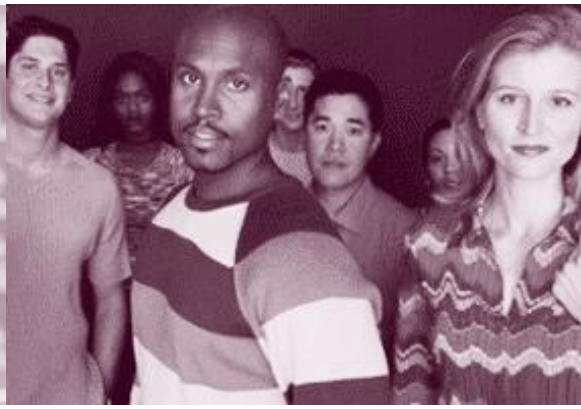
HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

A Centers for Disease Control and Prevention Project





Final Report 2013

ASHLIN Management Group

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Executive Summary

ASHLIN Management Group, Inc. (ASHLIN), was awarded a 2 year project by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) to develop and evaluate a replicable and sustainable model for HIV testing and linkage to care in community pharmacies and/or retail clinics. ASHLIN assembled a team of experts in the field to help assist in the process and development of this project and accomplished the objectives of this project by identifying and enrolling appropriate sites, training individuals from each site and maintaining records of HIV testing at each site, noting successes and challenges along the way and performing a cost analysis on the various models of HIV testing that were utilized at the enrolled sites.

ASHLIN was contracted to enroll 24 sites over the course of the project. Two of these sites were unable to continue with their participation in the project before any tests were conducted. The remaining 22 sites conducted testing during the time in which they participated in the project. These sites included a combination of both rural and urban locations. Sites utilized various models of HIV testing including some that had community pharmacists or nurses/nurse practitioners at the site perform the HIV testing to clients, some that worked with community based organizations (CBOs) and/or local health departments (HD) to provide the HIV testing at their pharmacy and/or retail clinic, and some that provided HIV testing through temporary employees such as pharmacy students and/or pharmacy residents.

At least 1 staff member from each site was required to attend a training offered by ASHLIN which incorporated the goals of the project; standard operating procedures on how to perform the rapid HIV test, how to counsel patients and refer patients for confirmatory testing if necessary; and utilize appropriate data collection tools. The training was performed by ASHLIN either live or via webinar for each site to allow for maximum participation. In addition to the ASHLIN training, OraSure Technologies, Inc., also provided onsite training for enrolled sites to train individuals on how to use the rapid HIV test and to perform quality assurance testing to ensure accuracy of results.

Through July 2013, a total of 1,540 rapid HIV tests were performed at all 22 sites. The number of tests performed at each site varied from 1 to 370 rapid tests. The mean number of tests performed at each site was 59 with a median of 37 tests per site. Of all 1,540 tests performed, 24 resulted in preliminary positives (1.6%). Preliminary positives were found in both rural and urban locales.

With the range of the number of HIV tests performed at each site being so wide, it was identified that some sites were presented with some challenges in implementing HIV testing. These challenges included the ability to obtain a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver to perform the rapid HIV test, the ability to work with local health departments to obtain necessary state regulation information to ensure appropriate legal

implications of offering and performing HIV testing at each site, maintaining testing sites due to site willingness to participate and level of interest, community pharmacy and/or retail clinic infrastructure and staffing concerns with some sites requiring IRB approval or temporary employees to perform the testing for workflow purposes, advertising of new services to the community and the willingness of clients to obtain testing especially in areas with perceived stigma.

A cost analysis was performed at the end of the study to assess feasibility and sustainability of HIV testing at these sites by taking into consideration the various models that were used in this project. The analysis focused on the use of rapid HIV testing in sites that utilized limited counseling which included educational material provided to the client about the rapid HIV test, the administration of the rapid HIV test, and then post-test counseling. The analysis found that the average cost per test was $10.92. Due to the increased time it would take for post-test counseling in preliminary positive results, it was determined that the cost per test for those results would be $24.15. The analysis also found that the cost per test did not vary based on the location of testing. It was determined that in rural areas the cost per test would be $9.92 while urban sites would cost $10.76. Lastly, it was determined that the cost to provide testing during a 3 hour event would be an additional cost of $404.

A successful model for HIV testing found in this project was one utilizing a rapid HIV test in a limited counseling site with dedicated employees to provide the testing on a consistent basis. Advertising efforts are imperative and collaborations with local health departments are necessary to promote the services in addition to assistance with regulation compliance.

Introduction

Background:

In 2006 the CDC recommended that all patients between the ages of 13 and 64 be screened for HIV regardless of risk factors and that individuals with high risk of HIV infection be screened annually.[1] Despite these recommendations it is estimated that close to 21% of HIV infected individuals in the United States are unaware of their status.[2] In 2009 the CDC held a focus group to discuss revising the guidelines for HIV counseling, testing and referral in non-health care settings to expand access for HIV testing in the community. This group identified barriers to testing which included costs, denial, stigma and fear of positive results.[3] Other barriers identified from studies included anonymity, cultural sensitivity, and possible discrimination.[4-6] Another study determined that 66% of clients of a public testing service would prefer to get tested for HIV in a public clinic versus 24% with a home self-test, 12% in a doctor's office, and 1% with a home specimen collection kit. This study also found that 62% of the population surveyed felt that privacy was an extremely important factor when determining where to get tested, 58% felt the same about linkage to care, 55% felt that way about accuracy and timing of the testing, and 35% felt that counseling was extremely important.[7] The purpose of this report is to help identify a model for HIV testing to overcome some of the barriers previously identified while expanding HIV testing services.

Brief overview of Project and Purpose of the Report:

ASHLIN was awarded a two year contract by the CDC to assist in the development and evaluation of a replicable and sustainable model for HIV testing and linkage to care in community pharmacies and/or retail clinics. The purpose of this report is to summarize the overall outcomes of ASHLIN's findings from their 2 year project.

The goals of the National HIV/AIDS strategy (NHAS) include (i) reducing new HIV infections, (ii) increasing access to care and improving health outcomes for people living with HIV, and lastly, (iii) reducing HIV related health disparities.[8] Studies have shown that individuals who are aware they are HIV-positive are less likely to engage in behaviors resulting in high risk for transmission.[9] It has also been shown that individuals who are identified earlier in their HIV progression, have better treatment outcomes than those diagnosed later in their disease state.[10] This project works towards providing the community accessible HIV testing sites to increase awareness of an individual's HIV status which is consistent with the NHAS.

Pilot Objectives:

The primary objective of this project was to determine how to best implement confidential HIV counseling and testing services in community pharmacies and/or retail clinics utilizing their respective staff as certified testing providers or through collaborations with other organizations that can provide the HIV testing at their respective sites.

<u>This objective was to be met by accomplishing the following eleven tasks:</u>

Task 1: Developing a process to evaluate potential community pharmacies and/or retail clinics to include in this project.

Task 2: Selecting the testing sites based on Task 1.

Task 3: Developing a standard operating procedure to be used at each testing site.

Task 4: Developing a curriculum regarding the project and a training schedule for the staff involved at each site.

Task 5: Training the staff at each site using the curriculum developed in Task 4.

Task 6: Developing a data collection tool and database to collect data for the project from each site in a systematic and retrievable manner for analysis.

Task 7: Implementing HIV testing at each site selected as per Task 1 and 2.

Task 8: Identifying barriers to expanding HIV testing in community pharmacies and/or retail clinics locally, regionally, and nationally.

Task 9: Conducting a cost analysis of providing HIV testing at the selected sites.

Task 10: Developing an "HIV-Testing in Pharmacy" model that a variety of pharmacies and/or retail clinics could implement.

Task 11: Developing and submitting reports and databases for the CDC to be able to develop important aspects of the project into manuscripts for publication.

Multiple models for training and HIV testing were to be used for comparison and to determine best practices for implementing HIV testing in community settings nationwide. The end deliverable is a Toolkit that can be used as a resource and provide key steps for other community pharmacies and/or retail clinics to initiate rapid HIV testing at their respective sites.

This report includes a brief overview of the purpose of this project; a description of the methods used to identify, develop and implement the testing at each site; a review of the available data sources that were evaluated to determine the overall findings of this project; and descriptive recommendations for the CDC on future HIV testing in similar locations.

Brief description of sites:

With the overall goal to routinize HIV testing, it is important and imperative to have accessible sites for testing in the community. In the United States (U.S.) there are approximately 59,000 retail pharmacies throughout the country. In urban areas it is estimated that consumers have the choice of up to 30 competing pharmacies within 2 miles. In rural areas, consumers have access to 14 pharmacies within 15 miles.[11] It is estimated that about 30% of the U.S. population currently lives within a 10 minute driving distance from a retail clinic. It is also estimated that millions of Americans utilize pharmacies on a weekly basis.[12] A review of the literature found that many pharmacies were interested in expanding their roles to preventative care including HIV testing.[13] With the recent success of pharmacies expanding their services to provide immunizations, syringe access programs and other preventative care needs, it was the goal of this project to pilot and determine the feasibility of offering rapid HIV testing in community pharmacies and/or retail clinics in rural and urban locales.[14]

The addition of rapid HIV testing to the skill sets of community pharmacists is consistent with the evolutionary changes that are occurring in current health care trends.[15,16] Up until now many customers would be required to go to health departments or clinical care sites such as sexually transmitted diseases clinics to obtain an HIV test. This may lead to increased travel time and stigma in order to obtain one's HIV status. By bringing HIV testing and counseling to local community pharmacies and retail clinics, this eliminates many of the barriers for HIV testing.[17]

A survey administered to pharmacy staff involved in the New York State Expanded Syringe Access Program found that 79.4% of the staff were very supportive of the idea of HIV testing within their pharmacy site. This study also determined that staff members were more likely to be in favor of in-pharmacy testing if they were in favor of in-pharmacy immunization and the syringe access program for intravenous drug users.[18] A study was also performed in 5 New York City based community pharmacies with high HIV prevalence which determined that close to 72% of eligible patients got tested for HIV with a 0.3% incidence rate of positivity. This showed that it was feasible to offer and perform HIV testing in a high HIV prevalent community.[19,20] A similar study performed in a New York City Emergency Department found similar results where about 75% of the patients who were offered testing agreed to be tested.[21]

Methods

How were sites selected:

To achieve Tasks 1 and 2 an Expert Panel (EP) was formed during Year 1 to assist ASHLIN and the CDC with identifying criteria for potential community pharmacies and/or retail clinics participating in this project. Individuals considered for the EP were those with:

i) Experience in community pharmacies and/or retail clinics including management, operational, staffing, and hands-on experience as a practicing pharmacist or nurse practitioner;

ii) Experience with providing non-traditional services in a community pharmacy and/or retail clinic setting, such as immunizations;

iii) Knowledge of urban and rural populations at risk for HIV and likely to seek HIV testing;

iv) Knowledge of the subgroups and cultures (attitudes, values, norms) of urban and rural populations at risk for HIV and likely to seek HIV testing; and/or

v) Experience with HIV testing, HIV rapid testing, and/or counseling and referrals, including curriculum development and training.

Members of the EP were recruited from organizations such as the Convenient Care Association, American College of Nurse Practitioners, National Community Pharmacists Association, National Association of Chain Drug Stores, American Pharmacists Association, Society of Infectious Diseases Pharmacists, health insurance companies, state health departments, American Society of Health Economists, CDC, National Association of Persons Living with HIV/AIDS, and the National Minority AIDS Council.

The EP provided assistance to ASHLIN on key tasks related to this project such as site selection, training curriculum, data collection, data analysis, and publications and presentations of final data reports.

In the first year ASHLIN was contracted to train 6 pharmacies and/or retail clinics to implement HIV testing. ASHLIN identified a list of potential pharmacies and retail clinics that met the selection criteria, which was provided to CDC for final selection.

For Year 2 of the project, ASHLIN was contracted to expand the number of sites while expanding to new rural and urban locations specifically in the southern United States. A previously published survey of providers in the rural south was evaluated to better understand

barriers to HIV testing in the community. It was not only determined that 40% of AIDS cases were reported in the southern United States but on average patients would travel 50 miles for any type of HIV care in those rural southern locations.[22]

ASHLIN vetted all additional sites for Year 2 with the assistance of the EP and organizations including the Rural Center for AIDS/STD Prevention, CDC, National Rural Health Association, and State and County resources. The selection criteria for Year 2 included i) community pharmacies and retail clinics; ii) various geographic locations including 25% of the sites being located in the Southeastern states where rates of HIV diagnoses are elevated; iii) rural and urban locations; iv) sites with high HIV prevalence or unmet needs for HIV testing as defined by the AIDS Service Organization, CDC Community Planning Group, AIDS Education and Training Center, National Minority AIDS Education and Training Center, and Howard University; v) sites where pharmacists or clinicians would provide the HIV testing; vi) feasible state and local regulations for rapid HIV testing; and vii) those that would participate in a readiness assessment using the Site Readiness Checklist found in Appendix A.

Site requirements:

Each site was required to be a community pharmacy or retail clinic committed to the project with available staff that was willing to conduct rapid HIV testing. A staff member from each site was required to participate in the required training as described below. Each site was also required to have a staff member designated to oversee and coordinate the onsite activities. The sites should have had a private space for testing, delivering results and a process in place to provide required referrals as needed. In addition to the staff requirements, each site was asked to have an up-to-date CLIA Certificate of Waiver. A Site Readiness Checklist (Appendix A) was developed by ASHLIN, and utilized during site visits to determine feasibility of the sites participation in the project. The checklist included basic demographics about the site, staff and clients, and readiness regarding, personnel, physical space, equipment, certifications, referral contacts, and staff knowledge and training. Lastly each site was required to have a signed independent subcontractor services agreement with ASHLIN (Appendix B). This communicated the project sites' tasks and deliverables as required for participation in this project. All project sites were asked to:

i) Identify staff for rapid HIV testing training and overall project training.

ii) Develop a local resource and referral list and relationship with the local health department.

iii) Provide rapid HIV testing services at their respective site.

iv) Provide clients with educational materials regarding HIV and HIV testing.

v) Select and utilize a confidential area for testing.

vi) And collect and provide data as needed for project evaluation.

Each site was required to report a narrative and testing logs to ASHLIN's Project Manager by the 10th day of each month which included the i) activities of the preceding month; ii) number of rapid HIV tests performed during the preceding month; iii) data collected using a standardized data collection tool; iv) and challenges and barriers that were encountered during the preceding month. The standardized data collection tool for Rapid HIV Antibody Test Results and Log of External Control Results can be found in Appendix C.

Each site chosen to participate in this project received compensation as outlined in each of their subcontracting agreements with ASHLIN to assist with HIV testing costs. The compensation covered costs for testing-related supplies such as latex free gloves, sterile wipes, timer, room thermometer, and biohazard bags. The chosen sites were also provided up to 200 rapid HIV testing kits and control kits at no costs. Assistance with the development of local referral lists and resources, including educational materials for customers were also provided by ASHLIN. Compensation did not include staff and/or personnel time to perform HIV testing, counseling and referrals.

How each site was trained:

ASHLIN, with the assistance of the EP and CDC, developed the standard operating procedures (SOPs), the curriculum and the data to be collected as noted in Tasks 3, 4, and 6. During the Year 1 meeting with the EP, a draft SOP was presented and revisions were made by ASHLIN. The final version of the SOPs was approved by the CDC. The Standard Operating Procedures Manual can be found in the Toolkit. This manual provided each site with a brief overview of the purpose and background of the project, a review of how to train staff members for rapid HIV testing, what to do before, during and after rapid HIV testing is performed, how to ensure quality control for all tests kits, how to maintain patient confidentiality, how to determine client readiness and obtain informed consent, how to communicate rapid HIV testing results to the patient, how to make necessary referrals, how to ensure cultural competency that is site specific, and how to market the offering of HIV testing and perform outreach to obtain clients.

The same process was used to develop the training curriculum for the community pharmacy and/or retail clinic staff that would be participating in this project. Main content areas were presented to the EP and CDC for feedback and was revised by ASHLIN and subsequently approved by the CDC. A comprehensive Toolkit was developed by ASHLIN and approved by the

CDC to assist pharmacies and retail clinics with training staff on how to conduct rapid HIV tests. The Toolkit included the assessment tools, the SOPs, curriculum and training materials, case studies and lessons learned, cost information, reimbursement options and resources and referrals. The complete Toolkit will be provided to the CDC by the end of this project.

The SOPs section of the Toolkit also included training on the deliverables that each site was responsible for and how to report data. Two data collection tools were drafted by ASHLIN and presented to the EP and CDC during the Year 1 meeting. Feedback was provided to ASHLIN and revisions were made by ASHLIN and approved by the CDC. The two data collection tools were the log of External Control Results and the log of Waived Rapid HIV Antibody Test Results which can be found in Appendix C. Participants were trained on how to utilize each of these logs during the training session. The log sheets were returned to ASHLIN on a monthly basis by each site and entered into a database which was developed, utilized and maintained by ASHLIN. This database included the names of each site, site readiness information (Appendix A), site characteristics, and log of HIV testing and external control assurance testing.

To accomplish Task 5, training for at least 1 staff member from each site was provided using the above Toolkit by ASHLIN at no cost to the participants. Each site was provided 1 copy of the Toolkit to be housed at the site, but the participant's guide was provided for each individual that attended the training. The training was a half day training session, approximately 4 hours, performed on site or via webinar by ASHLIN staff. Staff of the selected sites that were present for the training were then asked to train other staff members at their respective sites. Table 1 describes the number attendees from each site for each training session in addition to the number of staff that was later trained by the attendees.

In addition to the ASHLIN training, all sites underwent OraSure training for the use of the rapid HIV test. For Year 1 all OraSure training was developed and administered by either an ASHLIN staff member or a community pharmacist who had many years of experience administering the OraSure test. For Year 2 an agreement was implemented with OraSure Technologies, Inc. to provide the training to the sites. The training included 7 sessions which included:

i) Introductions and activation of prior knowledge of rapid HIV testing and epidemiology

ii) Local community needs for rapid HIV testing

iii) Requirements for permission and consent for HIV testing

iv) Learning to administer a rapid HIV test

v) Providing test results and referring for confirmatory testing

vi) Barriers to testing and reimbursement

vii) And wrap-up and assessment

Evaluation of the training sessions:

All trainees were asked to fill out an evaluation survey of each training session they attended. The survey was completed anonymously by each participant at the end of each training session. The evaluation form can be found in Appendix D. Participants were asked to evaluate the facilitators, the overall program content and the workshop facility. The survey was conducted using a Likert scale with '1' being Strongly Disagree, '2' being Disagree, '3' being Neutral, '4' being Agree, and '5' being Strongly Agree. ASHLIN also conducted an internal team meeting after each year's training sessions were completed. This meeting concluded with a summary of the training and issues and concerns that were brought up at each site's training session. After a review of each training session, an action plan for curriculum and training revisions was developed and implemented by ASHLIN.

Starting in August 2011 monthly reports were developed by ASHLIN and submitted to the CDC to fulfill Task 11. These reports included an update of activities as they pertain to each task identified in the Project Objectives and discussed any challenges and barriers that were identified during that time period.

To accomplish Task 9, ASHLIN subcontracted with Workforce and Economic Strategies (WES) to develop a cost estimate for providing rapid HIV testing in community pharmacies and/or retail clinics. Details of the cost estimate can be found under Data Sources in this document.

Results

What sites were selected:

Using the process developed in Task 1, the EP formed in Year 1 met initially on September 26, 2011 to fulfill Task 2. The EP was composed of 8 individuals. A description of these individuals can be found in Appendix E. As noted above, the EP in conjunction with the CDC helped determine candidates of community pharmacies and retail clinics nationwide. For Year 1, thirty-six sites were identified that met the criteria as stated in Methods under Site Requirements. Seven sites were listed as Tier 2 and would only be vetted if the other sites (Tier 1) could not participate for any reason. Six of the remaining 29 sites did not join the project for various reasons as described below:

- **CVS Caremark**, Woonsocket, RI (urban). This site was piloting another project which was deemed to be a conflict of interest for the rapid HIV testing project.

- **The Westbrook Clinic**, Harlingen, TX (rural). This site was nonresponsive after several attempts to contact them. Attempts were documented and a letter was distributed to the site notifying them of the discontinuation of their site from this project.

- **Pearson Drugs**, Lecompte, LA (rural). This site was nonresponsive after several attempts to contact them. Attempts were documented and a letter was distributed to the site notifying them of the discontinuation of their site from this project.

- **Norton Sound Health Pharmacy**, Nome, AK (rural). The pharmacy was eager to participate but there was a conflict with the Indian Health Board's corporate principle which led to the discontinuation of Alaska's participation in this project.

- **Brown's Shop Rite**, Philadelphia, PA (urban). This site is located in a supermarket and is affiliated with the Keystone Mercy Health Plan. After many discussions with ASHLIN, this site opted to not be included due to resistance by pharmacists secondary to other obligations.

- **A&G Pharmacy**, Aliquippa, PA (urban). The pharmacy initially stated they had a CLIA certificate of waiver for testing, but during the process of finalizing the site it was determined that they did not have the CLIA waiver in place. As this was one of the requirements, the pharmacy and ASHLIN were not able to establish an agreement.

Of the remaining sites, 6 were able to initiate rapid HIV testing within Year 1. This included: Walgreens (Washington, DC), Walgreens (Chicago, IL), Community Pharmacy (Washington, DC), East Pines Pharmacy (Riverdale, MD), Walgreens Take Care Clinic (Lithonia, GA), and Indian Health Board of Billings (Billings, MT). The remaining 15 sites were selected for Year 2 implementation including: Barney's Pharmacy (Augusta, GA), Okeechobee Discount Drugs (Okeechobee, FL), Freedom Pharmacy (Orlando, FL), Causey Pharmacy (Natchitoches, LA), Rite Aid Pharmacy (Atlanta, GA), Long's Drugs (Columbia, SC), Moose Pharmacy (Concord, NC), Osborn Drugs (Miami, OK), Bartell Drugs (Seattle, WA), H & W Drugs (New Orleans, LA), Family Medical Services (Bessemer, AL), University Pharmacy (Detroit, MI), Gateway Apothecary (St. Louis, MO), Family Pharmacy of Neosho (Neosho, MO), Teche Drugs (Lafayette, LA), Mike's Pharmacy (Oakland, CA),and University of Mississippi School of Pharmacy (2 sites in MS).

Mike's Pharmacy initially began testing with a CBO in Eastbay. This led to a budget of over $20,000 for this site. This budget included testing one day a week for 8 hours and additional costs for staff to conduct the testing. As a CBO was providing the testing, it was also questioned

whether there may be a conflict with the pharmacy or CBO receiving other funding from the CDC or health department. While trying to work through many of these issues, the pharmacy became unresponsive after several attempts to contact them. Attempts were documented and a letter was distributed to the site notifying them of the discontinuation of their site from this project.

Teche Drugs completed the ASHLIN and OraSure training after a subcontracting agreement was in place with ASHLIN. The pharmacy was sent test kits and materials to implement testing but then became unresponsive after several attempts to contact them. Attempts were documented and a letter was distributed to the site notifying them of the discontinuation of their site from this project.

The University of Mississippi served as two testing sites for the project, but utilized 5 area pharmacies to conduct HIV testing as part of their network. Testing was not offered every day at each site; however scheduled events at those testing sites were developed to implement HIV testing over a few months. In total 24 sites were included in this project for both Year 1 and 2, however Teche Drugs and Mike's Pharmacy were unable to initiate testing once enrolled.

How sites were trained:

Using the participant's guide and Toolkit as described in Tasks 3 and 4, five training sessions were implemented and offered to participating sites in Year 1 and 6 in Year 2 to fulfill Task 5. Table 1 describes the training dates and locations and the number of attendees for each training session from each site.

Table 1: Training Information for Each Site								
Project Year	**HIV Testing Site**	**Training Site**	**ASHLIN Training Date**	**OraSure Training Date**	**# of Attendees**	**# of Staff trained to conduct HIV testing**	**Methods of Training**	**Type of Site***
Year 1	Walgreen's Chicago	Chicago, IL	3-13-12	3-13-12	5	5	Live	Urban
	Walgreen's DC	Washington, DC	3-20-12	3-20-12	3	3	Live	Urban
	Walgreen's Take Care Clinic	Lithonia, GA	3-21-12 & 5-31-12	3-21-12 & 5-31-12	7	17	Live	Rural
	Indian Health Board of Billings	Billings, MT	3-30-12	3-30-12	4	4	Live	Rural
	Community Pharmacy	Presented from Atlanta, GA	7-9-12	7-9-12	1	1	Webinar	Urban
	East Pines Pharmacy				3	Testing conducted by HD and CBO		Urban
Year 2	Barneys Pharmacy	Atlanta, GA	10-26-12	10-26-12	4	7	Live	Rural
	Rite Aid			10-26-12	2	2		Urban
	Bartell Drugs	Presented from Atlanta, GA		11-14-12	3	6	Webinar	Urban
	Osborn Drugs			12-10-12	2	3		Rural
	Okeechobee Discount Drugs	Orlando, FL	11-1-12	11-1-12	2	5	Live	Rural
	Freedom Pharmacy				3	17		Urban
	Causey Pharmacy	New Orleans, LA	11-7-12	11-7-12	1	1	Live	Urban
	H&W Drugs				1	3		Urban
	Teche Drugs				1	1		Urban
	Moose Pharmacy	Columbia, SC	11-9-12	11-9-12	1	9	Live	Urban
	Long's Drugs				2	4		Rural
	University of Mississippi School of Pharmacy	Presented from Atlanta, GA	11-14-12	11-27-12	1	8	Webinar	Urban
	Family Medical Services			11-20-12	2	2		Urban
	University Pharmacy			12-10-12	3	5		Urban
	Family Pharmacy of Neosho			12-11-12	2	4		Rural
	Gateway Apothecary	Presented from Atlanta, GA	3-13-13	3-13-13	2	9	Webinar	Urban

*Sites were designated as either urban or rural based on the clientele they serve. A site was designated rural if it provided service to both rural and urban clients.

All participants of the training sessions were asked to complete an evaluation form about the training session. This form can be found in Appendix D. On average, all participants "Agreed" with the positive statements on the form in favor of the training sessions.

For Year 1, training sessions in Chicago, Washington, Lithonia, and Billings were done live at each site. The 5th training session of that year took place in Greenbelt, MD through a webinar. The trainers were located at the ASHLIN Southern Regional office in Atlanta, GA while the attendees were located at the ASHLIN corporate office in Greenbelt, MD. The webinar training went very well and was well perceived by the attendees. This led to the transition of offering webinar training for select participating sites in Year 2.

After the 1st year of training, it was also determined that many participants felt that they needed more hands-on training with the OraQuick Advance Rapid HIV test. The feedback from the participants and from the summaries of the internal meeting led to ASHLIN developing an agreement with OraSure Technologies, Inc. to provide onsite training for all remaining project participants.

ASHLIN provided each site up to 200 rapid HIV testing kits and the necessary number of control kits for quality assurance. Sites were given the ability to request more than the 200 rapid test kits initially assigned to them if available and warranted. By July 2013 one thousand five hundred and forty rapid HIV tests were administered among all of the selected sites with 24 of them being preliminary positives (1.6%). Of the preliminary positives, some patients were already diagnosed, refused referral, had an unknown follow-up, or were negative upon confirmatory testing. A detailed account for each preliminary positive can be found in Appendix F. Figure 1 states the number of rapid HIV tests that were performed during each month of this project. Figure 2 describes the number of rapid HIV tests that were performed by July 2013 at each participating site. Figure 3 classifies the outcomes of each preliminary positive result that was identified during this study. Figure 4 describes the number of rapid HIV tests administered in both rural and urban community pharmacy and/or retail clinic settings by July 2013. Figure 5 states the number of preliminary positives that were identified in both urban and rural sites. Lastly, Figure 6 states the time in minutes staff at each site spent on pre-test activities, non-patient engaged activities and post-test counseling.

Figure 1: Number of Rapid HIV tests Administered each month (n=1540)

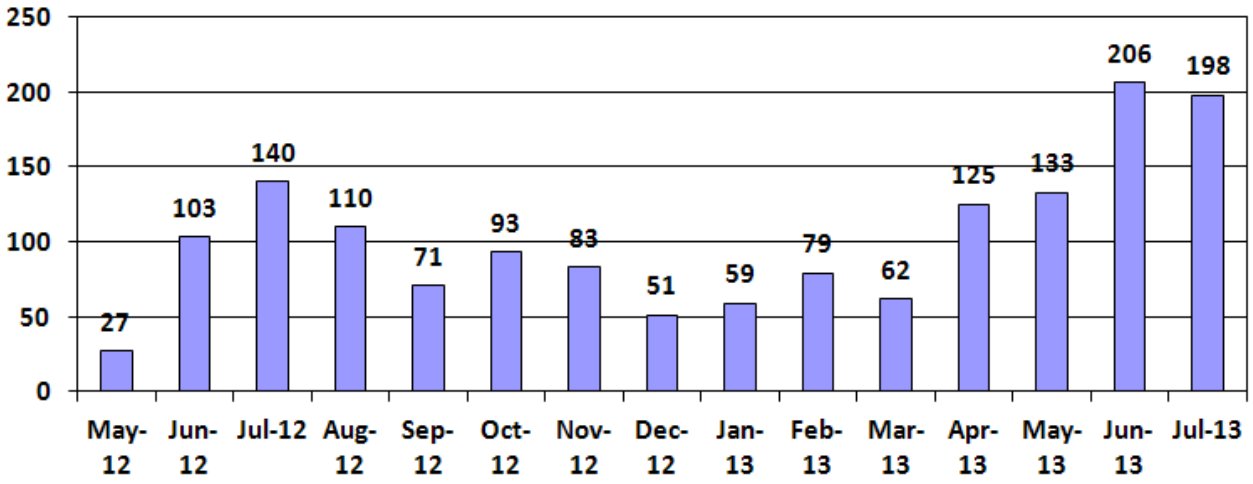

Figure 1 above shows the number of rapid HIV tests administered each month collectively by all sites. There were a total of 1540 tests conducted over 15 months from May 2012 to July 2013. There were 206 tests reported during June 2013, which was the highest number of tests reported collectively by all sites. National HIV Testing Day is observed each year during the month of June, which may explain the influx in numbers for both June 2012 and June 2013. The lowest number of tests reported was in the first month of testing, May 2012.

Figure 2: Number of rapid HIV tests performed by site by July 2013 (n=1540)

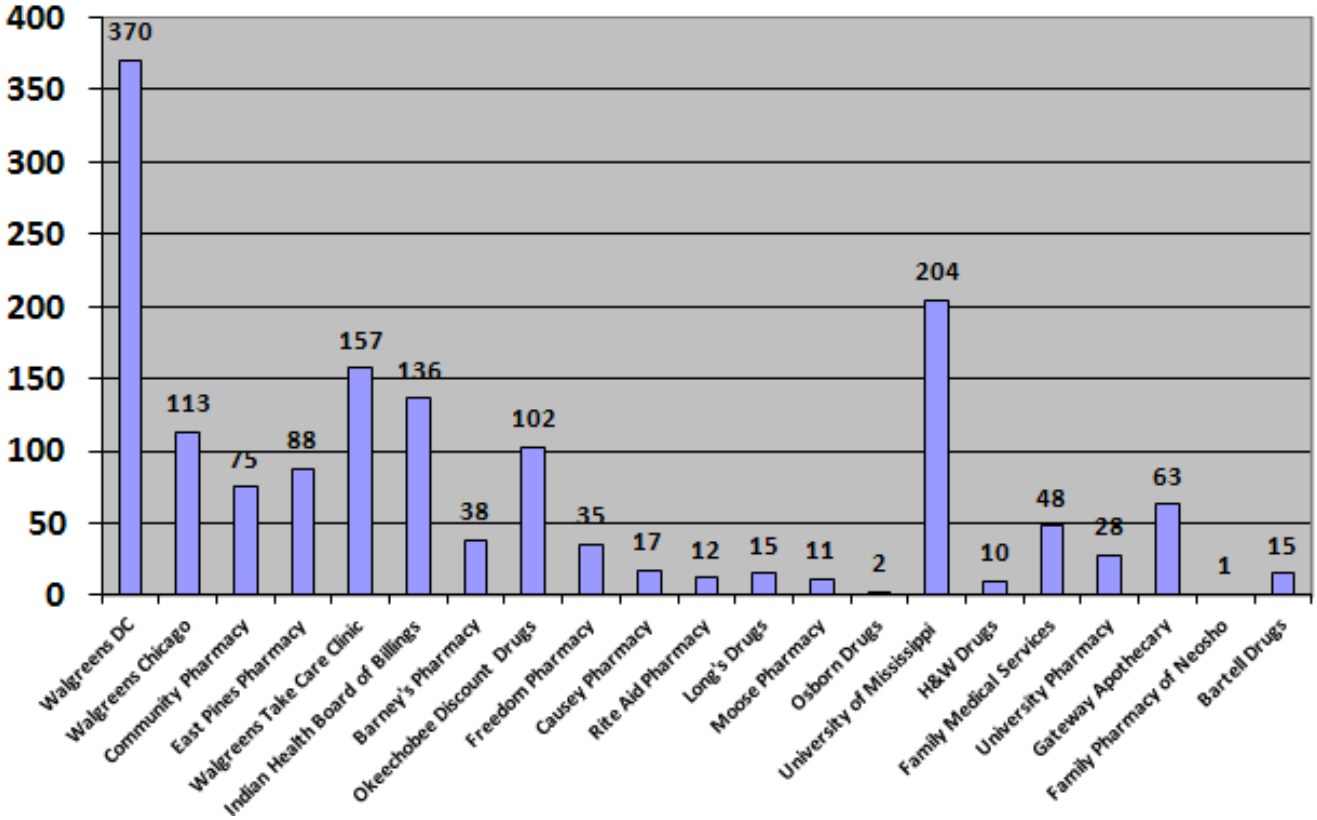

Figure 2 above shows the total number of tests conducted by site through July 2013. There were 22 sites that conducted testing throughout the project. Year 1 sites began conducting between May 2012 and July 2012, while Year 2 sites began conducting testing between December 2012 and May 2013 for various reasons (i.e. partnership development for linkage to care, staffing, etc.)

Figure 3: Outcomes of each Preliminary Positive Result (n=24)

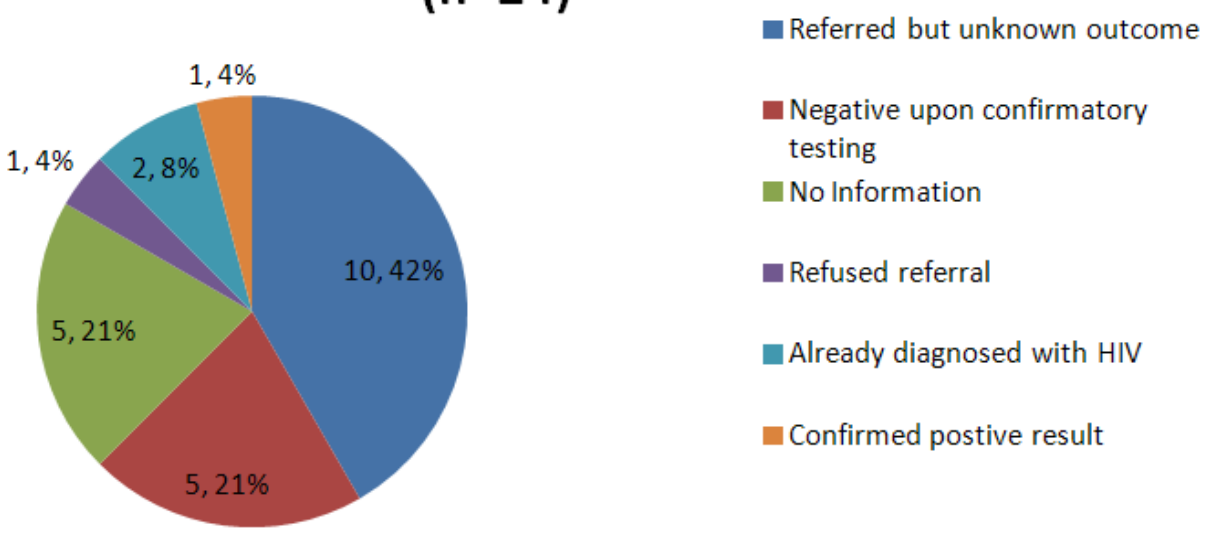

Figure 3 above shows a pie graph with the outcomes for the preliminary positive results reported throughout the project. Both the number and the percentage are provided for each outcome. There were a total of 24 preliminary positives reported between May 2012 and July 2013. Ten (10) of the clients that were referred for linkage to care services, but the results of the confirmatory test are unknown.

Figure 4: Average Total Test Times

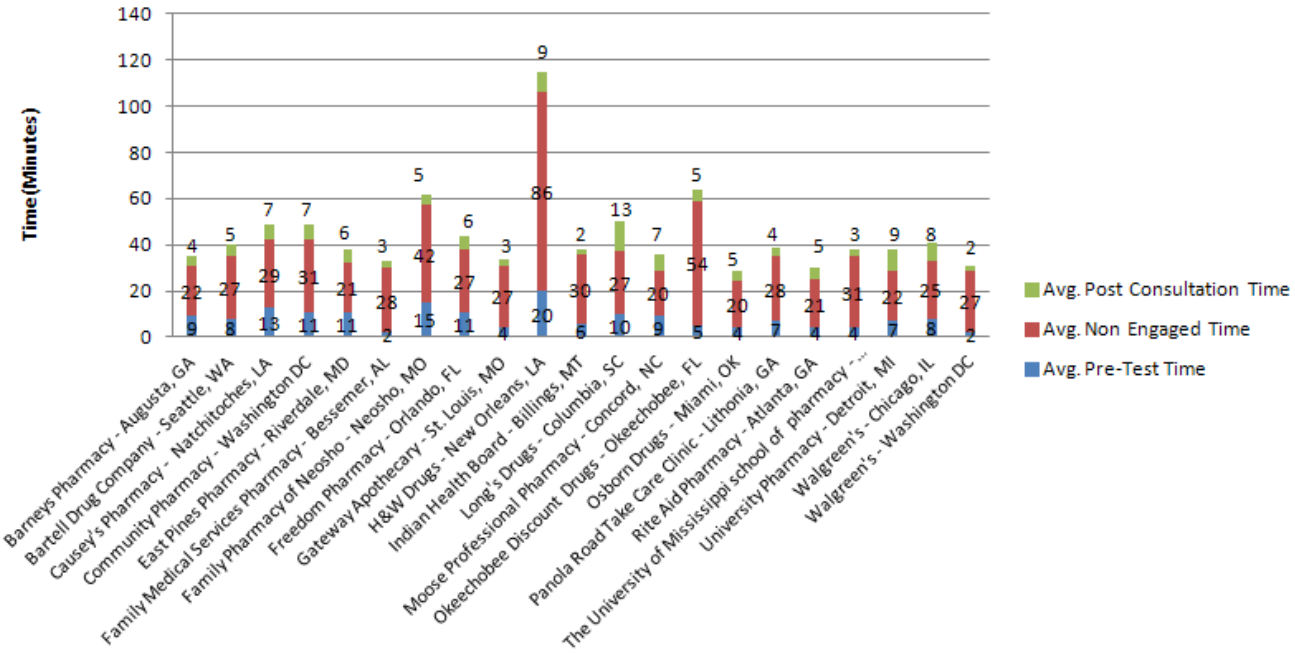

Figure 4 above shows data on the average total test times by site in a stack graph. The average post test times ranged from 2 minutes to 13 minutes, while average pretest times ranged from 2 minutes to 20 minutes. Average non-engagement times ranged from 21 minutes to 86 minutes, which includes the average test incubation time (processing time of at least 20 minutes for result reading). The gaps in time are attributed to clients returning after extended periods of time to receive their results (i.e. hours to a day later).

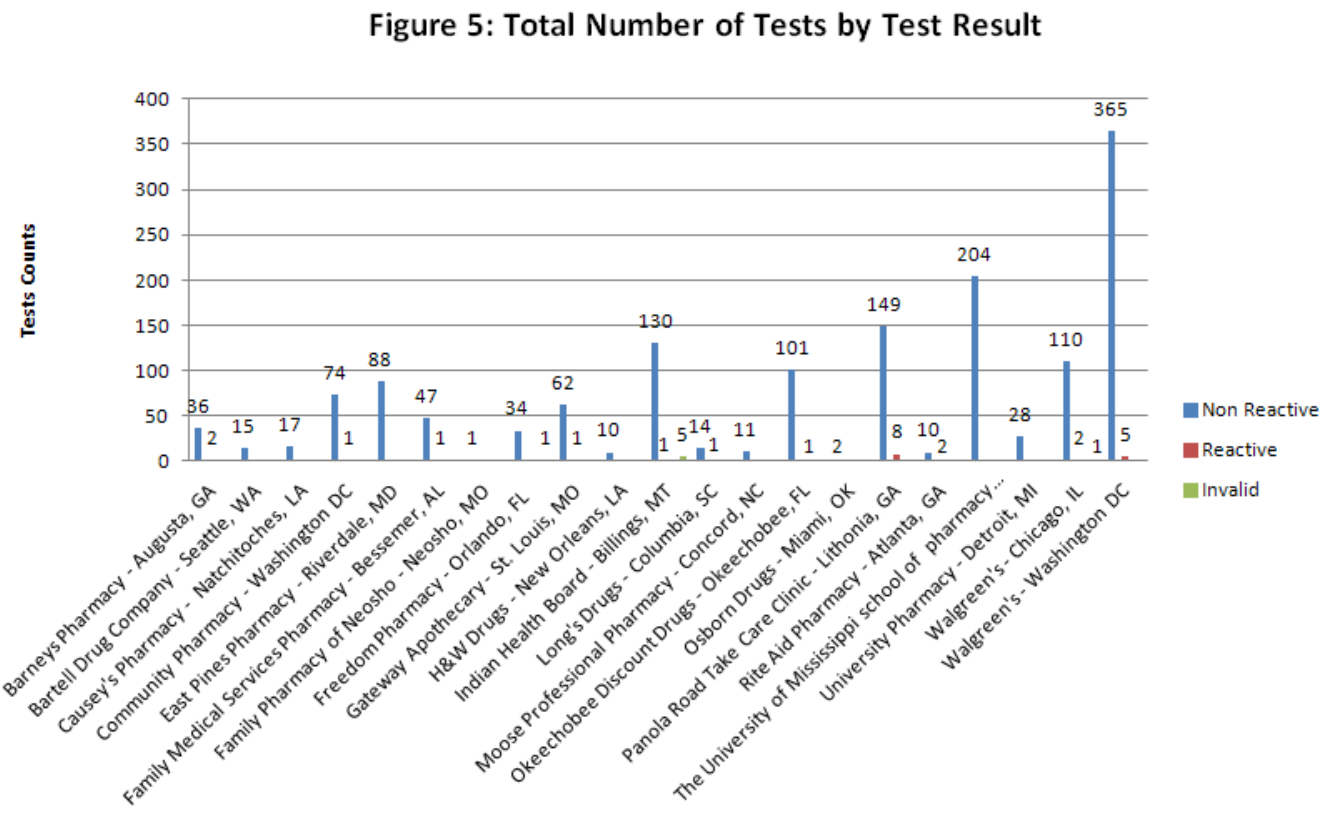

Figure 5 above shows the total number of tests conducted by the test result in a bar graph. The site that conducted the most tests was Walgreen's DC with 370 tests, while the site with the lowest number of tests conducted was Family Pharmacy of Neosho with 1 test. Walgreens Panola Road Take Care Clinic had the highest number of preliminary positives with a total of 8. Throughout the project there were a total of 24 preliminary positives reported cumulatively by all sites and 8 invalid tests reported. The remaining 1508 tests reported cumulatively by all sites the results were non reactive.

Reasons why the pharmacies began testing at different times throughout the project:

Project challenges and barriers were identified throughout the project and reported through monthly reports to the CDC to fulfill Task 8. The challenges identified served as the majority of the reasons why many of the pharmacies began testing at different times throughout the 2 year project. Challenges identified included:

CLIA Certificate of Waiver:

Any site conducting rapid HIV testing must have applied for and obtained a CLIA Certificate of Waiver or established an agreement to work under a laboratory that has already received the waiver. In addition to the CLIA Certificate of Waiver, some states have additional requirements that sites should be familiar with before implementing HIV testing. It was imperative for sites to work with their state and/or local health department to obtain important information on state specific regulations for HIV testing. A CLIA Certificate of Waiver application can be found on the Centers for Medicare and Medicaid (CMS) website and is a 4 page application. Once obtained, the waiver is valid for two years. For many Year 1 sites this was a challenge as the renewal process for the waiver needed to be initiated 9 months prior to the expiration of the waiver. Washington state and New York (with the exception of physician office laboratories in New York) have exemptions from the CLIA Certificate of Waiver but have their own requirements for testing. For other states, the time period and costs to obtain a waiver prolonged the initiation time of HIV testing at those respective sites. Maryland and California do not allow pharmacists to perform HIV testing and require laboratory directors or CBOs to perform the testing within the pharmacy. Reimbursement costs for those services seem to be a major challenge in those states. An example of this was seen with Mike's Pharmacy in Oakland, CA.

Health Departments:

Health department involvement varied from state to state but overall most health departments were engaged and very receptive to the project. Despite the continued interest by the health departments, due to budget cuts and other commitments, it seemed difficult for many health departments to maintain the level of commitment to the project needed for the sites. An example of this challenge was a site that completed its training with ASHLIN and OraSure but did not initiate testing until 6 months later due to waiting for the local health department to meet with them to discuss state regulations on HIV testing and referrals. Despite the increased wait time to meet with the department, once they met the pharmacy was able to initiate HIV testing. Other sites utilized individuals from the local health department and CBOs to provide HIV testing at their site due to state restrictions prohibiting pharmacists from administering HIV tests. ASHLIN provided the contact information for a point of contact at the state/local health department to all of the sites to assist with information on linkage to care and state regulations as well as to establish relationships for potential partnership.

Governmental budget cuts also seemed to be an issue for some health departments as many departments were provided funding to perform HIV testing. It was initially felt that this project would compete for HIV testing services that are currently being performed by the health departments. It was discussed that this project was not to compete with local health department

efforts but to collaborate with those departments to expand HIV testing services offered to local community pharmacies and/or retail clinics.

Maintaining Testing Sites:

As noted earlier in the Results section, thirty-six sites were identified as meeting the requirements for this project. Six of those sites were not enrolled due to various reasons. Four of those 6 sites were not enrolled due to becoming unresponsive to ASHLIN communication and two were enrolled but never initiated HIV testing. It is unclear if change in management, change in interest or other reasons caused the lack of communication between the sites and ASHLIN.

Internal Infrastructure:

The University of Mississippi School of Pharmacy provided testing in 5 sites in their local community. They underwent the training in November 2012 but did not initiate testing until April 2013 due to delays in finalizing the agreement with ASHLIN and having had to go through the Institutional Review Board (IRB) at the University for approval. The University requested to own the data collected from this study which was not granted due to the nature of this project and eventually was able to receive approval from the IRB to allow the initiation of HIV testing.

It was also found that at some sites, many customers elected to return the next day for their results of the HIV test as opposed to waiting approximately 20 minutes for the results that day. This caused for an increased amount of time between sample incubation and post-test interaction compared to sites that delivered the results during the same visit.

Rapid HIV Testing Training:

For Year 1 sites, training for the administration of the rapid HIV test was performed by either an ASHLIN staff member or a community pharmacist with experience using the rapid HIV test. After the Year 1 trainings were complete, ASHLIN had a debriefing to discuss ways to improve the trainings for the Year 2 sites. During the debriefing it was decided to partner with OraSure Technologies, Inc., who makes the OraQuick Advance Rapid HIV test, to be on site providing the training so a demonstration could take place in addition to providing the sites with the opportunity to ask questions throughout the training. This was implemented for all Year 2 sites.

Test Kit and Controls:

In February 2013, OraSure Technologies, Inc. was experiencing some delays in manufacturing tests and controls for the OraQuick Advance Rapid HIV test. This caused some delays for sites that had run out of the tests and controls and were awaiting more tests from the company. The usage of test kits for external control purposes also seemed to be a financial concern. At least 3 test kits needed

to be used to run the external controls to ensure the accurate detection of a nonreactive, reactive HIV-1, and reactive HIV-2 test result. The cost of shipping the external controls also varied based on the destination location. The cost of shipping up to 20 external control kits, which weighed approximately 14 pounds, ranged from $21 to $77. The cost of the external controls alone was $25 which results in the shipping costs being more than the cost of the external controls in most instances. The cost of running and shipping these controls with the test kits should be incorporated into the budgets for the community pharmacies and/or retail clinics performing the testing services.

Advertising and Community Outreach:

Each site enrolled in this project notified the community about offering free HIV testing services through various methods including, but not limited to, articles in local newspapers, flyers/posters at the site, flyers at local community centers, flyers in the customer bags, websites and through social media. Despite the advertising efforts some sites still did not yield an interest from the community. An example of this was seen with Family Pharmacy of Neosho in Neosho, MO. The pharmacy stapled advertisements about the free testing to the customer bags but it was determined that the low number of tests administered was due to the stigma surrounding HIV and other sexually transmitted infections in that local community. ASHLIN communicated some of these concerns to the local health department where perceived stigma was greatest and it was encouraged for sites to partner with local colleges/universities, rehabilitation centers, and other local clinics. Other sites had seen a great response to the advertisements initially but then a steady decline in interest for testing as seen in the Walgreen's Chicago site.

Technical Assistance:

It was found that some sites, such as the Walgreen's sites, had some delay in reporting their HIV testing data back to ASHLIN. This made data collection slow for ASHLIN and delayed monthly reports to the CDC. ASHLIN sent an email and reiterated the importance of timely submission of the monthly testing logs during quarterly meeting in order to ensure on time delivery of data analysis and reports to CDC. It was also determined that the logs were being filled out differently by each site. This provided ASHLIN the opportunity to update the pharmacies and retail clinics during quarterly meetings on how to properly complete the testing logs. ASHLIN provided a picture of the log in a screenshot via the webinar and reviewed each column, allowing time for question and answer. The updated logs and PowerPoint slides were made available to all participating sites via email and the ASHLIN Secured Online Collaborative Workspace (ASCOW). ASCOW is a secured online portal platform that connected all Year 1 and 2 sites and provided information and resources to the sites as needed. This portal could be used a discussion board and served as a method to receive important notifications to all sites through announcements and alerts. This portal was also used by the sites to deliver monthly reports to ASHLIN.

Staffing:

Though the majority of sites used pharmacists and nurses to provide the HIV testing, some sites used temporary employees such as pharmacy residents and students. This caused for a high rate of turnover of the testers. It was determined to ensure that at least 1 full time employee at each site was trained for the project and a process was in place at those sites to ensure that subsequent training took place for new employees using the Toolkit. ASHLIN was also available to provide additional training to new staff and/or provide technical assistance for training. Table 2 describes the occupation of the testers at each site.

Table 2: Occupation of Testers at each Site

Project Year	HIV Testing Site	Occupation of Testers	Type of Site*
Year 1	Walgreen's Chicago	Pharmacists	Urban
	Walgreen's DC	Pharmacists	Urban
	Walgreen's Take Care Clinic	Nurse Practitioners	Rural
	Indian Health Board of Billings	Nurses and Nurse Practitioners	Rural
	Community Pharmacy	Pharmacists	Urban
	East Pines Pharmacy	Health Department/ CBO staff	Urban
Year 2	Barneys Pharmacy	Pharmacists and Pharmacy Residents	Rural
	Rite Aid	Pharmacists	Urban
	Bartell Drugs	Pharmacists and Pharmacy Students	Urban
	Osborn Drugs	Pharmacy Residents	Rural
	Okeechobee Discount Drugs	Pharmacists and Pharmacy Technicians	Rural
	Freedom Pharmacy	Nurses and Pharmacy Students	Urban
	Causey Pharmacy	Nurses	Urban
	H&W Drugs	Pharmacists and Pharmacy Technicians	Urban
	Teche Drugs	Pharmacists	Urban
	Moose Pharmacy	Pharmacists, Pharmacy Residents and Pharmacy Students	Urban
	Long's Drugs	Pharmacists and Case Managers	Rural
	University of Mississippi School of Pharmacy (2 SITES)	Pharmacists	Urban
	Family Medical Services	Pharmacists and Pharmacy Residents	Urban
	University Pharmacy	Pharmacists, Pharmacy Residents and Pharmacy Students	Urban
	Family Pharmacy of Neosho	Pharmacists and Pharmacy Technicians	Rural
	Gateway Apothecary	Pharmacists and Marketing Manager	Urban

*Sites were designated as either urban or rural based on the clientele they serve. A site was designated rural if it provided service to both rural and urban clients.

Monthly Reports:

Since the initiation of this project, 19 monthly reports have been submitted to the CDC. These reports include an update of each task as identified in the Introduction section. The reports also included highlights from the respective month, an update on each pharmacy site, and rapid HIV test results for each month by site.

Data Sources

Multiple data sources were developed and utilized to produce this final report and to synthesize key findings and recommendations. A description of each data source can be found below including how and when it was developed and by whom. The final data sources can also be found in the appendices.

Literature Review

A literature review was performed at the beginning of this project to determine what is currently known about HIV testing in community sites such as pharmacies and retail clinics. This review included the current literature that supports the need to expand HIV services to more accessible locations. The literature review was used to help determine best practices for developing this project and identifying sites for participation. A list of references identified in this literature review can be found in Appendix G.

Master Database

ASHLIN developed a master database in Microsoft Access to accumulate all the data collected from the logs in Appendix C monthly from each site. The data collected from the sites was then entered into the database by an ASHLIN staff member. Quality assurance of the database was performed monthly, as well, to ensure accuracy of the data by another ASHLIN staff member. All analysis and reports from this data was retrieved by a data analyst. A final version of the master database will be provided to the CDC via mailed CDROM or another secured method at the conclusion of this project. This database includes the names of each site, site readiness information (Appendix A), site characteristics, and log of HIV testing and external control assurance testing.

Master Slide Presentation Set

A Microsoft PowerPoint presentation was developed by ASHLIN and presented to CDC regarding the data collected from the sites monthly reports and analysis of the master database. The slides in this presentation include the total number of HIV tests performed by site, the test results by site and by month, the number of tests performed each month since the beginning of Year 1, the time of day

the tests were performed, total number of tests performed based on type of setting such as rural and urban, and average test time including post-test counseling, pre-testing counseling and non-engaged time. The presentation is included in Appendix J. An electronic copy in PowerPoint will be provided to CDC with the Final Report.

Key Informant Interviews - Pharmacy Experiences

Near the end of the project term, key informants from the community pharmacies and/or retail clinics were surveyed anonymously by ASHLIN to collect information regarding each sites' staff's opinion on conducting HIV testing as part of this project. The survey was conducted on Survey Monkey and was sent to all staff at each site involved in the project. It was offered from July 23-30, 2013 for completion. All questions were drafted by ASHLIN and approved by the CDC. Questions asked to the key informants included thoughts on overall experience, identifying challenges and successes, current plans to continue testing past the completion of this project, current partnerships to provide the testing and referrals, and their opinion on how the in-home HIV testing would affect their sites ability to provide HIV testing.

There were a total of 23 respondents to the survey which represented 17 of the 22 sites that conducted rapid HIV testing. More than half of the respondents were satisfied or extremely satisfied by the technical assistance, training, and data collection tools from this project. Only 48% of the respondents were satisfied or extremely satisfied with the advertising aspect of this project. There were 5 major hurdles that were identified by the respondents which included advertising to obtain the clientele to administer the testing, social stigma and patient willingness to obtain testing, proper training for the individuals performing the testing, workflow concerns, and difficulty obtaining IRB approval to perform testing. However, despite training being a concern for some sites, 91% of respondents found that the training was helpful in preparing to conduct the HIV testing at their respective site. Seventy-seven percent (n=17) of the respondents stated that they would continue HIV testing after this project concluded with the majority of those sites requiring a partnership to sustain their testing efforts. Fifty-nine percent of respondents stated they would partner with their local health department to maintain HIV testing, 29% stated a partnership with an AIDS service organization, another 29% stated a partnership with a CBO and 41% stated other types of partnerships including those that may be able to help offset the costs of the rapid HIV test. Despite the potential for billing for this type of testing, 74% of respondents stated they would not be billing patients for the tests. Lastly, 87% of respondents felt that the in-home HIV tests would not cause an issue for those that wish to continue to offer HIV testing as most of the sites were eager to continue to offer the HIV testing for free. The results of this survey can be found in Appendix H.

Following the anonymous survey, ASHLIN contacted the pharmacies and retail clinics to obtain additional information on HIV testing sustainability. There were a total of 17 out of the 21

(University of Mississippi served as two pharmacies for the project, but is only counted once in the total) pharmacies that plan to continue providing HIV testing in some capacity post project and/or in the process of exploring options for continuing the service. The pharmacies planning to sustain HIV testing are listed in Table 3.

Table 3. Pharmacies Planning to Sustain Rapid HIV Testing

No.	HIV Testing Site	Location	Type
1	Barney's Pharmacy	Augusta, GA	Rural
2	Bartell Drugs	Seattle, WA	Urban
3	Community Pharmacy	Washington, DC	Urban
4	Family Medical Services (FMS)	Bessemer, AL	Urban
5	Family of Pharmacy of Neosho	Neosho, MO	Rural
6	Freedom Pharmacy	Orlando, FL	Urban
7	Gateway Apothecary	St. Louis, MO	Urban
8	H&W Drugs	New Orleans, LA	Urban
9	Indian Health Board (IHB)	Billings, MT	Rural
10	Longs Drugs	Columbia, SC	Rural
11	Moose Pharmacy	Concord, NC	Urban
12	Okeechobee Discount Drugs	Okeechobee, FL	Rural
13	The University of Mississippi School of Pharmacy	Jackson, MS	Urban
14	University Pharmacy	Detroit, MI	Urban
15	Walgreens Chicago	Chicago, IL	Urban
16	Walgreens DC	Washington, DC	Urban
17	Walgreens Panola Road Take Care Clinic	Lithonia, GA	Rural

Cost Estimate

A cost estimate for establishing rapid HIV testing in pharmacies and retail clinics was performed at the end of the 2 year project by WES and ASHLIN. This analysis developed a cost estimate for providing rapid HIV testing in community pharmacies and/or retail clinics and identified the components of costs and the cost differences between the varying testing sites used in this project. This analysis was performed using data collected from each site regarding time spent during the pre-test counseling, patient non-engaged/incubation period, and post-test counseling in addition to other site demographic information.

The data used for this analysis was obtained from each site's data collection forms that were submitted to ASHLIN monthly. The overall analysis provided a cost estimate for personnel, equipment, compliance, testing related advertisements and materials. The analysis was done using the model of a "rapid test sequence" that included acquiring the specimen at a "rapid service testing

site with limited counseling" which requires sites to give the client a copy of the manufacturer's educational brochure for rapid HIV testing, administer the rapid HIV test, and provide post-test counseling. The analysis evaluated the time it took for staff to complete 4 predefined categories including pre-test time, patient/pharmacist non-engaged time, total incubation time, and post-test consultation time. Four assumptions were used to conduct the analysis which included i) that there was no difference in the level of effort needed based on the type of reimbursement used for the rapid HIV testing; ii) that because ASHLIN provided sites with some project-related support, if sites were to have completed tasks that were done by ASHLIN, it would consume 5 hours of work effort for the site; iii) that each site utilized the materials developed by ASHLIN including training materials, counseling forms, and SOPs and lastly; iv) that no sites would undergo construction to develop a dedicated area for testing.

The overall costs were divided into fixed and variable costs. The variable costs included interaction, test, and shipping costs. The fixed costs include training, advertisement, compliance, start-up and administrative costs.

Using the 2012 national and state hourly wages it was determined that the median wage for pharmacists, nurse practitioners and pharmacy technicians were $56.09, $43.25 and $14.10, respectively. The wages in addition to the average pre and post test time was used to determine the interaction cost. The average pre and post test time had high variability from site to site but averaged 4 minutes each. This resulted in an average interaction cost of $10.92/test and $24.15/test for preliminary positives. The average interaction cost per test in rural and urban sites was not found to be significantly different at $9.92/test for the rural sites and $10.76/test for the urban locations.

This project utilized the OraQuick Advanced Rapid HIV 1/2 Antibody Kit which would cost $11 at a government rate and $18.85 at a retail cost. The government rate was used for this analysis. Further details on shipping of testing kits and controls can be found in Appendix I.

For the fixed costs, the training of each individual was based on the time and personnel wages. It was determined that the cost of training each individual for 4 hours ranged from $104.43 to $303.13. Advertising for these new services that will be provided at each site ranged from $102 to $288. It was also estimated that with many state and local health departments requiring sites to obtain a CLIA certificate of waiver, the average cost of obtaining this waiver and other licensures for testing was $167.50.

The potential costs for start-up supplies to implement a program such as this was estimated to be $2,080.41, which included disposable pads, disposable gloves, biohazard bags, timer/watch, labeling pen, writing pen, log book, file cabinet with lock, and refrigerator. The potential cost per employee

is about $218.35, while materials and labor are estimated to total $167.50. Since some sites only offered testing during events that were planned, a cost analysis was done to compare the event based testing and advertising costs. It was determined that the cost for event based testing was $404.

Further details of the cost estimate can be found in Appendix I.

Findings

Successes

Site Recruitment:

Though recruitment seemed to be a challenge in some sites, recruitment was done to provide this project with a diverse group of community pharmacies and retail clinics. It was clear there were some sites that were very successful in providing HIV testing and others that struggled with implementation and client recruitment. Overall there were 24 rural and urban sites included in this project.

Educational Training:

ASHLIN developed a training curriculum for the staff at each site involved in this project. This curriculum was developed and revised based on participant and trainer feedback. The evaluations of these training sessions were positive from the majority of the trainees. The implementation of webinar sessions in Year 2, allowed for less travel for the trainers and trainees, yet still allowed for face to face contact with the site staff. In addition to the training session, the development of the Toolkit allowed staff that were present at the training to return back to their respective sites and train other staff members on the project and rapid HIV testing. There were a total of 55 participants for the ASHLIN training but 116 individuals were eventually trained to provide HIV testing at their respective sites. ASHLIN has now developed the curriculum as an online module to help facilitate staff at each site to train other individuals interested in providing rapid HIV testing.

Collaborations:

Collaborations with CBOs and health departments were imperative in this project to ensure that all preliminary positives were referred for confirmatory testing appropriately. Ten (10) out of 22 sites that performed HIV testing identified at least 1 preliminary positive result. Though for the majority of these preliminary positives the pharmacy and/or retail clinic staff do not have the results of the confirmatory test, all sites participating in the project had a plan in place to ensure referrals were provided for these patients and the proper education, counseling and materials can be provided to those individuals.

These collaborations were also found to be useful to help with outreach and marketing. This allowed CBOs and health departments to expand where HIV testing was offered and to help ensure the preliminary positives had close follow-up.

Challenges

Site Recruitment:

Out of 36 sites that were identified as potential sites, as contracted, 24 sites were selected and approved by CDC. Two (2) of the 24 sites did not conduct any tests and were unable to continue their participation due to different reasons.

Although this project did not measure stigma, perceived stigma also played a major role in site recruitment. Low testing numbers could have been attributed to increased stigma around HIV testing and other sexually transmitted infections as seen with Family Pharmacy of Neosho. While perceived stigma played a large role in certain communities, advertising seemed to play a major role in recruitment of patients for testing. Despite efforts of advertising to already known clients as well as posting advertisements in local newspapers, it seemed many sites struggled with patient recruitment as only 2 sites reached its goal of administering at least 200 HIV rapid tests.

Lastly, one site that executed a subcontracting agreement and received training later became unresponsive to phone calls and emails. It was later decided to terminate the agreement with this site due to the lack of communication. This could be due to the increased work load of many who work in these sites. With the expanding role of pharmacists and aging population, this could potentially limit the time that staff members have to provide clients with rapid HIV testing, counseling and referrals when necessary especially with no funding to allow for a designated staff member to be in charge of patient recruitment and appropriate follow-up for preliminary positives and referrals.

It should also be noted that training of 17 of the 24 sites were conducted from October 2012 to December 2012. This allowed sites to begin testing a various times and gave some sites the opportunity to test for less than 1 year. This potentially could have impacted how many HIV tests could have been conducted at those sites.

Educational Training:

Despite the fact that ASHLIN has developed a training curriculum with a detailed Toolkit and an online training module program that can be used to train sites and new staff members that may join the team, it was imperative for many sites to have continuity of testing and referrals. Most sites utilized some form of temporary employees including pharmacy students, or residents. With the

high turnover of these staff members, continuity of having someone provide the testing seemed to be a concern. Of the 10 sites that utilized these temporary employees, the number of HIV tests provided at any one site ranged from 1 to 102 tests over the course of this project. The low testing numbers could be attributed to high turnover at each site in addition to other factors. It would be imperative for sites to have a plan in place to ensure that at least 1 permanent employee is also trained to provide testing or to train new staff as they become members of the site team.

Lastly, due to the various state regulations, it was a great challenge to develop a curriculum on HIV rapid testing in community pharmacies and/or retail clinics and standard operating procedures when regulations on who can test, how to log tests, and referral processes may be different for every state. This could be easily alleviated with the help of local health departments to help determine best practices and current regulations on HIV testing in the respective states.

Collaborations:

Though collaborations are useful to help identify state regulations and to facilitate referrals, outreach and marketing, these collaborations were often difficult to develop depending on the role of the health department in that community and their financial state. Some sites waited for the health department to become involved prior to initiating testing which delayed the start of their testing significantly. Some health departments were also hesitant to forego HIV testing to other sites such as pharmacies due to potential financial cut backs for local health departments if testing did not occur at their sites.

Many sites, such as the Walgreens Take Care Clinic in Lithonia, GA utilized local health departments to refer their preliminary positives to. Unfortunately, the sites did not have information on the results of the confirmatory test, although they have a protocol in place for referring clients to the local health department and other area clinics that offer confirmatory testing services. It is important to ensure the health departments have open communication with the referring site to ensure accuracy of testing and that clients are receiving confirmatory testing.

State Regulations:

States such as Maryland and California regulate who can provide HIV testing in the community and at this time pharmacists are not able to provide those services. This made it essential for sites in these states to utilize collaborations with local health departments and CBOs to provide the testing at the community pharmacies and retail clinics.

The District of Columbia has strict regulations on how to report preliminary positives to local health departments. As this was not a standard process needed for every state, a separate procedure needed to be in place for that location.

Lastly, CLIA Certificate of Waiver requirements also differed from state to state. This again made the use of standard operating procedures manual and training education difficult to streamline for all sites involved in this project. ASHLIN provided each pharmacy with information how to obtain a CLIA Certificate of Waiver upon initial communication with the pharmacies and retail clinics. ASHLIN also made sure each pharmacy received contact information for a state/local health department point of contact that would be able to provide additional information on state rules and regulations for HIV testing.

Summary and Key Recommendations

In this 2 year project 24 sites across the United States were enrolled in this project to implement rapid HIV testing and linkage to care in community pharmacies and/or retail clinics. Each site was trained through a curriculum that was developed by ASHLIN regarding the project and data collection as well as with OraSure to educate testers on the administration of the rapid HIV test. Over the course of 2 years 1,540 rapid HIV tests were performed across all sites with 1.6% of them resulting in a preliminary positive result. Despite the preliminary positive rate of 1.6%, it should be noted that 4 of the 24 positive tests were identified as patients who had already received a preliminary positive and/or confirmatory positive test result prior to being tested at the site.

Many sites were very successful in offering and administering the rapid HIV tests with one site having administered 370 tests by July 2013; however some sites found some challenges that made this task difficult. Challenges identified in this project included site recruitment due to community stigma and lack of interest. Community pharmacies and/or retail clinics can be high volume and fast-paced which makes it difficult to increase work load with little financial support if the need is not great in the community. By identifying sites that were interested in incorporating these services in locations with a high need or unmet need, resources were able to be utilized appropriately.

State and local regulations also played a major challenge for many sites in the project. As regulations around rapid HIV testing vary from state to state, it was imperative for sites to work with local health departments to determine the certifications and licensures needed to perform the rapid HIV tests according to state and federal regulations. The level of collaboration with the health department varied at each site as some had members of the department performing the rapid HIV testing, while others used the department as a consultant for regulatory concerns. These relationships took time to build and at times delayed the initiation of testing at some sites. The major regulation challenge was the need for a CLIA Certificate of Waiver. The obtainment of this waiver took time and personnel to ensure appropriate documentation. This cost was added to the start-up costs needed in the final cost estimate for this project.

Overall 24 sites were enrolled in this project over a 2 year time period. The sites were located in various locations in the United States and included both rural and urban locales. One thousand five hundred and forty tests were able to be administered to individuals presenting at these sites and a rate 1.6% preliminary positive results were found. This project identified a proposed model for HIV testing implementation in community pharmacies and/or retail clinics that entails staff interest at sites with a need for HIV testing. The successes of this project was shown through the training of the staff at the sites performing the testing, the advertising efforts of the sites to offer HIV testing and the communication and linkage to care for those with preliminary positive results. The importance of partnerships and collaborative efforts with state and local health departments as well as community based organizations was also identified as playing an invaluable role in assisting the pharmacies with acclimation to state regulations and development of site specific protocols for linkage to care. The majority of the sites included in this project stated they would continue HIV testing post completion of this project.

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APPENDICES

Appendix A: Site Readiness Checklist

CDC Community Pharmacy and Retail Clinic HIV Testing and Linkage to Care Project
SITE READINESS CHECKLIST

Site Name:

Assessment Date:

Name of Person Completing Form/Conducting Site Visit:

Site Point of Contact (POC) Name and Title:

Site POC Contact Information (Address, Phone, Fax, Email):

Names, Titles and Contact Information (Address, Phone, Email) for Other Key Contacts at Site:

Introduction:

Describe services and clientele:

Towns and Counties:

How many persons served per day, week, month, etc:

Is location servicing person(s) infected with HIV/AIDS and how many:

How many for meds, etc:

Is location participating in ADAP (Aids Drug Assistance Program) HRSA for cost meds:

SITE READINESS CHECKLIST FOR RAPID HIV TESTING			
Item	**Already Have in Place**	Need Minor Modifications to Have in Place	Need Major Effort and Resources to Have in Place
Personnel			
Management support for participation in project, including data collection requirements			
Identified project lead to coordinate onsite activities			
Staff available for conducting testing and making referrals (pharmacist, nurse practitioner, physicians assistant)			
All testing staff vaccinated against Hepatitis B			
Availability of volunteers or other organizations such as ASOs to assist with testing, if needed			
Physical Space			
Private space for testing and providing referrals			
Flat, clean, level surface to conduct testing and a well-lit area to read test results			
A waiting area large enough to accommodate the anticipated number of clients			
Secure (locked) space to maintain confidential client records (client name, contact information, preliminary test result, record of referrals and status of referrals, counseling notes), testing logs and other project data			

SITE READINESS CHECKLIST FOR RAPID HIV TESTING			
Item	**Already Have in Place**	Need Minor Modifications to Have in Place	Need Major Effort and Resources to Have in Place
Space to store educational materials for clients			
Space to store testing-related supplies and materials			
Equipment			
Storage/refrigeration space for test kits and control kits			
Disposal containers and funds/infrastructure for medical waste removal (used lancets, specimen loops, used test kits, soiled gloves, and other regulated medical waste)			
Access to a computer with an Internet connection			
Access to a telephone in a private area			
Certifications, Regulations and Procedures			
CLIA waiver and laboratory director (MD, NP, PA)			
Universal precautions and exposure control plan to protect staff from exposure to bloodborne pathogens			
Policies and procedures for post-exposure prophylaxis and evaluation and follow-up for staff performing finger sticks			
Quality assurance (QA) protocol to ensure testing services are carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse effects; this includes protocols for proper storage of test and control kits, running of			

SITE READINESS CHECKLIST FOR RAPID HIV TESTING			
Item	**Already Have in Place**	Need Minor Modifications to Have in Place	Need Major Effort and Resources to Have in Place
external controls, and procedures for trouble shooting for Invalid test results			
Disposal procedure for disposing of used lancets, specimen loops, used test kits, soiled gloves, and other regulated medical waste			
Referral Contacts and Relationships			
Referral source (e.g., health departments, ASOs) identified and relationship established for referring confirmatory testing for preliminary positive results, including names and contact information			
HIV referral sources and resources, including names and contact information			
Available referrals for post-exposure prophylaxis, including provider names and contact information			
Referral sources and resources for STD testing and treatment, including names and contact information			
Referral sources and resources for domestic violence, substance abuse, suicide, housing, and other social service needs, including names and contact information			
Staff Knowledge and Training			

SITE READINESS CHECKLIST FOR RAPID HIV TESTING			
Item	**Already Have in Place**	Need Minor Modifications to Have in Place	Need Major Effort and Resources to Have in Place
Knowledge of state laws pertaining to rapid HIV testing and disclosure of test results			
Knowledge of HIPAA and confidentiality requirements (client records, testing logs)			
Staff training in HIV counseling and testing, confidentiality, policies and procedures, and bloodborne pathogens			
Cultural competency with sexual and racial/ethnic minorities and languages spoken/written, and other target populations			
Knowledge and access to target population for outreach and marketing of services			
Marketing/outreach strategy/approach			

Site Visit Notes

RESOURCES TO ASSIST WITH START-UP OF RAPID HIV TESTING	
Resource	How to Access
Rapid HIV testing, including CDC's Rapid HIV Testing in Nonclinical Settings and Provisional Procedural Guidance for Community-Based Organizations Revised April 2006	www.cdc.gov/hiv/topics/testing/rapid
HIV testing locations in the United States	www.hivtest.org
Occupational Safety and Health Administration (OSHA)	www.osha.gov
Clinical Laboratory Improvements Amendments of 1988 (CLIA) Certificate of Wavier	www.cms.hhs.gov/clia
United States Department of Health and Human Services, Office of Minority Health's National *Standards for Culturally and Linguistically Appropriate Services in Health Care*	http://minorityhealth.hhs.gov
National Center for Cultural Competence, Georgetown University	http://gucchd.georgetown.edu/nccc/about.html
Health Insurance Portability and Accountability Act of 1996 (HIPAA)	www.hhs.gov/ocr/privacy
HIV Testing Laws and Regulations by State	www.nccc.ucsf.edu/consultation_library/state_hiv_testing_laws

Appendix B:

Independent Subcontractor Services Agreement

STATEMENT OF WORK
PROJECT SITES

Project Site Tasks

The specific tasks that each Project Site and ASHLIN will be required to perform are described as follows.

- Staff for Rapid HIV Testing Training and Participate in Training. Project sites will identify the number of staff to be trained on rapid HIV testing. Project sites will work with ASHLIN to determine the best date for a half-day, four-hour training and the location for the training (onsite at the project site). Project sites will ensure staff will participate in a pre-training online tutorial on rapid HIV testing (ASHLIN will provide the specifics for the website) that should be no longer than two (2) hours in duration, as well as participate in the onsite, four (4) hour training provided by ASHLIN.

  Obtain Supplies Needed for Rapid HIV Testing. ASHLIN will work with sites that require assistance with this. Examples of supplies include disposable gloves, biohazard disposal container, timer or watch, room thermometer, disinfectant wipes or bleach (for testing surfaces) and hand sanitizer. ASHLIN anticipates some of the project sites may already have some of the required supplies, which they use for other services. ASHLIN will timely provide each site with the rapid HIV test kits, a Standard Operating Procedures (SOP) Manual and a Training Agenda and Curriculum (for the onsite training)
  Ensure Project Site's CLIA Certification is Up-to-Date. Project sites will make sure their CLIA Certification is current. If a site does not have a CLIA Certificate, ASHLIN will provide assistance in securing one. A copy of the current CLIA Certificate must be submitted to ASHLIN, upon request, prior to the commencement of work.

- Develop a Local Resource and Referral List and Relationships with the Local Health Department. ASHLIN will develop a resource and referral list for HIV/AIDS care providers and clinics and confirmatory testing. Project sites can add additional resources to their lists including referrals for STD testing and treatment, HIV prevention counseling, and other social service needs. ASHLIN will provide assistance as requested to the sites with the development of this list. Project sites also will establish a working relationship, as necessary, with the local health department (HIV/AIDS office) and ASHLIN will provide assistance as needed to each site regarding this.

- Provide Rapid HIV Testing Services. ASHLIN will timely provide a sufficient number of testing kits and control kits and supplies for each Testing Site to perform a minimum of 200 patient screenings, and each project site will conduct a minimum of 200 HIV screenings over the project period (from initiation of testing as determined by each site in collaboration with ASHLIN until the end of July 2013), provide results to clients and

make needed referrals to local area providers or HIV/AIDS clinics for confirmatory testing and care.

- Provide Clients with Educational Materials. ASHLIN will provide a resource list of supplemental educational materials for project sites which contain culturally appropriate information concerning HIV and rapid HIV testing to be made available to clients. Each site may work with their local health department to obtain free educational materials and ASHLIN will coordinate and provide assistance to the sites with this.

- Select and Utilize a Confidential Area for Testing. Project sites and ASHLIN will select an area within the pharmacy or retail clinic to conduct rapid HIV testing. Sites may opt to have a separate area to talk with clients, obtain samples and deliver results, and a separate lab area in which to run the tests. The area used to talk with clients must be confidential (a room with a door that closes).

- Collect and Provide Data. Subcontractor will transmit aggregate and de-identified information only on a monthly basis to ASHLIN by fax or mail, which submission may be combined with the narrative report submission described below. Project sites will also participate in two (2) de-briefings by teleconference with ASHLIN staff regarding their experiences with providing rapid HIV testing.

DELIVERABLES AND REPORTS:

Each site is required to conduct a minimum of 200 screenings during the performance period, providing that ASHLIN has provided for an adequate amount and number of testing supplies, kits, and control kits. Failure to meet the required screening levels may result in termination of this agreement under the provisions of Paragraph 8.

A narrative report is due to ASHLIN's designated Project Manager by the 10th day of each month of task order performance and shall include the following information:

- Activities of the preceding month
- Number of Rapid HIV Tests performed during the preceding month
- Data collected using data collection tool
- Challenges/barriers encountered

Appendix C:

Data Logs

Log of Waived Rapid HIV Antibody Test Results

Pre-Test & Specimen Collection Time [1]		Test Record Number	Date of Test	Test Kit Lot Number	Kit Expiration Date	Test Incubation Time [2]		Test Result N= non reactive R= reactive I= Invalid	Time Post-test Interaction time [3]		If the Preliminary HIV Test was reactive:		Referral Notes [4]	Tester
Start	End					Start	End		Start	End	Do you know the result of the confirmatory test? Yes/No/ Don't Know	Result of confirmatory test? Positive/ Negative/ Don't Know		

[1] Pre-test and Specimen Collection Interaction Time. Start: Record time when client requests rapid HIV test. End: Record time when specimen collection is completed. If the client inquires about but does not receive a rapid HIV test, record the approximate start and end times of the interaction and enter "Client not tested" in Notes Column.

[2] Test Incubation Time. Start: Record time OraQuick specimen collection device is placed in buffer solution. End: Record time when test result is read.

[3] Post-Test Interaction Time. Start: Record time when client is brought to private space to report test results. End: Record time when client leaves private space.

[4] Referral Notes. Record referrals and note type (e.g. HIV clinical care/confirmatory testing, STD testing). If client requests but does not receive rapid HIV test, record the reason if known (e.g. recent exposure;
referred for EP evaluation.) Enter other important notes.

Log of External Control Results

Start Time for Test Set Up	Date	Room Temp	Control Kit Lot #	Control Kit Exp. Date*	Reason for External Control (A - G)[2]	Test Kit Lot #	Test Kit Exp. Date	End Time for Test Set Up	Control Test Incubation Time [3]		Date controls opened	Negative Control Result	Positive Control Result (HIV 1)	Positive Control Result (HIV 2)	Results Accept-able? [4]	Performed by and Reviewed Date
									Start	End						

*Exp. = Expiration

[1] **Time to Setup Control Test.** Start: Record time started setting up control test. End: Record time finished setting up control test and recording necessary information (i.e., lot #, expiration date).

[2] **Reason for External Control—Record one:**

- **A.** New operator
- **B.** New lot of test kits
- **C.** New shipment of test kits
- **D.** New box of test kits opened
- **E.** Temperature of storage area outside permissible range (<35 °F or >80°F)
- **F.** Temperature of testing area outside permissible range (<59°F or >99°F)
- **G.** Periodic test as required by site quality assurance protocol

[3] **Control Test Incubation Time.** Start: Record time Control Test specimen collection device is placed in buffer solution. End: Record time when test result is read.

[4] **Results are acceptable IF** Negative Control result = N **AND** Positive Control result = R. Enter Y (Yes) or N (No). **If N, take corrective action and document on reverse side of this form.**

Sample of Temperature Log for Test Room or Refrigerator

Thermometer Location: Acceptable Temperature Range*: to _____

Month and Year: _____					
Day	Temperature	Initials	Day	Temperature	Initials
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

* The acceptable range for test kit storage can be found on your product insert. Note: Periodically (e.g., every 6 months) check thermometer performance and document.

Corrective Action

Date	Identified Problem	Action Taken	Initials	Reviewed By

Appendix D:

Evaluation of Training

Evaluation of Training
ASHLIN CDC Rapid HIV Testing in Pharmacies/Retail Clinics and Linkage to Care Project
Date: **ASHLIN Trainer:**

FACILITATORS	**Strongly Disagree 1**	**2**	**3**	**4**	**Strongly Agree 5**
1. Explained the purpose of the session.					
2. Established a comfortable learning environment.					
3. Explained the subject content clearly and effectively.					
4. Paced the training appropriately.					
5. Took initiative to make things better.					
6. Seemed to be adequately prepared.					
7. Responded well to questions.					

OVERALL PROGRAM CONTENT	**Strongly Disagree 1**	**2**	**3**	**4**	**Strongly Agree 5**
8. The format was effective.					
9. The content was easy to follow.					
10. The content was relevant to my expectations.					
11. The content provided a working knowledge of the subject matter.					
12. The overall discussion was helpful.					

WORKSHOP FACILITY	**Strongly Disagree 1**	**2**	**3**	**4**	**Strongly Agree 5**
13. The facility was conducive to learning					
14. The facility was comfortable					

Comments:

Appendix E:

Expert Panel and Staff

CDC COMMUNITY PHARMAC /RETAIL CLINIC PROJECT EXPERT PANEL AND STAFF			
Name	Affiliation	Background	Contact Information
EXPERT PANEL			
Glen Pietrandoni, RPh, AAHIVP On the following Expert Panel Subcommittees: Site Selection and Site Readiness; SOPs; Cost and Reimbursement	Large Retail Chain HIV/AIDS Program	Head of Walgreen's HIV/AIDS Services; previously for Walgreens was a Pharmacy manager and a field sales manager. Is affiliated with the American Academy of HIV Medicine, SIDP, and the Gay and Lesbian Medical Association.	Email: glen.pietrandoni@walgreens.com
Michael Bogachek, PhD, MBA On the following Expert Panel Subcommittees: Site Selection and Site Readiness; SOPs; Cost and Reimbursement	Community Pharmacy Owner	Owner of a 12 year-old pharmacy company specializing in providing products/services to private and public entities in rural and urban locales; is AIDS Drug Assistance Program (ADAP) certified; and is a member of the National Community Pharmacists Association (NCPA).	Email: mbogachek@pharmalife.com
Maria Pajil Battle On the following Expert Panel Subcommittees:	Health Insurance Company, Keystone Mercy Health Plan	Oversees marketing, public affairs, and health promotion activities for a major health insurance company; experienced marketer and sales professional in the health insurance industry; special focus on community health and working with	Email: Maria.Battle@amerihealthmercy.com

CDC COMMUNITY PHARMAC /RETAIL CLINIC PROJECT EXPERT PANEL AND STAFF			
Name	Affiliation	Background	Contact Information
Site Selection and Site Readiness; Cost and Reimbursement; Marketing and Outreach		underserved populations; is a graduate of the Wharton School of Business with a degree in economics.	
LT Scott Wiegand, RPh On the following Expert Panel Subcommittees: Site Selection and Site Readiness; SOPs; Data Collection and Analysis	Staff Pharmacist and Director, HIV/AIDS Program	Serves in the U.S. Public Health Service and is a staff /clinical pharmacist for Rosebud Comprehensive Health Care Facility in South Dakota, an IHS clinic; director of local IHS HIV/AIDS program; participated in APhA Pharmacy-Based Immunization Training; currently developing an IHS clinic to monitor compliance and optimize pharmacotherapy of HIV clients.	Email: scott.wiegand@ihs.gov
Mara San Antonio-Gaddy, RN, MSN On the following Expert Panel Subcommittees: Site Selection and Site Readiness; SOPs; Curriculum and Training	Affiliated with the National Association of State and Territorial AIDS Directors (NASTAD)	Directs field services for New York State's Department of Health/AIDS Institute; including prevention and screening for HIV and STDs; experience in HIV prevention curriculum development and training, including rapid HIV testing; MSN includes an HIV/AIDS clinical specialty; currently a nurse planner for the School of Public Health in Albany, NY; has extensive experience working with the CDC and its grantees.	Email: mls07@health.state.ny.us

CDC COMMUNITY PHARMAC /RETAIL CLINIC PROJECT EXPERT PANEL AND STAFF			
Name	Affiliation	Background	Contact Information
Janet Teske, DNP On the following Expert Panel subcommittees: Curriculum and Training; Data Collection and Analysis	Affiliated with the Convenient Care Association	DNP with extensive experience in all aspects of retail clinic operations.	Email: janet.teske@aurora.org
Jessica Leston, MPH On the following Expert Panel subcommittees: TBD	Indian Health Services	Current lead on IHS's initiative to increase screening for HIV and STDs in IHS service units, including pharmacies; CDC-certified for rapid HIV testing.	Email: jdleston@gmail.com
Stephen Bailous On the following Expert Panel subcommittees: TBD	National Association of Persons Living with HIV/AIDS (NAPWA); Consumer	Supporting people living with HIV/AIDS since 1988; current head of treatment advocacy and community affairs at NAPWA; member of the National Black Gay Men's Advocacy Coalition (NGBMAC) and serves on numerous HIV/AIDS advisory groups; was Director of the PLWH/A initiatives for the NYC Mayor's Office and Health Department.	Email: sbailous@napwa.org

Appendix F:

Report on Preliminary Positives

CDC HIV Testing and Linkage to Care in Community Pharmacies and/or Retail Clinics
Report on Positive Test Results (May 2012 – July 2013)

The information provided is representative of information collected from the participating pharmacy sites from May 2012 through July 2013:

Total Number of Tests = 1540

Number of Preliminary Positives = 24

Number of False-Positives = 5

Percentage of Preliminary Positives to Total Tests = 1.6%

Percentage of False Positives to Total Tests Performed = 0.32%

Percentage of False Positives to Preliminary Positives = 21%

Since the inception of HIV testing at the Year 1 and Year 2 pharmacies, the data for all test results reported has been compiled and stored in a database. This report contains information on all the preliminary positive test results reported by the pharmacies each month. There are a total of **24** preliminary positives that have been reported between May 2012 and July 2013. The preliminary positives are separated by pharmacy and the report only includes information on the pharmacies that have reported at least 1 preliminary positive result to ASHLIN. The information within the tables contain the date the test was conducted, test kit number, summary, follow up information and post test interaction time for each test.

Indian Health Board (IHB) (Billings, MT)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	March 2013	6631965	IHB had a client come in to be seen presenting multiple systemic symptoms. The staff ran an HIV test and other lab work on the client. After the HIV test finished processing the pharmacist identified a faint line present. The site has a lab onsite that can provide confirmatory testing services, so the client was sent immediately to the lab for confirmatory testing.	The staff followed up on the preliminary positive result by reviewing the patient's medical records in the system. The labs showed that the result of the confirmatory test was nonreactive for both HIV 1 and 2. The site noted that other medical conditions can cause a preliminary positive result and provided that information in the document. The staff went on to explain that the patient has some	17 Minutes

				other significant medical issue.	

Barney's Pharmacy (Augusta, GA)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	December 2012	6631965	One of the pharmacists at the pharmacy was training another pharmacist on how to administer a rapid HIV test. The pharmacists received permission from the client to have both pharmacists in the room. The client informed the pharmacists that he had been tested once before while serving in the army. He found out about the testing services being offered at the pharmacy from an article printed in the local newspaper. The test was administered properly and there were no unexpected events that occurred during the testing process. While the client waited in the store area, the pharmacist went back into the testing area after the processing time ended to read the test and noticed a faint line. He then consulted with the pharmacy trainee and another pharmacist who has been trained to ensure he was correct in his reading.	A few days after the client was notified of his preliminary positive test result, the pharmacist spoke with the patient liaison at the HIV clinic. The patient liaison informed the pharmacist that the patient did come in for confirmatory test, which was conducted using a Western Blot. The results of the patients confirmatory test was negative (nonreactive).	10 Minutes
2	7/11/13	6634793	Client was referred to Georgia Regents University/Ryan White clinic for confirmatory testing and educated on the importance of follow-up. During the visit the patient informed	The pharmacy followed up with the patient and the patient's number had been disconnected.	11 Minutes

			the pharmacist that they had tested preliminary positive the week before at the health department, but did not believe it.		

Community Pharmacy (Washington, DC)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	December 2012	6629121	In December 2012 the pharmacist tested a client who came into the pharmacy for HIV testing services. As the test was processing she could see a faint line appearing in the window. She ran a control at the same time to make sure the tests were calibrated properly. The pharmacist invited the client back into the private area and told the client the results from the screening test were preliminary positive. She provided some information on HIV, and walked the client to the Rashbaum office (private doctor's office) for confirmatory testing. Each month the pharmacist at Community Pharmacy reports any preliminary positives to the health department as required by the District of Columbia.	The pharmacist followed-up with the client and the Rashbaum office to inquire about the test results from the confirmatory test three days after the test was conducted. Both the client and the staff at the doctor's office informed her that the result of the confirmatory test was negative (nonreactive). The pharmacist then submitted a report to OraSure Technologies to inform them of the false-positive.	40 Minutes

Walgreens DC (Washington, DC)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	June 2012	6629545	The client was a flight attendant who tested preliminary positive. She/he was leaving the next day	The pharmacy manager does not have record nor can she recall how they were informed, but	10 Minutes

			to go overseas. The pharmacy refers their clients to a non-profit clinic, Whitman-Walker, for confirmatory testing. The pharmacist who tested the client is no longer with the company.	received notice from either the client or the clinic that the results of the preliminary positive was nonreactive (negative). The pharmacy manager was reminded by ASHLIN that referrals and resources provided to clients should be captured in the notes section of the log each month and follow-ups with clients receiving a preliminary positive test result need to be documented as well.	
2	7/31/12	6629545	Referred to clinic for confirmatory testing	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	30 Minutes
3	8/31/12	6630439	No comments in data base	ASHLIN contacted the site during QA process, but the site didn't have any updates on confirmatory test result.	4 Minutes
4	9/30/12	6630439	Referred to clinic for confirmatory testing	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	7 Minutes
5	6/31/13	6634556	The client was referred to the Whitman-Walker clinic for confirmatory testing. The client did not speak English, but brought someone with her to translate the information and results. Walgreens has a protocol that if a client does not speak English the pharmacist can call the Walgreens hotline to request a translator to assist, which is another Walgreens Pharmacist.	Upon following up with the clinic, no information was available on the results of the confirmatory test.	8 Minutes

Walgreens Take Care Clinic (Lithonia, GA)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	May 2012	6629664	The Nurse Practitioner in the clinic reported that a client in their first month of testing had a preliminary positive test result. The client went to another facility to receive confirmatory testing. The location where the client was referred for confirmatory testing is unknown.	The Nurse Practitioner later followed up to inquire about the results of the confirmatory test. She was informed that the results from the confirmatory test were nonreactive. The Nurse Practitioner provided this information to the Walgreens corporate office. However, there is no record of when this information was updated at the corporate level. The Nurse Practitioner who provided the services at this time is no longer employed by Walgreens. The current staff at the Walgreen's Take Care Clinic has been informed by ASHLIN to record all future referrals in the "Notes" section and include the results from the confirmatory test on the monthly logs when submitted each month. If results are received after the date monthly logs are due, the clinic is to complete a Corrective Action Form including the updated information from their follow up with the client and/or confirmatory testing facility.	15 Minutes
2	5/31/2012	6629664	No information found in the data base.	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	9 Minutes
3	5/31/2012	6629664	No information found in the data base.	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test	15 Minutes

				result.	
4	8/31/2012	6630436	Client referred to the Health Department for confirmatory testing.	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	10 Minutes
5	8/31/2012	6630436	Client refused referral. He stated that he has his own primary doctor.	ASHLIN contacted the site and there were no further discussions with the client.	2 Minutes
6	9/30/2012	6630436	Client referred to the County Health Department for confirmatory testing.	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	10 Minutes
7	9/30/2012	6630436	Client referred to the DeKalb County Health Department for confirmatory testing.	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	12 Minutes
8	1/31/2013	6633056	Client referred to FCDHW for confirmatory testing appointment was set.	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	10 Minutes

Rite Aid (Atlanta, GA)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	1/14/2013	6633056	Client had received a preliminary positive blood test prior that he notified the pharmacist of after receiving his results. He was provided with information on some clinics.	Client has a physician.	4 Minutes
2	4/22/2013	4/22/2013	Patient had seen a doctor and thought that he may have been positive, but was not tests prior.	Client has a physician that he will see to seek confirmatory testing and services. The client received confirmatory testing, but the pharmacy was not informed of the result	6 Minutes

Gateway Apothecary (St. Louis, MO)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	4/11/2013	6634434	Client was already diagnosed with HIV prior to test but did not disclose this information to the pharmacist. The client is being treated and on medication.	The client is being treated and on medication.	4 Minutes

Walgreens Chicago (Chicago, IL)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	8/31/2012	6630169	Client wants a call from the pharmacist. No other information was noted.	ASHLIN contacted the site on 2 occasions but the site didn't have an update if Walgreens contact the client per their request (most recent contact by ASHLIN on 5-24-13).	9 Minutes
2	8/31/2012	6630169	Client referred to Clinic for confirmatory testing.	ASHLIN contacted the site on 2 occasions but the site didn't have any update on confirmatory test result.	23 Minutes

Family Medical Services (Bessemer, AL)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	7/30/2013	6635651	After the client received their results they were referred to the ADPH STI Division for confirmatory testing.	The pharmacy followed up with the client where the client would be receiving confirmatory testing services to provide the clients information. The HIV care coordinator has taken over the case at the Jefferson County Department of Health has taken over the case an arranged for the confirmatory testing and care coordination. The results of the confirmatory test were not	20 Minutes

				provided to the pharmacy.	

Long's Drugs (Columbia, SC)

No.	Date	Test Kit Lot No.	Summary	Follow up Information	Post Test Interaction Time:
1	7/22/2013	6631970	The pharmacy contacted the CBO they partnered with, SC HIV/AIDS Council, to schedule confirmatory testing for the patient immediately following providing the results.	The patient went to the CBO to receive a confirmatory test, which came back a confirmed positive. The patient was provided a case manager and they have already gone in for the intake process. The patient has a medical appointment at a local clinic in a few weeks. The pharmacy will follow the patient for 1 year (SC DHEC standards) to ensure they stay in care.	40 Minutes

Appendix G:

Reference List

Reference List of Abstracts, Journal Articles, Publications and Presentations

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Appendix H:

End of Project Survey Interview

End of Project Survey Interview

1. Rate your overall Experience with the following aspects of the project:

Answer Options	Extremely Dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Extremely Satisfied
Training	0	1	2	14	6
Data collection tools	0	0	3	13	7
Advertising	0	4	8	9	2
Technical assistance	0	2	2	12	7

2. What would you identify as being your success with the project:

Answer Options	Response Count
Screening Patients	12
Training	3
Advertising Services	2
Infrastructure	2
Dedication by Staff	1
Increase in Pharmacist role	1

3. What would you identify as being your challenges with the project:

Answer Options	Response Count
Advertising	8
Social Stigma	7
Training	3
Institutional Review Board Process	1
Infrastructure/Workflow	1

4. In preparing to conduct HIV testing, the following were helpful:

Answer Options	Response Count
SOPs	14
Marketing Materials	15
Training	21
Resource Assistance	13
Off-site Events	6
On-site Events	11
E. Other (please specify)	2

5. Do you plan to continue HIV testing services after the project ends:

Answer Options	Response Count
Yes	17
No	5

6. In order to continue HIV testing at my pharmacy, I will need support from a partner and if so who?

Answer Options	Response Count
Yes	17
No	6
Answer Options	**Response Count**
Health Department	10
Community Based Organization	5
AIDS Service Organization	5
Other	7

7. Do you plan to bill for you in-store HIV testing?

Answer Options	Response Count
a. Yes	6
b. No	17

8. Do you think the availability of in-home HIV tests will affect your ability to offer HIV testing in the pharmacy/retail clinic?

Answer Options	Response Count
A. Yes	3
B. No	20

Appendix I:

Cost Estimate

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Cost Estimate for Establishing Rapid HIV Testing In Pharmacies and Retail Clinics

Submitted to:
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National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP),
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EXECUTIVE SUMMARY

ASHLIN Management Group, Inc. (ASHLIN) contracted with Workforce and Economic Strategies (WES) to develop an ***economic cost estimate*** for ***providing rapid HIV testing in pharmacies and retail clinics*** (RCs) and to identify the components of costs and the cost difference in testing sites with varying characteristics. The estimate is based on an extrapolation of data from questionnaires and data collection forms developed by ASHLIN. The cost estimate will aid pharmacies and retail clinics in determining the time and costs involved in providing rapid HIV testing at their respective facilities.

ASHLIN and WES conducted an exhaustive analysis of the various HIV testing options that are available in the United States. However, for the purpose of brevity and targeted estimates, this report will focus on ***Rapid Testing Sequences*** and will also provide supplementary information for additional testing options.

This report outlines the analytical considerations and approach used to estimate the cost of providing an HIV testing program based in a community pharmacy and/or retail clinic. This analysis will estimate the costs to be incurred at the testing sites and does not take into account the expected costs for implementing such a program at the national or corporate level. This report is organized as follows:

> Section I: Cost Elements – Identifies the basic elements of the cost model, including rapid testing as well as ancillary fixed costs and variable costs
>
> Section II: Cost Model - Presents the methodology and approach to developing the analytical model
>
> Section III – Cost Estimate – Describes the cost estimate

Principal Findings. The average interaction cost is $10.92 per test. It is evident that more time was spent in the post-test consultation for reactive tests at an average interaction cost of $24.15 per test. The cost of testing performed in different communities did not vary significantly with rural area costing $9.92 per interaction compared to $10.76 in urban communities.

SECTION I: COST ELEMENTS

HIV Test Options

Currently, HIV testing technology in the United States consists of a wide variety of tests, including enzyme immunoassay tests, Western Blot test, Rapid Test, oral fluid tests, tests that detect antigen and antibodies, as well as the rapid oral fluid home test, most recently approved in 2012.[5] This report will focus primarily on the rapid oral test. Appendix E-1 briefly discusses additional types of tests available and identifies specific characteristics of the tests that might affect cost, such as the duration of the test, required number of tests, sensitivity, and follow-up requirements.

Rapid HIV Tests

Several types of rapid tests are currently available, each of which has different cost implications. One type requires a finger prick with a small needle to obtain a small blood sample. Other types require oral fluid. Rapid tests generate three possible outcomes: invalid, negative, or preliminary positive. If the test result is preliminary positive, a confirmatory test such as a Western Blot test[6], an Indirect Fluorescent Antibody (IFA)[7] test or a second rapid test from a different manufacturer must be performed. In addition, the provider will need to provide post-test counseling on: (1) the meaning of the preliminary positive test, (2) the need for repeated test and for confirmatory test, and (3) the importance of practicing safe sex and taking other precautions until the confirmatory test results are returned. These tests require at least one more follow-up test of high specificity to reduce the likelihood of false positives.

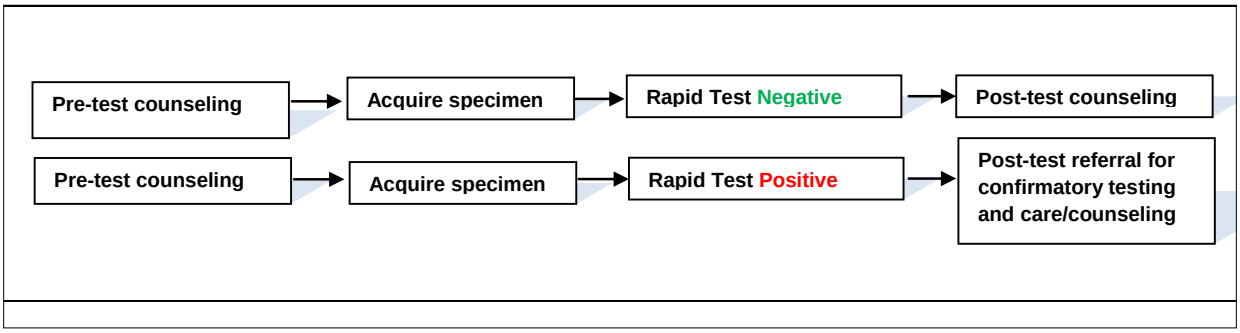
The Rapid Test Sequence is depicted in Figure 1.

[5] HIV Testing in the United States, U.S. Centers for Disease Control and Prevention, 2013

[6] *Western Blot (WB) Test:* The Western blot is the most common test used to confirm positive results from a rapid HIV test. Western Blot tests are given as a confirmatory test because it is less likely to give a false-positive. These tests do not require a follow-up test of high specificity to reduce the likelihood of false positives. This test costs more than the antibody and rapid tests because it is difficult to perform and requires highly technical skills. In addition to being expensive, these tests have limited commercial availability.

[7] *Indirect Fluorescent Antibody (IFA) Test:* The indirect fluorescent antibody (IFA) test also detects antibodies, but it is more expensive than a Western blot test so it is only used as a confirmatory test. These tests do not require a follow-up test of high specificity to reduce the likelihood of false positives.

Figure 1: Rapid Test Sequence



Types of Testing Sites

Given the range of testing options available, the cost of implementing a testing program at testing sites can be estimated for three possible types of testing sites, as described in Table 1. All test sites are required to provide counseling for pregnant women as recommended by the CDC.

Table 1: Types of Pharmacy Sites for HIV Testing Cost Estimates

Type A - Full-service Testing Site with Counseling (HIGH COST Option)
▪ Pre-test counseling and advice on the costs and benefits of various types of tests, their relative accuracy, their false positive and false negative rates, and recommended test sequence ▪ Full range of test options, including HIV Antibody, Rapid, WB/IFA, or Viral Load and Ag/Ab Combo Assay test ▪ Post-test counseling
Type B – Rapid service Testing Site with Full Counseling (MEDIUM COST Option)
▪ Pre-test counseling and advice on the costs and benefits of various types of tests, their relative accuracy, their false positive and false negative rates, and recommended test sequence ▪ Rapid Oral or Blood Test ▪ Post-test counseling
Type C – Rapid service Testing Site With Limited Counseling (LOW COST Option)
▪ Give the client a copy of the subject information pamphlet ▪ Rapid Oral or Blood Test ▪ Post-test counseling

Type A testing sites offer the full-range of recommended pre-testing counseling, which covers important information about HIV itself and about the testing process. This information can include:

1) Information about the range of available HIV tests—what they test for, how accurate they are, what they might not tell clients, and how long it will take for test results to come back;
2) Information about how HIV is transmitted and how clients can protect themselves while waiting for the results;
3) Information about privacy and confidentiality of test results; and
4) Test sequence if a test is positive and the sequence if a test is negative.

For post-test counseling, the provider provides clients with information on:

1) What the test results are and what they mean;
2) HIV prevention counseling, if the first test is negative;
3) The process of the confirmatory test if the first test is positive;
4) If test is positive, provider discusses what it means to live a healthy life with HIV and how the client can keep from infecting others, treatments for HIV to stop from progression to AIDS; and
5) Discuss how all HIV-positive test results must be reported to the state health department for data tracking, but assure clients that no personal information is ever shared in those reports.

Type B testing sites offer the full-range of counseling as Type A, but only offer a limited range of test methods, restricted to either Oral or Blood Rapid testing. The clients get the full benefit of information, faster test turn-around time of 20-40 minutes, and will only be required to do a single-visit as the pre-test, test, and post-test activities can occur in the same visit.

Type C testing sites provide information to clients about the rapid HIV test, including the manufacturer's educational brochure. The clients get the full benefit of information, faster test turn-around time of 20-40 minutes, and will only be required to do a single-visit as the pre-test, test, and post-test activities can occur in the same visit.

Cost Elements at Point-of-Care Testing Sites

In this report, we measured program costs, in terms of the cost per person tested and costs associated with the implementation of rapid HIV testing at twenty-two sites across the U.S. This section discusses the variable costs (material, labor, marketing, etc) associated with conducting a test plus the fixed costs of establishing and operating a testing site. Several key fixed costs of

the pharmacy and RC (overhead) are not included in this analysis. This was done to protect the privacy of the participating pharmacies and RCs and not to share publicly their pricing strategies and expenditures and how it relates to their competition.

The costs discussed in this study are important for planning and can vary depending on utilization, ownership, geographic location, staffing composition, and other factors. In order to create an effective cost analysis estimate, a dollar value must be assigned to each resource needed for the rapid HIV test in order to calculate costs associated with each activity. The following section identifies cost components related to establishing and operating a testing site:

1. **Start-Up Costs**
   Costs that are incurred at the beginning of program implementation are frequently referred to as "start-up costs". These costs can be consolidated for a national chain pharmacy operator so they are not repeatedly incurred at each site. These are costs that in the short run do not vary much with the level of activity. Pharmacies and retail clinics should consider whether equipment purchased may be used for other purposes or already existing equipment may be used; if so, costs from the testing perspective should be prorated on the basis of the expected useful life or depreciated values of the equipment.

2. **Facility Cost**
   Costs associated with the facility, including utilities expenditures, should be apportioned to each activity by determining the percentage of the total space that is used for the testing. Some pharmacies may opt to establish a dedicated area for testing, which may require new construction or a partitioned area. The average chain store averages more than 8,500 square feet per store and independent drugstores average 3,000 square feet per store.[8]

3. **Equipment Cost**
   During the start-up and on an ongoing basis, pharmacies will have to acquire, store and utilize appropriate equipment for performing tests and the cost of the additional items NOT included in the Master Shipping Carton:

   a. Clean, Disposable, Absorbent Workspace Cover
   b. Disposable Gloves (these are optional with oral swab)
   c. Biohazard Waste Container
   d. Timer or Watch (that can time 20-40 minutes)
   e. Labeling Pen (Sharpie)

[8] Downloaded from https://www.advisen.com/downloads/Industry_Report_Drugstores_2012_02_07_teaser.pdf (assessed March 1, 2013)

f. Writing Pen and Log Book for Recording Results
g. Safety goggles
h. File cabinets
i. Any other apparatus required at the individual site

4. **Certifications, Licensure, and Regulations Compliance Costs**

Another start-up cost to consider is the effort involved in obtaining certificates or licenses and compliance with state and local regulations. Many state Departments of Public Health (DPH) require that all sites obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate and state licenses. In addition, many states require sites that conduct any type of HIV testing to review laws and regulations governing HIV testing to ensure full compliance with regulations on viral serology. For rapid test sites, some states require a minimum of 2 documents: A current CLIA Certificate of Waiver, Compliance or Accreditation from CMS;

Either one of the following documents:

a. A state Clinical Laboratory License/Approval, with sub-specialty to perform clinical laboratory testing in Viral/HIV Serology; or
b. A state HIV Special Projects Waiver.

5. **Development Cost for Standard Operating Procedures (SOPs)**

To operate as HIV testing sites, pharmacies will need to develop standardized operating procedures and protocols beyond the current pharmacy operating policies and procedures. They include:

a. Protocols to maintain confidentiality and privacy throughout the entire testing process: written consent, test performance, disclosure of test results, and storage of records;
b. Test procedures which define materials and equipment required; steps to follow to perform the test; and safety precautions to protect clients and testing personnel;
c. Since all reactive rapid test results require confirmation through submission of a serum specimen, a follow-up testing procedure needs to be developed and tested;
d. Reagent handling protocols which define how to store and dispose of all reagents properly;
e. Internal Quality Control Procedures: Some states require that each qualitative method must be tested with a positive and negative control on each day of testing as part of internal quality;

f. External Quality Control procedures: Some states require both positive and negative controls to be run on each day of testing;

g. Documentation protocol: Some states require that providers produce documentation that controls have been run (such as the date, type of internal or external control, control test results, control lot number, and control expiration date, etc.)

h. Outside Review Protocols: Some states require an outside review by the state's Department of Public Health. These are periodic reviews that require procedures to handle site-based reviews by state officials.

6. <u>Personnel Costs</u>

Testing for HIV requires personnel to handle blood or oral fluid samples and to execute testing procedures with an infectious virus. Since retail clinics and pharmacies operate in a fast-paced environment, doing these tests will require additional trained personnel who are dedicated to proper HIV testing, safety, and control procedures. In addition to the time it takes to perform the requisite counseling and the tests themselves, other direct support costs for such personnel are needed to ensure that accurate and reliable test results are obtained. In order to administer HIV testing, personnel should be proficient in all aspects of HIV testing including (1) specimen collection; (2) test procedures; (3) test results reading and interpretation; (4) all record keeping procedures and reporting of results; and (5) biohazard safety procedures, including waste disposal. All training will also have assessments of trainees' ability to safely and accurately perform the testing.

7. <u>Safety Costs</u>

a. *Sanitization of Physical Space.* Pharmacies will need to disinfect the testing area appropriately before and after each test.

b. *Storage and Disposal.* Pharmacies will have to follow storage and disposal procedures for infectious or physically dangerous medical waste, including blood stained materials in *accordance* with State and Federal regulations, specifically storage and disposal of infectious or physically dangerous medical or biological waste state sanitary code; and OSHA Blood Borne Pathogen Regulations [29 C.F.R. 1910.1030].

c. *Specimen Collection Precautions:* On an ongoing basis, pharmacies will have to follow procedures to ensure blood and oral fluid collection tasks are done in an aseptic manner. These extra *procedures* will result in staff time devoted to such activities, but are necessary to protect both the clients and the pharmacy personnel.

8. **Counseling Costs**

   a. *Pre-test Counseling Cost:* Some states require that prior to HIV testing; the testing personnel should assess the client's readiness and capacity to test. Upon determining that the client is ready to test, the testing personnel should next explain (1) The purpose of the test; (2) The seroconversion period; (3) The Confidentiality of test results and reporting requirements; (4) What the test results will mean; and (5) What will happen if the tests result is positive and how the client may be referred to HIV treatment and care. Some states may require that this counseling occur prior to obtaining informed consent and a specimen for HIV testing. In some states, test sites which qualify as Routine Screening Provider status are not required to provide this counseling.

   b. *Post-test Counseling Cost:* Some states require that all test sites provide post-test counseling for all clients testing *HIV* positive. Doing so will require either additional time or additional personnel.

   c. *Referrals to Care and Support Services Costs:* Some states require that providers develop referral and linkage processes to case management services, primary health care, follow-up confirmatory testing, HIV Partner Services, syringe access and other services. Doing so will require either additional time or additional personnel.

9. **Project Management Oversight Cost**

   At these HIV testing sites, in order to minimize the operational impact on pharmacies in a retail setting, there must be provision for management oversight of the testing to ensure that the necessary staffing level, supplies, and confidential record systems are established and maintained. In addition, management oversight is important for activities such as (1) management of the HIV testing quality system program at each site; (2) development, implementation, and monitoring of a standard operating procedure for each type of HIV test; (3) ensuring that all testing is performed by staff who are properly trained and certified according to the national requirements; and (4) oversight of the recordkeeping system.

10. **Record Keeping Costs**

    a. *Test/Reagent Data Records*. Some states require that testing sites document all test/reagent data. These data include: lot number, record of reagent storage temperatures; date and time of specimen collection; time test was initiated; time result was read; temperature in the room when the test was performed; test result; quality control results; who performed the test, test kit storage logs

and confirmatory result logs. Sample temperature logs and external control logs may also be required in some locations. Doing so will require either additional time or additional personnel.

b. *Confirmatory Testing Records*. Some states require that provider's document in records that confirmatory serum testing was performed on all reactive client specimens. Doing so will require either additional time or additional personnel.

c. *Unconfirmed Reactive Results Records*. Some states will require that providers consult with the state DPH on appropriate state and federal guidelines for the reporting of unconfirmed reactive results.[9]

Some states require that all records are maintained by providers for a minimum number of years, or according to the CLIA certificate.

11. <u>Quality Assurance/Process Control Costs</u>

Process control refers to mechanisms employed at test sites to ensure correct testing procedures, suitable testing environment, and accurate and reliable tests results. These mechanisms and activities include monitoring, evaluation, and quality controls.

a. *Monitoring Costs:* Testing sites will need to continuously monitor the testing environment to ensure operational conditions are consistent with those recommended by the CDC. Areas of continuous monitoring include: temperature and storage conditions; labeling and recording instruments; data entry and reporting; safety procedures and emergency protocols. Training will also be required for those who conduct the monitoring, and this represents a recurring cost with employee turnovers.

b. *Quality Control Costs:* In addition to the continuous monitoring, periodic quality control procedures will be needed to ensure that all personnel are performing the tests accurately, in accordance with the highest standards. These periodic procedures will include device quality control and procedural quality control, described in Table 2. Periodic procedures also include measuring volumes of testing per staff, time required per staff, and other quality metrics as needed.

Since controls have to be purchased from a manufacturer or a reference laboratory, using them will incur some costs. Some state DPH will also require an external quality assurance review, typically conducted by the state DPH.

[9] The CDC requires that if a second (confirmatory) test yields either negative or indeterminate results, follow-up testing should be performed on a blood specimen collected 4 weeks after the initial reactive HIV rapid test result. (www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm)

Table 2. Types of Control for Process Quality Evaluation and Control

Type	Description
Device quality control	This type of control ensures that adequate quantity and quality of specimen, reagents, equipment, test kits, or test devices are always in the process. It also ensures that they are all functioning properly.
Procedural quality control	Using known positive and negative specimens or control materials, this type of control ensures that test personnel are following established operating procedures and that the tests are performed accurately .

12. **Vendor Interface and Inventory Cost**

Depending on the type of test site, different costs will be incurred for purchasing of test kits and maintaining a sufficient inventory. For all types of test sites, some cost will be incurred for developing and maintaining an inventory record for kits and supplies. Some effort will be required to determine re-order levels for each item in the inventory based on workload and usage to ensure a constant supply of reagents and no service interruption, or wasteful expiring of reagents and test kits.

13. **Information Management Cost**

The record keeping cost previously discussed primarily involves personnel time cost. Conversely, information management cost involves computer technology and computerized testing equipment. For example, a system for tracking specimens collected for quality control purposes would make it much easier to manage this aspect of the quality system function but would be costly to acquire and maintain. In addition, with such a computerized testing environment, some software system would be needed to assure accuracy, privacy, confidentiality, and reliability of data. The same considerations would apply when client information is transmitted or shared across computers in the same network of pharmacies.

14. **Incidence Management Cost**

Accidents and errors will occur with finite probability even in the most carefully controlled test environment. When they do occur, we anticipate that there will be a cost to investigate what happened and determine the cause of the error. Likewise, there will be a cost to implementing procedures to ensure the error does not recur.

15. **Insurance Management Cost**

Pharmacies must consider administrative costs for reimbursements from insurance carriers, contracts with State or local health departments, as well as Medicare and Medicaid. If pharmacist services are covered by insurance, additional costs to the

pharmacist arise from the need to verify coverage, complete and submit claim forms, follow insurer requirements for payment, reconcile claims, and wait for payment. Goods or services reimbursed through a third party will almost always cost more to provide than the same goods or services paid for directly by the consumer. [10]

16. **Marketing and Outreach Cost**
    There are costs associated with the development of material/content to educate clients about rapid HIV testing service.

SECTION II: COST MODEL

Background

ASHLIN in consultation with the CDC developed the criteria and methodology used to determine testing sites feasibility to participate in the project. ASHLIN utilized a combination of onsite visits and teleconferences to assess sites readiness. Once it was determined that the site met the minimum criteria, ASHLIN conducted a walk-through of the physical space and interviewed key pharmacy personnel. Upon being selected to participate in the project, ASHLIN provided each site with documentation discussing the program requirements for participation, background information on the purpose, intent and goal of the project, data collection and reporting requirements.

Data Collection Process

ASHLIN conducted training for the participating site's staff. The participants received instructions on how to properly administer the test and conduct appropriate control measures. Participants also received instruction on how to apply time and motion observations and requirements for completing the data logs. To ensure data accuracy, participants were strongly encouraged to complete the data collection forms as they progressed through the testing process or immediately after completing the testing. Each site used data collection forms developed by ASHLIN to collect the data.

Testing Observation Categories

Staff documented their activities into four broad predefined lists of activities:

[10] Carroll NV. Costs of dispensing private-pay and third party prescriptions in independent pharmacies. *J Res Pharm Econ.* 1991;3(2):3-16., Schafermeyer KW, Schondelmeyer SW, Thomas J, et al. Analysis of the cost of dispensing third party prescriptions in chain pharmacies. *J Res Pharm Econ.* 1992;4(3):3-24., Huey C, Jackson RA, Pirl MA. Analysis of the impact of third party prescription programs on community pharmacy. *J Res Pharm Econ.* 1995;7(2):57-72.

Table 3. Test Phases and Descriptions

Test Phase	Phase Description
Pre-test Time	Beginning of the test to Incubation Start Time
Patient/Pharmacist Non-Engagement Time	Incubation Start Time thru Post-Test Consultation Start Time. During this phase of the test, the Pharmacist is not required to be with the patient.
Total Incubation Time	Incubation Start Time thru Incubation End Time.
Post-test Consultation Time	Post-test Interaction Start Time thru Post-Test Interaction End Time. Post-Test Consultation Time is the time spent by the pharmacist with the patient to discuss test results.

These activities were used in order to facilitate data collection. Staff could easily identify activities and not have to make on-the-spot judgments about whether those activities were, for example, pre-testing versus post-testing.

Sample Testing

Rapid HIV testing took place between May 2012 and July 2013 at a total of 22 participating sites, which included twenty (20) community pharmacies, one (1) retail clinic and one (1) nurse run clinic at the Indian Health Board (IHB). The sample testing included sites operated under several different ownership structures (for profit, not-for-profit, sole-proprietorship, corporations, public and private) and were located in two types of communities: urban and rural. Table 4 provides the total number of tests conducted and results, categorized by start date of participation and by location.

Table 4. Summary of participating pharmacy sites, as of July 2013.

Pharmacy Sites	Location	Type	Testing Start Date	Total Tests Completed	Total Preliminary Positives
Year 1 Sites:					
Walgreen's DC	Washington, DC	Urban	July-12	370	5
Walgreen's Chicago	Chicago, IL	Urban	May-12	113	2
Community Pharmacy	Washington, DC	Urban	Jul-12	75	1
East Pines Pharmacy	Riverdale, MD	Urban	Jul-12	88	0
Walgreen's Take Care Clinic	Lithonia, GA	Rural	Jun-12	157	8
Indian Health Board of Billings (IHB)	Billings, MT	Rural	Jul-12	136	1
Year 2 Sites:					

Pharmacy Sites	Location	Type	Testing Start Date	Total Tests Completed	Total Preliminary Positives
Barneys Pharmacy	Augusta, GA	Rural	Dec-12	38	2
Okeechobee Discount Drugs	Okeechobee, FL	Rural	Feb-13	102	0
Freedom Pharmacy	Orlando, FL	Urban	Dec-12	35	0
Causey Pharmacy	Natchitoches, LA	Urban	Feb-13	17	0
Rite Aid Pharmacy	Atlanta, GA	Urban	Dec-13	12	2
Long's Drugs	Columbia, SC	Rural	May-13	15	1
Moose Pharmacy	Concord, NC	Urban	Jan-13	11	0
Osborn Drugs	Miami, OK	Rural	Jan-13	2	0
University of Mississippi School of Pharmacy (2 SITES)	Jackson, MS	Urban	Apr-13	204	0
H&W Drugs	New Orleans, LA	Urban	Mar-13	10	0
Family Medical Services	Bessemer, AL	Urban	Feb-13	48	1
University Pharmacy	Detroit, MI	Urban	Dec-12	28	0
Gateway Apothecary	St. Louis, MO	Urban	Mar-13	63	1
Family Pharmacy of Neosho	Neosho, MO	Rural	Jan-13	1	0
Bartell Drugs	Seattle, WA	Urban	Apr-13	15	0

Data Analysis

This section describes the methodology used to calculate the cost of implementing rapid HIV testing at pharmacies and RCs. The sites that began their participation in the first year of the project, 939 tests were conducted over a span of 13-15 months. For those sixteen (16) sites that began their participation in year two, 601 tests were conducted over a 2-8 month period. The data collected are used to estimate the start-up, operating, and other costs associated with planning and administering rapid HIV testing in a pharmacy or RC setting.

Rapid Test Sequence 1" and "Type C"

The cost estimate provided will only measure the cost associated with the ***"Rapid Test Sequence 1" and* "Type C",** depicted in Figure 2.

Figure 2: Direct Steps and Related Cost Considerations for a Rapid Test Sequence and Type C

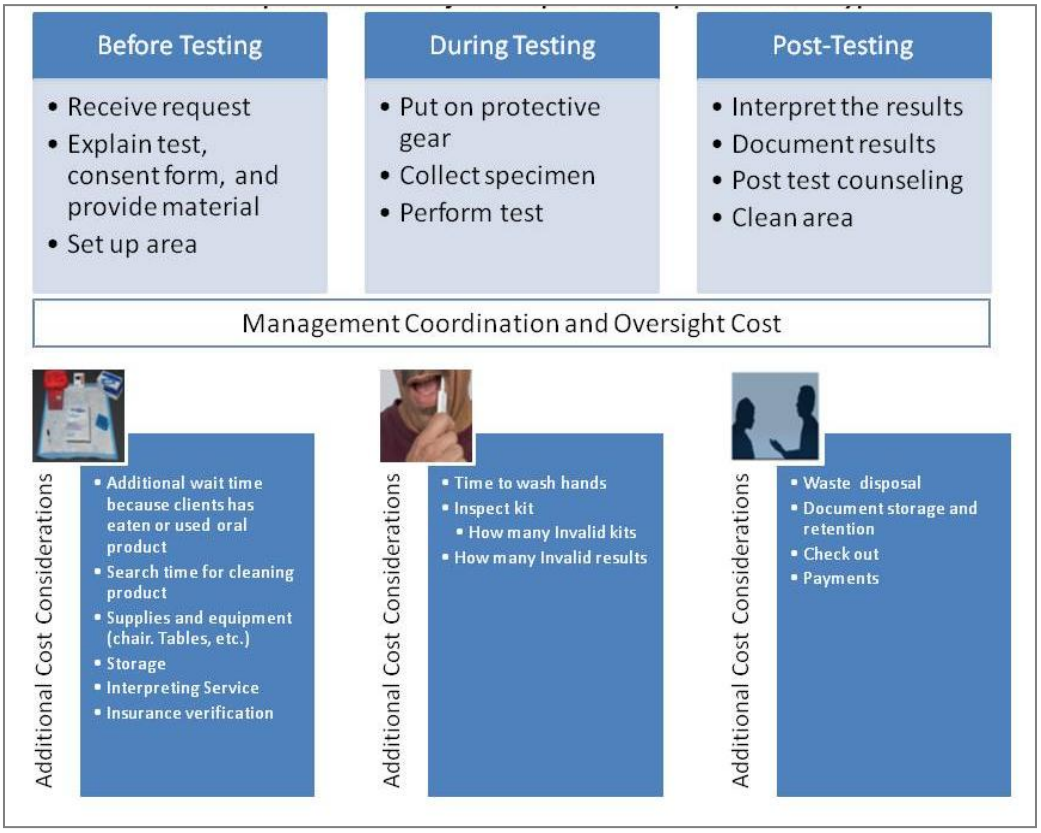
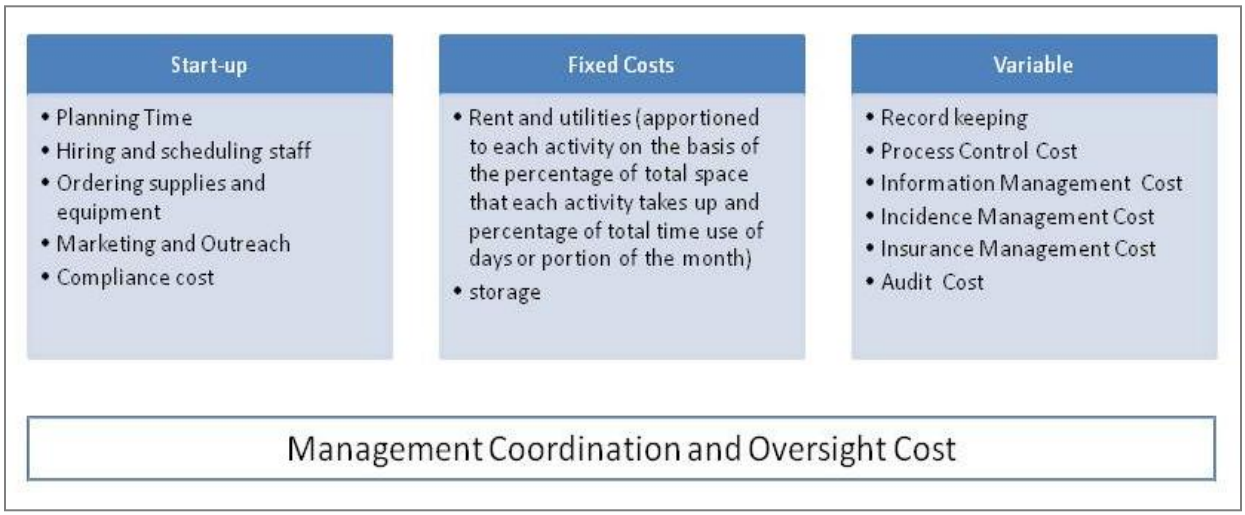


Figure 3: Indirect Steps and Related Cost Considerations for a Rapid Test Sequence and Type C



Time and Motion

A common tool used to gather detailed information on processes is time and motion observations. [11] This approach can be performed either through continuous observation or work sampling.[12] Historically, continuous observation is considered more accurate than work sampling.[13] In the continuous observation approach, an observer passively shadows an individual while recording the amount of time spent in each task being performed. The data used for this analysis are based on self-reported time utilization during the testing procedure.

The time spent administering the test by approximately eighty-five (85) pharmacy and RC staff during a two-year demonstration project with sites testing over up to 15 months was analyzed. The classification of staff included Pharmacists, Pharmacist Technicians, and Nurse Practitioners and the time spent by volunteers was not considered. The actual time observation was performed by trained staff to record the duration of each individual activity. Using digital watches, the staff recorded the activities that they performed on the 1540 tests conducted at the 22 sites.

Our primary outcome measure was the number of minutes spent per patient in each analysis category and the labor cost and other direct costs (equipment and materials) associated with administering and performing an OraQuick® Rapid HIV-1 Antibody Test. This cost estimate accounts for labor costs related to the pharmacy and RC staff administering the test, the pre-test interaction time and post-test interaction time, regardless of test results. This analysis does not take into account the value of volunteer time or donated materials but is aware of the cost implications of having to pay for those resources. Moreover, the use of "free" resources represents an opportunity cost that should be included in cost estimates that take into account societal cost.[14]

Key Assumptions

Our cost models are based on several key assumptions. First, given that the testing we performed at no cost to the customers, we assume that there exists no different level of effort

[11] Starren J, Chan S, Tahil F, White T. When seconds are counted: tools for mobile, high-resolution time-motion studies. Proceedings/AMIA Annual Symposium 2000;833–7.
[12] Wirth P, Kahn L, Perkoff GT. Comparability of two methods of time and motion study used in a clinical setting: work sampling and continuous observation. Med Care 1977;15: 953–60.
[13] Burke TA, McKee JR, Wilson HC, Donahue RM, Batenhorst AS, Pathak DS. A comparison of time-and-motion and self-reporting methods of work measurement. J Nurse Admin 2000;30:118–25.
[14] Future cost studies should consider the societal cost of providing HIV testing in pharmacies and/or retail clinics. Consideration should be given to developing a probabilistic measure of likely Testing-Type and sequence controlling for type of test site in a given geographical area and their outcomes. Future research should include all costs, regardless of payer, such as out-of-pocket expenses (expenses incurred by participants that are not accounted for in the testing costs), or productivity losses (i.e. work time used or earning lost because of time used to take the test).

required to process different types of administrative costs for reimbursements from insurance carriers, contracts with State or local health departments, and Medicare and Medicaid. Secondly, the administrative and support tasks, as well as the other project-related tasks performed by ASHLIN, would consume five (5) hours of work effort if conducted by the participating sites. Third, we assume that the sites used materials that were developed by ASHLIN. Such material would include training materials, record-keeping logs, and standard operating procedures.[15] Finally, our model considers that the average chain store averages more than 8,500 square feet per store and independent drugstores average 3,000 square feet per store.[16] Therefore, we assume that pharmacies and RCs would not construct a dedicated area for testing because some may already have a confidential counseling space/room, particularly the RCs. Although it is conceivable that a location may want to construct a dedicated testing area, it is more likely that most sites would preferably incur the cost of partitioning off an area.

Our cost model accounts for the costs of materials and personnel costs. A pharmacist or nurse practitioner would be responsible for managing and coordinating the program as well as following up on any questions or concerns that a participant may have. A pharmacy technician or similar occupation would be responsible for performing tasks, such as collecting contact information from participants and creating a database or filing system for the data collected from participants.

Limitations and Bias

The study has some limitations. One challenge to conducting a time and motion observation in pharmacy or retail clinics is the frequent interactions with customers/patients that are inherent to almost all positions within a pharmacy or retail clinic. For example, the Management Oversight cost of the testing sites was not disguisable or reported separately from the normal day-to-day supervision. Nevertheless, there are costs associated with minimizing the operational impact on pharmacies in a retail setting and there must be provision for management oversight of the testing to ensure that the necessary staffing level, supplies, and confidential record systems are established and maintained. Another hindrance that customer/patient interaction poses to time and motion observations is concerns for patient confidentiality, which limits accurately reporting lapsed time in a time and motion observation.

[15] Such costs should include the cost of reproducing the materials and the resources necessary to conduct the intervention (e.g., training manuals, counseling forms, letters) as well as postage.
[16] Downloaded from https://www.advisen.com/downloads/Industry_Report_Drugstores_2012_02_07_teaser.pdf (assessed March 1, 2013)

Self-report studies are also subject to an inherent bias.[17] Participants may overestimate their efforts, but underreporting is also a consideration if participants are extremely busy and recording activities at infrequent intervals, leading to inaccurate data. Cross-sectional studies are also subject to several forms of bias, including selection bias. Cross-sectional time studies should be interpreted in the context of the period during which the study was conducted. Seasonal variables can have a significant impact on data and results. However, we recommend that future projects utilize the continuous observation approach and use population based controls.

For the purpose of this project, we assigned a cost of $11 per kit, which was the cost of the OraQuick test kit available to CDC. In a typical retail environment the kit would be priced to cover its wholesale cost, shipping charges, a proportionate share of overhead (fixed and variable operating expenses), and a reasonable profit. Factors such as high overhead (particularly when renting in prime mall or shopping center locations), unpredictable insurance rates, shrinkage, seasonality, increases in product costs and shipping expenses, and sales or discounts will all affect the final pricing.

This report does not capture overhead expenses (those non-labor expenses required to operate a pharmacy or RC). Regardless of whether a pharmacy or RCs opt to conduct rapid HIV testing and no matter what the volume of sales is, these costs must be met every month. These expenses include rent or mortgage payments, depreciation on fixed assets (such as medical instruments and office equipment), salaries and associated payroll costs, liability and other insurance, utilities, and legal and accounting costs. These expenses will not change, regardless of whether a pharmacy or RC conducts a single test. However, fixed costs can change over a period of time, although the increase or decrease is normally not connected to sells.

This analysis does not include some costs mentioned above that are associated with testing, including; development cost for standard operating procedures; management oversight of the testing to ensure that the necessary staffing level, supplies, and confidential record systems are established and maintained (lost opportunity cost); information management cost related to computer technology and computerized testing equipment; cost to implement procedures to ensure that errors do not recur; for this project the kits were free to the participating sites but going forward pharmacies must consider administrative costs for reimbursements from insurance carriers, contracts with state or local health departments, as well as Medicare and Medicaid.

[17] Burke TA, McKee JR, Wilson HC, et al. A comparison of time-and-motion and self-reporting methods of work measurement. *J Nurs Admin.* 2000;30:118-125.

SECTION III: COST ESTIMATE

It is important to note that while fixed costs are constant over a period and variable costs generally rise, the fixed and variable costs per unit do the opposite. The fixed cost per unit decreases as the activity level increases, while the variable cost per unit remains constant, since each additional test adds the same variable cost. Labor cost is typically a fixed cost; however, for the purpose of this study it is reflected as a variable cost. In actuality it is a "lost opportunity cost" or the value of reduced productivity. In other words, it is the cost of time lost due to an individual performing a different task than what they would normally perform. When this occurs, the pharmacy or RCs incurs the cost of lost opportunity. The purpose here is to illustrate the amount of time and cost related to this new activity.

The next section estimates the costs we identified, such as personnel, equipment, compliance, and testing related advertisements and materials.

Wages

An important cost component in this analysis is the wage rate for staff. The 2012 median U.S. wage rate for Pharmacists is $56.09, with median wage rates in the states of the test sites ranging from $51.69 to $59.51. The 2012 median U.S. wage rate for Pharmacy Technicians is $14.10, with median wage rates in the states of the test sites ranging from $11.88 to $18.90. Two of the sites were staffed with Nurse Practitioners and 2012 median U.S. wage rate for Nurse Practitioners is $43.25, with median wage rates in the states of the test sites ranging from $40.71 to $41.39. See Tables 5, 6, and 7 for more detailed wage information.

Table 5. National and State wages for Pharmacists in select states, 2012[18]

Location	Pay Period	2012				
		10%	25%	Median	75%	90%
United States	**Hourly**	$42.93	$49.69	$56.09	$64.28	$70.15
	Yearly	$89,300	$103,400	$116,700	$133,700	$145,900
Alabama	**Hourly**	$41.24	$49.89	$56.98	$66.17	$72.11
	Yearly	$85,800	$103,800	$118,500	$137,600	$150,000
District of Columbia	**Hourly**	$42.39	$48.74	$55.50	$64.59	$70.06
	Yearly	$88,200	$101,400	$115,400	$134,300	$145,700
Georgia	**Hourly**	$44.87	$49.53	$55.05	$62.16	$68.88

[18] Source: U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics. http://www.bls.gov/oes/tables.htm.

Location	Pay Period	2012				
		10%	25%	Median	75%	90%
	Yearly	$93,300	$103,000	$114,500	$129,300	$143,300
Florida	Hourly	$46.36	$49.64	$54.75	$61.66	$68.85
	Yearly	$96,400	$103,300	$113,900	$128,300	$143,200
Illinois	Hourly	$32.92	$47.95	$55.04	$63.28	$70.07
	Yearly	$68,500	$99,700	$114,500	$131,600	$145,700
Louisiana	Hourly	$37.71	$47.10	$52.63	$58.48	$68.27
	Yearly	$78,400	$98,000	$109,500	$121,600	$142,00
Maryland	Hourly	$39.98	$48.35	$53.60	$59.47	$67.38
	Yearly	$83,200	$100,600	$111,500	$123,700	$140,200
Michigan	Hourly	$35.28	$48.24	$53.71	$59.97	$69.84
	Yearly	$73,400	$100,300	$111,700	$124,700	$145,300
Mississippi	Hourly	$36.06	$48.57	$56.22	$64.93	$71.02
	Yearly	$75,000	$101,000	$116,900	$135,100	$147,700
Missouri	Hourly	$47.17	$51.18	$57.49	$65.23	$70.37
	Yearly	$98,100	$106,500	$119,600	$135,700	$146,400
Montana	Hourly	$38.29	$47.30	$51.69	$55.69	$59.76
	Yearly	$79,600	$98,400	$107,500	$115,700	$124,300
North Carolina	Hourly	$44.89	$51.21	$59.51	$66.66	$71.00
	Yearly	$93,400	$106,500	$123,800	$138,700	$147,700
Oklahoma	Hourly	$38.77	$47.22	$51.97	$56.78	$65.41
	Yearly	$80,600	$98,200	$108,100	$118,100	$136,100
Pennsylvania	Hourly	$39.09	$47.38	$52.49	$57.68	$66.70
	Yearly	$81,300	$98,600	$109,200	$120,000	$138,700
South Carolina	Hourly	$46.13	$50.39	$56.45	$64.47	$70.03
	Yearly	$95,940	$104,800	$117,420	$134,100	$145,670
Washington	Hourly	$46.65	$50.06	$55.38	$62.78	$68.99
	Yearly	$97,000	$104,100	$115,200	$130,600	$143,500

Table 6. National and State wages for Pharmacy Technician in select states, 2012[19]

Location	Pay Period	2012				
		10%	25%	Median	75%	90%
United States	Hourly	$9.89	$11.69	$14.10	$17.22	$20.38
	Yearly	$20,600	$24,300	$29,300	$35,800	$42,400
Alabama	Hourly	$8.59	$10.01	$11.88	$14.23	$17.30
	Yearly	$17,900	$20,800	$24,700	$29,600	$36,000
District of Columbia	Hourly	$11.97	$14.48	$18.26	$22.71	$31.32
	Yearly	$24,900	$30,100	$38,000	$47,200	$65,100
Georgia	Hourly	$8.75	$10.46	$12.80	$15.36	$18.03
	Yearly	$18,200	$21,800	$26,600	$31,900	$37,500
Florida	Hourly	$9.86	$11.33	$13.37	$15.76	$18.06
	Yearly	$20,500	$23,600	$27,800	$32,800	$37,600
Illinois	Hourly	$10.09	$11.63	$13.76	$16.53	$18.66
	Yearly	$21,000	$24,200	$28,600	$34,400	$38,800
Louisiana	Hourly	$10.22	$11.93	$13.67	$16.06	$18.26
	Yearly	$21,300	$24,800	$28,400	$33,400	$38,000
Maryland	Hourly	$10.23	$12.16	$14.40	$17.49	$21.30
	Yearly	$21,300	$25,300	$30,000	$36,400	$44,300
Michigan	Hourly	$9.19	$10.91	$13.15	$15.56	$17.98
	Yearly	$19,100	$22,700	$27,400	$32,400	$37,400
Mississippi	Hourly	$8.81	$10.27	$12.34	$14.53	$17.23
	Yearly	$18,330	$21,360	$25,670	$30,220	$35,830
Missouri	Hourly	$9.68	$10.82	$12.87	$15.33	$18.43
	Yearly	$20,100	$22,500	$26,800	$31,900	$38,300
Montana	Hourly	$11.96	$13.08	$15.01	$17.52	$19.88
	Yearly	$24,900	$27,200	$31,200	$36,400	$41,400
North Carolina	Hourly	$8.95	$10.63	$13.05	$15.85	$18.27
	Yearly	$18,600	$22,100	$27,100	$33,000	$38,000
Oklahoma	Hourly	$9.18	$10.46	$12.33	$14.42	$17.25
	Yearly	$19,100	$21,800	$25,600	$30,000	$35,900
Pennsylvania	Hourly	$9.15	$10.92	$13.42	$16.45	$18.82

[19] Source: U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics. http://www.bls.gov/oes/tables.htm.

Location	Pay Period	2012				
		10%	25%	Median	75%	90%
	Yearly	$19,000	$22,700	$27,900	$34,200	$39,100
South Carolina	Hourly	$9.34	$11.12	$13.29	$15.93	$18.51
	Yearly	$19,430	$23,140	$27,650	$33,130	$38,500
Washington	Hourly	$14.50	$16.31	$18.90	$21.78	$24.31
	Yearly	$30,200	$33,900	$39,300	$45,300	$50,600

Table 7. National and State wages for Nurse Practitioners in select states, 2012[20]

Location	Pay Period	2012				
		10%	25%	Median	75%	90%
United States	Hourly	$30.82	$37.70	$43.25	$51.21	$57.93
	Yearly	$64,100	$78,400	$90,000	$106,500	$120,500
Georgia	Hourly	$29.58	$34.94	$40.71	$45.99	$55.04
	Yearly	$61,500	$72,700	$84,700	$95,700	$114,500
Montana	Hourly	$31.75	$37.28	$41.39	$45.70	$54.85
	Yearly	$66,000	$77,500	$86,100	$95,100	$114,100

Interaction Cost

The pre-test and post-test cost of each test is equal to the number of staff minutes multiplied by their salary per minute for this task. The salary per minute is the base salary level and fringe benefits, which are calculated at 30 percent of salary.[21] The salary per minute was necessary to calculate the true cost of each task because task times were measured as the number of minutes necessary to complete the task rather than elapsed time.

Time spent and cost for administering Rapid HIV testing in the sampled sites between 2012 and 2013 are listed in Table 8. Contextual assessment of the time study revealed two important findings: (1) The average pre-test time, the beginning of the test through incubation start time, took four minutes on average but ranged as high as thirty-five minutes; (2) The average post-test consultation time, the time spent by the pharmacist with the patient to discuss the test results, took four minutes on average, but ranged as high as fifty-five minutes. The wide variation is attributable to the depth at which the tester provides consultation and the test result.

[20] Source: U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics. http://www.bls.gov/oes/tables.htm.
[21] Source: http://www.bls.gov/news.release/eci.nr0.htm

For the total interaction cost, we added the pre-test time costs to the post-test time cost to obtain the total personnel cost for the activity. Table 8 shows that the average interaction cost is $10.92 per test. It is evident that more time is spent during the post-test consultation time for reactive tests at an average interaction cost of $24.15 per test. The cost of testing performed in different communities did not vary significantly with rural areas costing $9.92 per interaction compared to $10.76 in urban communities. The information provided in Table 8 is representative of data collected through July 30, 2013.

Table 8. Summary of Interaction Time and Cost of Rapid HIV Testing

Site	Pre-Testing Time						Post-Testing Time					
	Number	Mean	Max	Min	Median	Std	Mean	Max	Min	Median	Std	Total
		4	35	1	3	4	4	55	1	3	5	8.00
		Pre Testing Labor Cost					Post Testing Labor Cost					
		Mean	Max	Min	Median	Std	Mean	Max	Min	Median	Std	Total
All	1540	$5.31	$42.70	$1.15	$3.66	$5.09	$5.61	$67.10	$1.15	$3.66	$5.70	$10.92

Site	Pre-Testing Time						Post-Testing Time					
	Number	Mean	Max	Min	Median	Std	Mean	Max	Min	Median	Std	Total
Urban	1095	4	35	1	3	4	4	55	1	3	5	8.00
Rural	445	4	23	1	3	4	4	53	1	3	4	8.00

Site		Pre Testing Labor Cost					Post Testing Labor Cost					
	Number	Mean	Max	Min	Median	Std	Mean	Max	Min	Median	Std	Total
Urban	1095	$5.38	$42.70	$1.19	$3.69	$4.80	$5.38	$67.10	$1.19	$3.69	$5.87	$10.76
Rural	445	$5.14	$28.07	$1.15	$3.66	$4.44	$4.78	$64.32	$1.15	$3.64	$4.90	$9.92

Test Result	Pre-Testing Time						Post-Testing Time					
	Number	Mean	Max	Min	Median	Std	Mean	Max	Min	Median	Std	Total
Non-reactive	1516	4	35	1	3	4	4	55	1	3	4	8.00
Reactive	24	6	23	1	4	6	13	40	2	10	10	19.00

Site		Pre Testing Labor Cost					Post Testing Labor Cost					
	Number	Mean	Max	Min	Median	Std	Mean	Max	Min	Median	Std	Total
Non-reactive	1516	$5.27	$42.70	$1.15	$3.66	$5.05	$4.92	$67.10	$1.15	$3.66	$5.23	$10.19
Reactive	24	$7.45	$28.07	$1.15	$4.33	$7.05	$16.70	$50.05	$2.44	$12.20	$12.85	$24.15

Source: WES calculation of data collected by ASHLIN

Table 9 shows the interaction time for each site through the end of July 2013. The analysis reveals that there is wide variation in the interaction time within and across sites. The interaction data were derived from the raw time-and-motion data for each interaction and are the actual time spent on the pre and post test interaction as reported by each site. As expected, at most sites the mean and the standard deviation decreased as testing became more frequent.

Table 9. Sites Interaction Time for Rapid HIV Testing

Site	Pre-Testing Time						Post-Testing Time				
	Number	Mean	Max	Min	Median	Std	Mean	Max	Min	Median	Std
Year 1											
1. Walgreen's DC	370	2	20	1	2	1	2	40	1	1	3
2. Walgreen's Chicago	113	7	35	1	5	6	8	55	1	6	7
3. Community Pharmacy	75	9	30	1	10	5	7	40	1	5	7
4. East Pines Pharmacy	88	9	25	5	10	4	6	20	5	5	2
5. Walgreen's Take Care Clinic	157	5	23	1	1	4	4	15	1	1	3
6. Indian Health Board of Billings (IHB)	136	3	19	1	2	3	2	18	1	2	3
Year 2											
1. Barneys Pharmacy	38	8	19	2	7	5	4	11	2	3	2
2. Okeechobee Discount Drugs	102	3	9	1	2	1	5	53	1	3	6
3. Freedom Pharmacy	35	8	20	1	6	6	6	11	2	5	2
4. Causey Pharmacy	17	9	15	4	10	4	7	10	3	7	2
5. Rite Aid Pharmacy	12	3	6	1	3	2	5	9	1	6	3
6. Long's Drugs	15	9	15	1	10	4	13	40	5	12	9
7. Moose Pharmacy	11	8	12	5	8	2	7	15	4	6	4
8. Osborn Drugs	2	4	5	2	4	2	5	5	4	5	1
9. University of Mississippi School of Pharmacy (2 sites)	204	3	9	1	3	2	3	10	1	3	2
10. H&W Drugs	10	10	20	2	10	6	9	15	5	10	3
11. Family Medical Services	48	2	4	1	1	1	3	20	1	2	3
12. University Pharmacy	28	7	20	1	5	4	9	25	1	5	7
13. Gateway Apothecary	63	3	10	1	2	2	3	32	1	2	5
14. Family Pharmacy of Neosho	1	15	15	15	15	n/a	5	5	5	5	n/a
15. Bartell Drugs	15	6	15	3	5	3	5	12	2	5	3

Source: WES calculation of data collected by ASHLIN

Table 10 shows the variable and fixed costs for administering rapid HIV testing in a pharmacy and RC setting and Table 11 shows the total cost. Earlier we discussed limitations of this analysis as it relates to fixed costs in a pharmacy and RC. The compliance, advertising, and start-up supplies fixed costs remain constant regardless of the number of customers tested. Variable

costs (pre and post test counseling, testing kits, controls, and shipping cost) will vary with the number of customers tested.

Administrative and Shipping Costs

Sites experienced varying costs related to purchasing of test kits and maintaining a sufficient inventory. On average five (5) hours of labor is required monthly to develop and maintain an inventory record for kits and supplies. Although ASHLIN performed most of the required effort for ordering, some effort was required to determine re-order levels for each item in the inventory based on workload and usage to ensure a constant supply of reagents and no service interruption or wasteful expiring of reagents and test kits.

Table 10 also shows the administrative support cost, which includes, inventorying and ordering additional testing kits and the parcel cost of shipping associated with the testing kit and the control instrument. The administrative support work activities would typically be performed by a technician.

Table 10. Mean Interaction and Related Cost of Rapid HIV Testing

Sites	Number of Tests	Months in the Project	Mean Interaction Cost (per test)	OraSure Testing Kit Shipping Costs (per shipment)	OraSure Control Shipping Costs (per shipment)	Average Training Cost (per person)	Total Advertising Cost (program duration)	Compliance & Reporting (per month)	Admin Support Cost (per month)
Year 1									
1. Walgreen's DC	370	12	$4.97	$13.52	$77.08	$295.26	$146.08	$18.45	$121.43
2. Walgreen's Chicago	113	15	$17.73	$18.68	$139.69	$292.81	$110.08	$18.30	$91.50
3. Community Pharmacy	75	12	$20.31	$13.52	$77.08	$295.26	$171.08	$18.45	$121.43
4. East Pines Pharmacy	88	12	$17.39	$12.91	$64.48	$285.15	$140.20	$106.93	$95.76
5. Walgreen's Take Care Clinic	157	13	$11.60	$18.68	$139.69	$216.58	$102.40	$18.30	$85.12
6. Indian Health Board of Billings (IHB)	136	12	$6.08	$26.23	$237.60	$220.19	$120.08	$68.75	$99.82
Year 2									
1. Barneys Pharmacy	38	8	$14.87	$18.68	$139.69	$228.65	$127.40	$146.43	$85.12
2. Okeechobee Discount Drugs	102	6	$8.62	$21.04	$142.05	$203.21	$131.96	$72.82	$88.91
3. Freedom Pharmacy	35	8	$16.61	$18.68	$139.69	$109.38	$131.96	$72.82	$88.91
4. Causey Pharmacy	17	6	$19.01	$26.74	$223.92	$279.99	$134.36	$35.00	$90.91
5. Rite Aid Pharmacy	12	8	$10.11	$18.68	$139.69	$292.87	$127.40	$18.30	$85.12

Sites	Number of Tests	Months in the Project	Mean Interaction Cost (per test)	OraSure Testing Kit Shipping Costs (per shipment)	OraSure Control Shipping Costs (per shipment)	Average Training Cost (per person)	Total Advertising Cost (program duration)	Compliance & Reporting (per month)	Admin Support Cost
6. Long's Drugs	15	3	$27.86	$14.77	$96.55	$242.91	$131.32	$75.08	$88.38
7. Moose Pharmacy	11	7	$20.51	$14.77	$96.55	$179.28	$104.40	$237.44	$86.78
8. Osborn Drugs	2	7	$9.22	$14.77	$223.92	$276.48	$123.64	$34.56	$81.99
9. University of Mississippi School of Pharmacy (2 SITES)	204	4	$7.95	$18.68	$139.69	$299.09	$123.72	$37.39	$82.06
10. H&W Drugs	10	5	$22.75	$24.37	$221.55	$210.90	$109.36	$105.00	$90.91
11. Family Medical Services	48	6	$6.00	$18.68	$139.69	$303.13	$120.04	$37.89	$79.00
12. University Pharmacy	28	8	$18.20	$14.77	$96.55	$285.74	$288.00	$35.72	$87.45
13. Gateway Apothecary	63	3	$7.48	$18.68	$139.69	$279.47	$102.96	$38.23	$85.59
14. Family Pharmacy of Neosho	1	7	$25.49	$26.74	$223.92	$187.16	$102.96	$76.46	$85.59
15. Bartell Drugs	15	4	$13.18	$14.77	$251.54	$104.43	$176.20	$36.83	$125.69

Source: WES calculation of data collected by ASHLIN

Table 11. Total Cost of Rapid HIV Testing

Sites	Number of Tests	Months in the Program	Total Interaction Cost	OraSure Testing Kits Used Costs	Total Shipping Costs	Total Training Cost	Total Other Consumables	Total Advertising Cost	Total Compliance & Reporting	Total Admin Support Cost	Total Cost
Year 1											
1. Walgreen's DC	370	12	$1,840.45	$4,070.00	$362.40	$885.78	$ 228.86	$146.08	$221.45	$1,457.16	$9,212.18
2. Walgreen's Chicago	113	15	$2,003.33	$1,243.00	$633.48	$1,464.06	$ 69.90	$110.08	$274.51	$1,372.50	$7,170.86
3. Community Pharmacy	75	12	$1,523.05	$825.00	$181.20	$295.26	$ 46.39	$171.08	$221.45	$1,457.16	$4,720.59
4. East Pines Pharmacy	88	12	$1,530.31	$968.00	$154.78	$855.46	$ 54.43	$140.20	$1,283.18	$1,149.12	$6,135.48
5. Walgreen's Take Care Clinic	157	13	$1,821.87	$1,727.00	$1,266.96	$1,859.45	$ 97.11	$102.40	$237.95	$1,106.56	$8,219.30
6. Indian Health Board of Billings (IHB)	136	12	$808.93	$1,496.00	$1,055.32	$220.19	$ 84.12	$120.08	$824.97	$1,197.84	$5,807.45
Year 2											
1. Barneys Pharmacy	38	8	$564.98	$418.00	$316.74	$1,600.52	$ 23.50	$127.40	$1,171.46	$680.96	$4,903.56
2. Okeechobee Discount Drugs	102	6	$879.49	$1,122.00	$652.36	$1,016.07	$ 63.09	$131.96	$436.91	$533.46	$4,835.34
3. Freedom Pharmacy	35	8	$581.33	$385.00	$316.74	$1,859.45	$ 21.65	$131.96	$582.54	$711.28	$4,589.95
4. Causey Pharmacy	17	6	$323.16	$187.00	$250.66	$279.99	$ 10.52	$134.36	$209.99	$545.46	$1,941.14
5. Rite Aid Pharmacy	12	8	$121.36	$132.00	$158.37	$585.73	$ 7.42	$127.40	$146.43	$680.96	$1,959.67
6. Long's Drugs	15	3	$417.93	$165.00	$222.64	$971.64	$ 9.28	$131.32	$225.24	$265.14	$2,408.19
7. Moose Pharmacy	11	7	$225.57	$121.00	$222.64	$1,613.50	$ 6.80	$104.40	$1,662.11	$607.46	$4,563.48
8. Osborn Drugs	2	7	$18.43	$22.00	$238.69	$829.44	$ 1.24	$123.64	$241.92	$573.93	$2,049.29

Sites	Number of Tests	Months in the Program	Total Interaction Cost	OraSure Testing Kits Used Costs	Total Shipping Costs	Total Training Cost	Total Other Consumables	Total Advertising Cost	Total Compliance & Reporting	Total Admin Support Cost	Total Cost
9. University of Mississippi School of Pharmacy (2 SITES)	204	4	$1,622.56	$2,244.00	$633.48	$2,392.72	$ 126.18	$123.72	$149.55	$328.24	$7,620.45
10. H&W Drugs	10	5	$227.49	$110.00	$245.92	$632.71	$ 6.19	$109.36	$524.98	$454.55	$2,311.20
11. Family Medical Services	48	6	$290.97	$528.00	$633.48	$606.27	$ 29.69	$120.04	$227.35	$474.00	$2,909.80
12. University Pharmacy	28	8	$509.57	$308.00	$333.96	$1,428.69	$ 17.32	$288.00	$285.74	$699.60	$3,870.88
13. Gateway Apothecary	63	3	$471.51	$693.00	$633.48	$2,515.24	$ 38.97	$102.96	$114.69	$256.77	$4,826.62
14. Family Pharmacy of Neosho	1	7	$25.49	$11.00	$250.66	$748.63	$ 0.62	$102.96	$535.23	$599.13	$2,273.72
15. Bartell Drugs	15	4	$197.64	$165.00	$798.93	$626.59	$ 9.28	$176.20	$147.31	$502.76	$2,623.71

Certifications, Licensure, and Regulations Compliance Costs

Compliance requires that pharmacies and RCs adopt and implement a variety of activities related to conducting rapid HIV testing. These activities are often performed by a professional level staff with the responsibility of ensuring that the site in compliance as well as responding to penalties for non-compliance. Many state Departments of Public Health (DPH) require that all sites obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate and state licenses in order to conduct testing. The average cost involved in obtaining certificates or licenses and compliance **with state and local regulations was $167.50.** Table 10 shows that the cost of compliance varies significantly by the site's ownership. Corporate sites reported low compliance costs while smaller sites reported compliance cost that are substantially higher.

Quality Assurance Costs and Considerations

OraSure requires testing facilities using the OraQuick Rapid HIV Test product to purchase a separate package containing the OraQuick Rapid HIV Test Controls. The controls are necessary for quality control purposes. The approximate cost for external controls is $25, but shipping fees are an additional cost that varies based on the recipients address. Pharmacies and Retail Clinics may want to consider the volume of tests they can expect when purchasing controls in an effort to manage and reduce costs by ordering in bulk. Once the individual package is opened, controls have a shelf life of 8 weeks. Pharmacies and Retail Clinics providing rapid HIV testing should always have a box of controls available in the event they need to run controls (i.e. loss of power, new tester, training staff, etc.).

One of the limitations of this project was the submission of accurate data from the pharmacies and retail clinics on the number of controls conducted during the time they participated in the project. Unfortunately, some sites were not compliant with the reporting schedule provided during trainings and outlined in the standard operating procedures provided to each site. Pharmacies and Retail Clinics planning to provide rapid HIV testing should develop standard operating procedures, as was done for this project, that outlines the process for when, how and why to run controls. A suggestion would be to run controls once every 1-2 months based on testing volume. Another consideration for Pharmacies and Retail Clinics is that in order to run controls, three (3) test kits must be used from the lot (i.e. an order of 25, 50 or 100 test kits sent in the same package). The cost to run controls at a rate of $11 per test kit ($275/box of 25 test kits) is $33 for each time you run controls. If a Pharmacy or Retail Clinic is paying for the test kits and controls rather than receiving them free through the health department or some other source of funding, this will need to be considered in the budget for test kits and controls.

Pharmacy and RC Staff Training

There were a total of fifty-five (55) pharmacy and RC staff trained in the ASHLIN-administered trainings to ensure proper testing techniques, how to perform the test and controls and conduct data recording, but additional staff were trained using the ASHLIN training and curriculum materials by the designated staff person on-site at the pharmacy/retail clinic for a total of one hundred and fifteen (115) trained pharmacy and RC staff. The level of training participation varied widely between the sites. For example, only one (1) staff person participated in the training from Community Pharmacy, Indian Health Board of Billings, and Causey Pharmacy compared to as many as seven (7) from the Walgreen's Take Care Clinic. Walgreens Take Care Clinic had a total of 17 Nurse Practitioners (NP) who were trained to conduct rapid HIV testing (additional NPs were trained after the ASHLIN training). The individuals trained are in the rotation to staff the take care clinic at that site and are all prepared to provide any service offered at the take care clinic. Freedom Pharmacy also had a total of seventeen (17) individuals trained to conduct HIV testing. There were three (3) staff persons trained along with fourteen (14) pharmacy student volunteers who provided testing at the pharmacy and off-site testing events. The training was conducted by experienced ASHLIN personnel, who assisted with navigating the data entry tool and to correctly identifying each activity. Pharmacy and RC staff then underwent, on average, a four (4) hour training session and as shown in Table10 the average cost to train one individual ranged from $104.43 to $303.13.

Start-up supplies and associated cost

Non-personnel costs include the materials and resources necessary to perform the test and the cost of the OraQuick Advanced Rapid HIV-1/2 Antibody Test kit. The government and suggested retail cost rates were $11.00 and $18.85, respectively. The estimate accounts for the cost of additional supplies needed to administer the test which may not be included with the testing kit. As shown in Table 11, is the total cost for other consumables, which includes the per test cost for Disposable Chux Pads at $.51 each,[22] Disposable Gloves at $.10 each,[23] and Biohazard Bags at $.004 each.[24]

In Appendix I1, Table E1b provides a list of start-up supplies and their associated cost; however, none of the sites reported incurring costs for start-up supplies. In addition to the interaction time expended by staff persons, there is also cost associated with advertising. The majority of sites reported that they used the advertisement materials developed by ASHLIN and as a result

[22] Latex-free.-Large Capacity: 11.8 Fluid oz. (150 count).-Extra Large Capacity: 16.0 Fluid oz. (100 count).-Ultra Large Capacity: 19.3 Fluid oz. (50 count). Options: -Available in Large, Extra Large or Ultra. $45.99-$56.99

[23] Sizes Small, Medium, and Large - 1000 Gloves Per Case, Packed in 10 Boxes of 100 Gloves; Size X-Large - 950 Gloves Per Case, Packed in 10 Boxes of 95 Gloves; $49.90 per case.

[24] This cost is calculated by using $.39 per bag, and 100 tests per bag.

their advertising cost was substantially reduced. The average advertisement costs ranged from $102 to $288 with the majority of the activity costs attributable to the distribution of materials.

In our model, we did not account for the cost of reproducing materials and overhead costs.[25] An additional potential cost is the cost of constructing a private room for conducting rapid HIV testing. The estimated cost to construct a private room within an existing facility is roughly $7,500.[26] Average dimensions for the room would be 6 feet by 5-7 feet.

Site managers should also consider whether equipment purchases may be used for other purposes or already existing equipment may be used; if so, costs should be prorated on the basis of the expected useful life or depreciated values of the equipment.

Event-based

In addition to the interaction time expended by staff on onsite, there are also costs associated with conducting event-based testing. For those sites that conducted event-based testing the average duration was three hours and was supported by an average of two staff incurring an average cost of nearly $404.00 per event. Table 13 shows the sites that opted to conduct event-based testing to include the number of tests performed. For more detailed information on the events, that information can be found in Appendix E1. The University of Mississippi School of Pharmacy and Okeechobee Discount Drugs were anomalies. These sites hosted thirteen (13) and eight (8) events, respectively. The University of Mississippi hosted the most events and their average duration was one (1) hour longer than the average of all sites. The University of Mississippi average labor cost to host an event was $579, which was $175 higher than the sample mean. Some sites also reported that they incurred a cost to purchase materials in support of the event. The most frequently reported cost was $25; however, Bartell Drugs reported a cost of $450.

[25] Overhead costs are a way of accounting for fixed costs such as maintenance and the opportunity costs of owning land, buildings, and equipment. In normal business accounting, these fixed costs are divided and charged by labor costs or some other reasonable method. Gold et al. recommend including overhead costs unless there is temporary excess supply of these resources.[25] Retail Clinics typically do not charge overhead costs to their primary activity-medical -on the basis of the paid labor costs of those services. In our case, they may have to decide what else might be done with the program resources (renting out rooms, other clinic activities) in deciding whether to do these programs.

[26] The following information was provided by Bartell Drugs in Seattle, WA regarding the construction of a private area for testing.

Table 12. Summary of Event-based of Rapid HIV Testing[27]

Event-Based Testing Cost				
Material	**Labor**	**Cost**	**Staff**	**Duration**
$135.00	$268.94	$403.94	2	3 hours

Source: WES calculation of data collected by ASHLIN

Table 13. Summary of Event-based Rapid HIV Testing

Pharmacy	Number of Events	Number of Tests	Average number of staff	Average Duration
Walgreens DC	0	-	-	-
Walgreens Chicago	0	-	-	-
East Pines	0	-	-	-
Community Pharmacy	0	-	-	-
Indian Health Board	1	19	1	6
Walgreens Take Care Clinic	1	-	-	-
Family Medical Services	3	43	5	5
Freedom Pharmacy	3	26	1	2
Okeechobee Discount Drugs	8	93	2	2
Barney's Pharmacy	1	6	1	7
Rite Aid	0	-	-	-
Causey Pharmacy	0	-	-	-
H&W Drugs	0	-	-	-
The University of Mississippi School of Pharmacy	13	205	2	4
Family Pharmacy of Neosho	0	-	-	-
Moose Pharmacy	0	-	-	-
Longs Drugs	1	5	1	7
Bartell Drugs	0	-	-	-
Osborn Drugs	0	-	-	-
University Pharmacy	1	7	-	5
Gateway Apothecary	6	49	1	2
Total	38	453	-	-

[27] Our study has a number of limitations, and the results should be considered exploratory. Our sample size was small, so we could not make meaningful comparisons between the Pharmacy and RCs, and we might also have missed a small but important difference in time utilization. In addition, due to none inclusion of transition times as part of each activity, the absolute time committed to an activity may be longer than the total values reported.

CONCLUSIONS

Other pharmacies and RCs could benefit from this analysis, which provides insight regarding the type of costs associated with administering rapid HIV tests in different non-traditional settings. In summary, this analysis could be an excellent resource for Pharmacies and RCs and could be used to make evidence-based recommendations.

APPENDIX I1 Additional Data

Table I1a Overview of training costs

Training				
Year 1 Sites:	**# of staff trained:***	**Occupation**	**Duration**	**Training Cost**
Year 1 Sites				
1. Walgreen's DC	3	Pharmacists only	4	$885.78
2. Walgreen's Chicago	5	Pharmacists only	4	$1,464.06
3. Community Pharmacy	1	Pharmacists only	4	$295.26
4. East Pines Pharmacy	3	HD staff & CBO Staff	4	$855.46
5. Walgreen's Take Care Clinic	17	Nurse Practitioners	4	$3,681.81
6. Indian Health Board of Billings (IHB)	1	Nurses and Nurse Practitioners	4	$220.19
Year 2 Sites				
1. Barneys Pharmacy	7	5 Pharmacists & 2 Pharmacy Residents	4	$1,600.52
2. Okeechobee Discount Drugs	5	Pharmacists & Pharmacy Techs	4	$1,016.07
3. Freedom Pharmacy	17	Nurse and Unpaid Pharmacy Students	4	$4,951.59
4. Causey Pharmacy	1	Nurse	4	$279.99
5. Rite Aid Pharmacy	2	Pharmacists only	4	$585.73
6. Long's Drugs	4	Pharmacists and Other (1-Case Coordinator)	4	$971.64
7. Moose Pharmacy	9	4 Pharmacists and 5 Pharmacy Students	4	$1,613.50
8. Osborn Drugs	3	Pharmacy Residents	4	$829.44
9. University of Mississippi School of Pharmacy (2 sites)	8	Pharmacists only	4	$2,392.72
10. H&W Drugs	3	Pharmacists & Pharmacy Techs	4	$632.71
11. Family Medical Services	2	Pharmacists & Pharmacy Residents	4	$606.27
12. University Pharmacy	5	Pharmacists, Pharmacy Residents & Pharmacy Students	4	$1,428.69
13. Gateway Apothecary	9	Pharmacists & Marketing Manager	4	$2,515.24
14. Family Pharmacy of Neosho	4	Pharmacists & Pharmacy Techs	4	$748.63
15. Bartell Drugs	6	Pharmacists & Pharmacy students	4	$441.93
Total Trained:	**115**			
Average Persons Trained Per Site:	**5.48**			
Average Cost of Training	**$1,195.70**			
Average Cost Per Person Trained	**$218.35**			

Table I1b List of Start-up Supplies and Associated Costs

Compliance and Reporting Cost:	
Materials	$20.00
Labor	$147.50
Total	$167.50
Training Cost:	
Training per employee	$218.35
Average Training Cost Per Site	$1,195.70
Supplies:	
Disposable Pads	$57.00
Disposable Gloves	$50.00
Biohazard Bags	$45.00
Timer or Watch	$14.99
Labeling Pen (Sharpie)	$1.87
Writing Pen	$2.57
Log Book for Recording Results	$2.50
File Cabinet	$189.99
Lock for File Cabinet	$16.44
4.6 cubic foot Pharmacy/Vaccine Refrigerator	$1,700.00
Total Supplies	**$2,080.41**

Source: WES calculation of data collected by ASHLIN

Table I1c Overview of event-based testing.

ASHLIN CDC Pharmacy/Retail Clinic Testing Event Log						
No	**Pharmacy**	**Event Site**	**Date of Testing Event**	**Number of Tests**	**Total number of staff testing at Event**	**Avg Hours**
1	Walgreens DC	On site	6/2012 & 6/2013	Onsite HIV Awareness testing event. Unknown how many tests/event	-	-
2	Walgreens Chicago	On site	6/2012 & 6/2013	Onsite HIV Awareness testing event. Unknown how many tests/event	-	-
3	East Pines	No Events	-	-	-	-
4	Community Pharmacy	No Events	-	-	-	-
5	Indian Health Board	Diabetic Screening event on-site	4/18/2013	19	1	6 hrs
6	Walgreens Take Care Clinic	On site	6/1/2012	Onsite HIV Awareness testing event. Unknown how many tests/event	-	-
7	Family Medical Services	Unknown	2/7/2013	19	2	4.5 hrs
		On-site	6/27/2013	5	1	7.5 hrs
		Pearson Rehab. Center	7/30/2013	19	2	4 hrs
8	Freedom Pharmacy	Unknown	1/8/2013	14	11	2 hrs
			5/4/2013	6	1	1.25 hrs
			7/30/2013	6	1	1.25 hrs
9	Okeechobee Discount Drugs	Unknown	7/8/2013	11	1	2 hrs
			5/14/2013	5	2	1.50 hrs
			7/12/2013	9	1	1.25 hrs
			5/24/2013	9	2	2.5 hrs
			4/18/2013	13	1	4 hrs
			3/14/2013	19	2	2 hrs
			3/8/2013	11	2	1.75 hrs
			2/25/2013	16	2	1.75 hrs
10	Barney's Pharmacy	Unknown	5/24/2013	6	1	6.75hrs
11	Rite Aid	No Events	-	-	-	-
12	Causey Pharmacy	No Events	-	-	-	-
13	H&W Drugs	No Events	-	-	-	-
14	The University of Mississippi School of Pharmacy	Mosby Drugs	7/1/2013	28	4	4.75 hrs
		Jackson Medical Mall	7/1/2013	9	2	3.75 hrs
		Jackson Medical Mall	7/8/2013	17	2	2.5 hrs
		Jackson Medical Mall	7/15/2013	12	2	3.25 hrs

ASHLIN CDC Pharmacy/Retail Clinic Testing Event Log						
No	**Pharmacy**	**Event Site**	**Date of Testing Event**	**Number of Tests**	**Total number of staff testing at Event**	**Avg Hours**
		Jackson Medical Mall	7/22/2013	17	2	3.25 hrs
		Jackson Medical Mall	7/29/2013	4	1	1.25 hrs
		Funderburks Drugs	6/3/2013	13	1	4.25 hrs
		Southern Discount Drugs	6/21/2013	10	2	5 hrs
		Webs Pharmacy	6/27/2013	1	1	1 hr
		NJC Health Fair	6/29/2013	27	1	3 hrs
		Jackson Medical Mall	5/24/2013	27	3	5.5 hrs
		Jackson Medical Mall	4/15/2013	28	3	3.75hrs
		UMC Student Union	4/12/2013	12	2	4.5 hrs
15	Family Pharmacy of Neosho	No Events	-	-	-	-
16	Moose Pharmacy	No Events	-	-	-	-
17	Longs Drugs	Nat. HIV Testing Day On-site	6/27/2013	5	1	7 hrs
18	Bartell Drugs	No Events	-	-	-	-
19	Osborn Drugs	No Events	-	-	-	-
20	University Pharmacy	Nat. HIV Testing Day On-site	6/27/2013	7	2	4.75 hrs
21	Gateway Apothecary	Postal Worker Health Fair	7/21/2013	11	1	4 hrs
		Murphy Blair Apts	6/18/2013	12	2	1.5 hrs
		Grandview Apts	6/7/2013	5	1	1.5 hrs
		Parkview Apts	6/24/2013	10	1	1.5 hrs
		Metropolitan Apts	6/27/2013	4	1	1.5 hrs
		Babyboomers event	4/11/2013	7	1	1.5 hrs

I1d OraSure Control Shipping Costs per Testing Site City Breakdown

Site Name	City/State	Testing Kit Cost	Control Cost
Walgreens Take Care Clinic	Lithonia, GA	$ 18.68	$139.69
Okeechobee Discount Drugs	Okeechobee, FL	$ 21.04	$142.05
Community Pharmacy	Washington, DC	$ 13.52	$ 77.08
Freedom Pharmacy	Orlando, FL	$ 18.68	$139.69
Gateway Apothecary	St Louis, MO	$ 18.68	$139.69
Family Medical Services	Bessemer, AL	$ 18.68	$139.69
East Pines Pharmacy	Riverdale, MD	$ 12.91	$ 64.48
Indian Health Board	Billings, MT	$ 26.23	$237.60
Walgreens Chicago	Chicago, IL	$ 18.68	$139.69
Walgreens DC	Washington, DC	$ 13.52	$ 77.08
Barney's Pharmacy	Augusta, GA	$ 18.68	$139.69
Rite Aid	Atlanta, GA	$ 18.68	$139.69
Causey Pharmacy	Natchitoches, LA	$ 26.74	$223.92
H&W Drugs	New Orleans, LA	$ 24.37	$221.55
University of Mississippi	Jackson, MS	$ 18.68	$139.69
Family Pharmacy of Neosho	Neosho, MO	$ 26.74	$223.92
Moose Pharmacy	Concord, NC	$ 14.77	$ 96.55
Longs Drugs	Columbia, SC	$ 14.77	$ 96.55
Bartell Drugs	Seattle, WA	$ 14.77	$251.54
Osborn Drugs	Miami, OK	$ 14.77	$223.92
University Pharmacy	Detroit, MI	$ 14.77	$ 96.55

*as of May 2013

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Appendix J:

Master Slide Presentation Set

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

METHOD

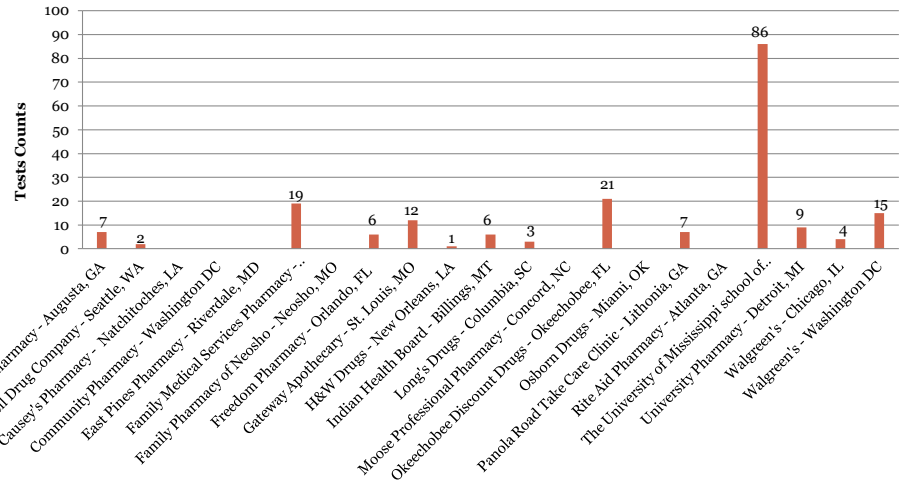
Test Phase	Phase Description
Total Test Time	Beginning of the test thru Post-consultation End Time
Pre-test Time	Beginning of the test to Incubation Start Time
Patient/Pharmacist Non-engaged	Incubation Start Time thru Post-interaction Start Time. During this phase of the test, the Pharmacist is not required to be with the patient
Total Incubation Time	Incubation Start Time thru Incubation End Time
Post-test Consultation Time	Post-test Interaction start time thru Post-test interaction end time. Post-test consultation time is the time spent by the pharmacist with the patient to discuss test results.

Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed

(July 2013; n = 198)

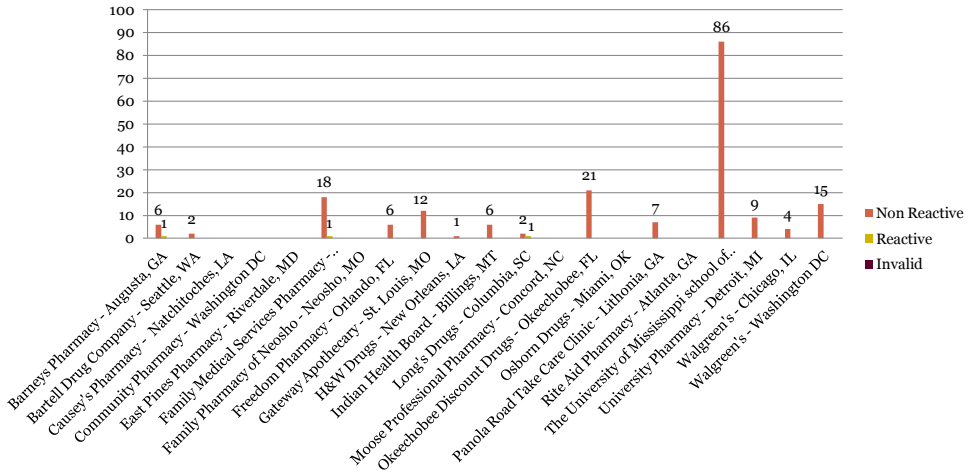


Data reported through 07/31/13

ASHLIN Management Group

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed by Test Result
(July 2013; n= 198)

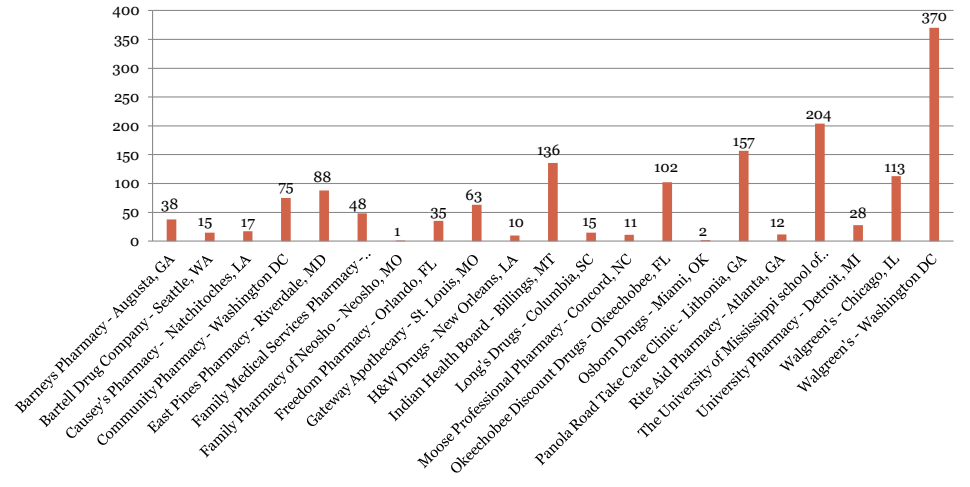


Data reported through 07/31/13

ASHLIN Management Group

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed
(Cumulative May 2012 – July 2013)
(n = 1540)

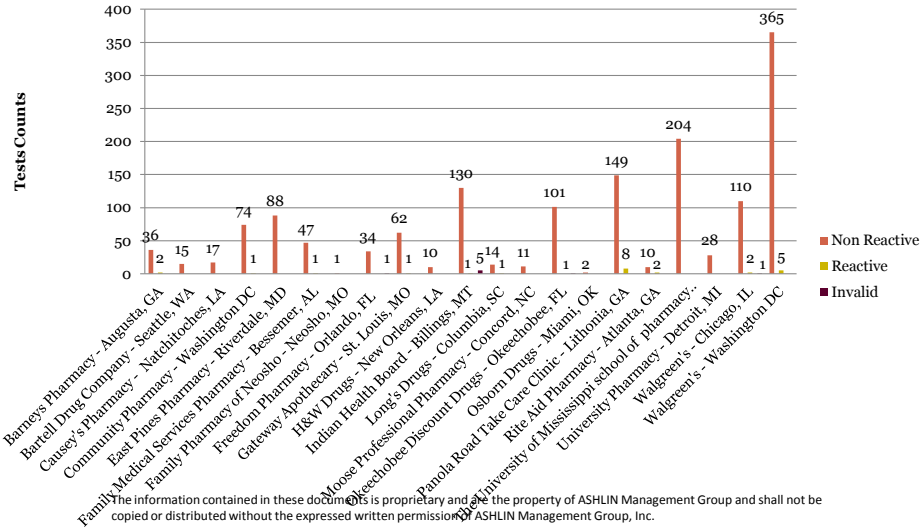


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed: Test Result

(Cumulative May 2012 – July 2013)
(n = 1540)

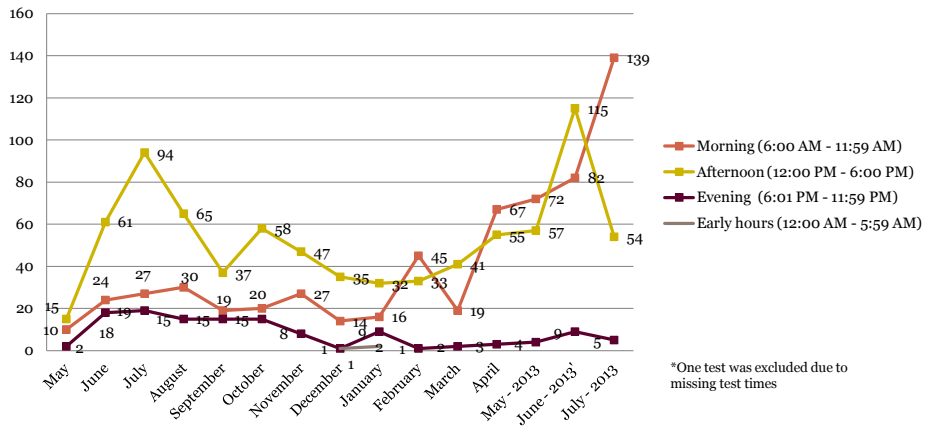


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed by Time of Day Across All sites

(Cumulative May 2012 – July 2013)
(n = 1539*)



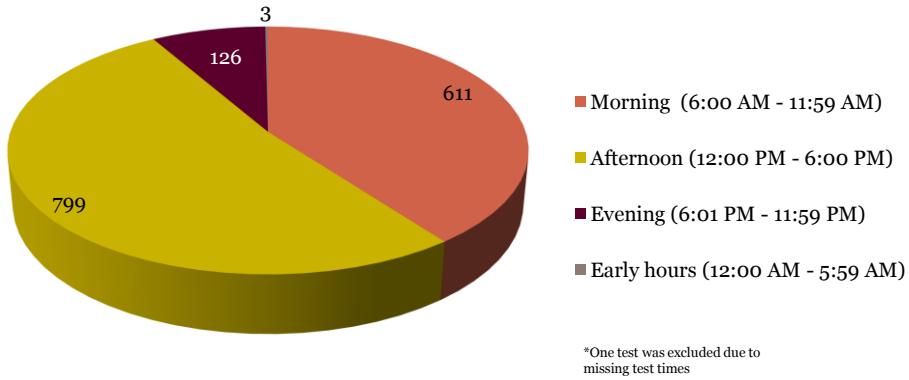
*One test was excluded due to missing test times

Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed by Time of Day Across All sites

(Cumulative May 2012 – July 2013)
(n = 1539*)



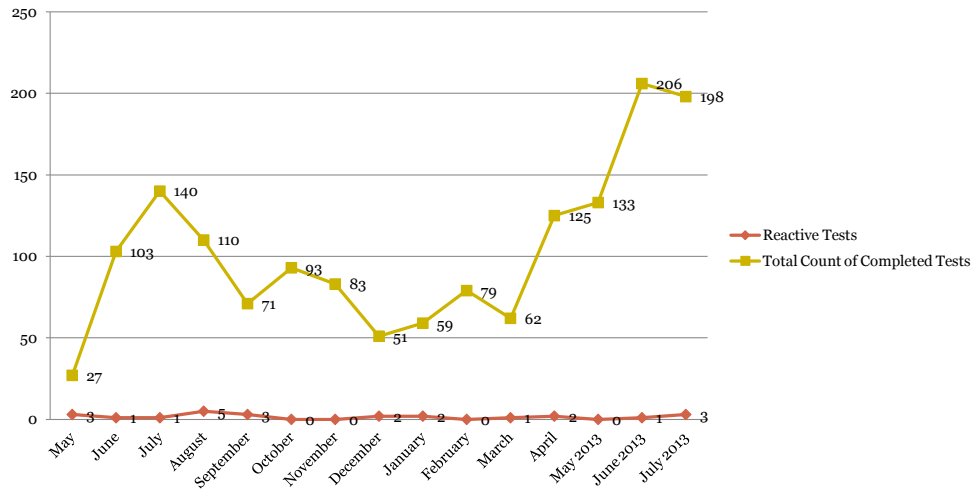
*One test was excluded due to missing test times

Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Performed Tests and Reactive Tests For Each Month - All Sites

(Cumulative May 2012 – July 2013)
(n = 1540)

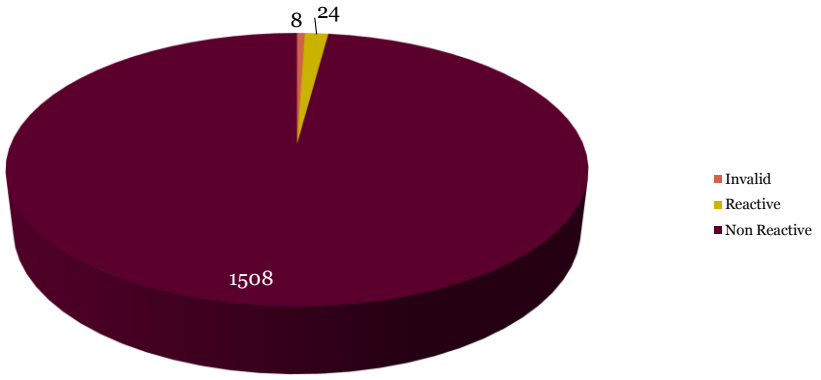


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed by Test Result Across All sites

(Cumulative May 2012 – July 2013)
(n = 1540)

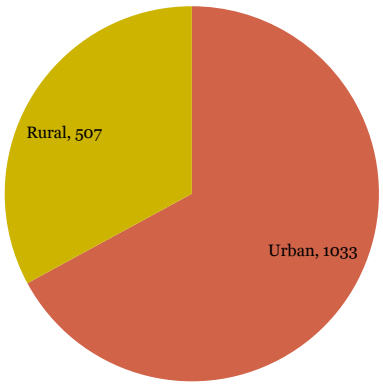


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed: Rural vs Urban

(Cumulative May 2012 – July 2013)
(n = 1540)

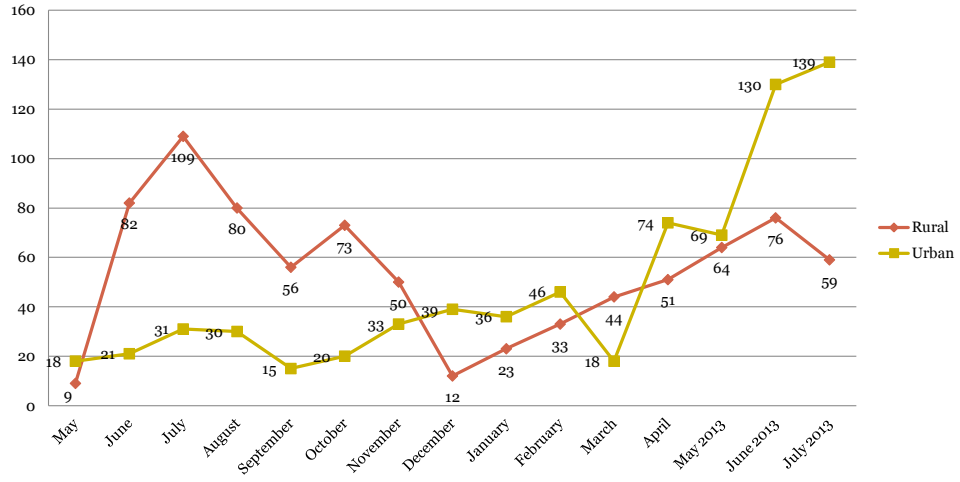


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Total Tests Performed: Rural vs Urban

(Cumulative May 2012 – July 2013)
(n = 1540)

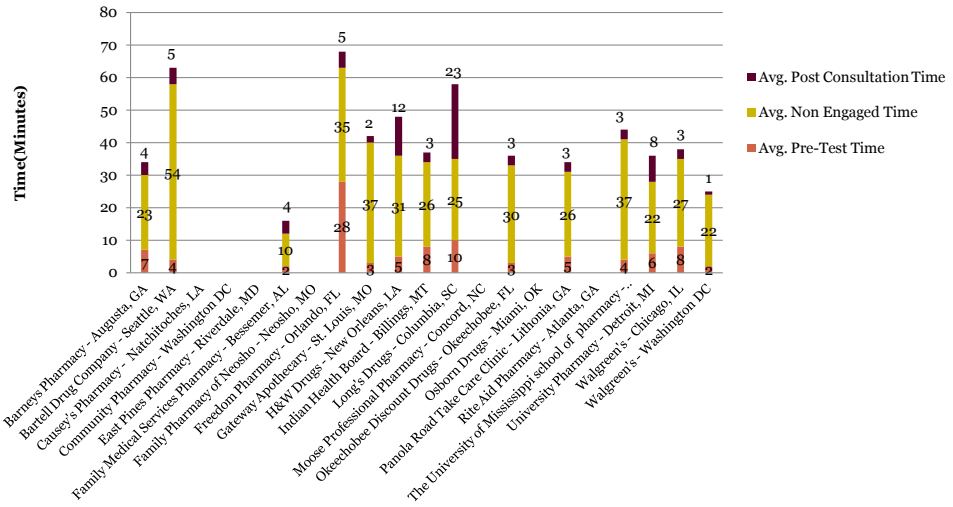


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Avg Total Test Times

July 2013

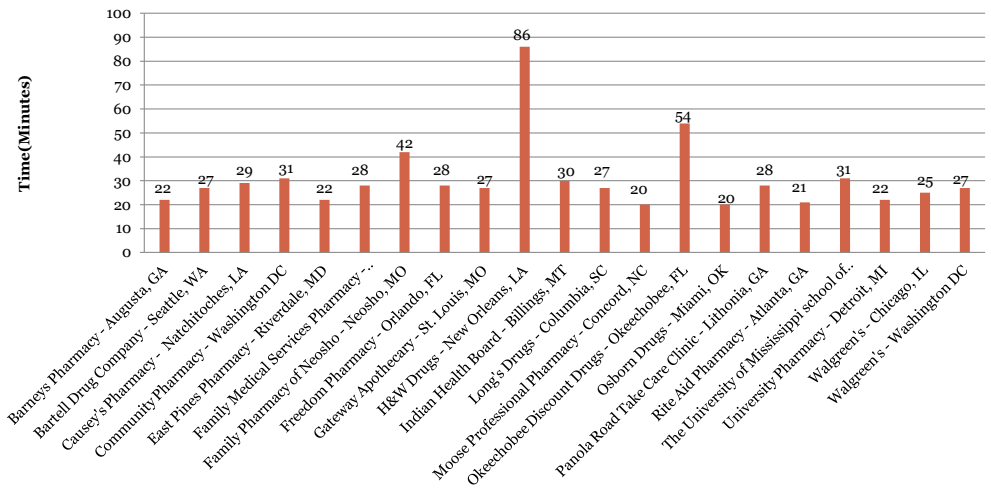


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Avg Patient/Pharmacist Non-Engagement Time

(May 2012 – July 2013)

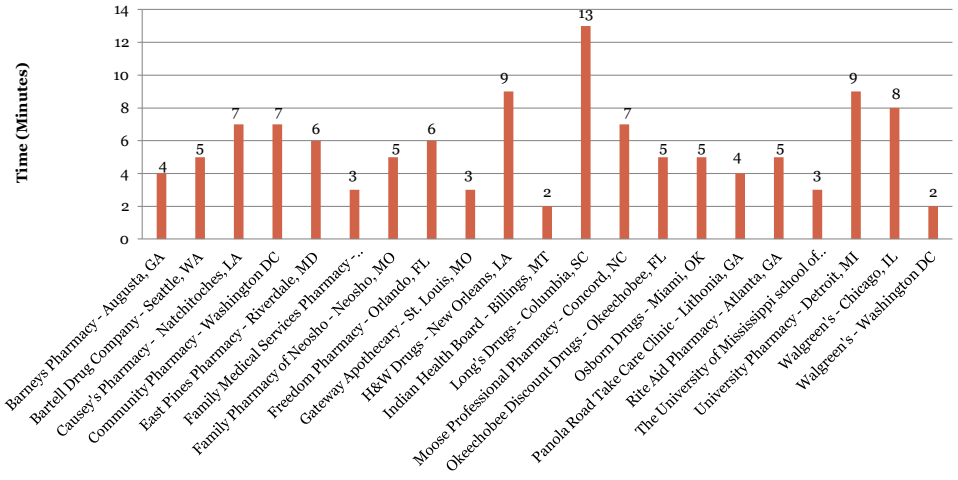


Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Avg Post Test Interaction Time

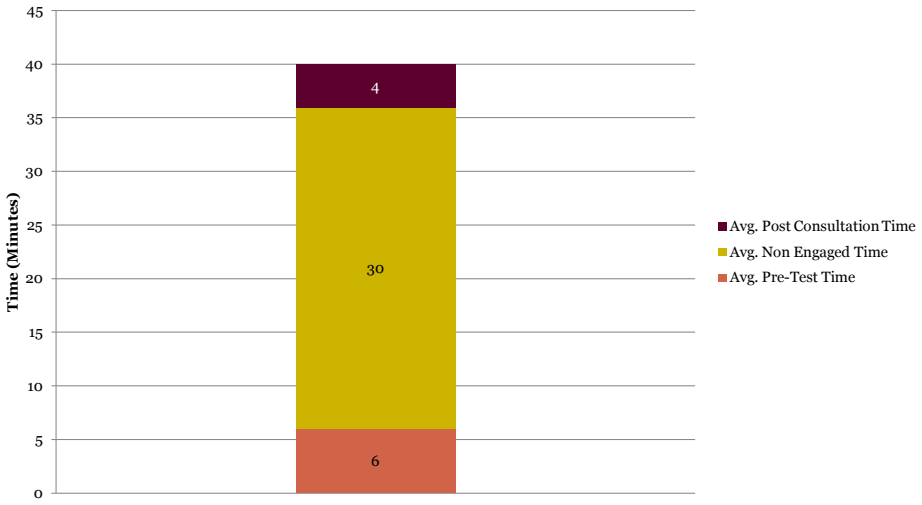
(May 2012 – July 2013)



Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

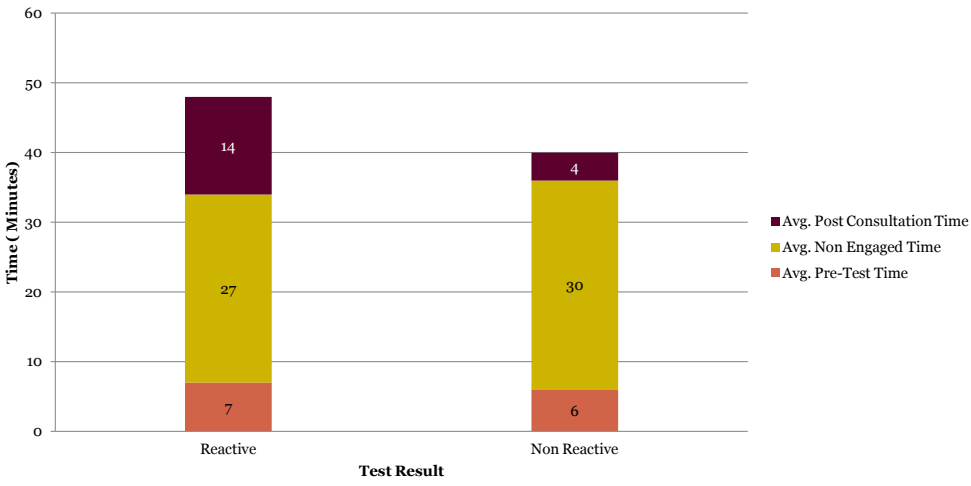
Avg Total Test Times
(Cumulative May 2012 – July 2013)



Data reported through 07/31/13

HIV Testing and Linkage to Care in Community Pharmacies and Retail Clinics

Average Total Test Time by Test Result
(Cumulative May 2012 – July 2013)



Data reported through 07/31/13

SITE LEVEL STATISTICS			
SITE NAME	TOTAL NO. OF TESTS (MAY 2012 – JULY 2013)	AVERAGE NO. OF TESTS PERFORMED PER MONTH	RANKINGS BASED ON SITE LEVEL STATISTICS
Barneys Pharmacy - Augusta, GA	38	5	45th Percentile
Bartell Drug Company – Seattle, WA	15	4	33rd Percentile
Causeys Pharmacy - Natchitoches, LA	17	3	24th Percentile
Community Pharmacy- Washington DC	75	5	45th Percentile
East Pines - Riverdale, MD	88	6	57th Percentile
Family Medical Services Pharmacy – Bessemer, AL	48	12	79th Percentile
Family Pharmacy of Neosho - Neosho, MI	1	1	2nd Percentile
Freedom Pharmacy - Orlando, FL	35	6	57th Percentile
Gateway Apothecary – St. Louis, MO	63	13	83rd Percentile
H&W Drugs – New Orleans , LA	10	2	12th Percentile
Indian Health Board- Billings, MT	136	9	69th Percentile
Longs Drugs – Columbia, SC	15	5	45th Percentile
Moose Professional Pharmacy - Concord, NC	11	2	12th Percentile
Okeechobee Discount Drugs – Okeechobee, FL	102	20	88th Percentile
Osborn Drugs – Miami, OK	2	2	12th Percentile
Panola Road Take Care Clinic- Lithonia, GA	157	10	74th Percentile
Rite Aid Pharmacy - Atlanta, GA	12	3	24th Percentile
The University of Mississippi School of Pharmacy – Jackson, MS	204	51	98th Percentile
University Pharmacy - Detroit, MI	28	4	33rd Percentile
Walgreen's - Chicago, IL	113	8	64th Percentile
Walgreen's - Washington DC	370	25	93rd Percentile

PROGRAM SUMMARY STATISTICS	
Total No. of Tests Run (All Months):	1540
Monthly Average No. of Tests conducted across all sites:	103
Standard Deviation:	51
25th Percentile:	67
50th Percentile:	93
75th Percentile:	129
95th Percentile:	200

SITE LEVEL STATISTICS		
SITE NAME	AVERAGE NON ENGAGED TIME (MINUTES)	RANKINGS BASED ON SITE LEVEL STATISTICS
Barneys Pharmacy - Augusta, GA	22	21st Percentile
Bartell Drug Company – Seattle, WA	27	43rd Percentile
Causeys Pharmacy - Natchitoches, LA	29	69th Percentile
Community Pharmacy- Washington DC	31	81st Percentile
East Pines - Riverdale, MD	22	21st Percentile
Family Medical Services Pharmacy – Bessemer, AL	28	60th Percentile
Family Pharmacy of Neosho - Neosho, MI	42	88th Percentile
Freedom Pharmacy - Orlando, FL	28	60th Percentile
Gateway Apothecary – St. Louis, MO	27	43rd Percentile
H&W Drugs – New Orleans , LA	86	98th Percentile
Indian Health Board- Billings, MT	30	74th Percentile
Longs Drugs – Columbia, SC	27	43rd Percentile
Moose Professional Pharmacy - Concord, NC	20	5th Percentile
Okeechobee Discount Drugs – Okeechobee, FL	54	93rd Percentile
Osborn Drugs – Miami, OK	20	5th Percentile
Panola Road Take Care Clinic- Lithonia, GA	28	60th Percentile
Rite Aid Pharmacy - Atlanta, GA	21	12th Percentile
The University of Mississippi School of Pharmacy – Jackson, MS	31	81st Percentile
University Pharmacy - Detroit, MI	22	21st Percentile
Walgreen's - Chicago, IL	25	31st Percentile
Walgreen's - Washington DC	27	43rd Percentile

PROGRAM SUMMARY STATISTICS	
Mean:	30 minutes
Standard Deviation:	29 minutes
25th Percentile:	20 minutes
50th Percentile:	23 minutes
75th Percentile:	30 minutes
95th Percentile:	53 minutes

Data reported through 07/31/13

SITE LEVEL STATISTICS		
SITE NAME	AVERAGE PRETEST TIME (MINUTES)	RANKINGS BASED ON SITE LEVEL STATISTICS
Barneys Pharmacy - Augusta, GA	9	67th Percentile
Bartell Drug Company – Seattle, WA	8	57th Percentile
Causeys Pharmacy - Natchitoches, LA	13	88th Percentile
Community Pharmacy- Washington DC	11	81st Percentile
East Pines - Riverdale, MD	11	81st Percentile
Family Medical Services Pharmacy – Bessemer, AL	2	5th Percentile
Family Pharmacy of Neosho - Neosho, MI	15	93rd Percentile
Freedom Pharmacy - Orlando, FL	11	81st Percentile
Gateway Apothecary – St. Louis, MO	4	19th Percentile
H&W Drugs – New Orleans , LA	20	98th Percentile
Indian Health Board- Billings, MT	6	36th Percentile
Longs Drugs – Columbia, SC	10	74th Percentile
Moose Professional Pharmacy - Concord, NC	9	67th Percentile
Okeechobee Discount Drugs – Okeechobee, FL	5	31st Percentile
Osborn Drugs – Miami, OK	4	19th Percentile
Panola Road Take Care Clinic- Lithonia, GA	7	45th Percentile
Rite Aid Pharmacy - Atlanta, GA	4	19th Percentile
The University of Mississippi School of Pharmacy – Jackson, MS	4	19th Percentile
University Pharmacy - Detroit, MI	7	45th Percentile
Walgreen's - Chicago, IL	8	57th Percentile
Walgreen's - Washington DC	2	5th Percentile

PROGRAM SUMMARY STATISTICS	
Mean:	6 minutes
Standard Deviation:	6 minutes
25th Percentile:	2 minutes
50th Percentile:	4 minutes
75th Percentile:	7 minutes
95th Percentile:	15 minutes

Data reported through 07/31/13

SITE LEVEL STATISTICS		
SITE NAME	AVERAGE POST TEST CONSULTATION TIME (MINUTES)	RANKINGS BASED ON SITE LEVEL STATISTICS
Barneys Pharmacy - Augusta, GA	4	29th Percentile
Bartell Drug Company – Seattle, WA	5	45th Percentile
Causeys Pharmacy - Natchitoches, LA	7	74th Percentile
Community Pharmacy- Washington DC	7	74th Percentile
East Pines - Riverdale, MD	6	62nd Percentile
Family Medical Services Pharmacy – Bessemer, AL	3	17th Percentile
Family Pharmacy of Neosho - Neosho, MI	5	45th Percentile
Freedom Pharmacy - Orlando, FL	6	62nd Percentile
Gateway Apothecary – St. Louis, MO	3	17th Percentile
H&W Drugs – New Orleans , LA	9	90th Percentile
Indian Health Board- Billings, MT	2	5th Percentile
Longs Drugs – Columbia, SC	13	98th Percentile
Moose Professional Pharmacy - Concord, NC	7	74th Percentile
Okeechobee Discount Drugs – Okeechobee, FL	5	45th Percentile
Osborn Drugs – Miami, OK	5	45th Percentile
Panola Road Take Care Clinic- Lithonia, GA	4	29th Percentile
Rite Aid Pharmacy - Atlanta, GA	5	45th Percentile
The University of Mississippi School of Pharmacy – Jackson, MS	3	17th Percentile
University Pharmacy - Detroit, MI	9	90th Percentile
Walgreen's - Chicago, IL	8	83rd Percentile
Walgreen's - Washington DC	2	5th Percentile

PROGRAM SUMMARY STATISTICS	
Mean:	4 minutes
Standard Deviation:	5 minutes
25th Percentile:	2 minutes
50th Percentile:	3 minutes
75th Percentile:	5 minutes
95th Percentile:	11 minutes

Data reported through 07/31/13