National Collaborating Centre for Infectious Diseases

Alberta Health Services

Syphilis and HIV Point-Of-Care Testing Pilot Project

Alberta Health Services' Edmonton STI Clinic

Public Health Outreach Team

Summary Report for the National Collaborating Centre for Infectious Diseases

January 2013

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Abstract

This report represents a summary of a pilot research project using point-of-care tests (POCT) to rapidly diagnose and provide immediate management for syphilis and human immunodeficiency virus (HIV). It summarizes the experiences of the Public Health Outreach Team (PHOT) in delivering HIV and syphilis POCT from February 2011 until December 2012. It provides an overview of the training required to accommodate and initiate this POCT project, quality assurance details, challenges experienced throughout the study, and the implications for the future of offering HIV POCT in practice, outside of a research project setting.

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Background and Introduction

In 2008, the National Collaborating Centre for Infectious Disease (NCCID) partnered with Alberta Health Services (AHS) to develop a "Learning Site", involving the Edmonton Public Health Outreach Team (PHOT)[1]. One of the functions of this Learning Site focused on the logistical evaluation of a pilot project using point-of-care tests (POCTs) to rapidly diagnose and provide immediate management/referral for syphilis and human immunodeficiency virus (HIV). This pilot research project to evaluate the performance and acceptability of syphilis and HIV POCT in outreach populations was initiated on February 14, 2011, by the Edmonton PHOT.

Point-of-care syphilis tests had not been previously evaluated in clinical settings in Canada and HIV POCT had not been previously carried out or evaluated at the point-of-care (POC) in Alberta. The PHOT offered eligible individuals 18 years of age and older, treponemal syphilis POC testing (SD Bioline Syphilis 3.0 Test, Standard Diagnostics, Inc., Korea) and HIV POC testing (INSTITM HIV-1/HIV-2 Rapid Antibody Test, BioLytical™ Laboratories, Richmond, Canada), using whole blood from a finger prick specimen. POC results were compared to standard testing from simultaneously collected serum specimens. A treponemal-specific enzyme immunoassay (EIA) (Architect Syphilis TP Microparticles, Abbott Laboratories, Illinois, USA) was the initial screen for standard syphilis testing. Quantitative RPR titre was obtained on all samples tested reactive by the syphilis EIA. A line immunoassay (INNO-LIA Syphilis, Innogenetics NV, Ghent, Belgium) was used as the confirmatory test for samples submitted from individuals with no history of confirmed syphilis serology. For standard HIV testing a third generation EIA (AxSym® HIV 1/2 gO, Abbott Laboratories, Illinois, USA) was the initial screen.

On June 14, 2011 ProvLab began using a fourth generation EIA (Architect® HIV Ag/Ab Combo, Abbott Laboratories, Illinois, USA) as the initial screening test. Samples tested reactive by standard EIA screen from individuals with no history of confirmed HIV serology were tested by a second EIA (Biorad Genetic Systems HIV-1/HIV-2 PLUS O EIA, BioRad Laboratories, California, USA) and HIV Western Blot (Genetic SystemsTM HIV-1 Western Blot, BioRad Laboratories, California, USA).

The testing was offered to individuals at existing outreach sites, including correctional and addictions facilities and community based settings such as inner city health centres, drop-in centres, as well as sites accessed by men who have sex with men (MSM) such as bathhouses. The study received funding from both the Public Health Agency of Canada and the Edmonton Inner City Health Research Network and received in-kind support from AHS. The project was

[1] For more information, please see NCCID Purple Paper entitled "Lessons learned from the Edmonton Learning Site: A partnership between the National Collaborating Centre for Infectious Diseases (NCCID) and Alberta Health Services-Edmonton STI Clinic (AHS-Edmonton STI Clinic)" available at http://www.nccid.ca/files/Purple_Paper_Note_mauve/Learning_Site_Final_EN.pdf

concluded on August 29, 2012 when the study met the planned recruitment of 1000 participants for both syphilis and HIV POCT.

In December 2011, a partnership agreement between NCCID and Alberta Health Services (the Edmonton Learning Site) was established to document the ongoing challenges and processes of delivering syphilis and HIV POCT in outreach settings. Detailed research findings will be published elsewhere. This report documents challenges encountered throughout the study; processes such as training, quality assurance, and service delivery considerations required to undertake the pilot; and implications for the future. The purpose of documenting the activities during this project was to gather information that may help other jurisdictions in their considerations and planning to undertake similar activities. As a result of this partnership it is possible to share the experiences from this pilot.

The Team

The project team included the Principal Investigator for the study/Medical Director of the Edmonton Sexually Transmitted Infection (STI) Clinic and PHOT (both considered part of 'the Learning Site'), a Clinical Study Coordinator (RN), a Laboratory Study Coordinator from the Alberta Provincial Public Health Laboratory (ProvLab), five RNs, and three community health representatives (CHRs – also known as outreach support workers). The Medical Director provided medical oversight for the project including direction regarding the testing and management of results. The Clinical Study Coordinator was responsible for the day-to-day operations and coordination of the project, including overseeing documentation and data collection, and for the clinical leadership and support throughout the study. The Laboratory Study Coordinator coordinated kit inventory and distribution, proficiency testing and training on use of the kits, and technical troubleshooting regarding the kits. The RNs and CHRs were responsible for the front line delivery of the POCT. The RNs were responsible for explaining the POCT, obtaining written informed consent (as the testing was being done in a research context), obtaining the relevant clinical and sexual history, and providing appropriate pre- and post-test counseling. The CHRs provided support in recruiting and connecting with potential participants, organizing supplies, testing, and documentation.

Training

A half-day training session was held prior to the project start date with all PHOT members. None of the PHOT members had any prior experience with POCT, therefore, it was critical to develop robust support materials/resources and training for the staff. The laboratory study coordinator reviewed the technical aspects of both the syphilis and HIV POC kits, including the administration instructions for each kit. Positive and negative controls were made available for

each kit to let the staff see what a positive and negative result will look like. Furthermore, the staff were able to perform POCT on each other to practice the technical skills required to administer the test. A double-sided colour document was prepared by the laboratory study coordinator, entitled "Quick Guide to POC Testing and Interpretation", for the staff to refer to in the field. This provided brief pictorial and written directions for the administration of each kit and interpretation of the various test results that may occur. This training session allowed for a dialogue between study staff, the coordinators, and the principal investigator, to address any questions and concerns prior to the start of the study. Furthermore, the session allowed staff to gain some comfort in learning how to use the kits and ask questions about the administration of the tests. The clinical study coordinator reviewed the Procedural Manual for the project which included consent and data collection procedures, testing and treatment algorithms for both HIV and syphilis, pre- and post-test HIV counseling, and quality assurance procedures.

Quality Assurance and Incident Procedures

The Procedural Guidelines for the study included a section outlining quality assurance procedures, including a technical troubleshooting guide for incidents such as an invalid test (no control spot present) or parallel testing discrepancy (POC test positive, standard test negative and POC test negative and standard test positive). The Procedural Guidelines outlined the appropriate actions for each of these incidents (See Appendix A: Technical Trouble Shooting Guide).

In order to ensure the integrity of the testing materials, a control and proficiency testing program needed to be in place. This required both positive and negative controls to be run on each new box of kits as well as monitoring of the daily temperature where the kits were stored. It was originally thought that this would be done by the study staff at the STI Clinic; however, there were concerns about consistency in how this would be done (i.e. would several staff be responsible for this?) as well as the time and expertise that would be required. The laboratory study coordinator from ProvLab offered to house the majority of the kits at ProvLab and distribute them to the PHOT. She performed the positive and negative controls on each new box prior to its distribution and was also responsible for monitoring the daily storage temperatures for the kits.

POCT Kits

POCT requires numerous supplies – the kit itself, alcohol swabs, lancets, diluents/clarifying solutions, and pipettes. Both the HIV and syphilis POCT kits came packaged alone and not with these additional supplies. The laboratory study coordinator pre-packaged each kit with an alcohol swab, lancet, and pipette in a biohazard bag. For the HIV kit, each biohazard bag also contained the three additional bottles (sample diluents, colour developer, clarifying solution) that the test required. This saved considerable time for the study staff in the field as all the supplies were located in one spot and to replenish their supply they only had to worry about re-stocking the pre-packaged biohazard bags, as opposed to worrying about multiple supplies that are packaged separately.

Testing Sites

The majority of tests were offered at sites already visited by the PHOT, where relationships had already been established with the staff and clients. Sites included inner city health and support agencies, provincial correctional facilities, addictions treatment facilities, MSM sites (e.g. bathhouses, bars). One significant site-specific issue was related to a staffing change at one of the MSM sites (bathhouse) where the testing was offered each week. There was both a change in the management of this site and in the Community Education Facilitator of the partner agency (local AIDS service organization), who was instrumental in establishing the partnership and providing information about the POCT to patrons of the facility. These changes resulted in a temporary interruption in being able to offer the testing at the site and a drop in recruitment over a period of weeks. This highlights the importance of building relationships and establishing trust with the staff and clients of agencies where POCT is being offered to hard to reach populations.

Challenges

Time Management and Capacity

One concern raised by the PHOT was about how much additional time would be required to offer the testing, obtain written consent, perform additional data collection and documentation, and perform the POC HIV and syphilis testing. This concern was exacerbated by the fact that it takes 20 minutes to confirm a negative syphilis POCT result. It was of particular concern for the high-volume sites visited by the PHOT, including the addictions treatment and correctional facilities where there is a high uptake of testing. The team expressed that they did

not feel they had sufficient time to offer this additional testing at high-volume sites, unless they were seeing and testing fewer individuals.

Several strategies were explored with staff to address this. For example, one of the nurses suggested elimination of one of the forms required for data collection for the study as the majority of this information would be captured on the chart. It was subsequently determined that the form could be eliminated and that all the documentation would take place on the client chart, eliminating double charting and simplifying the process for the nurses and outreach support staff.

The staff also thought it might help to have two staff members at the high-volume sites. For the addictions treatment sites, a CHR routinely accompanied the RN. This wasn't the case for the Remand Correctional Centre where the RN was generally on her own for testing. However, In order to meet the existing STI testing demands at this site and introduce POC testing we added an additional RN to this site for approximately 6 months. An Edmonton Provincial Corrections Partner Notification Nurse (EPCPNN) position was created within the STI Program, which resulted in a dedicated RN to offer STI testing for the Edmonton Area correctional facilities including the Remand Centre. The RN who was hired for this position had already provided support to the POCT project at correctional facilities, so was comfortable with delivering the testing. The EPCPNN provided STI testing clinics at these facilities 5 days per week. Eventually, she was able to offer the POC testing to all clients she saw for STI testing and was able to deliver the testing on her own as she had more dedicated time at these facilities. It was believed that once the PHOT became more familiar with offering and delivering POCT as part of their routine practice, time concerns would become less of an issue. Despite initial reluctance by the PHOT to offer the testing at high-volume sites, as reflected by the small numbers tested in the first three weeks of the study, there was a gradual increase in the number of tests conducted per week. Following the introduction of the testing, the RNs explained how they began to organize their assessment/testing process differently to accommodate the POC testing. For example, they would start by obtaining consent for the POC testing, perform the POC testing/standard testing, and while they were waiting for the syphilis result (which takes 20 minutes for a confirmed negative), they would then obtain their clients' histories and provide them with counseling. By the time they finished their history-taking and counseling they would be able to provide the syphilis test result to the clients, as 20 minutes would have passed. Additionally, the RNs reported that having the support of a CHR was very helpful. The CHR would help with the set up and administration of the tests and the paperwork, while the RN performed the history taking, counseling, as well as treatment if necessary.

Supplies

An ongoing challenge, expressed by staff during the initial training session, regarded the pipettes used to obtain the blood specimen. It was difficult to retrieve the blood without the introduction of air bubbles in either of the two pipettes provided for the training. Initially, the staff were unsure if this was related to a lack of experience in using pipettes or to the pipettes themselves. The laboratory study coordinator agreed that they were challenging to use and would look at obtaining other pipettes. After trying four different pipettes the majority of staff identified one pipette (Extended Fine Tip, 1.5ml Small Bulb Sterile Transfer Pipettes, DiaMed Lab Supplies, Mississauga ON) which they preferred.

BioLytical™, the manufacturer of the POC HIV kit, supplies a pipette with the HIV kit and have requested that this pipette be used to perform the test. The laboratory study coordinator attended a training session held by a BioLytical™ representative in Calgary on the HIV POC kit and learned that the pipette was not being used correctly. Upon learning the correct way to use the pipette, the laboratory study coordinator held a training session with the PHOT in June 2012. Following this training session, the staff reported that they found this pipette much easier to use; however, they still had some issues in obtaining an adequate sample with this pipette, particularly when conditions were not ideal (e.g., poor lighting, a "jumpy" client , calloused hands, etc). The Laboratory Study Coordinator continued to supply the preferred pipette and the BioLytical pipette for the remainder of the study. Although the BioLytical™ pipette is still not preferred by the PHOT, this issue highlights the critical need for thorough training and description on the use of all equipment required to perform the POCT for any future orientation sessions held with new staff.

Another concern expressed by the PHOT initially was about the amount of supplies that the staff would have to carry to accommodate the testing: lancets, pipettes, alcohol swabs, and information/consent forms. The concern was addressed to some extent with assistance from ProvLab in pre-packaging all the supplies required to perform for each in separate biohazard bags. This assisted the PHOT team in carrying the supplies in a more efficient manner versus having to pack each item separately. In addition, it is noteworthy that outside of a research study, information and consent forms would not generally be required.

Of note, the POC HIV kit would also significantly shorten the time for each assessment if this test alone were conducted, since it provides a result within 60 seconds[2].

[2] The syphilis point-of-care test is currently not licensed in Canada, so the test could not be offered beyond the scope of the research project.

Incident Contact and Discrepant Results

One of the first incidents encountered by one of the RNs was a testing discrepancy for a client who reported a previous history of syphilis but her POC syphilis test was negative. The RN attempted to call the STI Clinic to contact the study coordinator and/or the RNs responsible for syphilis follow-up who have access to the Provincial STD Database, to determine the client's past history of syphilis and to report the testing discrepancy to determine if any further steps were required. Neither the study coordinator nor the community office RNs was available when the RN called (and she was put on hold for an extended period of time). She was unable to reach anyone before the client left that day. The testing RN was at an extremely busy and high-volume inner city agency so it was difficult for her to ask the client to wait for an extended period of time or to have the time to wait on hold herself. This incident highlighted the importance of ensuring there is an adequate back-up available for the staff in the field conducting the POC testing. Alternatively, remote access to the Provincial STD Database which includes prior history and treatment information should be explored, ideally from portable electronic devices. The clinical study coordinator reviewed the options for contacting him and/or the Principal Investigator for the study, for guidance on management of positive results and quality assurance incidents as described above.

One of the more challenging experiences encountered during the study was delivering a false positive HIV test. The RN counseled the clients immediately following the positive POC HIV tests, explaining that the results were preliminary positive tests and needed to be confirmed by standard testing, as indicated in the study procedural manual. The clients' experienced considerable stress in being given a positive POC HIV result and having to wait days to receive the results of the confirmatory testing, which in the end turned out to be negative. The experience of having false positive HIV POC tests reinforces the importance of having procedures in place to deal with any test result discrepancies. The study Procedural Manual outlines the appropriate actions for this type of incident. (See Appendix A: Technical Trouble Shooting Guide).

Post-Study Implications

Although the HIV and syphilis POC research study concluded at the end of August 2012, the PHOT felt that it was critical to continue to offer HIV POCT as part of their program. The PHOT would not be able to continue offering syphilis POCT as the kit is not licensed for use in Canada. The PHOT team recognized that the HIV POCT had become part of their standard of care at most of their Outreach sites over the last 1.5 years and removing this testing from the PHOT

standard of care would potentially risk the relationship that had been established with some of the agencies and their clients. With the assistance of external funding, the PHOT was able to purchase a supply of HIV POC kits from BioLytical™ and have continued to offer the HIV POCT at most of their sites. It is hoped that this will be sustained in the future as part of routine programming.

Conclusions

- Syphilis and HIV POCT can be successfully introduced and delivered in a variety of outreach and non-standard health settings including correctional facilities, inpatient addiction treatment sites, community based facilities, and sites visited by MSM (e.g. bathhouse).
- A multidisciplinary team integrating clinical and laboratory (technical) leadership and support is critical in introducing and delivering syphilis and HIV POCT in Outreach settings.
- The introduction of syphilis and HIV POCT in a front-line outreach program requires thorough training and support materials for all staff involved in delivering the testing.
- Quality assurance and incident procedures must be in place for programs delivering syphilis and HIV POCT. These procedures need to be accessible and understood by the staff delivering these tests.

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Appendix A (Technical Trouble Shooting Guide)

	Description	Action	
Invalid test result	No control spot/line present with or without test spot	Report result as invalid Notify ProvLab Notify Medical Director	
Parallel testing discrepancy	POC test reactive. Standard ProvLab testing Negative.	Notify: ProvLab and Medical Director	
Parallel testing discrepancy	POC test negative. Standard ProvLab testing Positive.	Notify: ProvLab and Medical Director	
Controls unacceptable	Positive control has a non-reactive test spot/line Negative control has reactive test spot/line on negative control test.	If:	Then:
		Control is unacceptable or invalid	Repeat test with new control sample
		Repeat control test is acceptable (positive control is reactive, negative control non-reactive)	Record on incident report and control sheets. Proceed with testing.
		Repeat control is acceptable	Open a new package of kits and test with new kit and control.
		Repeat control with new kit is acceptable	Proceed with testing with new package of test kits. Notify ProvLab and forward unacceptable kits to ProvLab.
		Repeat control with new kit is unacceptable	Discontinue testing. Notify ProvLab and forward unacceptable kits to ProvLab. You will be notified when testing can be resumed.