.30–0.80)	12	7925	0.30 (0.20–0.40)	0.50 (0.30–1.0)	16	16,726	0.20 (0.10–0.30)	1.1 (0.50–2.5)

*Annual incidence rates (I) were calculated using the formula: $I = (n/N) \times (365.25/170) \times (100\%)$.

†Figures for HIV-negative persons were estimated using citywide survey data for people who tested for HIV in a public setting.

significantly higher for men than for women (0.58 vs. 0.16% per year, RR = 3.6, 95% CI: 2.6–5.0). HIV incidence rates among testers increased with age and were significantly higher among persons in each 5-year age group between 30–49 years compared with those aged 25–29 (Table 1, Fig. 1). The HIV incidence rate was 2.5% per year (95% CI: 2.1–2.8) among MSM testers (RR 20.8, 95% CI: 11.4–38.1 relative to all heterosexual testers [ie, male and female]). Incidence rates were also significantly higher for IDU testers (0.78% per year, 95% CI: 0.61–0.94, RR 6.5, 95% CI: 3.9–11.0) and persons

with unreported risk (0.31% per year, RR 2.6, 95% CI: 1.6–4.1) when compared with heterosexual testers. The incidence rate was higher among persons tested at community-based organizations compared with those tested in the city's 10 STD clinics (RR = 2.3, 95% CI: 1.3–4.2).

Among male testers, the incidence rates rose with age and peaked in the 35- to 39-year age group (Fig. 1) and were significantly higher for male testers aged 30–34 (RR = 2.6, 95% CI: 1.1–6.2) and 35–39 (RR 3.6, 95% CI: 1.5–8.4) when compared with those aged 25–29 years (Table 1). Relative to

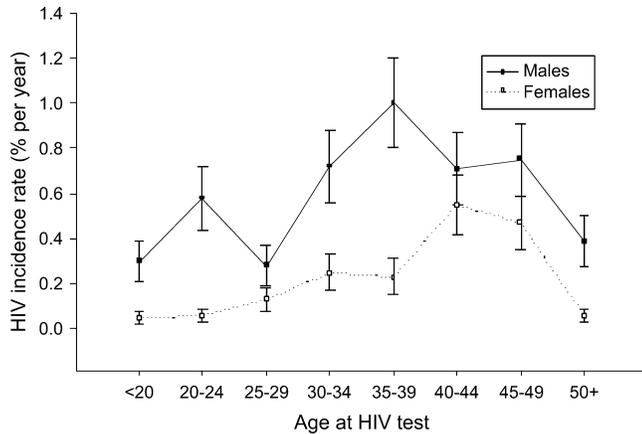


FIGURE 1. Estimated annual HIV incidence rates (% per year) and 95% CIs among persons tested for HIV in public settings during 2001 (n = 113,832 by age and sex, New York City, 2001).

male heterosexuals, incidence rates were significantly higher among male IDUs (RR 22.5, 95% CI: 10.4–48.5) and MSM testers (RR 21.7, 95% CI: 11.8–39.7) and men with no reported risk (RR 4.2, 95% CI: 2.0–8.8). Among female testers, incidence rates increased with age and peaked in the 40- to 44-year age group (RR 4.2, 95% CI: 1.8–10.2) (Fig. 1). Incidence rates were significantly higher among female testers with no reported risk (RR 1.9, 95% CI: 1.1–3.5) relative to women with documented heterosexual risk and were highest for women tested in New York City correctional facilities (1.1% per year, 95% CI: 0.89–1.3) (Table 1).

For male and female testers combined, HIV incidence rates peaked at ages 35–39 among non-Hispanic whites (1.2% per year) and at later ages among persons of non-Hispanic black, Hispanic, and A/PI/NA race/ethnicities (Fig. 2). Non-Hispanic black testers had the highest HIV incidence rates, regardless of age, with the exception of the peak among non-Hispanic whites 35–39 years of age.

Multivariate Analysis

In Poisson regression analysis (Table 2), rates among testers were significantly higher for men than women (RR = 2.8, 95% CI: 2.0–3.9) after controlling for race/ethnicity, age, and borough of residence, each of which was also a significant predictor of HIV incidence among men and women combined. A/PI/NA testers had significantly lower incidence rates relative to non-Hispanic white (RR 0.16, 95% CI: 0.05–0.59). HIV incidence was significantly higher in persons in each 5-year age group between 30–49 years compared with those aged 25–29. Persons testing in the Bronx had significantly lower adjusted HIV incidence relative to persons testing in Manhattan (RR 0.57, 95% CI: 0.37–0.89).

Among men, the only factor independently associated with HIV incidence among testers was being in the A/PI/NA race/ethnicity category. Males aged 30–34, 35–39, and 45–49 years had higher incidence rates than those aged 25–29. Among female testers, women aged 40–44 and 45–49 years had an adjusted RR of 3.5 (95% CI: 1.4–8.4) and 3.0 (95%

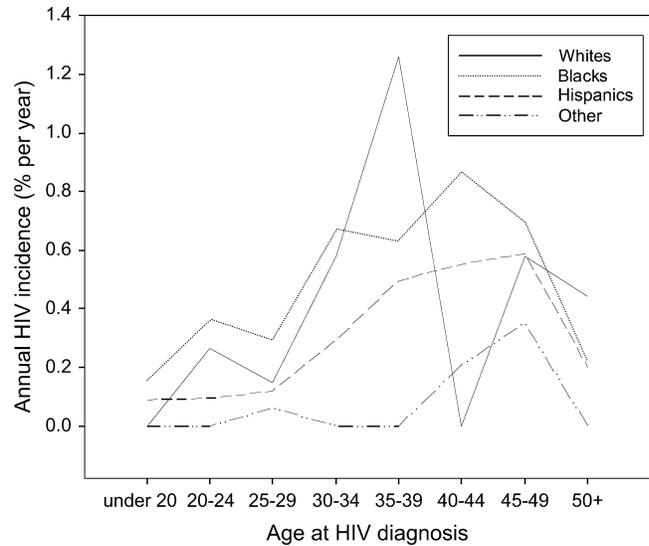


FIGURE 2. Annual HIV incidence rates (% per year) among persons tested for HIV in public settings during 2001 (n = 113,832) by age and race/ethnicity, New York City, 2001.

CI: 1.0–9.0), respectively, when compared with women aged 25–29 years. With an apparent trend toward increased incidence, non-Hispanic black women appeared to have higher incidence rates than non-Hispanic white women (adjusted RR 5.6, 95% CI: 0.76–40.6). An interaction term for sex and age in the full model was significant at *P* < 0.05, suggesting that the relationship between age and HIV incidence is different for male and female testers.

Assessing the Representativeness of the Study Population

Table 3 shows the demographic and risk characteristics for all 6356 persons in whom HIV was diagnosed in New York City during 2001 by testing laboratory (NYCPHL and NYSWCL vs. other). Of these 6356, 37% had developed AIDS by December 31, 2002 (ie, had established HIV infection at the time of HIV diagnosis in 2001), and this proportion was higher among persons diagnosed in nonpublic settings. Persons with HIV (non-AIDS) in the study sample (n = 1022) were significantly more likely to be female, minority, younger, from Manhattan, and heterosexual than persons with HIV (non-AIDS) who were not included in the study sample (persons whose Western blot test was not performed at the New York City or NYS public laboratories).

DISCUSSION

This is the first investigation to combine the S/LS-EIA testing algorithm with delinked population-based HIV/AIDS surveillance data to derive estimates of HIV incidence among persons testing for HIV. The HIV incidence rate among persons testing for HIV in public settings in New York City was estimated to be 0.29% (95% CI: 0.20–0.38) per year using data from a study population that comprised 27% of those in whom HIV was diagnosed in New York City during 2001.

TABLE 2. Crude and Adjusted Rate Ratios and 95% CIs for HIV Incidence Among 113,832 Persons Testing for HIV in New York City During 2001

	Total		Males Only		Females Only	
	Crude RR (95% CI)	Adjusted RR (95% CI)	Crude RR (95% CI)	Adjusted RR (95% CI)	Crude RR (95% CI)	Adjusted RR (95% CI)
Sex						
Male	3.6 (2.6–5.1)*	2.8 (2.0–4.0)*	—	—	—	—
Female	1.0 (ref)	1.0 (ref)	—	—	—	—
Race/ethnicity						
White	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)
Black	1.1 (0.63–2.0)	1.6 (0.84–3.0)	0.92 (0.49–1.7)	1.1 (0.56–2.2)	5.2 (0.71–37.7)	5.5 (0.75–40.0)
Hispanic	0.58 (0.18–1.9)	1.0 (0.52–2.0)	0.77 (0.40–1.5)	1.0 (0.49–2.1)	1.7 (0.22–12.5)	2.1 (0.28–15.9)
Asian/Pacific Islander/ Native American	0.29 (0.08–1.0)	0.16 (0.05–0.59)*	0.81 (0.23–2.9)	0.25 (0.07–0.90)*	NA	NA
Age at Diagnosis						
Under 20	0.59 (0.25–1.4)	0.65 (0.27–1.5)	1.1 (0.34–3.4)	1.2 (0.37–4.0)	0.38 (0.10–1.4)	0.31 (0.08–1.2)
20–24	1.1 (0.59–2.1)	1.2 (0.61–2.2)	2.1 (0.87–5.0)	2.4 (0.95–6.0)	0.46 (0.15–1.4)	0.39 (0.13–1.2)
25–29	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)
30–34	2.3 (1.3–4.2)*	2.2 (1.2–4.2)*	2.6 (1.1–6.2)*	2.8 (1.1–7.1)*	1.9 (0.82–4.5)	1.9 (0.81–4.5)
35–39	3.1 (1.7–5.6)*	2.7 (1.5–5.1)*	3.6 (1.5–8.4)*	4.2 (1.7–10.3)*	1.8 (0.68–4.6)	1.6 (0.61–4.1)
40–44	3.6 (1.9–6.8)*	2.7 (1.4–5.3)*	2.5 (1.0–6.4)	2.7 (0.98–7.2)	4.2 (1.8–10.2)*	3.5 (1.4–8.4)*
45–49	3.5 (1.7–7.3)*	2.7 (1.3–5.8)*	2.7 (0.97–7.4)	3.1 (1.1–8.9)*	3.6 (1.2–10.8)*	3.0 (1.0–9.0)*
50+	1.2 (0.53–2.9)	1.0 (0.43–2.4)	1.4 (0.49–4.0)	1.6 (0.54–4.8)	0.46 (0.06–3.6)	0.40 (0.05–3.2)
Borough of Residence						
Manhattan	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)	1.0 (ref)
Bronx	0.51 (0.33–0.79)*	0.57 (0.37–0.9)*	0.65 (0.38–1.1)	0.61 (0.35–1.1)	0.52 (0.25–1.1)	0.53 (0.25–1.1)
Brooklyn	0.80 (0.53–1.2)	0.82 (0.54–1.3)	0.74 (0.43–1.3)	0.71 (0.42–1.2)	1.14 (0.58–2.3)	1.1 (0.53–2.1)
Queens + Staten Island†	0.49 (0.30–0.80)*	0.67 (0.4–1.1)	0.74 (0.40–1.4)	0.75 (0.40–1.4)	0.48 (0.20–1.1)	0.62 (0.26–1.5)

*Significant at 0.05 level.

†There were no Staten Island residents diagnosed with early stage HIV infection, so Staten Island testers were combined with Queens.

Among women testing for HIV, the highest incidence rates were among women aged 40–49 years (0.5% per year) and those tested in New York City correctional facilities (1.1% per year, 95% CI: 0.89–1.3). Among men testing for HIV, the highest incidence rates were among IDUs (2.7% per year, 95% CI: 2.3–3.1) and MSM (2.5% per year, 95% CI: 2.1–2.8). These data have immediate implications for intensification of HIV prevention planning efforts in New York City, particularly among male IDUs and MSM.

Age was an independent predictor of HIV incidence in men and women testing for HIV, with older persons having higher incidence than younger persons. There was a significant interaction between sex and age in the Poisson regression models, and the HIV incidence estimates peaked later for women than for men (Fig. 1), both findings that may provide insight into HIV transmission patterns among middle-aged persons in New York City. For example, a higher HIV incidence rate among middle-aged persons compared with younger persons may suggest obvious differences such as riskier behavior, or less obvious ones such as a higher HIV prevalence rate among the sex partners of middle-aged persons. However, the observed differences could also be due to differences in testing practices among older vs. younger persons in our study. Populations that test more frequently are more likely to be diagnosed in the early stages of HIV infection, resulting in

artificially higher incidence rates compare to populations with lower testing frequencies.

Previous investigations have used the S/LS-EIA algorithm as an epidemiologic tool to estimate and compare HIV incidence rates in convenience samples and high-risk cohorts. Using remnant sera from routine syphilis screening performed at New York City DOHMH STD clinics, the NYCDOHMH found incidence rates among MSM testers in 1999 to be 3.2% per year.²⁴ A retrospective investigation of patients evaluated for sexually transmitted infections at STD clinics in 9 US cities found incidence rates of 0.8% per year, with the highest rates of HIV incidence (7.1% per year) among MSM; the incidence rates remained constant over the study period (1994–1997).⁶ Studies conducted among HIV testers at San Francisco’s public STD clinic have found overall incidence rates of 1.5% per year; in that study, the HIV incidence rates were consistently highest among MSM (5.3% per year), persons with an HIV-positive partner (8.6% per year), and persons with an active STD (1.0%–6.7% per year, depending on the STD).^{7–14} The S/LS-EIA algorithm was also applied to persons participating in CDC’s Young Men’s Survey (YMS) I and II, which was conducted among MSM aged 15–25 who frequented gay venues in 7 US cities, including New York City, during 1994–2000.¹⁵ The YMS studies estimated HIV incidence to be 2.5% per year among young MSM who attend

TABLE 3. Total New HIV Diagnoses in New York City During January 1, 2001–December 31, 2001

	Total New HIV Diagnoses n (%)	NYCPHL or NYSWCL			Other Laboratories			P- χ^2 †
		Total n (%)	HIV (non-AIDS) n (%)	AIDS* n (%)	Total n (%)	HIV (non-AIDS) n (%)	AIDS* n (%)	
Total	6356 (100)	1522 (100.0)	1022 (100)	500 (100)	4522 (100.0)	2659 (100)	1863 (100)	
Sex								
Male	4141 (65.2)	948 (62.3)	613 (60)	335 (67)	3002 (66.4)	1712 (64.4)	1290 (69.2)	0.0131
Female	2215 (34.8)	574 (37.7)	409 (40)	165 (33)	1520 (33.6)	947 (35.6)	573 (30.8)	
Race								
White	972 (15.3)	91 (6.0)	67 (6.6)	24 (4.8)	854 (18.9)	563 (21.2)	291 (15.6)	<0.0001
Black	3401 (53.5)	903 (59.3)	594 (58.1)	309 (61.8)	2313 (51.1)	1276 (48)	1037 (55.7)	
Hispanic	1868 (29.4)	498 (32.7)	343 (33.6)	155 (31)	1274 (28.2)	772 (29)	502 (26.9)	
Asian/Pacific Islander	91 (1.4)	29 (1.9)	17 (1.7)	12 (2.4)	60 (1.3)	33 (1.2)	27 (1.4)	
Native American	8 (0.1)	1 (0.1)	1 (0.1)	0 (0)	6 (0.1)	3 (0.1)	3 (0.2)	
Unknown	16 (0.3)	0 (0.0)	0 (0)	0 (0)	15 (0.3)	12 (0.5)	3 (0.2)	
Age at diagnosis								
Under 20	180 (2.8)	36 (2.4)	28 (2.7)	8 (1.6)	133 (2.9)	105 (3.9)	28 (1.5)	<0.0001
20–24	381 (6)	143 (9.4)	100 (9.8)	43 (8.6)	197 (4.4)	141 (5.3)	56 (3)	
25–29	629 (9.9)	189 (12.4)	145 (14.2)	44 (8.8)	411 (9.1)	287 (10.8)	124 (6.7)	
30–34	1045 (16.4)	275 (18.1)	196 (19.2)	79 (15.8)	717 (15.9)	455 (17.1)	262 (14.1)	
35–39	1275 (20.1)	298 (19.6)	196 (19.2)	102 (20.4)	911 (20.1)	551 (20.7)	360 (19.3)	
40–44	1053 (16.6)	233 (15.3)	149 (14.6)	84 (16.8)	781 (17.3)	426 (16)	355 (19.1)	
45–49	781 (12.3)	152 (10.0)	93 (9.1)	59 (11.8)	598 (13.2)	323 (12.1)	275 (14.8)	
50+	1012 (15.9)	196 (12.9)	115 (11.3)	81 (16.2)	774 (17.1)	371 (14)	403 (21.6)	
Borough of Residence								
Manhattan	1764 (27.8)	425 (27.9)	309 (30.2)	116 (23.2)	1267 (28.0)	821 (30.9)	446 (23.9)	<0.0001
Bronx	1576 (24.8)	457 (30.0)	296 (29)	161 (32.2)	1013 (22.4)	649 (24.4)	364 (19.5)	
Brooklyn	1764 (27.8)	351 (23.1)	258 (25.2)	93 (18.6)	1325 (29.3)	676 (25.4)	649 (34.8)	
Queens	843 (13.3)	247 (16.2)	139 (13.6)	108 (21.6)	563 (12.5)	293 (11)	270 (14.5)	
Staten Island	114 (1.8)	12 (0.8)	7 (0.7)	5 (1)	100 (2.2)	50 (1.9)	50 (2.7)	
Other/unknown	295 (4.6)	30 (2.0)	13 (1.3)	17 (3.4)	254 (5.6)	170 (6.4)	84 (4.5)	
Transmission risk								
MSM	1478 (23.3)	335 (22.0)	228 (22.3)	107 (21.4)	1090 (24.1)	704 (26.5)	386 (20.7)	<0.0001
IDU history	978 (15.4)	218 (14.3)	150 (14.7)	68 (13.6)	711 (15.7)	398 (15)	313 (16.8)	
Heterosexual	1313 (20.66)	419 (27.5)	276 (27)	143 (28.6)	829 (18.3)	440 (16.5)	389 (20.9)	
Transfusion history	48 (0.76)	15 (1.0)	10 (1)	5 (1)	26 (0.6)	10 (0.4)	16 (0.9)	
Perinatal transmission	39 (0.61)	1 (0.1)	0 (0)	1 (0.2)	38 (0.8)	33 (1.2)	5 (0.3)	
Unknown/under investigation	2487 (39.13)	533 (35.0)	358 (35)	175 (35)	1820 (40.2)	1069 (40.2)	751 (40.3)	
Presumed perinatal transmission	9 (0.14)	1 (0.1)	0 (0)	1 (0.2)	8 (0.2)	5 (0.2)	3 (0.2)	

*AIDS diagnosis as of 12/31/2002.

†For comparison of HIV (non-AIDS) cases in public and private settings.

gay venues nationally and 7.6% per year among such young MSM in New York City.

The findings from previous studies that used the S/LS-EIA to estimate HIV incidence, while generalizable to their target populations (STD clinic attendees and young MSM frequenting gay venues), are difficult to interpret in the context of the larger HIV epidemic. Our HIV incidence estimates for all public venue testers (0.29% per year) and MSM testers (2.6% per year) were lower than those found in previous investigations of high-risk cohorts, both longitudinal⁶ and cross-sectional,^{24–26} presumably reflecting the fact that our incidence estimates may be closer to HIV incidence rates in the general population of New York City.

Populations With Incidence Estimates >1% Per Year

The high incidence rates observed among male IDUs, MSM, and women in correctional facilities tested for HIV in New York City observed in this investigation could reflect the fact that these populations test more frequently than others (ie, are more likely to be diagnosed in the early stage of HIV infection than persons who test less frequently). But it is also possible that there was a higher HIV incidence among persons in these risk groups during 2001, and they are therefore currently most in need of effective interventions to reduce HIV transmission.

Male Injecting Drug Users

Male testers with a history of IDU had an incidence rate of 2.7% per year. HIV-positive persons with a history of IDU constitute 20% of all diagnosed persons living with HIV/AIDS (PLWHAs) in New York City. Needle exchange programs became available to IDUs in New York City in the 1990s, and by the late 1990s the rate of new HIV infection among street recruited IDUs and IDUs in drug treatment programs (male and female) was at an all-time low of approximately 1.0%–1.7% per year,²⁷ making the current finding of 2.7% per year among male IDUs somewhat surprising. Currently, there are 10 needle exchange programs operating in 3 of New York City's 5 boroughs (Manhattan, Brooklyn, and the Bronx). Recent state legislation established the Expanded Syringe Access Program, which decriminalizes possession of hypodermic needles and allows the sale of clean needles to those who request them at pharmacies and other locations throughout New York City's 5 boroughs. The reduced incidence among IDUs historically associated with the introduction of needle exchange programs and the Expanded Syringe Access Program suggests that these programs should be more actively promoted. Given the high prevalence of PLWHAs who inject drugs in NYC, prevention strategies for HIV-infected persons with a history of IDU should focus on prevention of transmission to sex partners as well as needle-sharing partners of IDU.

Men Who Have Sex With Men

The higher incidence of HIV among MSM testing for HIV observed in this investigation (2.5% per year) is not unexpected given the YMS incidence estimates of 7.6% per year among young MSM in New York City recruited during 1994–2000.¹⁵ MSM constitute 19% of all diagnosed PLWHAs in New York City. Also, the recently described phenomenon of syphilis transmission among MSM with long-standing, previously diagnosed HIV infection suggests that HIV-positive MSM in New York City are engaging in increased rates of high-risk sexual behavior, which presumably also results in an increase in HIV transmission.²⁸ The elevated incidence rate in MSM may be the result of a resurgence of HIV transmission in this community not just due to untested positives, but also by those who know their HIV status and continue to engage in high-risk behavior.

Women in New York City Corrections

Women tested for HIV in New York City correctional facilities had the highest HIV incidence rates of any other group of women examined in this investigation. Possible factors associated with higher HIV incidence in this population include recent infection associated with incarceration such as drug use (injecting or exchange of sex for drugs) or sex work. However, HIV rates in this population have not been well characterized in New York City, and this finding merits further investigation.

Study Limitations

Although our investigation was population based, our study population included only 27% of persons in whom HIV

was diagnosed in New York City during 2001. As shown in Table 3 the 1022 persons with HIV (non-AIDS) diagnoses during 2001 in our sample differ statistically from those not in our sample, though these differences were not large. These individuals would have been included in the incidence calculations if their specimens had been available for LS-EIA testing. Incidence rates estimated from our study population, therefore, may not be reflective of incidence rates among all testers. The HIV incidence rates among testers in public settings likely differ from those tested in private settings. Specifically, persons testing in private settings may be at lower risk for HIV infection but also test less frequently and may be more likely to be diagnosed with later stage HIV infection. This latter point was true for our sample (Table 4) and suggests that our HIV incidence rate estimates among public venue testers overestimate that among all testers in New York City.

Another important limitation of the present investigation is that risk data for persons who tested HIV negative in this investigation were not available at the individual level (since only HIV-positive tests are reportable in New York State). Although persons in our study population in whom HIV was diagnosed for the first time during 2001 were more likely to have complete risk data than others diagnosed during 2001 (Table 4), approximately one-third of new HIV diagnoses were missing information on transmission risk, though among those included in the incidence calculations, this proportion was lower (21%).

Because risk information was collected and classified differently for HIV-positive persons and HIV-negative persons, there may have been potential for bias in the risk-specific incidence rate calculations. For example, if certain risk groups were underrepresented in the telephone survey, incidence rates would tend to be overestimated in those groups. Additionally, though risk data from New York City CHS 2002 for people who tested for HIV at public clinics could be used in univariate analyses, they could not be incorporated into Poisson regression analyses due to small sample size and lack of precision of the risk estimates upon stratification by sex, race/ethnicity, age, and borough. Further, estimates of HIV incidence among IDUs derived from the CHS may be biased because the CHS was a household telephone survey, and some high-risk populations may not have been fully represented.

Although we had a testing population of >115,000 people that included 151 early-stage HIV infections, the numerator in the HIV incidence rate calculation was too small to provide useful incidence estimates at the neighborhood level among persons testing for HIV, where most interventions for HIV ultimately take place. Moreover, since the likelihood of testing HIV positive at a public site is at least in part dependent on the tester's geographic proximity to a public site, geographic analyses are subject to bias when data are limited to public testers only. To provide useful neighborhood-level data, LS-EIA data on HIV diagnoses in all settings are needed.

Of the 1223 HIV (non-AIDS) diagnoses eligible for LS-EIA testing, 179 (10.3%) had insufficient quantity for testing. Our estimates underestimate HIV incidence among public venue testers because they do not adjust for this. It is possible that specimens with insufficient quantity for LS-EIA testing had a higher proportion of early infections than those with

enough serum available. Specimens with an insufficient amount of serum to permit LS-EIA testing may be more likely to be incident infections as the serum may have been used up by performance of multiple serologic tests to confirm a borderline positive result on S-EIA and Western blot testing (ie, in the early stages of HIV infection). Had these specimens had adequate volume for testing, the overall incidence rate may have been slightly higher than 0.29% per year. If these specimens had a similar proportion of early infections as those successfully tested with the LS-EIA (14.8%), the overall incidence rate could be as high as 0.32% per year (95% CI: 0.20–0.38). In the extreme case that all 179 specimens were early infections, then the overall incidence rate would rise to 0.62% per year (95% CI: 0.48–0.76).

Another important limitation is our assumption that the 113,681 HIV-negative specimens represented 113,681 persons. However, since names were not available for HIV-negative specimens, the number of persons associated with these specimens is unknown. Of the 97,152 negatives at the New York City PHL, we estimated that as many as 10%–20% of the HIV-negative tests represent individuals with >1 negative test result. Assuming 10%–20% were duplicates, the overall incidence rate estimates would be 0.32%–0.36% per year.

Finally, though the LS-EIA is not without its limitations, the performance characteristics of the test have been characterized as suitable for epidemiologic purposes^{16,17} (ie, estimating incidence rates and, in particular, trends in incidence rates).

CONCLUSION

The CDC's national strategic plan is to reduce the number of new HIV infections by 50% from an estimated 40,000 to 20,000 by the end of 2005. To monitor New York City's progress toward this goal, an estimate of the annual number of new HIV infections is needed. An estimated 500,000 New Yorkers are tested for HIV each year. If the incidence rate of 0.29% per year (95% CI: 0.20–0.38) is applied to all testers, the associated annual number of new infections in 2001 would be 1450 (95% CI: 1000–1900). In the future, a more accurate estimate of the number of new HIV infections could be obtained if the LS-EIA test could be applied to the remaining 72% of diagnostic specimens from persons in whom HIV is diagnosed (non-AIDS) in nonpublic settings in New York City whose diagnostic specimens are not currently available for LS-EIA testing.

The New York City DOHMH and other state and local health departments, in cooperation with the CDC, are currently developing a more comprehensive HIV incidence surveillance by combining existing HIV/AIDS surveillance data with new laboratory serologic testing algorithms that can estimate the timing of HIV infection among all persons testing for HIV.¹⁶ In areas with high HIV prevalence such as New York City, the dynamic and heterogeneous nature of the underlying forces of HIV transmission necessitates an epidemiologic monitoring tool that is both population based and an accurate barometer of current HIV transmission patterns. With complete, individual-level data on HIV testing history and risk, and the capability of testing a large proportion of all HIV (non-AIDS) diagnoses as

determined through population-based HIV/AIDS surveillance, the possibility of obtaining population-based HIV incidence estimates beyond testers exists. Such a tool will aid public health officials in planning primary prevention of new HIV infections, prevention resource allocation, and for monitoring the effectiveness of HIV prevention programs.

This initial investigation has derived higher estimates of HIV incidence among male IDUs, which have been previously reported to be on the decline in New York City.²⁷ This may be due to a more accurate estimation of HIV incidence among IDUs but could also be heralding an increased level of HIV transmission, such as that observed among MSM in this and previous investigations in New York City.¹⁵ These data highlight the need to strengthen existing programs aimed at preventing parenteral and sexual transmission of HIV among IDUs and MSM in New York City.

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