Budgetary Impact of Compliance With STI Screening Guidelines in Persons Living With HIV

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Introduction: The 2015 Centers for Disease Control Sexually Transmitted Diseases Treatment Guidelines recommend annual screening of all people living with HIV (PLWH) for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and syphilis; annual *Trichomonas vaginalis* screening is recommended for HIV-infected women. The study objective was to evaluate the budgetary impact of sexually transmitted infection (STI) screening. We hypothesized that recommended STI screening is costly and would not be covered in full by insurers.

Methods: This cost analysis evaluates charges and reimbursement for recommended screening for the above 4 STIs. This study projects the net yield (reimbursement minus expenditures) of providing tests to eligible PLWH receiving care at an urban HIV clinic in Birmingham, AL. Four scenarios evaluated the net yield when different laboratory providers, rates of compliance, and Ryan White Program fund availability were examined.

Results: The number of patients receiving care at our HIV clinic from August 2014 to August 2015 was 3163 (768 female and 2395 male patients). Annual screening for *N. gonorrhoeae*, *C. trachomatis*, syphilis, and *T. vaginalis* would lead to a mean net loss of $129,416, $118,304, $72,625, and $13,523, respectively. Most costly scenarios for a health system include the use of a regional laboratory (−$1,241,101) and lack of Ryan White HIV/AIDS Program funding (−$85,148).

Discussion: Compliance with STI screening practices is costly. Sustainability will require critical analysis of true costs and cost-effectiveness of STI screening tests in PLWH. Providers, policy makers, and insurers each have a role in ensuring the provision of these evidence-based services to PLWH.

Key Words: sexually transmitted infections, screening, cost, PLWH

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INTRODUCTION

Sexually transmitted infections (STIs), including *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Treponema pallidum* (syphilis), and *Trichomonas vaginalis*, are common among people living with HIV (PLWH) and can facilitate the transmission of HIV.[1] The current 2015 Centers for Disease Control (CDC) sexually transmitted disease treatment guidelines recommend annual screening (with more frequent screening for those with high-risk behaviors) of all PLWH for *N. gonorrhoeae*, *C. trachomatis*, and syphilis in addition to annual screening for *T. vaginalis* among HIV-positive women.[2] Furthermore, extragenital STI testing is recommended in men who have sex with men (MSM).[2] Despite these recommendations, annual screening for *C. trachomatis*, *N. gonorrhoeae*, and syphilis occurs in less than half the number of PLWH in the United States,[3–5] and rates of *T. vaginalis* screening in HIV-positive women are similarly low.[6]

To improve the screening, diagnosis, and treatment of STIs among PLWH, several policies have reduced barriers to and encouraged the delivery of recommended STI screening tests among this population. Since 2010, the Patient Protection and Affordable Care Act (ACA) has required non-grandfathered health insurance plans and new insurance plans to provide certain United States Preventive Services Task Force–recommended services free of charge to insured patients, including screening for *N. gonorrhoeae*, *C. trachomatis*, and syphilis.[7] Additionally, the National Committee for Quality Assurance has included *C. trachomatis* screening in the Healthcare Effectiveness Data and Information Set, a quality measurement tool used to compare health plans.[8] In some situations, failure to comply with recommended screening practices can be punitive. Many health systems serving PLWH receive financial support via the Ryan White Care Act Program (Title III Early Intervention Services), but funds may be withheld from participating clinics that are consistently noncompliant with recommended screening practices.[9] Despite these measures, compliance with STI screening guidelines remains suboptimal[3,4,6] and underscores persistent barriers to STI screening, including limited clinic resources, lack of awareness of screening needs on the part of the patient and the provider,[10–13] and lack of insurance, which is especially relevant in Medicaid nonexpansion states like Alabama. The financial implications of recommended STI screening in PLWH are also not known but understanding budgetary effects is important for the sustainability of recommended STI screening practices.[14]

With this in mind, the objective of this study was to identify the budgetary impact of recommended STI screening

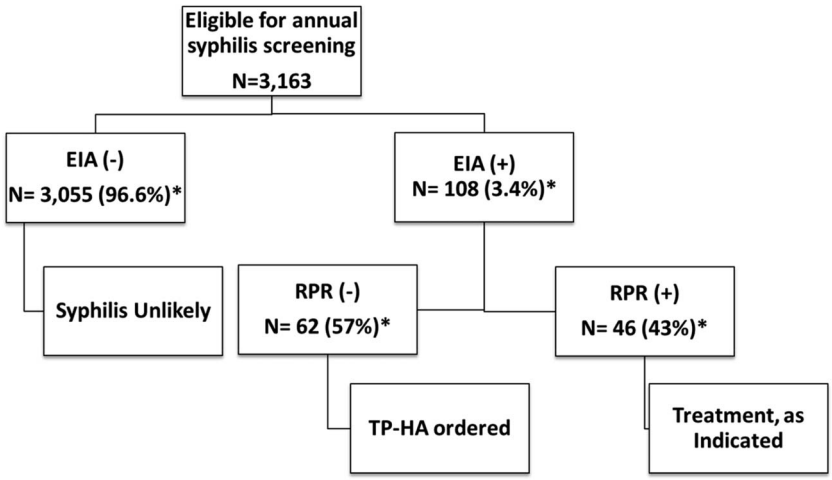

FIGURE 1. Reverse syphilis screening method and number of eligible (%) HIV-infected patients at an academically affiliated HIV clinic.* Percentage of eligible persons taken from published data.[5]

(*N. gonorrhoeae*, *C. trachomatis*, syphilis, and *T. vaginalis*) among asymptomatic PLWH at the University of Alabama at Birmingham 1917 HIV Clinic, a high-volume, urban HIV clinic in Birmingham, AL. We hypothesized that compliance with recommended STI screening practices is costly and that insurance enrollment does not ensure complete reimbursement of screening services. Four scenarios evaluated the costs associated with different laboratory providers, rates of compliance, and Ryan White Program fund availability.

METHODS

Eligibility

The sample population came from the HIV clinic affiliated with the University of Alabama at Birmingham. Eligibility was defined as HIV clinic patients meeting criteria for *C. trachomatis*, *N. gonorrhoeae*, syphilis ± *T. vaginalis* screening according to 2015 CDC Guidelines. These 4 STIs were selected because of their prevalence and strength of evidence supporting routine screening in PLWH.[2,6] Also, the need for frequent screening, relative to other STIs like hepatitis B, makes it imperative to understand the resources involved in screening for these 4 STIs. Unlike CD_4 cell counts, which are recommended less frequently for PLWH who are well-controlled on antiretroviral therapy, STI screening guidelines are not likely to decrease in frequency or number of sites in this high-risk population.[15] By determining the number of patients who meet criteria for the above STI tests, this analysis projected costs if eligible patients received STI screening at the frequency recommended based on their biological sex and transmission risk factor (eg, heterosexual versus MSM). The outcomes assessed were expenditures, reimbursement, and net yield related to annual screening practices for the 4 aforementioned STIs.

Expenditure and Reimbursement

Because of the absence of data on laboratory expenditures, in both our institution and the literature, costs were calculated using laboratory charges. Screening costs for *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* were based on nucleic acid amplification tests (NAATs) charges. Of note, charges and reimbursements for NAATs were identical regardless of specimen (urine, cervical, urethral), making this analysis applicable to all scenarios. The reverse syphilis screening algorithm and venipuncture charges were included in the charge for syphilis screening.[16] This relatively new reverse syphilis screening algorithm was used in this analysis because it has been widely adopted by clinics, laboratories, and institutions including ours. The first step relies on an antitreponemal antibody, and, for the purposes of this analysis, charges related to use of an enzyme immunoassay (EIA) were used. We assumed that 3.4% of patients would have a positive EIA and meet criteria for reflex rapid plasma reagin (RPR), and 57% of those would have a nonreactive RPR necessitating confirmatory testing via a *Treponema pallidum* hemagglutinin assay (Fig. 1). These assumptions were made based on data obtained in 5 diverse STI testing sites.[17] First, we used a "regional charge," which was set at 75% of charges for the above tests available at peer institutions in the southeastern United States. To account for this region-specific laboratory charge, we performed additional analyses using charges assigned by a national clinical laboratory service to understand cost outcomes when charges vary. Charges for these laboratory tests are incurred to the health system at our institution and reimbursements, in turn, are collected by the health system. Unlike vaccines, for example, which are a service provided directly by our clinic (because of 340b discounts), laboratory services are not processed by, charged to, or reimbursed to our clinic.[18,19] As the clinic relies on the health system to perform these tests (or contract with an external laboratory), this cost analysis was performed from the perspective of the health system.

To calculate reimbursement generated by laboratory testing, our billing database was queried for insurance reimbursements for the *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* NAAT tests, syphilis screening tests, and venipuncture. These reimbursements are termed "fees" for Medicaid and Medicare patients and "allowables" for the commercially insured. We classified insurers into 4 categories: Alabama Medicaid, Medicare, Commercial Insurance,

TABLE 1. Summary of Screening Tests Analyzed According to Sex and Sexual Behavior for PLWH Receiving Care at an Academically Affiliated HIV Clinic

	Women, N = 768		MSM, N = 1844 (77%)		Heterosexual Men, N = 551 (23%)	
Condition Screened	**Frequency**	**Sites Tested**	**Frequency**	**Sites Tested**	**Frequency**	**Sites Tested**
T. vaginalis	Annual	1	NA	NA	NA	NA
C. trachomatis	Annual	1	Annual	2	Annual	1
N. gonorrhoeae	Annual	1	Annual	2	Annual	1
Syphilis	Annual	1	Annual	2	Annual	1

and Uninsured. We analyzed patients based on these 4 categories according to the most recent clinic insurance data (May 2016) to account for ongoing ACA marketplace enrollment.[20] Commercial insurance included all third-party insurers, excluding Medicaid, Medicare, and Ryan White HIV/AIDS Program (RWHAP) and other state or federally funded programs. We assumed that all commercial insurers reimbursed at the same rate and used the "allowable" used by one commercial insurer, which covers the largest percentage of privately insured patients in our clinic.[19] We assumed that no claims were denied by the respective insurer, which is conditional upon documenting medical necessity among other requirements. For primary analysis, we assumed screening of uninsured patients was reimbursed in full through the RWHAP, which allows funds for eligible health systems serving underserved populations, including PLWH.[21] Of note, the laboratory provider or health system may not receive reimbursement that is greater than the actual laboratory charge, as this may unethically influence the number of tests ordered and is considered inducement.[22]

Scenarios

We used the average number of patients seen annually in our HIV clinic based on data collected from August 2014 to August of 2015 to calculate the cost of screening eligible patients for *T. vaginalis*, *C. trachomatis*, *N. gonorrhoeae*, and syphilis[6] (Table 1). As some screening recommendations and frequencies of screening differ by sex and HIV transmission risk (eg, heterosexual vs male who has sex with men), these demographics were also incorporated.[23] Based on previous research in our clinic cohort, we assumed that 77% of men with HIV were MSM.[23] We assumed annual *T. vaginalis* screening for female PLWH and annual *C. trachomatis*, *N. gonorrhoeae*, and syphilis screening for all females and heterosexual males. We assumed MSM would receive annual *C. trachomatis, N. gonorrhoeae,* and syphilis screening according to guidelines, and each *N. gonorrhoeae* and *C. trachomatis* screening would incorporate testing of 2 of 3 potential sites (oral, anal, and/or urine), as this was thought to reflect the most common practice in our clinic based on the sexual practices of our patient population. As the 3 sites (oral, anal, and urine) all incur the same charge and are reimbursed identically across all insurers, it was not necessary to distinguish between sites. Heterosexual men were assumed to have screening in only one site (oral, anal, or urine). The base case (scenario 1) assumed 100% uptake of recommended screening practices and relied on regional laboratory charges. Scenario 2 calculated the cost of providing laboratory testing using a national clinical laboratory service: charges were assigned based on this laboratory's fees, and reimbursement was included based on each insurer's respective reimbursement for each STI test. Like scenario 1, this simulation assumed that 100% of eligible patients received screening. Although screening all eligible patients for recommended STIs is ideal and evidence-based, we conducted

TABLE 2. Expenditures and Reimbursement for 4 STI Screening Tests Recommended for PLWH Receiving Care at an Academically Affiliated HIV Clinic

	Expenditure		Reimbursement		
Screening Test	**National Laboratory Charge ($)**	**Regional Laboratory Charge ($)**	**Medicare Fee ($)**	**AL Medicaid Fee ($)**	**Commercial Allowable ($)***
N. gonorrhoeae NAAT	21	100	30.71	28	23.01
C. trachomatis NAAT	21	109	30.71	28	23.01
T. vaginalis NAAT	35	84	30.71	0	23.01
Anti-treponemal antibody EIA	18	85	18.03	16	13.52
RPR	4 (with TPHA)†	68	5.82	5	4.36
TPHA	4 (with RPR)†	85	18.03	16	13.52
Venipuncture	6	14	3.00	2.45	3.45

Commercial Insurer refers to the private plan used by a majority of commercially insured patients in our population.

*For national laboratory service charges, Commercial Insurance Allowable is listed. For all regional laboratory charges, we assumed Commercial Insurer only reimburses 17.5% of the charge (listed in expenditure column 2) as this is the case at our institution. All values are in USD, 2016.

†The national laboratory service charged $4 for both RPR and TPHA combined and does not allow individual purchase.

TPHA, *Treponema pallidum* hemagglutinin assay.

TABLE 3. Mean Net Yield for 4 STI Screening Tests Recommended for PLWH Receiving Care at an Academically Affiliated HIV Clinic

Screening Test	Mean Net Yield ($) (Min, Max)
T. vaginalis NAAT	−13,523 (−43,172, −2246)
Syphilis algorithm	−72,625 (−279,930, −1518)
N. gonorrhoeae NAAT	−118,304 (−436,7708, 0)
C. trachomatis NAAT	−129,416 (−481,222, 0)

All values are in USD, 2016.

scenario 3 to account for adjusted screening practices based on published data of actual screening rates in large cohorts of PLWH.[5,6] Uptake rates in this scenario were suboptimal: 52%, 39%, 39%, and 77% for *T. vaginalis, C. trachomatis, N. gonorrhoeae*, and syphilis, respectively. Scenario 3 relied on charges from the above referenced national clinical laboratory service, and reimbursement was included based on each insurer's respective reimbursement for each STI test provided by this laboratory service. Finally, we calculated the costs of providing recommended STI screening to all eligible patients without the availability of RWHAP funds for uninsured individuals (scenario 4).

Data Analysis

For each of the screening tests, we collected the reimbursement per test, including venipuncture when relevant, across insurers. Next, we calculated the "net yield" for each laboratory test, including venipuncture (syphilis), according to insurance status. Net yield is equal to the reimbursement for the laboratory test minus the cost for each test. Mean net yield is the mean cost to screen for a test when averaged across all scenarios. All analyses were conducted using Microsoft Excel 2010 (Redmond, WA).

RESULTS

The number of patients receiving care at our HIV clinic from August 2014 to August 2015 was 3163 (768 female and 2395 male patients). Additional demographics of this cohort have been previously published.[6] A majority were commercially insured (47%), followed by Medicare (26%), Uninsured (15%), and Alabama Medicaid (12%). There was great variation in the reimbursement for each test according to insurer type (Table 2). For example, Alabama Medicaid does not reimburse for *T. vaginalis* testing. Medicare, however, covers almost the entire charge of this test when provided through the national laboratory service. Furthermore, there is great variation in STI test charge based on the type of test and the laboratory. The national laboratory assigned a charge of $35 to perform a *T. vaginalis* NAAT, whereas the regional laboratory (75% of peer institutions) more than doubled that charge to $84. There was no evidence of patient cost-sharing for these tests.

Mean net yields, or averages, were obtained for each of the tests and each of the 4 scenarios. Annual screening for *N. gonorrhoeae* and *C. trachomatis* were consistently the most expensive, leading to a mean net loss of $118,304 and $129,416, respectively, in our clinic population (Table 3). Screening for syphilis in our clinic would lead to an annual mean net yield of −$72,625, with a range of −$1518 (scenario 3) to −$279,930 (scenario 1). Annual screening for *T. vaginalis* was the least costly leading to a mean net yield of −$13,523, with a range of −$2246 (scenario 3) to −$43,172 (scenario 1).

Net yield was calculated to understand the financial implications of providing all recommended tests according to differing expenditure and reimbursement scenarios (Table 4). Net yield calculated from most to least costly are as follows: scenario 1 (−$1,241,101), scenario 4 (−$85,148), scenario 2 (−$5809), and scenario 3 (−$3415).

DISCUSSION

There is a large battery of STI screening tests recommended for PLWH and others with high-risk sexual behaviors.[2] We identified test-specific features for 4 STIs and economic scenarios in which routine testing is most costly for the health system. We also identified gaps in insurance coverage for recommended screening tests. Screening for *N. gonorrhoeae* and *C. trachomatis* in PLWH were consistently the most expensive. This is in part because of the number of tests (at all sites of sexual contact) required in MSM, which represent 77% of the men in our clinic. Syphilis was the next most costly owing to additional confirmatory tests required for some in the 3-step reverse syphilis screening algorithm. Notably, in some high-risk patients, screening for these STIs is recommended up to every 3 months leading to even greater clinic losses.[2]

With the passage of the ACA in 2010, recommended preventive services, like STI screening, are to be covered by new plans and non-grandfathered plans in full with no patient

TABLE 4. Mean Net Yield of 4 Annual STI Screening Scenarios for PLWH Receiving Care at an Academically Affiliated HIV Clinic

Inputs	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Expenditures	Regional laboratory charge	National laboratory charge	National laboratory charge	National laboratory charge
Reimbursement	Insurer, RWHAP	Insurer, RWHAP	Insurer, RWHAP	Insurer
Uptake	100% of eligible	100% of eligible	<100% of eligible†	<100% of eligible†
Annual net yield	−$1,241,101*	−$5809*	−$3415*	−$85,148*

*All values are in USD, 2016.
†Percentage of eligible persons taken from published data.[5,6]

cost-sharing. Our analysis did not reveal any evidence of patient cost-sharing for these preventive services; however, some plans do not completely cover all STI screening tests for eligible clients. For example, screening female PLWH for *T. vaginalis* is not covered by Alabama Medicaid despite recommendations for annual screening by the CDC.[2] Furthermore, the commercial insurer, which represents the largest percentage of our clinic's privately insured patients, covered only a portion of the laboratory expenditures related to *T. vaginalis* and syphilis screening. This partial coverage leaves several dollars per test per patient unreimbursed to be absorbed by the health system or clinical laboratory performing the test. Partial coverage of screening tests, when applied to a clinic serving greater than 3000 patients, adds up to significant losses over the course of a year.

This gap in reimbursement underscores the need for continued RWHAP funds in the ACA era to provide preventive services for uninsured and underinsured PLWH. RWHAP is the largest federal fund specifically designed to ensure comprehensive treatment and support services for PLWH.[9] In the last 3 years, our uninsured patient population declined from 34% to 15%, but the healthcare coverage of newly insured PLWH is only as comprehensive as their new commercial plan allows.[19] When commercial insurers provide incomplete coverage of tests by setting their reimbursement lower than the health system can feasibly perform (or contract with another entity to perform) a test, clinics and health systems serving PLWH must continue their reliance on RWHAP funds for the comprehensive care of underinsured PLWH. Not surprisingly, as demonstrated in scenario 4, net losses increased from $4000 to $38,000 annually when RWHAP "safety net" funds were unavailable.

In studying the charges and reimbursement of 4 evidence-based STI screening tests, we found additional areas in need of further study. In cases where tests are conducted outside the clinic by the health system or an external laboratory, clinic providers and administrators may have limited access to data related to expenditures, revenue, and net yield of STI screening tests, limiting the potential for research. Additionally, our data suggest that charges and reimbursements are so complex and varied at the patient, insurer, and laboratory level, that cost-effectiveness research is extremely challenging. Heterogeneity because of differing ACA marketplace provisions, Medicaid expansion status, and state Medicaid plans will further complicate a large-scale assessment. In reviewing the literature, we found a lack of data on true STI testing costs, including direct costs for processing the results and indirect costs related to equipment, phlebotomy, specimen storage, and record-keeping. The limited data that were available on STI screening demonstrates that the reverse syphilis screening algorithm, which has been adopted by many institutions, including ours, may be less cost-effective and lead to unnecessary treatment in some cases.[24,25] This lack of knowledge significantly impairs the ability to study financial barriers to STI screening in PLWH.

This study has several limitations. Our analysis relied on the number of PLWH eligible for STI screening according to the demographics and sexual behaviors observed in one urban HIV clinic in the Southeastern United States. This may limit generalizability to other clinics that, for example, serve more female patients and incur more costs related to *T. vaginalis* screening, which is only recommended for women at this time. To understand the costs associated with syphilis screening, we assumed that rates of anti-treponemal antibody seroprevalence and RPR, *Treponema pallidum* hemagglutinin assay positivity rates were similar to those obtained by others.[17] This estimate likely underestimates anti-treponemal antibody seroprevalence because it included populations with both a low and a high prevalence of syphilis. Because seroprevalence leads to additional confirmatory testing, underestimating seroprevalence leads to underestimation of costs. An ideal study would incorporate actual STI screening and detection rates in our clinic, but understanding which tests were ordered for *screening* as opposed to *diagnostic* purposes was not feasible in our study. Identifying STI screening tests would require comprehensive review of provider documentation notes to exclude signs or symptoms of STI, but many tests were ordered by ancillary staff and documentation was limited. Because compliance with *N. gonorrhoeae, C. trachomatis*, and syphilis screening recommendations in our clinic population is unknown, we relied on screening rates observed in a large, multisite cohort of PLWH.[5] Finally, because of the rapid uptake of NAATs, recent adoption of the reverse screening algorithm and anti-treponomal EIA, and changes in laboratory test vendors, our regional laboratory did not have contemporary data on the actual costs of laboratory tests. Thus, costs were assigned based on (1) regional laboratory charges, set at 75% of charges at peer institutions, and (2) a national, clinical laboratory's charges. The former charges are significantly greater, which suggests they are a poor representation of true costs. For this reason, the latter charges were used in scenarios 2 through 4 to represent a more accurate surrogate for laboratory costs.

Our analysis examines 4 scenarios that are likely experienced at other facilities, which aim to provide comprehensive care for PLWH. The results support our hypotheses that evidence-based STI testing is costly and is not completely reimbursed by insurance. These findings are consistent with a well-documented phenomenon: laboratory services place a financial burden on institutions.[26–28] To provide sustainable STI screening services for PLWH, administrators and providers must carefully analyze the costs of evidence-based STI screening and identify cost-conscious options for STI testing, particularly outsourcing of tests.[29] Researchers and funding agencies should prioritize comparative effectiveness analyses to inform decision-making related to screening tests. Policy makers should continually evaluate the comparative cost-effectiveness of screening tests, especially when including novel tests such as the reverse syphilis screening algorithm and point-of-care STI tests in guidelines.[30] Finally, insurers should be held accountable to ACA mandates by ensuring that coverage of laboratory testing is adequate given the budget impact of STI screening, and RWHAP funds should be reserved for uncompensated costs related to STI screening of those who are not eligible for ACA enrollment. Understanding the complex economics of STI testing will require

thoughtful analysis of testing costs, including both compensated and uncompensated expenditures related to resources and personnel, at both the institution and the national level, which is essential to ensuring sustainable STI screening practices for all high-risk populations.

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