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Evaluation of nucleic acid amplification testing (NAAT) in the early identification of HIV in high-risk persons in Fulton County, Georgia

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Abstract

Evaluation of nucleic acid amplification testing (NAAT) in the early identification of HIV in high-risk persons in Fulton County, Georgia

By Neil Gupta, MD

Background: Acute HIV infection (AHI) is characterized by rapid viral replication and lack of detectable antibodies in the early stages of infection. Because standard testing relies on antibody detection, failure to detect AHI when individuals are highly contagious is a missed opportunity for prevention. In 2012, the Fulton County Department of Health & Wellness (FCDHW) received funds to implement nucleic acid amplification testing (NAAT) to detect AHI among persons from high-morbidity zip codes in Metropolitan Atlanta. This report evaluates the outcomes and cost-effectiveness of the program after 12 months of implementation.

Methods: AHI was defined as a positive NAAT test in a patient with a negative HIV antibody test between August 2012 and January 2014. Process measures for testing, laboratory, and outreach were reviewed. A cost analysis was performed from the FCDHW program perspective to evaluate the incremental costs of conducting NAAT after rapid antibody testing. Using estimates from previous models, an AHI positivity rate $\geq 0.1\%$ and program cost $\leq$\$24,876 per new HIV infection were set as thresholds for cost-effectiveness.

Results: Eighty-six new HIV infections were detected by antibody testing alone. Among 4,686 NAAT tests conducted, 3 cases of AHI were identified (AHI positivity rate 0.06% [95% CI: 0.01 – 0.19]). The median turnaround time for NAAT results was 22 (15-35) days. No case successfully initiated antiretroviral therapy. The rate of AHI in men who have sex with men (MSM) was 0.69% [95% CI: 0.08–2.49], which was significantly higher than the overall AHI positivity rate ($p=0.015$). The estimated program cost per additional HIV infection identified by NAAT was \$70,600.

Conclusions: The use of NAAT among individuals from high-morbidity zip codes improved HIV case identification by 3.5%; however, strong evidence for cost-effectiveness is lacking. Based on these data, future efforts should consider targeting NAAT to those with behaviors at highest risk for exposure to HIV (e.g., MSM), rather than targeting specific geographic areas. In addition, decreasing turnaround time for laboratory results and improving outreach to individuals with AHI will be critical in order to realize the full potential benefits of implementing NAAT in this setting.

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BACKGROUND

Human immunodeficiency virus (HIV) is a single-stranded RNA virus that compromises an individual's immune system by infecting host CD4 helper T-lymphocytes, cells critical in mounting an appropriate immune response to specific pathogens. The virus is believed to have been transmitted to humans from non-human primates in Africa, possibly as far back as the 19th century, and later spread to other parts of the world through global travel. Since the early 1980s, when case reports of rare illnesses associated with immune deficiency began to surface (1, 2), much has been learned about the epidemiology of HIV disease and the natural history of the virus.

Epidemiology of HIV disease

There were an estimated 47,500 new HIV infections in the United States in 2010 (3). Although incidence rates have been relatively stable over recent years, certain groups continue to be disproportionately affected. New HIV infections among black women decreased by over 21% from 2008 to 2010; however, rates among men who have sex with men (MSM) aged 13-24 increased by approximately the same amount over this time period (3). Young black MSM represent the largest number of new HIV infections compared to any other subgroup by race, age, sex, and risk-behavior (3). Several factors have been hypothesized for this increase, including greater risk of sexual exposure to HIV within a high-prevalence group, lack of awareness of HIV status, stigma and homophobia, and socioeconomic barriers to testing and care.

Among the United States and 6 territories, Georgia had the 6th highest rate of HIV infections and 2nd highest rate of AIDS diagnoses among adults and adolescents in 2011 (4). In addition, Metropolitan Atlanta ranked 8th in diagnoses of HIV infection among metropolitan statistical areas studied in 2011 (4). Fulton County, located within metropolitan Atlanta, had the highest prevalence of HIV infection in the state of Georgia, with a crude rate of 1,489 HIV infections and 844 AIDS diagnoses per 100,000 population in 2012 (5). Among these new HIV infections, 55% occurred among blacks and 63% occurred among MSM (5).

Laboratory testing for HIV

The most common way to detect HIV is through commercially-available assays that detect antibodies to HIV in the serum. Newer methodologies have also been developed that allow detection of antibodies from other specimens, such as the urine or saliva (6, 7). Moreover, improvements in rapid test technology allowed for highly sensitive and specific tests to be readily available during the clinical encounter (8), which can provide individuals from difficult-to-reach populations test results within 30 minutes. As newer technologies improved over the years, these assays were commonly categorized into four successive generations, each generation demonstrating improved capacity to detect HIV earlier in the infection course.

Although older generation assays are sensitive in diagnosing HIV several weeks after infection, other direct methodologies must be used in the early stages of infection before an individual begins producing HIV-specific antibodies. Nucleic acid amplification testing (NAAT) is one such technology that can directly detect HIV RNA

as early as 11 days after infection with the virus (9). In contrast, second-generation rapid antibody tests may not be able to detect HIV until approximately 26 days later (10). Pooling specimens of HIV RNA for NAAT testing is a cost-saving method to screen large groups of individuals for early HIV infection (11). Using this technology, the sera of multiple individuals are combined into a single pool and tested for HIV viral RNA. If a pool is positive, it is subsequently subdivided into smaller pools until the individual HIV RNA-positive specimen(s) is identified. Studies have demonstrated that incorporating pooled NAAT to standard antibody testing algorithms can improve detection of HIV (12-16). However, the yield and overall cost-effectiveness of NAAT screening is optimal only when implemented in settings with high HIV incidence (12).

Stages of HIV disease

Acute HIV infection (AHI) is the first stage of HIV disease characterized by rapid viral replication and lack of detectable antibodies, commonly referred to as the 'window period.' During this period, individuals may complain of flu-like symptoms, such as fever, night sweats, fatigue, and joint pain; however, some individuals may be asymptomatic. Though the clinical course varies, evidence suggests that severe symptoms may be associated with a more rapid progression of the HIV clinical course (17) and the course appears to be mediated more by host factors than viral characteristics. The duration of AHI varies from days to weeks, with the average course lasting approximately 14 days.

Though it is difficult to determine to what degree AHI contributes to HIV transmission (18-20), it has been estimated that transmission from an infected individual

to a previously uninfected individual when the former is in the acute phase accounts for as many as 11.4% of all new sexually-acquired HIV infections (20); the proportion among MSM is estimated to be as high as 22–29% (21). The potential for transmission during AHI is amplified by high plasma viral loads (on the order of 100 times higher than during non-acute HIV infection (22, 23)) and the fact that individuals are often unaware of their HIV status. Because standard testing for HIV relies on antibody detection, failure to detect persons with AHI during the window period is a missed opportunity for prevention. Detection of AHI can reduce HIV transmission by facilitating access to care and early initiation of antiretroviral therapy. Moreover, there is evidence that diagnosing persons with AHI can reduce transmission-risk behaviors (24).

The stage following AHI is often referred to as chronic HIV infection or clinical latency. During this period, a host's immune system generally reaches equilibrium with viral replication, causing a decline in the viral load when compared to the acute phase. Although individuals may be asymptomatic during this period, they continue to have active viral replication and are still able to transmit the virus. Although some may remain clinically asymptomatic for over a decade, individuals progress at various rates; evidence suggests that high levels of RNA may be associated with more rapid progression of disease (25).

Acquired Immune Deficiency Syndrome (AIDS) is the stage of disease characterized by a severely compromised immune system and susceptibility to multiple opportunistic infections. The Centers for Disease Control and Prevention (CDC) classifies AIDS by a CD4 count <200 cells/ mm^3 or an individual with HIV infection with an AIDS-defining condition (26). Survival rates vary based on the AIDS-defining

event; the estimated median survival times in one study ranged anywhere from 3 to 51 months depending on the type of illness and number of AIDS-defining conditions reported (27).

Overview of Fulton County Project EDDI

The Fulton County Department of Health & Wellness (FCDHW) is the largest county health department in Georgia, covering a 535 square mile area and providing public health services to approximately 88% of the city of Atlanta. To address the burden of HIV infections in the county, FCDHW received approximately $1.4 million from CDC to conduct a demonstration project over 3 years. The program — Project EDDI (Enhanced Detection to Decrease HIV Infection) — was designed to improve detection of undiagnosed HIV among African American adults and men having sex with men (MSM) in high-morbidity areas.

The objectives of the program were to identify HIV-infected persons early in order to initiate antiretroviral therapy, reduce transmission risk behaviors, and test partners in networks where active transmission is ongoing. Using 2009 HIV surveillance data, 18 zip codes with the highest HIV prevalence were identified as target areas (Table 1). Under the Project EDDI protocol, pooled NAAT testing was added to second generation rapid antibody testing for all persons from high-morbidity zip codes seeking sexually transmitted diseases (STD) services at the Aldredge clinic in downtown Atlanta. This report evaluates the early outcomes and cost-effectiveness of the program after approximately 12 months of implementation.

METHODS

Program Evaluation: Stakeholders of the NAAT program (e.g., staff involved in program operations, health department leadership, funding agencies) were identified and engaged in the program evaluation design. Front-line program staff members were interviewed in detail about the process for intake, registration, phlebotomy, lab processing/ shipping, partner services, and linkage to care and were also asked about challenges with program implementation.

HIV Testing: All clients seeking STD services at the FCDHW Aldredge clinic were offered opt-out HIV testing. After obtaining consent, a phlebotomist obtained blood and interviewed clients about HIV risk factors. HIV antibody tests were processed on-site at the laboratory using the OraQuick Advance Rapid HIV-1/2 Antibody Test (OraQuick; OraSure Technologies). For logistical purposes, the eligibility criteria for NAAT testing were revised during the demonstration period based on the date of testing and the client's zip code (Table 1). Specimens from clients with a negative rapid antibody test who met the date and location eligibility criteria for NAAT testing were shipped to a contracting laboratory (LabCorp, Laboratory Corporation of America; Burlington, NC) for pooled NAAT testing. All clients with a positive NAAT test and negative rapid antibody test were given a presumptive diagnosis of AHI.

Partner Services and Linkage to Care: All clients diagnosed with HIV through NAAT were contacted by a trained disease investigator specialist (DIS) from FCDHW; an initial

interview was conducted at the clinic or at the client's home. Clients were interviewed about demographic characteristics, HIV risk factors, and sexual partners. They also received education about HIV and completed a risk reduction plan. During the initial interview session, the client's blood was drawn for repeat HIV antibody testing and confirmatory testing. Following the interview, all named sexual partners were contacted by a DIS and tested for HIV. Clients with confirmed HIV diagnoses met with a linkage coordinator at FCDHW to complete enrollment paperwork for clinical care, obtain baseline clinical laboratory tests (including CD4, and HIV viral load), and schedule an initial visit with a medical provider. Partners newly diagnosed with HIV, or previously diagnosed with HIV and not in care, also met with a linkage coordinator to complete enrollment paperwork for clinical services.

Program Cost Analysis: The incremental costs of NAAT (i.e., costs in excess of conducting rapid antibody testing alone) were estimated through staff interviews and review of testing records. Only staff salaries, travel, and laboratory costs specific to NAAT testing, and HIV infections identified through NAAT, were included. Salaries were calculated with the assumption that staffing positions were filled during the entire demonstration period. Expenses for obtaining initial blood specimens (e.g., phlebotomy staff, needles, and biohazard containers) were not included as these specimens would be required for rapid antibody testing alone in the absence of NAAT. Costs to conduct NAAT were evaluated from the FCDHW program perspective; actual contractual costs with LabCorp were included rather than the costs of reagents and equipment to conduct NAAT. DIS travel and labor costs were evaluated based on the number of HIV infections

identified via NAAT and the number of corresponding partners identified. As the primary objective of the demonstration project was to evaluate the effectiveness of NAAT in detecting AHI among clients from high-morbidity risk zip codes in Fulton County, only those clients from high-morbidity zip codes (Table 1) were included in the cost analysis.

The threshold for cost-effectiveness was adapted from a previous analysis by Hutchinson, et al. evaluating the use of pooled NAAT after rapid antibody testing in three public health settings (12). Using the same assumptions in the calculation of cost per quality-adjusted life year (QALY) gained from HIV infections averted because of pooled NAAT testing (12), an acute HIV positivity rate >0.1% was used as a threshold for cost-effectiveness in this analysis. Using a similar model to Hutchinson and colleagues, Farnham, et al. found that testing program costs ≤ $22,909 (in 2009 dollars) per new HIV diagnosis were found to be cost-effective (28); a threshold of ≤ $24,876 (adjusted to 2013 dollars with a 8.6% cumulative rate of inflation) was used as a measure of cost-effectiveness in this analysis.

The evaluation sought to answer the following questions:

Primary evaluation questions:

Among persons from high-morbidity zip codes in Fulton County seeking STD services:

1. Does the use of pooled NAAT identify acute HIV infection in ≥ 0.1% of those with a negative rapid HIV antibody test?
2. Are the incremental program costs of pooled NAAT ≤ $24,876 for each additional HIV infection identified by NAAT, among those with a negative rapid HIV antibody test?

Secondary evaluation questions:

3. Among persons of high-morbidity zip codes in Fulton County seeking STD services, is the overall AHI rate different than the rate across specific HIV risk categories (male-to-male-sexual contact, injection drug use [IDU], high-risk heterosexual contact) ?

4. Among persons eligible for NAAT, what proportion
    - Receives NAAT testing for acute HIV infection?
    - Receives pretest counseling?

5. Among persons diagnosed with acute HIV infection, what proportion
    - Receive their HIV test result within 15 days?
    - Receive education to reduce transmission (complete risk reduction plans)?
    - Are referred to comprehensive services?
    - Are successfully linked to clinical care and attend their first medical appointment within 90 days?
    - Initiate treatment?
    - Receive partner services?

6. Among partners of patients diagnosed with acute HIV infection, what proportion
    - Are contacted?
    - Receive enhanced HIV testing and counseling?
    - Have a positive HIV test result?

Because the primary objective of the demonstration project was to determine the effectiveness of NAAT in identifying AHI among persons from high-morbidity zip codes in Fulton County, only those clients residing in one of the 18 high-morbidity zip codes (Table 1) were included in the analysis of evaluation questions #1-4. However, because this analysis also provided an opportunity to evaluate process measures for general services provided by the health department (e.g., linkage to care, partner services) irrespective of how or from where clients were diagnosed, all clients diagnosed with AHI through this program, regardless of zip code, were included in the analysis of evaluation questions #5-6.

The 95% confidence intervals for AHI positivity rates were obtained using exact methods, treating AHI as a Poisson parameter. A hierarchical variable was used to create mutually exclusive risk categories (MSM, IDU, high-risk heterosexual contact, other risk) based on risk of exposure to HIV (Table 2). Statistical associations comparing the overall AHI positivity rate to the AHI rate in each risk category were calculated using exact methods assuming a Poisson distribution (alpha=0.05). The expected number of AHIs in each category was calculated by multiplying the overall AHI rate by the number of persons in each risk category. Demographic data, HIV risk factors, and testing information were obtained from EvaluationWeb (Luther Consulting, LLC; Carmel, IN), a CDC-leased program that collects data on persons tested for HIV for use in program evaluation. Data for the period August 1, 2012 through January 22, 2014 were used for this analysis. Clinical and laboratory information were obtained from Fulton County's electronic record system, M&M (Mitchell and McCormick; Stone Mountain, GA) and STD MIS (STD Management Information System; CDC; Atlanta, GA). Partner services

and linkage information was obtained through interviews with Fulton County DIS (Table 2). All statistical analysis was performed using SAS software, version 9.3 (SAS Institute Inc., Cary, NC). The Emory IRB was consulted and determined that this project does not require IRB review because it does not meet the definition of "research" with "human subjects" as set forth in Emory policies and procedures.

RESULTS

Program Implementation:

Staff were interviewed in detail about the resources, activities, outputs, and outcomes of the program (Appendix A: Logic Model) and also reported several challenges with program implementation. Although the demonstration period began in August 2012, the timeline for distribution of funds from CDC could not be aligned with the timeline and local policies for hiring health department staff. Therefore, all program staff positions could not be filled during the initial phases of program implementation. During this time (Period 1), NAAT tests were inadvertently conducted on clients residing outside the target zip codes. Also, because of competing priorities with concurrent HIV testing programs, the health department staff was not able to continue daily NAAT testing throughout the duration of the demonstration period; during Period 3, NAAT tests were conducted on Wednesdays only (Table 1).

Staff also noted some challenges with the contracting laboratory. They reported that although specimens were being shipped to the contracting laboratory, actual NAAT testing was sub-contracted to another outside laboratory in California. Specific protocols for NAAT testing would not be disclosed to health department staff and although specimens were reportedly tested using pooled NAAT technology, specimens were not being charged as would generally be expected for this service. Rather than two rates for testing (i.e., a flat cost per NAAT specimen tested, plus an additional fee to deconstruct pools with a reactive test), only a flat fee of $12/ specimen was charged to the health department. Ongoing discussions and negotiations with the laboratory caused a suspension of NAAT testing between November 9, 2012 and May 6, 2013.

HIV testing:

There were 5,107 HIV testing events in clients from high-morbidity zip codes at the FCDHW STD clinic during the entire demonstration period; all clients received pre-test counseling. Among these, 196 (3.8%) previously diagnosed HIV infections and 86 (1.7%) new HIV infections were confirmed or identified by antibody testing (Table 3). Over 97% of eligible clients received a NAAT test. Of the 4,686 NAAT tests conducted, 3 were positive (AHI positivity rate: 0.06% [0.01 – 0.19]). Approximately 500 additional NAAT tests were conducted among clients outside the target high-morbidity zip codes; though based on small numbers of events, the rate of new HIV infections was relatively similar to that among the target population (Table 3). However, one additional AHI was detected by NAAT during Period 1 in a client living outside the target zip code areas.

Approximately 50% of clients receiving NAAT were female, 96% were black, and over half were less than 30 years of age (Table 4). Using a hierarchical variable to characterize HIV risk factors based on the most likely risk of exposure to HIV, over 85% of clients were classified as having high-risk heterosexual contact; whereas, approximately 290 (6.2%) clients reported male-to-male sexual contact (Table 4). The rate of AHI in MSM was 0.69% [95% CI: 0.08–2.49], which was significantly higher than the overall AHI positivity rate (p=0.015) (Table 5).

Follow-up of AHI cases and partner services

All four AHI cases (from all zip codes) were included in the evaluation of general process measures (specifically, follow-up of newly identified HIV-infected persons and partner services). Three (75%) AHI cases were male; all reported male-to-male sexual

contact (Table 6). Two (50%) cases reported injection drug use and all reported at least one high-risk sexual risk factor for HIV (such as sex without condoms, sex while intoxicated, or sex in exchange for money/ drugs).

The median duration between the time of NAAT testing and time the FCDHW laboratory received the results was 22 (15-35) days (Table 6). In one case, the contracting laboratory reported it had telephoned the health department with positive NAAT results but was unable to reach a staff member; the health department only became aware of the positive NAAT result three weeks later when performing a routine follow-up of NAAT tests from the prior month.

All four AHI cases were contacted by a DIS; however, one client refused to participate in the interview despite numerous attempts to engage them in care. The median duration between the time of NAAT testing and the initial DIS contact/ interview date was 28 (22-53) days; thus, no client received their HIV test result within the 15-day program performance target established by the health department. Three cases received appointments for medical care; however, noncompliance with medical appointments was common. Two cases attended their initial appointments but failed to follow-up with a medical provider, and one case did not attend a single clinic appointment. No case successfully initiated antiretroviral therapy. AHI case-patients named 7 sexual partners in the prior 12 months; 3 of these were out of jurisdiction and referred to their respective health departments for follow-up and testing. Among the 4 partners who could be named and followed-up in Fulton County, all 4 (100%) were contacted and interviewed by a DIS and all were previously known to have HIV (Table 6).

Program Cost Analysis:

The estimated cost to conduct NAAT among persons with a negative HIV rapid antibody test from high-morbidity zip codes during the demonstration period was $211,700. The majority of expenses were salaries and benefits ($147,000) and contractual costs with an outside laboratory to perform NAAT ($56,200) (Appendix B). Expenses for DIS salaries and related travel costs were estimated to be low (~ $600) as these are directly proportional to the number of AHI cases identified. Overall, the incremental program cost for conducting NAAT per additional HIV infection identified by NAAT was approximately $70,600 (Appendix B).

DISCUSSION

The use of NAAT technology among persons from high-morbidity zip codes in Fulton County identified 3 cases of acute HIV among 4,686 clients tested at the FCDHW STD clinic. In addition to the 86 new HIV infections identified by rapid antibody testing, use of NAAT testing increased HIV case identification by 3.5%. Total program costs were estimated at $70,600 per additional HIV infection identified by NAAT; this was substantially higher than the cost-effective threshold of ≤$24,876 used for this analysis. Similarly, the AHI positivity rate in this setting was 0.06% (0.01% – 0.19%), which was lower than the ≥0.1% threshold for cost-effectiveness; however, more data are necessary to improve the precision of this estimate. Rates of AHI positivity in other settings, including municipal STD clinics, have ranged from 0.02% to 0.2% (13-15).

The 0.1% cost-effectiveness threshold used in this analysis is likely a conservative estimate. As illustrated by Hutchinson, et al. (12), use of NAAT after rapid antibody testing was determined to be cost-saving when AHI positivity rates were ≥ 0.1%; however, even when AHI positive rates fell below 0.06%, the estimated costs were less than $100,000 per QALY gained, which fell into generally acceptable cost-effectiveness ranges (29, 30). Moreover, this model did not take into consideration the benefits of immediate ARV therapy for persons with AHI as guidelines at the time did not recommend ARV treatment unless the CD4 count was ≤ 350 cells/μL. Current guidelines recommend antiretroviral therapy for all persons with HIV, regardless of CD4 count (31); these changes in clinical practice could translate to more QALYs gained, and additional HIV infections averted, through earlier ARV therapy for clients identified by NAAT.

Theoretical models for cost-effectiveness, however, cannot reliably predict the value of an HIV testing program without also taking into consideration evidence from the field. Several process measures identified in this evaluation highlight some of the challenges in gaining maximum benefit from NAAT testing in this population, including delays in receiving laboratory results and challenges in initiating newly identified cases on antiretroviral therapy (Table 6). The assumptions of the cost-effectiveness model (12) estimated total transmissions averted, in part, as a function of the number of days an individual with AHI was aware of their HIV status while in the acute phase. The assumption behind this model is that a person may change their sexual risk factors during a time when the viral load is high and there is higher probability for transmission.

In this evaluation, however, the median turnaround time for a positive NAAT result was 22 days (Table 6). If, based on previous estimates (9, 10), we assume that a NAAT test and rapid HIV antibody test are detectable approximately 11 days and 37 days after infection, respectively, the average asymptomatic person with AHI might present for testing at the mid-point of this period (~ day 24). If we account for the lag in receiving NAAT results, then the health department might not be aware of a person with AHI until ~46 days after infection. Even a client presenting when HIV is first detectable by NAAT might not gain maximum benefit from AHI screening — the median duration between the NAAT test and DIS interview, when the client undergoes risk reduction counseling and begins the linkage to care process, was 28 (22–53) days. This suggests that AHI cases may not have been reached until after the acute phase of rapid viral replication had passed (32), limiting potential benefits from reducing high-risk behaviors during this period. However, the use of NAAT may still contribute to reductions in HIV

transmission during the non-acute period, as it decreases the length of time individuals were unaware of their HIV status had they not otherwise been diagnosed through NAAT; current recommendations for HIV testing in adults and adolescents recommend that persons at high risk for HIV be tested at least annually (33).

Lack of strong evidence for cost-effectiveness in this setting may be reflective of the target population for testing. Several studies illustrate that NAAT is most cost-effective when used in high incidence settings (12, 34). Although the goal of the demonstration project was to target a high-incidence population by focusing on zip codes in Fulton County where the morbidity of HIV is known to be highest, preliminary data from this program show there were no substantial differences between HIV positivity rates for both newly established and acute HIV infections, when comparing clients from target zip codes to all zip codes (Table 3). However, these comparisons are based on a relatively small number of testing events.

In contrast to targeting by geographic location, stratifying by HIV behavioral risk factors might identify sub-groups with higher HIV incidence. Among adults and adolescents newly infected with HIV in Georgia in 2012, 49% were MSM, whereas 17% were heterosexual (5). In contrast, among clients tested with NAAT in the FCDHW STD clinic, >85% were classified as heterosexual, whereas only 6% were MSM (Table 4). In this evaluation, the prevalence of AHI was significantly higher in MSM compared to the overall AHI prevalence ($p=0.015$). The small number of AHI cases, however, limits our ability to asses for effect modification or confounding using multivariate analysis.

In order to improve the yield of NAAT and maximize cost-effectiveness in the future, further risk stratification and restriction of NAAT to the highest risk groups

should be considered. MSM can be easily screened for during the HIV test pre-counseling process using the current testing form (Appendix C). If NAAT were restricted to this risk category (n=290), the AHI positivity rate of 0.69% (0.08–2.49) would be substantially higher than the 0.1% threshold for cost-effectiveness used in this analysis. Moreover, because this represents only 6% of the total NAAT testing volume, estimated total program costs would be substantially reduced by limiting testing to this risk category. It is important to note, however, that although this strategy would result in more favorable cost-effectiveness parameters, it would have failed to detect one AHI case in a heterosexual woman.

Because NAAT is only used for those with a negative screening antibody test, the yield of NAAT will ultimately depend on the type of assay used for the initial screening (15). During the demonstration period, the FCDHW laboratory was using Oraquick (OraQuick; OraSure Technologies) — a second generation rapid antibody test that generally detects HIV ~26 days later than NAAT (10). However, CDC recently published a new HIV diagnostic algorithm using a fourth-generation HIV-1/2 immunoassay that demonstrated increased ability to detect HIV early in the infection course, including during AHI (22). If, as proposed, such protocols are to be adopted for general use and implemented at FCDHW as an initial screening assay, the overall yield and cost-effectiveness of implementing NAAT would have to be reconsidered in that setting.

This evaluation is subject to several limitations. First, because the precision of our process and outcome measures is dependent on the number of AHI cases identified, the small number of AHI cases should be taken into consideration when drawing conclusions from these estimates. Second, because phlebotomists have not received extensive training

on pre-test counseling and eliciting sexual histories, HIV risk factor information obtained from the phlebotomist at the time of testing may not accurately reflect true behaviors. Third, as stated previously, FCDHW staff faced several barriers in communicating with the contracting laboratory; thus, quality assurance of NAAT testing in the laboratory could not be assessed. Also, because the protocol for NAAT testing was occasionally revised or interrupted and staff were often asked to perform other tasks when not operating at full volume, it was difficult to assess the degree of salary support dedicated to NAAT-specific activities compared to what it might have been had the program been running in a more consistent fashion. Lastly, because only data on individual HIV testing events were collected, an evaluation based on the number of unduplicated clients served by the program could not be assessed.

SUMMARY

The use of NAAT technology among clients from high-morbidity zip codes at the FCDHW STD clinic improved HIV case identification by 3.5%; however, strong evidence for cost-effectiveness of the program is lacking. If rapid HIV antibody testing is used as an initial screening assay in the future, consideration should be given to targeting NAAT to those with behaviors at highest risk for exposure to HIV (e.g., MSM), rather than targeting specific geographic areas. In addition, decreasing turnaround time for laboratory results and improving outreach and linkage to comprehensive care for individuals with AHI will be critical in order to realize the full potential benefits of implementing NAAT in this setting.

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Table 1. Eligibility criteria for NAAT among clients at the FCDHW Aldredge STD clinic — August 2012 to January 2014

	Testing date	Day of test	Zip code
Period 1	08/01/2012 – 11/09/2012	Monday – Friday	All zip codes
Period 2	05/06/2013 – 10/11/2013[1]	Monday – Friday	Target zip codes[2]
Period 3	10/12/2013 – 01/22/2014	Wednesdays only	Target zip codes[2]

Abbreviation: FCDHW, Fulton County Dept. of Health & Wellness; NAAT, nucleic acid amplification testing; STD, sexually transmitted diseases

[1] NAAT testing was held from 11/9/2012 – 5/6/2013 during laboratory contract negotiations

[2] Target high-morbidity zip codes (30303, 30305, 30306, 30308, 30309, 30310, 30311, 30312, 30313, 30314, 30315, 30316, 30318, 30324, 30331, 30342, 30344, 30349) based on 2009 GA surveillance data

Table 2. Select variables used in evaluating a NAAT testing program at the FCDHW Aldredge STD clinic — August 2012 to January 2014

Variable	Coding	Data source	Notes
Age_range; Client_Zip_Code; Date_of_Contact; Gender; MSM; IDU; Previously_Identified_HIV_Positi; Race_ethnicity_combined; Submitted_form_id; Test_technology; Test_result	Character	EvaluationWeb[1]	Variables obtained directly from EvaluationWeb
Risk	Character	EvaluationWeb[1]	Mutually exclusive categories: ='MSM' if male reports anal sex with male = 'IDU' if reports injection drug use and non-MSM = 'high-risk heterosexual' if non-MSM, non-IDU, and reports one of the following: • sex with HIV + partner • sex with IDU • sex with MSM • sex without condom = 'other risk' if none of above
Acute	Numeric	EvaluationWeb[1]	=1 if status='new_acute'
CatC	Numeric	EvaluationWeb[1]	=1 if NAAT conducted
Date	Numeric	EvaluationWeb[1]	Date format
Eligible	Numeric	EvaluationWeb[1]	=1 if eligible time period
Period	Numeric	EvaluationWeb[1]	=1: 8/1/12 – 11/9/12 =2: 5/6/13 – 10/11/13 =3: 10/12/13 – 1/22/14 (Wed only)
Status	Numeric	EvaluationWeb[1]	Manually coded: previous, new_acute; new_estab; negative based on testing results
Zip	Numeric	EvaluationWeb[1]	=1 if high-morbidity zip code
Education		DIS Interview	
NAAT to DIS contact		DIS Interview	
Partners contacted/ tested		DIS Interview	

Abbreviation: DIS, disease investigator specialist; FCDHW, Fulton County Dept. of Health & Wellness; IDU, injection drug use; MSM, men who have sex with men; NAAT, nucleic acid amplification testing; STD, sexually transmitted diseases

[1]EvaluationWeb (Luther Consulting, LLC; Carmel, IN) version 3.0, 2/15/2013

Table 3. HIV test characteristics and results among clients at the FCDHW Aldredge STD clinic — August 2012 to January 2014

	Period 1[1] All zip[2] (n=2,442)	Period 1[1] Target zip[2] (n=1,905)	Period 2[1] Target zip[2] (n=2,908)	Period 3[1] Target zip[2] (n=294)	**Total All zip[2] (n=5,644)**	**Total Target zip[2] (n=5,107)**
Previous positives (% of total)	97 (4.0)	77 (4.0)	107 (3.7)	12 (4.1)	**216** **(3.8)**	**196** **(3.8)**
New positives (non-acute) (% of total)	50 (2.1)	36 (1.9)	48 (1.7)	2 (0.7)	**100** **(1.8)**	**86** **(1.7)**
Eligible for NAAT testing (% of total)	2295 (94.0)	1792 (94.1)	2753 (94.7)	280 (95.2)	**5328** **(94.4)**	**4825** **(94.5)**
NAAT tests conducted (% of NAAT eligible)	2228 (97.1)	1742 (97.2)	2677 (97.2)	267 (95.4)	**5172** **(97.1)**	**4686** **(97.1)**
Acute HIV infections (% of NAAT tests; 95% CI)	1 (0.04)	0 (0)	3 (0.11)	0 (0)	**4** **(0.08; 0.02-0.20)**	**3** **(0.06; 0.01 – 0.19)**

Abbreviation: FCDHW, Fulton County Dept. of Health & Wellness; NAAT, nucleic acid amplification testing STD, sexually transmitted diseases
[1]Period 1: Aug 1, 2012 – Nov 9, 2012; Period 2: May 6, 2013 – Oct 11, 2013; Period 3: Oct 16, 2013 – January 22, 2014
[2]All zip: Clients from all zip codes; Target zip: Clients from high-morbidity zip codes in Fulton County (Table 1)

Table 4. Demographics and risk factors of clients from high-morbidity zip codes receiving NAAT testing at the FCDHW Aldredge STD clinic (n=4,686) — August 2012 to January 2014

	n	(%)
Gender		
Transgender	1	(0)
Male	2325	(49.6)
Female	2357	(50.3)
Unknown[1]	3	(0.1)
Age Range (years)		
13 to 19	395	(8.4)
20 to29	2217	(47.3)
30 to 39	975	(20.8)
40 to 49	574	(12.3)
50 to 59	380	(8.1)
60 and over	145	(3.1)
Race/ Ethnicity[2]		
Hispanic	41	(0.9)
White	124	(2.7)
Black/ African American	4499	(96.0)
Asian	3	(0.1)
American Indian or Alaska Native	2	(0.0)
Native Hawaiian or Pacific Islander	5	(0.1)
Multi-race	7	(0.2)
Unknown[1]	5	(0.1)
HIV Risk Factor[3]		
MSM	290	(6.2)
IDU	4	(0.1)
High-risk heterosexual[4]	4064	(86.7)
Other risk	328	(7.0)

Abbreviation: FCDHW, Fulton County Dept. of Health & Wellness; IDU, injection drug use; MSM, men who have sex with men; NAAT, nucleic acid amplification testing; STD, sexually transmitted diseases

[1] Includes Don't know, Not asked, Declined, Invalid, or Missing

[2] Data obtained from hierarchical variable, "Race/ Ethnicity" in EvaluationWeb, version 3.0, 2/15/2013

[3] Hierarchical, mutually exclusive categories

[4] Includes sex with HIV-positive partner, sex with IDU, sex with MSM, sex without using a condom

Table 5. Prevalence of acute HIV infection, by HIV risk factor, among clients from high-morbidity zip codes receiving NAAT testing at the FCDHW Aldredge STD clinic (n=4,686) — August 2012 to January 2014

	Prevalence of AHI among those with risk factor		P[1]
	n	(%)	
MSM (n=290)	2	(0.69)	0.015
IDU, non-MSM (n=4)	0	(0)	0.997
High-risk heterosexual[2] (n=4064)	1	(0.02)	0.267
Other risk (n=328)	0	(0)	0.811

Abbreviation: FCDHW, Fulton County Dept. of Health & Wellness; IDU, injection drug use; MSM, men who have sex with men; NAAT, nucleic acid amplification testing; STD, sexually transmitted diseases

[1]Exact probability assuming a Poisson distribution, compared to overall AHI prevalence (0.06%)

[2] Includes sex with HIV-positive partner, sex with IDU, sex with MSM, sex without using a condom

Table 6. Characteristics of clients from *all* zip codes with acute HIV infection identified by NAAT testing at the FCDHW Aldredge STD clinic (n=4) — August 2012 to January 2014

	n	(%)
Demographics		
Gender		
Male	3	(75)
Female	1	(25)
Age, median years (range)	31	(20-37)
Race		
White	1	(25)
Black/ African American	3	(75)
Education		
High school diploma	2	(50)
Bachelor's degree	1	(25)
Unknown	1	(25)
Single marital status	4	(100)
HIV Risk Factor[1]		
MSM	3	(75)
IDU	0	(0)
High-risk heterosexual[2]	1	(25)
Test follow-up duration, median days (range)		
NAAT date to lab received date	22	(15-35)
Lab result received date to DIS interview date	9	(1-18)
NAAT date to DIS interview date	28	(22-53)
Partner Services Information		
Contacted by DIS for interview	4	(100)[3]
Received education to reduce transmission	3	(75)
Referred to comprehensive services	3	(75)
Attend first medical appointment within 90 days	2	(50)
Initiated ARV treatment	0	(0)
Received partner services	4	(100)
Partners named	4	
Partners contacted (% of partners named)	4	(100)
Received HIV testing (% of partners contacted)	4	(100)[4]

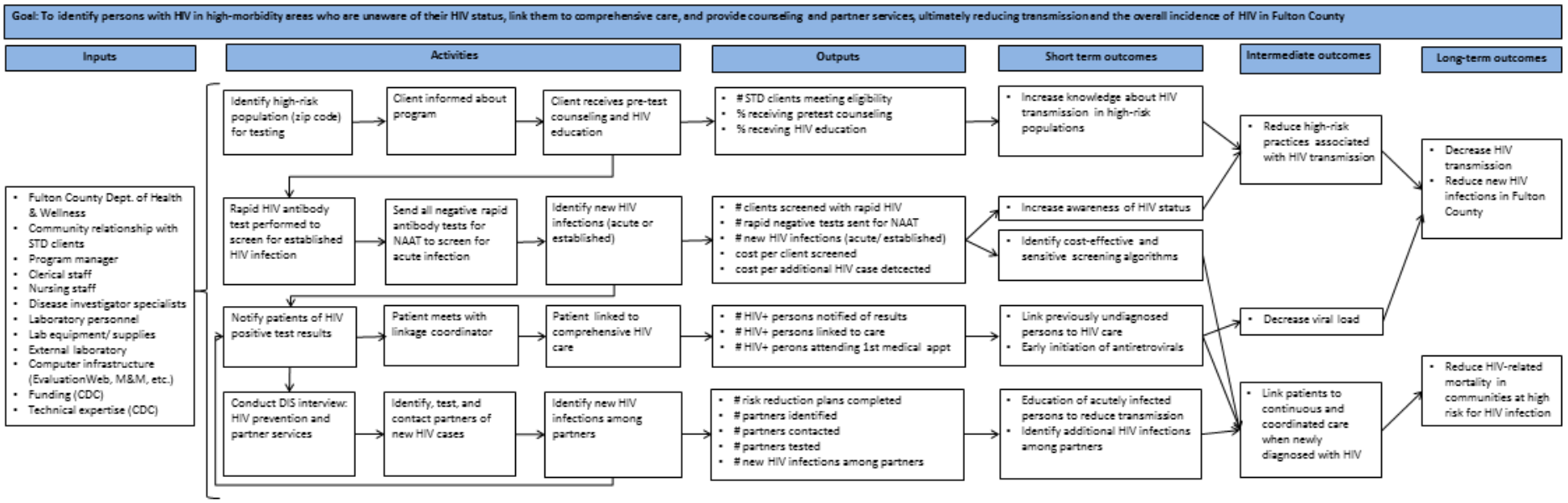
Abbreviation: DIS, disease investigator specialist; IDU, injection drug use; MSM, male-to-male sexual contact; NAAT, nucleic acid amplification testing; STD, sexually transmitted diseases

[1] Hierarchical, mutually exclusive categories

[2] Includes sex with HIV-positive partner, sex with IDU, sex with MSM, sex without using a condom

[3] One client was contacted by DIS but refused to participate partner services and linkage to care

[4] All four were previous positives


Goal: To identify persons with HIV in high-morbidity areas who are unaware of their HIV status, link them to comprehensive care, and provide counseling and partner services, ultimately reducing transmission and the overall incidence of HIV in Fulton County
Inputs
Activities
Outputs
Short term outcomes
Intermediate outcomes
Long-term outcomes
Fulton County Dept. of Health & Wellness
Community relationship with STD clients
Program manager
Clerical staff
Nursing staff
Disease investigator specialists
Laboratory personnel
Lab equipment/ supplies
External laboratory
Computer infrastructure (EvaluationWeb, M&M, etc.)
Funding (CDC)
Technical expertise (CDC)
Identify high-risk population (zip code) for testing
Client informed about program
Client receives pre-test counseling and HIV education
STD clients meeting eligibility
% receiving pretest counseling
% receving HIV education
Increase knowledge about HIV transmission in high-risk populations
Reduce high-risk practices associated with HIV transmission
Decrease HIV transmission
Reduce new HIV infections in Fulton County
Rapid HIV antibody test performed to screen for established HIV infection
Send all negative rapid antibody tests for NAAT to screen for acute infection
Identify new HIV infections (acute or established)
clients screened with rapid HIV
rapid negative tests sent for NAAT
new HIV infections (acute/ established)
cost per client screened
cost per additional HIV case detcected
Increase awareness of HIV status
Identify cost-effective and sensitive screening algorithms
Notify patients of HIV positive test results
Patient meets with linkage coordinator
Patient linked to comprehensive HIV care
HIV+ persons notified of results
HIV+ persons linked to care
HIV+ perons attending 1st medical appt
Link previously undiagnosed persons to HIV care
Early initiation of antiretrovirals
Decrease viral load
Conduct DIS interview: HIV prevention and partner services
Identify, test, and contact partners of new HIV cases
Identify new HIV infections among partners
risk reduction plans completed
partners identified
partners contacted
partners tested
new HIV infections among partners
Education of acutely infected persons to reduce transmission
Identify additional HIV infections among partners
Link patients to continuous and coordinated care when newly diagnosed with HIV
Reduce HIV-related mortality in communities at high risk for HIV infection

	Period 1 (8/1/12 – 11/9/12) All zip codes Daily testing (N=2,442)	Period 1 (8/1/12 – 11/9/12) Target zip codes Daily testing (N=1,905)
Testing information		
Number of previous positives (% of total)	97 (3.97%)	77 (4.04%)
Number of new positives (non-acute) (% of total)	50 (2.05%)	36 (1.89%)
Number eligible for NAAT testing (% of total)	2295 (93.98%)	1792 (94.07%)
Number of NAAT tests conducted (% of eligible)	2228 (97.08%)	1742 (97.21%)
Number of acute HIV infections (% of NAAT tested)	1 (0.04%)	0 (0.00%)
Number of partners named	1	0
Program costs		
Salaries		
Weeks in period	14	14
Total FTEs	2.73	2.73
Total salaries	$30,630.64	$30,482.03
Fringe benefits applied at 43% of all salaries	$13,171.17	$13,107.27
Total salaries and benefits	**$43,801.81**	**$43,589.30**
Travel		
Travel to notify/ interview HIV-positive clients	$4.00	$0.00
Travel to conduct partner services	$1.25	$0.00
Total travel	**$5.25**	**$0.00**
Laboratory		
Extra specimen tube for each NAAT ($1.55)	$3,458.97	$2,704.46
Outside lab to perform NAAT ($12.00 each)	$26,736.00	$20,904.00
Repeat HIV Ab test ($10.69 for each + NAAT)	$10.69	$0.00
Confirmatory Western blot ($52.00 each + NAAT)	$52.00	$0.00
Shipping costs included in NAAT standard rate	$0.00	$0.00
Office supplies (paper, pens, folders) : $20/ week	$280.00	$280.00
Total lab and supplies	**$30,537.66**	**$23,888.46**
Total program costs for the period	**$74,344.72**	**$67,477.75**

Abbreviation: Ab, antibody; FTE, full-time equivalent staff position; NAAT, nucleic acid amplification test

	Period 2 (5/6/13 – 10/11/13) Target zip codes Daily testing (N=2,908)	Period 3 (10/16/13 – 1/22/14) Target zip codes Wednesday testing (N=294)
Testing information		
Number of previous positives (% of total)	107 (3.68%)	12 (4.08%)
Number of new positives (non-acute) (% of total)	48 (1.65%)	2 (0.68%)
Number eligible for NAAT testing (% of total)	2753 (94.67%)	280 (95.24%)
Number of NAAT tests conducted (% of eligible)	2677 (97.24%)	267 (95.36%)
Number of acute HIV infections (% of NAAT tested)	3 (0.11%)	0 (0.00%)
Number of partners named	6	0
Program costs		
Salaries		
Weeks in period	23	14
Total FTEs	2.73	1.82
Total salaries	$50,629.59	$21,683.57
Fringe benefits applied at 43% of all salaries	$21,770.72	$9,323.93
Total salaries and benefits	**$72,400.32**	**$31,007.50**
Travel		
Travel to notify/ interview HIV-positive clients	$12.00	$0.00
Travel to conduct partner services	$7.50	$0.00
Total travel	**$19.50**	**$0.00**
Laboratory		
Extra specimen tube for each NAAT ($1.55)	$4,156.04	$414.52
Outside lab to perform NAAT ($12.00 each)	$32,124.00	$3,204.00
Repeat HIV Ab test ($10.69 for each + NAAT)	$32.07	$0.00
Confirmatory Western blot ($52.00 each + NAAT)	$156.00	$0.00
Shipping costs included in NAAT standard rate	$0.00	$0.00
Office supplies (paper, pens, folders) : $20/ week	$460.00	$280.00
Total lab and supplies	**$36,928.11**	**$3,898.52**
Total program costs for the period	**$109,347.93**	**$34,906.02**

Abbreviation: Ab, antibody; FTE, full-time equivalent staff position; NAAT, nucleic acid amplification test

	Total All zip codes (N=5,644)	Total Target zip codes (N=5,107)
Testing information		
Number of previous positives (% of total)	216 (3.83%)	196 (3.84%)
Number of new positives (non-acute) (% of total)	100 (1.77%)	86 (1.68%)
Number eligible for NAAT testing (% of total)	5328 (94.40%)	4825 (94.48%)
Number of NAAT tests conducted (% of eligible)	5172 (97.07%)	4686 (97.12%)
Number of acute HIV infections (% of NAAT tested)	4 (0.08%)	3 (0.06%)
Number of partners named	7	6
Program costs		
Salaries		
Weeks in period	51	51
Total FTEs	7.28	7.28
Total salaries	$102,943.80	$102,795.19
Fringe benefits applied at 43% of all salaries	$44,265.83	$44,201.93
Total salaries and benefits	**$147,209.63**	**$146,997.12**
Travel		
Travel to notify/ interview HIV-positive clients	$16.00	$12.00
Travel to conduct partner services	$8.75	$7.50
Total travel	**$24.75**	**$19.50**
Laboratory		
Extra specimen tube for each NAAT ($1.55)	$8,029.53	$7,275.02
Outside lab to perform NAAT ($12.00 each)	$62,064.00	$56,232.00
Repeat HIV Ab test ($10.69 for each + NAAT)	$42.76	$32.07
Confirmatory Western blot ($52.00 each + NAAT)	$208.00	$156.00
Shipping costs included in NAAT standard rate	$0.00	$0.00
Office supplies (paper, pens, folders) : $20/ week	$1,020.00	$1,020.00
Total lab and supplies	**$71,364.29**	**$64,715.09**
Total program costs for the period	**$218,598.67**	**$211,731.70**

Abbreviation: Ab, antibody; FTE, full-time equivalent staff position; NAAT, nucleic acid amplification test

Cost analysis of target zip codes:	
Total program costs	$211,731.70
Program costs per NAAT specimen tested (n=4,686)	$45.18
Program costs per new HIV infection identified by NAAT (n=3)	**$70,577.23**
Cost analysis of all zip codes:	
Total program costs	$218,598.67
Program costs per NAAT specimen tested (n=5,172)	$42.27
Program costs per new HIV infection identified by NAAT (n=4)	**$54,649.67**

CITY OF ATLANTA (Fulton County Department of Health & Wellness) — **PART ONE**

F0000020994

Program Announcement (select only one)

- ☐ PS12-1201 Category A
- ☐ PS12-1201 Category B
- ☐ PS12-1201 Category C
- ☐ Other: _____
- ☐ PS11-1113
- ☐ PS10-1003
- ☐ PS08-803
- ☐ MSM Testing Initiative

Session Date (M M D D Y Y Y Y)

Agency ID Name/Number

Site ID Name/Number

Site Type (enter type code from page 2) F ·

Site Zip Code

Site County

Client ID

Date of Birth (M M D D Y Y Y Y) (enter 01/01/1800 if unknown)

Client State

Client County

Client Zip Code

Client Ethnicity

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Don't Know
- ☐ Declined

Client Race (check all that apply)

- ☐ American IN/AK Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native HI/Pac. Islander
- ☐ White
- ☐ Don't Know
- ☐ Declined

Client Assigned Sex at Birth

☐ Male ☐ Female ☐ Declined

Client Current Gender Identity

- ☐ Male
- ☐ Female
- ☐ Declined
- ☐ Additional specify: _____
- ☐ Transgender M2F
- ☐ Transgender F2M
- ☐ Transgender unspecified

Previous HIV Test?

- ☐ Yes → If Yes, what is the client's Self Reported Result?
  - ☐ Negative
  - ☐ Positive
  - ☐ Preliminary Positive
  - ☐ Indeterminate
  - ☐ Don't know
  - ☐ Declined
  - ☐ Not Asked
- ☐ No
- ☐ Don't Know
- ☐ Declined
- ☐ Not Asked

Sample Date (M M D D Y Y Y Y)

	HIV Test 1	HIV Test 2	HIV Test 3
Worker ID			
Test Election	☐ Test not offered ☐ Anonymously ☐ Confidentially ☐ Declined Testing	☐ Test not offered ☐ Anonymously ☐ Confidentially ☐ Declined Testing	☐ Test not offered ☐ Anonymously ☐ Confidentially ☐ Declined Testing
Test Technology	☐ Conventional ☐ Rapid ☐ NAAT/RNA Testing ☐ Other	☐ Conventional ☐ Rapid ☐ NAAT/RNA Testing ☐ Other	☐ Conventional ☐ Rapid ☐ NAAT/RNA Testing ☐ Other
Test Result	☐ Positive/Reactive ☐ Negative ☐ Indeterminate ☐ Invalid ☐ No Result	☐ Positive/Reactive ☐ Negative ☐ Indeterminate ☐ Invalid ☐ No Result	☐ Positive/Reactive ☐ Negative ☐ Indeterminate ☐ Invalid ☐ No Result
Result Provided	☐ Yes ☐ No ☐ Yes, client obtained results from another agency	☐ Yes ☐ No ☐ Yes, client obtained results from another agency	☐ Yes ☐ No ☐ Yes, client obtained results from another agency
If Results NOT provided, why?	☐ Declined Notification ☐ Did not return/ Could not locate ☐ Other	☐ Declined Notification ☐ Did not return/ Could not locate ☐ Other	☐ Declined Notification ☐ Did not return/ Could not locate ☐ Other

Choose one if

- ☐ Client completed a behavioral risk profile
- ☐ Client was not asked about behavioral risk factors
- ☐ Client was asked, but no behavioral risks identified
- ☐ Client declined to discuss behavioral risk factors

In the past 12 months has the client identified the following:

	Male	Female	Transgender
Vaginal or Anal Sex with	☐	☐	☐
Without using a condom	☐	☐	☐
With a person who is an IDU	☐	☐	☐
With a person who is HIV +	☐	☐	☐

Has the client had vaginal or anal sex with an *MSM*? **FEMALE ONLY** ☐ Yes

Has the client used injection drugs? ☐ Yes

If yes, did client share drug injection equipment? ☐ Yes

Additional Risk Factor(s) (enter two digit code from page 2): 1 _____ 2 _____ 3 _____ 4 _____

Optional Session Activities	1	-	3	-	
Optional Session Activities	2	-	4	-	
Local Use Field	L1		L3		
Local Use Field	L2		L4		