2014 HIV Diagnostics Survey

The Association of Public Health Laboratories (APHL) periodically surveys its members to assess their HIV diagnostic testing capabilities, capacities and practices. Past surveys have documented changes in the types of specimens public health laboratories (PHLs) receive, the test kits they use, and the testing strategies that they implement. Since the last survey was conducted in 2012, the Centers for Disease Control and Prevention (CDC) and APHL published a new HIV diagnostic testing algorithm (June 2014)[1] leading to significant changes in the way HIV testing is conducted in PHLs.

BACKGROUND

The new laboratory HIV diagnostic testing algorithm (2014) recommends initial testing with an antigen/antibody combination immunoassay (IA) which if reactive is followed by an HIV-1/HIV-2 antibody differentiation IA. Specimens negative or indeterminate by the antibody differentiation IA should receive a nucleic acid test (NAT). This algorithm allows for the identification of acute and established HIV infections. Acute HIV infection is the early period of infection when HIV RNA is detectable but HIV antibodies are not.1 Identification of acute HIV infection is critical because the risk of HIV-1 transmission from persons with acute and early infection is much higher than that from persons with established infections.[2–5]

The goal of this survey was to determine current practices of HIV testing, including implementation and impediments to implementation of the HIV diagnostics laboratory testing algorithm and the use of new and emerging assays. Findings from the current survey will be used to guide APHL's education and technical assistance activities, and to inform policy development and advocacy. This issue brief summarizes the findings of the 2015 survey.

METHODS

From March-June 2015, APHL fielded its fifth survey to assess the HIV diagnostics capabilities, capacities and practices among public health laboratories in the United States to 99 state and local PHLs. In all, 77 laboratories responded (48 state PHLs and 29 local PHLs), but only 74 (75%) respondents reported that they conducted HIV testing at the time of the survey. Of the 74, 48 of 51 (94%) state PHLs and 26 of 48 (54%) local PHLs performed HIV testing.

A 26-question online tool was created by the APHL HIV and Viral Hepatitis Subcommittee and administered through Qualtrics, a web-based survey instrument. Unless otherwise specified, "respondents" refers to all survey respondents (one response per public health laboratory) that conduct HIV testing in their laboratory. Survey questions addressed laboratory workforce, type and sequencing of assays, supplemental testing, barriers and facilitators to implementing the laboratory HIV diagnostic testing algorithm (2014), and billing/reimbursement practices and Hepatitis C Virus (HCV) testing practices. With the rapid evolution of new treatments for HCV,

screening and diagnosis of HCV infection are an increasing public health priority. This survey presented an opportunity to gather timely information on PHL practices for HCV testing.

Respondents were asked to provide data on current (March-June 2015) HIV and HCV testing practices and HIV testing volumes during the 2014 calendar year (i.e., January 1, 2014-December 31, 2014); therefore all responses are for this time period unless otherwise indicated.

Data from this survey were compared to previous HIV surveys conducted by APHL in 2006,[6] 2009,[7] and 2012.[8] The 2006 HIV Diagnostics Survey covered testing data from January 1-December 31, 2005, the 2009 HIV Testing Practices Survey covered testing data from July 1, 2008-June 30, 2009 and the 2012 HIV Testing Practices Survey covered testing from January 1-December 31, 2011. All testing practices (e.g. test kit usage) were analyzed using all survey respondents unless otherwise noted. In order to properly evaluate trends in testing volume, data were compiled for a subset of 41 public health laboratories that completed the 2006, 2009, 2012 and 2015 HIV surveys (7 local and 34 state public health laboratories). In analyses of the responses of laboratories that were using the laboratory HIV diagnostic testing algorithm (2014), laboratories that reported using an antigen/antibody combination immunoassay, a supplemental antibody differentiation immunoassay, and access to a nucleic acid test (NAT) (in-house or through referral to another laboratory) were included (n=41).

WORKFORCE

APHL requested laboratories indicate the number of full-time equivalents (FTEs) that were employed for HIV testing. Of the responding laboratories, the median was 2.0 FTEs. The lowest number of FTEs employed was 0.25 and the highest was 8. The subset of laboratories that responded to surveys from 2009 to 2015 reported an average of 2.7 (range 0-12) in 2015 compared to an average of 2.9 in 2012 and 2.9 in 2009.

ADOPTION OF THE LABORATORY HIV DIAGNOSTIC TESTING ALGORITHM (2014)

The 2015 survey is the first survey fielded after the laboratory HIV diagnostic testing algorithm (2014) was published and included several questions about the adoption of the algorithm. A majority of PHLs (72%), 35 state PHLs and 18 local PHLs, responded that they had adopted the recommended algorithm. To assess assay utilization in the algorithm further questions were asked which revealed discrepancies (Table 1). The total number of PHLS that have adopted the laboratory HIV diagnostic testing algorithm was 41 of 74 (55%), or 28 of 48 (58%) state and 13 of 28 (46%) local PHLs. Of note, the majority of respondents reported adoption of the laboratory HIV diagnostic testing algorithm prior to its publication in June 2014 35/53 (66%).

Table 1: Summary of responses about adoption of the laboratory HIV diagnostic testing algorithm (n=74)

	"Yes" to Adoption[a]	Using Lab Based Ag/Ab Combo IA[b]	Using Supplemental Ab Differentiation IA[c]	Access to HIV-1 NAT: (in-house NAT, refer NAT)	Using laboratory HIV diagnostic testing algorithm[d]
State	35	32	36	33 (14, 19)	28
Local	18	13	21	28 (7,14)	13
Total	**53**	**45**	**57**	**54 (21,33)**	**41**

a) The first four columns of data correspond to 4 unique questions that all respondents were asked, b) antigen/antibody combination immunoassay, c) antibody differentiation immunoassay, d) This number was calculated based on responses to the 4 previous questions to determine which labs are using the laboratory HIV diagnostic testing algorithm as prescribed in the publication.[1]

ASSAY UTILIZATION

The utilization of different types of immunoassays has changed markedly over the last several surveys (Table 2). The laboratory HIV diagnostic testing algorithm (2014) recommends using an antigen/antibody combination immunoassay for the initial screening test in the algorithm. In 2014, 64% of responding laboratories used an antigen/antibody combination immunoassay for their initial test while 33% used an antibody immunoassay. This is a marked shift from 2011 testing when 77% of responding PHLs utilized an antibody immunoassay and 22% used an antigen/antibody combination immunoassays compared to 2014. The use of earlier versions of the antibody immunoassays continues to decline since the initial survey in 2005.

Following a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) an HIV-1/HIV-2 antibody differentiation assay should be used. In 2014, 57 (77%) PHLs (21 local and 36 state) reported utilizing the Multispot HIV-1/HIV-2 Rapid test (Geenius™ was not FDA-approved at the time of survey). In the previous survey (2012), only six laboratories were utilizing this type of supplemental test. A small number of laboratories continue to use the HIV-1 western blot (WB) (15%, n=10) or IFA (3%, n=2) as a supplemental test, which is considerably fewer than the number of laboratories using these assays in 2011 (HIV-1 WB n=43, IFA n=9). Six laboratories (8%) referred specimens to another laboratory for supplemental testing, and one (1%) used an HIV NAT assay for the initial supplemental test. The APHL HIV and Viral Hepatitis subcommittee in coordination with ASM continues to encourage the transition from HIV-1 WB and IFA to antibody differentiation immunoassays to distinguish HIV-1 from HIV-2 infections and reduce the number of discordant results between the initial and supplemental antibody tests.[9]

Table 2: Summary of HIV Immunoassay Utilization for Screening Serum/Plasma Specimens[a,b]

Type of Assay	Name of Immunoassay	2005 (n=60)	2008 (n=52)	2011 (n=60)	2014 (n=70)
antigen/ antibody combination immunoassays	Abbott Architect HIV Ag/Ab			9 (15%)	17 (24%)
	Bio-Rad GS HIV Combo Ag/Ab EIA			4 (7%)	28 (40%)
	Subtotal	**n/a**	**n/a**	**13 (21.6%)**	**45 (64%)**
antibody immunoassays	Bio-Rad GS HIV-1/HIV-2 Plus O EIA	9 (15%)	39 (75%)	36 (60%)	15 (21%)
	Abbott HIV AB HIV 1/2	7 (12%)	2 (4%)	1 (2%)	
	ADVIA Centaur HIV 1/O/2 Enhanced		3 (6%)	3 (5%)	3 (4%)
	Ortho VITROS Anti-HIV 1+2 Immunoassay			2 (3%)	2 (3%)
	Bio-Rad Plus rLAV EIA	7 (12%)	5 (10%)		
	Avioq HIV-1 Microelisa			4 (7%)	3 (4%)
	bioMerieux Vironostika HIV-1	37 (62%)			
	Subtotal	**60 (100%)**	**49 (94%)**	**46 (76.6%)**	**23 (33%)**
rapid HIV assays	Uni-Gold Recombigen HIV			1 (1.6%)	
	Clearview STAT PAK Assay		2 (4%)		1 (1%)
	OraQuick ADVANCE		1 (2%)		
	Alere Determine HIV Combo				1 (1%)
	Subtotal	**0 (0%)**	**3 (6%)**	**1 (1.6%)**	**2 (3%)**

a) Number of laboratories using each assay (% of total), b) some PHL only perform supplemental testing only and do not perform screening with an immunoassay

HIV-1 NAT is suggested for samples that were reactive with the antigen/antibody combination immunoassay and were nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay. This test is critical to identify potentially acute cases but is only necessary for a small number of specimens and is prohibitively expensive for all PHLs to have available in-house. The in-house availability of HIV-1 NAT remained relatively consistent with 21 respondents in both the 2015 (28%) and 2012 (32%) survey. However, the number of laboratories that are now referring specimens to other laboratories has increased from 34% (15 of 44) in 2011 to 62% (33 of 53) in 2014. Specimens that were referred were either sent to another public health laboratory 27 (82%), a commercial laboratory 3 (9%), CDC 2 (6%) or a clinical laboratory 1 (3%). Five (9%) PHLs indicated they intend to implement HIV NAT in the next 12 months. Four of the five indicated that they would implement a qualitative assay, while one reported plans to implement a quantitative assay. Thirty-nine (74%) of the 53 public health laboratories not currently offering NAT have no plans to implement molecular testing for HIV, and the remaining nine (17%) respondents were not sure.

The 21 PHLs performing HIV-1 NAT in their laboratory were asked to indicate all the reasons that the assay is used in their laboratory: 17 (81%) indicated they perform molecular testing for detection of acute infection, 15 (71%) for follow-up of discordant results, 11 (52%) for clinical management, and 2 (10%) use it for detection of HIV-1 in infants. HIV-1 NAT pooled testing is performed by 4 (5.4%) PHLs on seronegative specimens with a median pool of 24 specimens and a range 16-256 specimens per pool.

HIV SPECIMEN TYPES AND TESTING VOLUMES

In 2014, the total number of specimens received for HIV testing by the 74 responding PHLs was 1,304,859. The median number of specimens received per laboratory was 6,931. The lowest number of specimens received by a responding lab was 22 and the highest was 211,188. The majority of specimens received were serum 777,262 (60%), or serum/plasma (unable to distinguish) 294,236 (23%). The remainder of the sample types were whole blood 163,094 (13%), oral fluid 52,050 (4%), plasma 16,626 (1.3%), dried blood spot 1,496 (0.1%), other 50 (0%), and unknown 8 (0%). Collectively 96% were serum, plasma or whole blood.

We continue to see the trend of decreased HIV testing by public health laboratories in 2014. Based on the subset of 41 laboratories that responded to the four most recent surveys, a peak was seen in 2005 at 1,700,513 with a drop over time to the low of 925,275 in the current 2015 survey. There has been a coincident decrease in oral fluid specimens tested in public health laboratories (Figure 1 and 2), although the number of laboratories performing oral fluid testing has varied slightly. Of the 41 laboratories responding to all four surveys, 22 accepted oral fluid specimens in 2006, 25 in 2009, 23 in 2011, and 22 in 2015. Overall, there was a decrease of 46% in overall volume of tests performed and an 86% drop in oral fluid specimens tested in PHLs since 2005.

Respondents indicated that 19,146 HIV infections were identified, reflecting an overall positivity rate of 1.5%. The positivity rate in 2015 was similar to the positivity rate for the total number of laboratories that responded in 2011 (1.9%). Of these HIV infections, 683 (0.005%) were reported as "Positive HIV-1 Consistent with Acute or Early Infection." The 683 acute infections were reported from 29 PHLs of which 19 PHLs were using the laboratory HIV diagnostic testing algorithm (2014) as prescribed accounting for 202 (29.6%) of the total acute or early infections.

Figure 1: HIV Specimen Types Received at PHLs in 2014

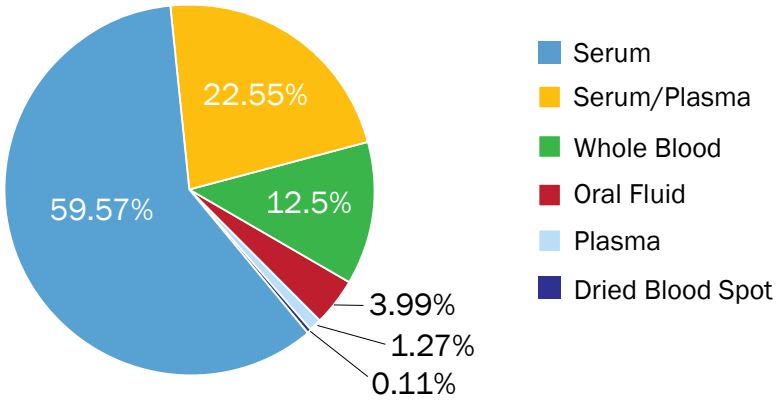
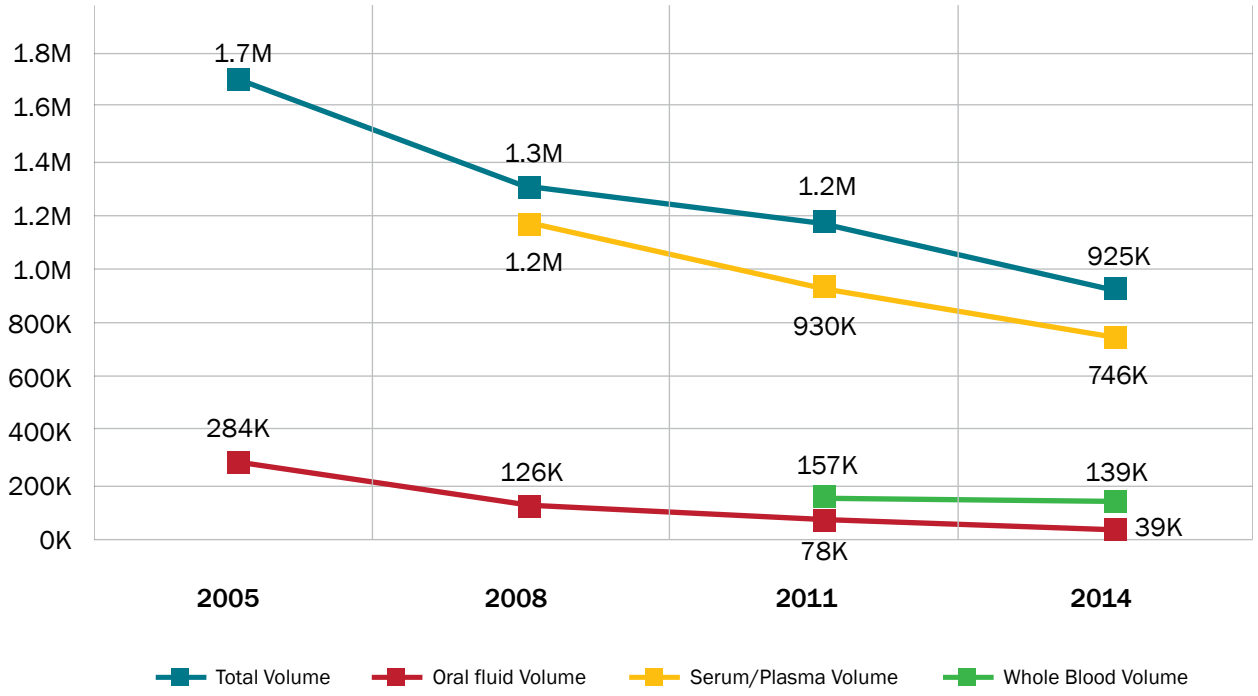


Figure 2: HIV Testing Volume Trends for PHL System, 2005 - 2014



Comparison of total and oral fluid specimen volume for laboratories that completed all APHL HIV surveys. The 2005 survey data cannot be parsed to determine test volume for serum/plasma or whole blood. The 2008 survey data cannot be parsed to determine whole blood volume.

The other PHLs that reported results as "Positive HIV-1 Consistent with Acute or Early Infection," six were using an antibody screening immunoassay, two were using the HIV-1 WB as the supplemental test, one was utilizing the Alere Determine assay for the screening test, and one PHL responded 'not available' for the screening assay. Following the laboratory HIV diagnostic testing algorithm (2014) provides a very reliable mechanism to identify acute HIV infections. Alternative diagnostic testing algorithms that utilize either antibody immunoassays for screening or HIV-1 WB for supplemental testing are less effective at identifying acute or early infections.

Using an algorithm that includes an HIV-1/HIV-2 antibody differentiation assay for supplemental testing can also help identify cases of HIV-2 infection in the absence of any FDA-approved HIV-2 WB, HIV-2 IFA or HIV-2 NAT.[1] Twelve laboratories (10 state, 2 local PHLs) of 57 using an antibody differentiation immunoassay reported the collective identification of 30 HIV-2 positive samples in 2014. Nine of the 12 laboratories used Multispot as a supplemental antibody differentiation assay. The other three laboratories reported utilization of either the APTIMA HIV-1 NAT, HIV-1 WB or HIV-1/HIV-2 differentiation IFA as their supplemental test. In a separate question, all PHLs that were using Multispot (n=57) were asked what their laboratory would do if it was reactive for HIV-2 only and they could select all that apply. The top two responses were to report out an HIV-2 positive result 33 (58%) and/or to refer specimen to or consult with CDC 32 (56%). There were 6 (11%) respondents that responded "other," of which three noted that no HIV-2 reactive samples have been identified thus far, one recommend a follow-up specimen be submitted one month later, one would notify the state PHL and one would notify the state epidemiologist. An additional 2 (4%) PHLs reported that they would perform additional testing (HIV-2 NAT).

CONFIRMATION OF RAPID REACTIVE SAMPLES

PHLs not only perform primary testing for HIV diagnosis, but they also receive samples tested at external point of care (POC) sites such as at provider offices or clinics by rapid HIV test for confirmation. The laboratory HIV diagnostic testing algorithm (2014) recommends that all serum/plasma specimens should be tested with a laboratory antigen/antibody combination immunoassay even if it was tested elsewhere using a rapid HIV test. While this is a recommendation, laboratories must also respond to the needs within their jurisdiction so they may use alternative testing algorithms for specimens tested by rapid HIV tests at outside facilities.

In 2014, 65 (88%) of the responding laboratories received specimens that were pre-screened as reactive on a rapid HIV test at POC sites. A total of 6,997 specimens were received at PHLs (from the 23 PHLs that could determine whether there was pre-screening) which was 1.2% of the total specimens received at those laboratories. The other 42 PHLs were unsure how many specimens they received that were prescreened as reactive during the time period. The majority of responders, 40 PHLs (62%) were usually aware of the type of specimen used for the rapid test. The laboratories that were aware of the specimen type used for the rapid reactive test were also asked to report the sample type sent to the laboratory for follow-up testing. In cases where a prescreened blood rapid test was reactive, in a majority of cases laboratories received serum 28 (70%), with other sample types including plasma 6 (15%), serum/plasma (undistinguishable) 6 (15%), whole blood 6 (15%), oral fluid (12.5%), not applicable 2 (5%), dried blood spot (1 (2.5%) or other 1 (2.5%). If the prescreened sample was oral fluid, the major sample type laboratories received was either serum 13 (48%), oral fluid 13 (48%), whole blood 5 (19%), serum/plasma (unable to distinguish) 4 (15%), plasma 3 (11%). The majority of specimens 5,618 (89.8%) prescreened as reactive by a rapid test were also reported as HIV-1 positive by the laboratory (Table 3). However, there were also discordant results with the percentage varying between the sample types. Four hundred three (9.5%) serum, plasma or serum/plasma samples and 184 (11.1%) of oral fluid specimens had discordant results (reported as negative, indeterminate, or inconclusive after follow-up testing in the laboratory). The volume and number of discordant samples was lower for dried blood spot, with only 9 (2.3%) with discrepant findings (reported as indeterminate or inconclusive).

TRENDS IN ORAL FLUID TESTING

The only FDA-approved laboratory based IA for oral fluid is the Avioq HIV-1 Microelisa System but several PHLs have performed validations of antibody or antigen/antibody combination immunoassays for off-label use with oral fluids.10 Of the 74 public health laboratories that responded to the survey, 55 (74%) reported that they did not conduct any screening of oral fluid specimens in 2014 and 19 (26%) that do conduct screening of oral fluid specimens. An additional seven PHLs receive oral fluids but only for confirmation of reactive rapid tests not primary screening. Eleven (58%) PHLs utilize the FDA-approved Avioq HIV-1 Microelisa System, four (21%) use the Bio-Rad (GS) HIV-1/HIV-2 Plus O immunoassay off-label, three (16%) are utilizing an antigen/antibody combination immunoassay and one the remaining laboratory used the Oraquick Advance rapid test. Of the 19 respondents that screen oral fluid specimens, 15 (79%) utilize the OraSure HIV-1 WB to confirm those results. Two of the 19 (11%) respondents request a serum specimen if the oral fluid screen is reactive and two (11%) laboratories send specimens to a reference laboratory for the oral fluid WB.

Table 3: Final Results reported from PHLs on specimens received after a reactive rapid test was performed at an outside laboratory by sample type

Sample Type (n= # of PHLs)	Not Tested	Positive for HIV-1	RNA Positive (Acute Infection)	Indeterminate	Inconclusive	Negative	Total
Serum/ Plasma (n=22)	20	3762	20	33	11	359	4205
Oral Fluid (n=11)	0	1479	N/A	80	1	103	1663
DBS (n=3)	1	377	N/A	4	5	0	387
Total	**21**	**5618**	**20**	**117**	**17**	**462**	**6255**

IMPEDIMENTS TO ADOPTING NEW TECHNOLOGIES AND ALGORITHMS

Many factors are involved in implementing new technologies and testing strategies particularly in publicly funded organizations. The survey asked specific questions about impediments to implementing different aspects of the testing algorithm. For those laboratories that have not yet implemented an antigen/antibody combination immunoassay (n=24), the three greatest impediments were Cost/Funding 13 (62%), other 9 (43%) and workforce 8 (38%). Other cited obstacles for bringing on the assay included low volume (33%), no perceived need (24%), physical/laboratory space (14%) and regulatory issues (10%).

When asked to rank the top three reasons for not implementing an antibody differentiation immunoassay the responding laboratories (n=13) indicated cost/funding (85%), HIV testing volume too low to warrant a change (46%) and no perceived need (39%). Workforce (23%), other (23%) and state regulations require WB (8%) were other cited impediments.

Impediments to implementing HIV-1 NAT were ranked by the 39 laboratories that do not currently offer HIV-1 NAT and do not plan to bring it on in the next 12 months. Following the same trend, cost/funding was the most commonly cited reason (90%), while low volume (87%) was almost as frequently cited. Other impediments cited included no perceived need (23%), workforce (18%), physical/laboratory space (18%), other (10%), and regulatory issues (3%). These impediments highlight the continued and ongoing resource and budget challenges faced by PHLs today.

OUTREACH, TRAINING, EDUCATION ON THE RECOMMENDED LABORATORY TESTING ALGORITHM

PHLs often serve as a resource for the other laboratories in their jurisdiction, and for epidemiologists and program staff as well. A majority of PHLs 43 (58%) provided outreach, training or education of the laboratory HIV diagnostic testing algorithm (2014) since it was released. They interacted with their HIV program (95%), clinicians (51%), POC testing sites (35%), hospital laboratories (30%), commercial laboratories (2%) and other (15%). The other responses covered a wide range of entities including: STD clinics, family planning clinics, correctional facilities, public health nurses, public health/health department clinics, STD program staff, infection preventionists and disease intervention specialists

(DIS). The nature of the outreach or training included individual meetings (70%), sending literature (61%), promotion of CDC and/or APHL publications or webinars (40%), webinar (23%), items in newsletter (21%) and other (21%). Other methods for outreach included teleconferences, state-wide Laboratory Response Network (LRN) meetings, as needed by phone or email, in-person seminars, presentation at in-service meetings, targeted communication by email and mailings.

REIMBURSEMENT METHODS

Health department capacity to participate in third-party reimbursement for HIV/AIDS and viral hepatitis services is essential in the context the Affordable Care Act. Funding for HIV diagnostic testing and other prevention services have become increasingly constrained. Federal funders require that health departments seek reimbursement from health insurers when possible.

Table 4: Reimbursement/Billing Practices

	State	Local	Total
Seeking Reimbursement for HIV Testing? (n=74)			
Currently Billing for HIV Testing	24	14	38 (51%)
Plan to implement in next 12 months (n=74)	3	2	5 (7%)
No plans to implement billing in next 12 months (n=74)	19	5	24 (39%)
Don't know if PHL is billing for HIV testing (n=74)	2	5	7 (10%)
For those currently billing, which payers? (n=38)			
Medicaid	17	9	26 (68%)
Medicare	9	7	16 (42%)
Private	8	7	15 (40%)
Other	9	4	13 (34%)
Not sure	1	0	1 (3%)
For those currently billing, what mechanism? (n=38)			
Health Department bills insurers directly	7	10	17 (45%)
Health Department bills providers	5	3	8 (21%)
Other	6	1	7 (18%)
Not sure	6	0	6 (16%)
For those currently billing, is an intermediary used (e.g. insurance benefits manager)? (n=38)			
Yes	5	2	7 (18%)
No	16	10	26 (68%)
Not sure	3	2	5 (13%)
For those currently billing, where does revenue go? (n=38)			
Laboratory	14	5	19 (50%)
Earmarked for HIV testing (n=19)	3	2	5 (25%)
To lab to a ceiling, remainder to general fund (n=19)	1	0	1 (5%)
General Laboratory funding (not earmarked) (n=19)	10	3	13 (68%)
Health Department General or Other Fund	2	4	6 (16%)
State General Fund	4	0	4 (11%)
Jurisdictional fund	0	3	3 (8%)
Not sure	4	1	5 (13%)
Other	0	1	1 (3%)

Leveraging revenue available through third-party reimbursement can help public health laboratories and HIV prevention programs to continue to provide essential services and carry out core public health functions.

Resources for Billing & Reiumbursement

NCHHSTP Billing Resources:
http://www.cdc.gov/nchhstp/preventionthroughhealthcare/resources.htm

Other CDC Billing Resources:
http://www.cdc.gov/vaccines/programs/billables-project/resources.html

NCSD Resources:
http://www.ncsddc.org/third-party-billing-practices

Approximately half, 38 (51%) of surveyed PHLs currently bill Medicaid, Medicare or other third party payers for HIV diagnostic testing and while an additional five plan to implement billing in the next 12 months, 24 (32%) PHLs have no plans to implement billing in the next 12 months (Table 4). Of the 38 PHLs that currently bill, the top payers billed are Medicaid 26 (68%), Medicare 14 (42%), private insurance 15 (40%), and other payers 13 (24%). The mechanism of seeking reimbursement also varied with 17 (45%) of health departments billing insurers directly, with the remainder split between the health department billing the provider 8 (21%), not sure 6 (16%) and other 7 (18%). For those respondents that indicated other, the following responses were given: Title X Billing of Medicaid only (n=1), the laboratory bills (n=1), bill through a state agency (n=1), intradepartmental program activities under state and federal programs (n=1), contract with third party company (n=1), and use of a clearinghouse (n=2). In a separate but related question, 7 (18%) PHLs used an intermediary to seek reimbursement while most 26 (68%) did not and a few 5 (13%) were not sure whether an intermediary was used or not.

For the 38 PHLs that seek reimbursement, half (n=19) stated that the revenue went to the laboratory. Of those 19, five PHLs had the money earmarked for HIV testing and one PHL received funding to a ceiling amount and the rest went to a general fund while the remainder indicated it went to general laboratory funding. For the other PHLs, the revenue went to the health department general or other fund 6 (16%), the state general fund 4 (11%), other jurisdictional general fund 3 (8%) with an additional five PHLs not sure (13%) or reporting other 2 (5%).

In the survey we also asked all respondents (n=74) what factors or issues prevented the laboratory from not billing for HIV testing services. The top three reasons were the lack of IT infrastructure needed to pursue reimbursement 24 (32%), lack of mechanism to collect revenue obtained through a third party reimbursement 17 (23%) and the staff lacks knowledge about billing and reimbursement 16 (22%). Other responses included: statutory/regulatory prohibitions 12 (16%), challenges in contracting with third party payers 10 (14%), majority of clients do not have insurance 9 (12%), laboratory lacks capacity to follow-up on unpaid bills 7 (10%), lack capacity to support providers in implementation 6 (8%), not cost effective to invest in infrastructure and personnel to begin billing 6 (8%) and poor reimbursement rates 3 (4%). For those PHLs that responded “other”, the specified reasons included that the lab doesn’t bill for any testing and/or offers testing free of charge, policy decisions, and central billing happens within the health department. Resources for learning more about billing and reimbursement are available through several partners.

TESTING FOR HEPATITIS C VIRUS

The rapid evolution of effective treatment regimens for HCV infection, provides an important prevention opportunity for public health departments. Screening for HCV is a key public health strategy for the prevention and control of HCV and as such, health departments and their PHL partners are building capacity to implement testing programs. In addition health department HCV programming is frequently integrated into existing HIV prevention programming and therefore

testing is also becoming increasingly integrated. To understand the current public health capacity to implement and expand testing for HCV, this survey included several questions intended to obtain a snapshot of current PHL capacity to respond to public health efforts to expand HCV testing.

Forty-five (61%) of the responding PHLs also perform HCV testing in addition to HIV testing. A majority 42 (93%) perform HCV antibody IA-laboratory based, with HCV RNA qualitative and HCV quantitative testing being offered by 11 (24%) PHLs, HCV genotyping 6 (6%), HCV antibody IA-point of care 2 (4%) and 1 laboratory performing HCV genetic relatedness testing. All respondents were asked to indicate whether they would add any HCV testing in the next year, 17 (59%) have no plans, 10 (35%) were not sure and 2 (7%) laboratories plan to add HCV antibody testing. Interestingly, the diagnostic testing approaches for HCV is also likely to evolve with FDA approving the first assay with a dual-claim for detection and monitoring.

CONCLUSION

The data from the 2015 HIV Diagnostics Survey revealed several interesting findings and trends compared to previous surveys. Between the 2012 and 2015 survey there was a major shift towards adoption of newer technologies including the uptake of antigen/antibody combination immunoassays (64% of PHLS) and antibody differentiation assays (77% of PHLs). There are only a few laboratories that continue to use HIV-1 WB, IFA as supplemental assays. While this is an encouraging trend, new technologies continue to emerge and PHLs must continue to adapt to new and emerging technologies to identify HIV infection as early as possible and facilitate linkage to medical care and public health intervention strategies. Cost/funding and insufficient workforce continue to be the major impediments to implementing new assays in PHLs. However, these challenges also present opportunities to explore increased integration of testing including HIV, HCV, and other sexually transmitted diseases.

The overall testing volume has continued to decline since APHL began surveying in 2005 with the lowest volumes to date noted in 2015 and a 46% decrease in total volume and 85% drop in oral fluid specimens tested in PHLs. This parallels the decrease reported by health department HIV prevention programs to NASTAD. These decreases in PHL testing volume could be the result of increased rapid testing by health departments and the shifting of testing to clinical settings which utilize clinical and commercial laboratories over PHLs.

PHLs perform primary HIV testing as well as confirmation of reactive rapid tests. According to the data in this survey, upwards of 10% of specimens sent to PHLs from reactive rapid tests were not confirmed by the laboratory based HIV testing algorithms. This highlights the difficulty with using rapid testing in the outpatient setting without proper follow-up and raises the question of how much early and acute infections might be missed using this strategy.

APHL and CDC will continue to explore opportunities to assist public health laboratories in responding to new and emerging technologies and mechanisms to assist with billing for HIV testing. APHL will continue to work with federal, state, local, non-governmental, and corporate partners to address HIV testing challenges and improve HIV testing practice in the country's public health laboratories.

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