Targeting the Use of Pooled HIV RNA Screening to Reduce Cost in Health Department STD Clinics: New York City, 2009–2011

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ABSTRACT

Objective. Staff at public New York City sexually transmitted disease (STD) clinics screen patients for acute HIV infection (AHI) using pooled nucleic acid amplification tests. AHI screening is expensive but important for populations at high risk of acquiring HIV. We analyzed if targeting AHI screening in STD clinics could reduce program costs while maintaining AHI case detection.

Methods. From January 2009 through May 2010, we screened all patients with negative rapid HIV tests for AHI. Using risk information on cases detected during this universal screening period, we developed criteria for targeted AHI screening and compared case yields and testing costs during 12 months of universal screening (June 2009 through May 2010) vs. 12 months of targeted screening (June 2010 through May 2011).

Results. During the defined period of universal screening, we identified 40 AHI cases, and during targeted screening, we identified 35 AHI cases. Because of targeting efforts, the number needed to test to find one AHI case dropped from 1,631 to 254. With targeted screening, it cost an average of \$4,535 per case detected and 39.3 cases were detected per 10,000 specimens; using universal screening, \$29,088 was spent per case detected and 6.1 cases were detected per 10,000 specimens processed.

Conclusion. Targeted screening identified similar numbers of AHI cases as when screening all clinic patients seeking HIV testing, but at one-seventh the cost.

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During the acute phase of human immunodeficiency virus (HIV) infection (AHI), infected people are often unaware of their condition, as AHI symptoms—which include fever, sore throat, fatigue, myalgia, lymphadenopathy, rash, joint pain, night sweats, and diarrhea—are nonspecific.¹ During AHI, patients are highly viremic (and, thus, highly infectious), and antibodies to HIV have not yet developed.² This stage of infection, therefore, is not detected by traditional antibody tests. Detecting AHI requires nucleic acid amplification or antigen tests and enables infected people to adopt safer behaviors and be linked to earlier treatment and care, all of which may reduce HIV transmission.^{3,4} A multisite study conducted in 14 clinics in New York City (NYC); Los Angeles, California; and four counties in Florida from 2006 to 2008 found that AHI screening, when added to point-of-care rapid testing, increased HIV detection by 8.2% across all sites; in three NYC clinics, 24% more HIV infections were detected using AHI screening than with HIV detection using rapid antibody tests alone (seven cases detected by nucleic acid amplification testing [NAAT]; 22 cases detected by rapid test).⁵ NAAT is an important tool for identifying AHI, and NAAT pooling methods (pNAATs) help to contain the costs of screening.⁶ By 2009, the NYC Department of Health and Mental Hygiene (NYC DOHMH) had implemented routine AHI screening via pNAAT for all patients with negative rapid HIV tests in all of its sexually transmitted disease (STD) clinics. At that time, the NYC DOHMH joined just a handful of state and local health departments in the United States that were routinely using pNAAT.⁷

While AHI screening increased HIV detection in NYC STD clinics, it came at a considerable cost. Annualized other-than-personnel costs of this screening were more than \$1 million, or approximately \$30,000 per new diagnosis, which was as much as 16 times greater than the average cost of routine opt-out HIV screening in health-care facilities in the U.S.⁸ We present our evaluation of a strategy to reduce program costs while maintaining a high level of AHI case detection among clinic patients.

METHODS

The NYC DOHMH Bureau of Sexually Transmitted Disease Control (BSTDC) operates nine clinics throughout the city's five boroughs. Services provided include rapid HIV testing on an opt-out basis, testing and treatment for other STDs, hepatitis A and B vaccinations, emergency contraception, substance abuse screening and intervention, and behavioral health programs targeted at reducing sexual risk of HIV and other infections.

The clinics have offered HIV testing since 1989, with rapid HIV testing using OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test (OraSure Technologies, Inc., Bethlehem, Pennsylvania) on blood sample (via finger stick) on-site (or via laboratory-based standard enzyme immunoassay/Western blot test when rapid testing is not available) since 2004. All clinic patients receiving services also test for HIV, unless they choose to opt out.

During 2007, the BSTDC phased in routine AHI screening via pNAAT, and it was fully implemented at all clinic sites by December 2009. For pNAAT, patients testing for HIV using the rapid test had their blood drawn in one 5.0 milliliter plasma preparation tube, spun down, and sent either to the NYC DOHMH Public Health Laboratories (PHL) or to National Genetics Institute in California for processing. By the end of 2010, the local PHL processed all pNAAT specimens.

PHL uses a qualitative HIV ribonucleic acid (RNA) assay (APTIMA HIV-1 RNA; Gen-Probe Inc, San Diego, California), in a one-stage 16:1 pooling scheme. Pools with no detection of HIV-1 RNA are reported out as “HIV-1 Pooled NAAT Not Detected” or negative; in pools with detectable virus, each of the 16 specimens is retested using individual NAAT and confirmed with viral load quantification. PHL simultaneously reports qualitative and viral load results to the STD clinic provider.

After receiving a negative rapid result, clinic staff educates patients on the differences between detection using the OraQuick rapid test and the NAAT, counsels them regarding their outstanding AHI test result, and encourages them to avoid risky behavior while waiting for NAAT results. Although anonymous testing is available, only patients who have chosen to test confidentially will receive NAAT testing, as contact information is necessary to provide results to patients. PHL transmits positive results to BSTDC staff, who immediately contact patients to return to the STD clinic for notification, HIV counseling, partner services, and linkage to HIV medical care.

PHL estimated the costs of using pNAAT to screen for AHI at \$17.84 per specimen, which included costs of the assay, retesting of individual specimen pools according to pool positivity rates, bimonthly environmental wipe testing, and other non-personnel costs associated with performing tests and reporting results.

Using medical record data, BSTDC staff systematically reviewed cases of AHI from January 2009 through May 2010 (universal screening). Using demographic and reported risk data from cases detected during universal screening, we developed criteria for targeting AHI screening, which was implemented in May 2010. We assessed these criteria via self-administered

screening questions at the point of triage prior to patients receiving clinical care. The triage screening tool included questions about what services the patient was seeking at the current visit, what symptoms they may have been experiencing, and whether or not the patient had engaged in or been exposed to any of the risk criteria listed on the tool. Upon meeting with the triage staff person, dates of exposure were assessed. If exposure occurred within the previous two months but more than 10 days before the visit, the patient was screened for AHI. If exposure occurred within the previous 10 days, the patient was counseled and advised to return within the next week for further testing. If the exposure occurred within the previous 72 hours, the patient was counseled and referred for non-Occupational Post-Exposure Prophylaxis (nPEP) where indicated.

We compared case yields, characteristics of AHI patients, and costs of testing during 12 months of universal screening vs. 12 months of targeted screening. Additionally, we compared demographic and STD history profiles of case patients who tested AHI positive and AHI negative during targeted screening to further characterize factors associated with positivity. We tested the differences between the two groups with chi-square and t-tests for categorical and continuous variables, respectively. All reported cases were matched in the NYC HIV registry to confirm acute HIV diagnosis; none of the cases were found to be diagnosed before

testing positive in the STD clinic; therefore, all were included in this analysis.

RESULTS

From June 2009 through May 2010, we routinely screened 65,220 antibody negative specimens using pNAAT, yielding 40 AHI cases (6.1 cases/10,000 specimens), which are described in Table 1. Risk data collected after HIV infection was confirmed revealed 32 cases (80%) were men who have sex with men (MSM), one case (3%) was a male reporting exchange sex (for money, drugs, or both), five cases (13%) were males with unknown risk, one case (3%) was a transgender woman reporting sex with MSM, and one case (3%) was a female who reported sex with an HIV-infected partner (data not shown). The median age of case patients was 26 years (range: 18 to 64, data not shown). The majority of patients (73%) were people of color, and 35% were previously diagnosed with an STD (Table 1). Previous STD was defined by either a clinical or self-reported diagnosis of one or more of the following: syphilis, chlamydia, gonorrhea, nongonococcal urethritis, herpes, and genital warts, as documented in the patient's electronic medical record.

Based on characteristics of AHI cases identified during universal screening, we determined that patients should undergo targeted screening if they engaged in or experienced any of the following in the two months

Table 1. Universal and targeted AHI cases: New York City STD clinics, 2009–2011

Characteristics	Universal screening (June 1, 2009–May 31, 2010) N (percent)	Targeted screening (June 1, 2010–May 31, 2011) N (percent)
Total specimens screened for AHI	65,220	8,898
Total AHI cases detected	40 (0.06)	35 (0.04)
Gender		
Female	1 (3)	0 (0)
Male	38 (95)	35 (100)
Transgender (male to female)	1 (3)	0 (0)
Median age (in years)	26	26
Men who have sex with men	32 (80)	35 (100)
Race/ethnicity		
Non-Hispanic black	16 (40)	14 (40)
Hispanic	13 (33)	8 (23)
Non-Hispanic Asian	0 (0)	3 (9)
Non-Hispanic white	8 (20)	10 (29)
Other/unknown	3 (8)	0 (0)
Previous STD diagnosis ^a	14 (35)	23 (66)

^aPrevious STD includes clinical and self-reported diagnosis of one or more of the following: syphilis, chlamydia, gonorrhea, nongonococcal urethritis, herpes, and genital warts.

AHI = acute human immunodeficiency virus infection

STD = sexually transmitted disease

before their STD clinic visit: (1) sex with another male (for males only), (2) sex with a person with HIV infection, (3) sex with an MSM (for females only), (4) sex with a person who uses injection drugs, (5) exchange of sex for drugs or money, (6) shared injection drug equipment, or (7) was a victim of sexual assault. We encouraged anyone who reported risk behavior within the previous 10 days to return for repeat screening in the following two weeks. Those who reported risk behavior within the previous 72 hours were evaluated and referred for nPEP where indicated.

Under the targeted screening protocol from June 2010 through May 2011, we screened 8,898 specimens using pNAAT, resulting in 35 cases (39.3 cases/10,000 specimens), all of whom were MSM. The median age of case patients was 26 years (range: 19 to 49, data not shown); the majority of patients (71%) were people of color, and 66% (23/35) were previously diagnosed with an STD (Table 1). As a result of targeting efforts, the number of tests needed to find one AHI case was reduced from 1,630 to 254. AHI detection rates among those tested during universal screening vs. targeted screening rose from 0.06% to 0.40% (data not shown). Table 2 presents calculated annual case finding results and costs. The average cost per case identified dropped more than sixfold, from \$29,088 to \$4,535. When all testing was transitioned to the local PHL (as a result of the 85% decrease in test volume), turnaround time of specimen collection to receipt of results dropped from 16 days to 10 days (data not shown).

Among the 7,380 individuals tested only during the targeted screening period, there were no significant differences between AHI-positive and AHI-negative people with regard to male sex (100% vs. 92%, $p=0.23$) and age (mean age of 28 vs. 27 years, $p=0.25$). However, AHI case patients were significantly more likely than AHI-negative cases to report sex with a man (100% vs. 81%, $p=0.01$), be non-Hispanic black (40% vs. 21%, $p=0.008$), and have a prior STD diagnosis made in the STD clinic (60% vs. 24%, $p<0.001$) (data not shown).

DISCUSSION

With its high level of viremia and nonspecific clinical symptoms, AHI contributes disproportionately to ongoing HIV transmission.⁹ Testing for AHI using pNAAT significantly increases the case detection rate compared with using antibody tests alone,⁶ facilitating early treatment initiation and potentially reducing HIV transmission. It has been shown that simple behavior-based criteria can guide targeting with pNAAT¹⁰ and that such targeting, particularly for MSM, can improve its yield.¹¹ Indeed, we found that our targeted screening effectively identified a comparable number of AHI cases as screening all clinic patients seeking HIV testing, but at a fraction of the cost. While a higher cost per identified case of AHI may be considered acceptable given the potential to interrupt onward transmission of HIV, it may be difficult to absorb these high costs during a time of reduced economic resources. Cost savings associated with conducting 85% fewer tests may be diverted to other diagnostic and prevention services aimed at improving the sexual health of urban clinic patients.

AHI case patients tended to be young, with 60% younger than 30 years of age. We observed a higher percentage of STD history among patients testing positive for AHI in the targeted group than in the universal group (66% vs. 35%), which may be expected as a result of the targeted group all having been identified as higher risk. However, we also found that among the targeted group, patients with AHI had significantly higher rates of STD than those who tested negative (60% vs. 40%, $p<0.001$). This finding suggests a possible association between STD history and HIV seroconversion and may be considered in targeted screening in addition to reported behavioral risk factors. Patients who tested AHI positive (i.e., case patients) were more likely than those who tested AHI negative to be non-Hispanic black. Although HIV incidence in the U.S. has been relatively stable, it has been increasing

Table 2. Annualized cost savings^a of targeted AHI screening, based on data from New York City STD clinics, 2009–2011

Program indicators	Universal screening	Targeted screening
Number of pooled AHI specimens per month	5,435	742
Annual cost of pooled AHI screening	\$1,163,525	\$158,740
Annual case yield	40	35
Average cost per AHI case identified	\$29,088	\$4,535

^aAll amounts given in U.S. dollars.

AHI = acute human immunodeficiency virus infection

STD = sexually transmitted disease

among young MSM, particularly black MSM, a group captured by our targeted screening. There was an estimated 48% increase in new HIV infections (12% annually) in young, black MSM nationally from 2006 to 2009.¹² In NYC, new HIV case rates among MSM aged 18–29 years (5,956/100,000 population) and black MSM (8,781/100,000 population) were found to be more than twice and three times the overall MSM rate, respectively.¹³ The disproportionate incidence of HIV among black MSM is due in large part to the high prevalence of HIV among their sexual partners (e.g., other black MSM)¹⁴ and a high burden of other STDs that facilitate HIV transmission;^{15,16} prevalence among black MSM is estimated to be 28%, almost double the prevalence among white MSM. High rates of HIV infection for black MSM are also partly attributable to undetected or late diagnosis of HIV infection; in 2008, 59% of HIV-infected black MSM were unaware that they were infected.¹⁷

Ensuring access to and encouraging HIV testing among young MSM of color to detect infections in their earliest stages is crucial to reduce disparities. To this end, the NYC DOHMH and partnering agencies have successfully implemented large-scale initiatives to increase voluntary HIV testing so that every resident aged 13–64 years in two boroughs highly affected by the HIV epidemic (i.e., Brooklyn and the Bronx) learns his or her HIV status and has access to quality care and prevention.^{18,19} Whether or not health departments and other clinics conducting HIV testing use pNAAT for screening, RNA testing (or referral for it) should be available to diagnose primary infections in the highest-risk individuals, particularly those presenting with symptoms.

Although we encourage adding targeted screening in high-risk populations, this strategy may best be implemented in clinical sites, where large-volume laboratory testing is available and phlebotomy services are already in place to further minimize costs associated with pNAAT. Implementing risk-based AHI screening increased HIV detection in NYC STD clinics; however, this method may not be cost-effective for other clinic sites. Hutchinson et al. found that NAAT screening was cost-effective only in sites where HIV incidence was high (e.g., community clinics that primarily serve MSM) and that municipal STD clinics must see an AHI positivity rate of approximately 0.4% for pNAAT screening to be considered cost-effective.²⁰ While this threshold is met at the NYC STD clinics (AHI positivity was 0.4% in 2011 and 2012), other sites may need to consider alternatives if HIV incidence and AHI positivity rates make this practice cost-prohibitive. Fourth-generation tests, which detect HIV infection before rapid tests but

are less sensitive than NAAT, could also be used as an alternative in settings where NAAT is not feasible.^{21,22}

While NAAT decreases the time period for HIV detection, it does not eliminate it; therefore, it may miss very early seroconversions. In cases of suspected acute infections that fall within the undetectable period, we provide patients with risk-reduction counseling and advise them to retest, either by NAAT or enzyme immunoassay. Finally, patients may engage in riskier behaviors after receiving a negative rapid result when they may in fact be in the acute phase of HIV infection. The potential impact of receiving a negative HIV result on risk behavior underscores the importance of limiting the turnaround time between receipt of AHI result and providing result to the patient and providing risk-reduction messages during posttest counseling sessions, when negative rapid test results are provided and NAAT results are still outstanding.

Juusola et al. developed a model of HIV transmission to assess the cost-effectiveness of testing strategies, including increasing HIV antibody testing among MSM, symptom-based viral load testing, and adding viral load testing to annual antibody screening.²³ The team also used initiation of antiretroviral therapy for chronically HIV-infected people with cluster of differentiation 4 count ≤ 350 cells/microliter to calculate costs and quality-adjusted life years for each strategy. They found that adding symptom-based viral load testing to antibody screening yielded greater health benefits and was cost-effective although substantially more expensive than antibody testing alone. Prior to 2011, MSM who presented to NYC STD clinics with symptoms were tested for AHI using individual NAAT instead of pNAAT. However, we found that symptoms alone were not specific enough to predict AHI, and individual NAATs were significantly more costly. Of 204 specimens tested from 2009 to May 2011, one patient tested positive for AHI. As a result of the low yield and high cost of symptom-based testing, we modified the individual NAAT protocol to include patients presenting with current or recent viremia and known exposure to HIV to be excluded from the pool.

Limitations

There were a few limitations to our approach and issues to consider in the routine implementation of AHI screening. While targeted screening contains costs, it also runs the risk of missing cases that do not fall into or openly identify as one of the designated risk categories. During universal screening, we identified five of 40 AHI cases for whom risk category was unknown. As the targeted screening criteria we developed excluded those with unknown risk, it can miss up to 13% of

HIV cases in the acute stage. Our cost estimates did not include personnel services; however, we have no reason to believe that personnel costs associated with targeted screening would differ from those incurred during universal screening.

CONCLUSIONS

Using a data-driven approach, we were able to cut the cost per AHI case identified by 85%. Such an approach may make screening more feasible and affordable in settings with patients at high risk of newly acquired HIV, such as HIV testing and counseling sites, STD clinics, and jails. Prevention strategies aimed at AHI patients can have a great impact on the epidemic, but only if measures are in place to ensure prompt and successful delivery of services. Such measures include limiting turnaround time from specimen collection to notification, patient education on AHI symptoms and transmission related to high viremia, and intensive risk-reduction counseling for those suspected of AHI after specimen collection but before return of results. Furthermore, for AHI detection to result in effective treatment and prevention opportunities, we must ensure linkage to care for newly diagnosed patients who, irrespective of immune status (cluster of differentiation 4 count), are poised to benefit from immediate initiation of antiretroviral therapy;³ comprehensive partner services, including the offer of postexposure prophylaxis to recent partners; and treatment adherence and viral load suppression in all infected people to minimize the onward transmission of HIV.^{4,24}

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