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Jennifer Quinn Belfry

University of Massachusetts Boston, jqfish@gmail.com

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Introduction of HIV Point-of-Care Testing in Adolescent Primary Care: A Quality Improvement Project

Jennifer Quinn Belfry, DNP, MSN, FNP-BC, AAHIVS
College of Nursing and Health Science, University of Massachusetts Boston

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Project Committee
Faculty Advisor: Eileen Stuart-Shor, PhD, ANP-BC, FAHA, FAAN
Practice Site Mentor: Manuela Pires Tambollio, RN
Committee Mentor: Elizabeth Russet, DNP, FNP
Abstract

Background
HIV, first identified in 1981, remains a persistent public health problem affecting 1.1 million Americans today. Detection is a critical first step to ending the HIV epidemic and the CDC recommends universal HIV screening for all patients 13-64 years of age regardless of risk factors. HIV screening rates are suboptimal especially in adolescent and young adult populations who face unique barriers to screening. The aim of this project was to improve HIV screening rates in adolescent and young adult patients at a large, urban FQHC.

Local Problem
In the state of Rhode Island, 1 in 10 persons living with HIV are unaware of their HIV diagnosis with a disproportionate burden of undiagnosed disease falling on adolescents and young adults. At a large FQHC in Providence, R.I., screening rates for adolescents and young adults have been noted to be low.

Methods
A systematic review of the literature revealed six applicable interventions to improve HIV screening rates for the target population. HIV point-of-care testing was the focus of this quality improvement project as research demonstrated it improves screening rates and it aligned with existing clinical workflows. This project was guided by the Chronic Care Model to develop and implement a HIV point-of-care testing protocol in adolescent and young adult primary care. Rapid Plan-Do-Study-Act cycles and Lewin’s Change model steered this process change.

Intervention
A HIV point-of-care testing protocol was developed and implemented over a 12-week project focused on universal screening for patients 15-25 years of age. Staff received training and follow up survey regarding acceptance of the new protocol. Patient education on HIV screening and safe sex practices was standardized in this protocol.

Results
The introduction of a HIV point-of-care testing protocol resulted in a 16.3% increase in completed HIV screenings from baseline. The project was met with general support from staff with feasibility challenges noted.

Conclusions
HIV point-of-care testing improves HIV screening rates in adolescent and young adult patients. Future quality improvement cycles should address the clinic time constraints and ways to cover the costs of testing to achieve sustainable outcomes.
Introduction

The Human Immunodeficiency Virus (HIV), first identified in the U.S. in 1981, remains a persistent public health problem affecting 1.1 million Americans today. The HIV epidemic reached a turning point in 2016 when new HIV infection rates decreased for the first time (CDC surveillance data, 2021). To end the HIV epidemic, the Centers for Disease Control and Prevention (CDC) issued a goal to decrease new HIV infection rates by 90% by the year 2030 (CDC, 2021). Universal HIV screening advances that goal because earlier identification of HIV infection decreases spread of disease (USPSTF, 2019). Since 2006, national guidelines have recommended one-time universal HIV screening for all persons 13 to 65 years of age in all healthcare settings, yet HIV screening rates remain suboptimal.

Problem Description

Universal HIV screening is considered a standard of care in the U.S. healthcare system, yet screening rates continue to lag this goal. Current guidelines from the CDC, USPSTF, ACOG, and AAP\(^1\) are in accordance with recommendations for universal HIV screening at least once for all persons 15 to 64 years of age (CDC, 2019; USPSTF, 2019; AAP, 2021; ACOG, 2020). The CDC and ACOG also recommend universal HIV screening for persons 13 to 15 years of age. Despite wide dissemination of these guidelines, HIV screening rates in the U.S. remain inadequate, with CDC estimates that 40% of American have completed HIV screening once in their lifetime (CDC surveillance data, 2021).

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In the U.S., Adolescents and young adults are the least likely to receive HIV screening, but account for the most new HIV diagnoses. Patel, et al. (2020) explored HIV screening rates in the U.S. from 2010 to 2017 and found that for persons 18-24 years of age, HIV screening rates decreased in that time frame to 31.5% in 2017. The HIV screening rate for all persons 18-64 years of age was estimated to be 45.9% in 2017. Young adults and adolescents face unique challenges to complete HIV screenings, including HIV stigma, low health literacy, low perceived risk, lack of access to testing, and confidentiality concerns (Gamarel, K., et al., 2018; Schnall, R. et al., 2015).

In 2021, the highest number of new HIV diagnoses occurred in persons 25-29 years of age followed by those 20-24 years of age (CDC surveillance data, 2021). The combination of high HIV incidence and low HIV screening rates results in more adolescents and young adults who are unaware of their HIV status. For example, 2019 CDC data show 44.3% of persons living with HIV 13-24 years of age were unaware that they had HIV (CDC surveillance data, 2021). These undiagnosed persons are highly likely to spread HIV to others and more likely to be diagnosed with AIDS at the time of HIV diagnosis (CDC surveillance data, 2021). In the U.S., the median time from initial HIV infection to diagnosis is 3 years (CDC surveillance data, 2021). Increases in adolescent and young adult screening rates will decrease the average time to diagnosis and limit further spread of HIV.

**Local Problem**

In the state of Rhode Island, the Rhode Island Department of Health (RIDOH) estimates that one in every ten people living with HIV are undiagnosed (RIDOH, 2019). In 2021, most new HIV diagnoses (49%) occurred in emergency rooms or hospitals, and 29% of new cases were concurrently diagnosed with AIDS, indicating a delay in HIV diagnosis (RIDOH, 2021).
Most new HIV diagnoses occurred in young people between the ages of 18 and 35: 53.6% (RIDOH, 2021). The combination of delayed HIV diagnoses and the skew of younger persons being newly diagnosed indicates a need to improve HIV screening rates for adolescents and young adults to combat the spread of HIV in the state.

In Rhode Island, HIV prevalence and incidence is concentrated in Providence County. From 2015-2019, the most new HIV diagnoses occurred in Providence County (RIDOH, 2019). RIDOH data from 2021 showed 40.6% of all persons newly diagnosed with HIV lived in Providence County (RIDOH, 2021). This is in line with national trends as Providence County is the most urban area in the state and includes areas of low income.

A large Federally Qualified Health Center (FQHC) in Providence, R.I., where this quality improvement project was implemented, was uniquely positioned to combat the HIV epidemic in Rhode Island. This FQHC served a diverse patient population with more than half of the patients qualifying for Medicaid and the majority living in Providence County. CDC data from 2019 demonstrated that HIV disproportionately affected people from racial and ethnic minorities, lower socioeconomic backgrounds, and urban areas (CDC, 2021). These populations also experienced barriers to preventative care, such as HIV screening, due to social determinants of health (Crepaz, N, et al., 2023).

Electronic medical record data at this FQHC demonstrated a disparity in HIV screening rates across age cohorts. In 2022, 66% of all patients eligible for HIV screening, 15-65 years of age, had completed HIV screening at least once. For adolescents and young adults, 15-25 years of age, only 54% of patients completed HIV screening at least once. For pediatric patients, 15-18 years of age, the HIV screening rate was 15% of patients ever tested for HIV. In comparison, the CDC determined the national HIV screening rate for persons 13 to 64 years of age to be less than
40% of people ever being tested for HIV from 2016-2017 data (CDC Press Release, 2019). Improving adolescent and young adult HIV screening rates at this FQHC has the potential to combat the spread of HIV in Providence, the area in the state with the highest HIV incidence.

**Available Evidence**

A PRISMA guided literature review was undertaken to explore interventions to improve adolescent and young adult HIV screening rates in the outpatient setting. The databases searched were PubMed, Google Scholar, and Cumulative Index of Nursing and Allied Health Literature (CINAHL). Search terms included adolescent, pediatric, HIV testing, HIV screening, primary care, outpatient, rapid HIV testing, point-of-care HIV testing. Inclusion criteria for this review were English language, peer-reviewed articles published between 2007 and 2022 and were limited to U.S.-based study populations. Articles with data collection prior to the 2006 CDC universal HIV screening guidelines were excluded. Articles related to perinatal HIV screening or emergency room HIV screening were excluded. Articles without outcome measurement of HIV screening rates were excluded. Fourteen articles relevant to this project’s purpose were selected. These studies revealed six unique interventions shown to improve HIV screening in the outpatient setting and are summarized in Table 3: Evidence Summary (Appendix A).

The first of these interventions was a nurse-led testing protocol with point-of-care HIV testing. A standing order for HIV screening granted nurses leeway to offer point-of-care HIV testing to patients. The use of point-of-care HIV tests increased receipt of results and acceptability of screening among diverse study populations (Anaya, et al., 2008; Crumby, et al., 2016; Smith, et al., 2021).
Two studies also employed point-of-care HIV testing; however, one focused on health educators conducting HIV screening, and the second study omitted who initiated screenings, but implied provider-initiated orders (Arrington-Sanders, et al., 2018; Mullins, et al., 2010). Importantly, the populations in these studies were adolescents and young adults 13-25 years of age with the majority of patients identifying as African American (Arrington-Sanders, et al., 2018; Mullins, et al., 2010). Both studies showed increased HIV screening rates from implementing point-of-care HIV testing programs (Arrington-Sanders, et al., 2018; Mullins, et al., 2010).

Two studies explored the mechanism of screening in identifying new HIV diagnoses in a population: universal screening versus targeted screening. Mullins, et al., examined how the 2006 CDC guidelines for universal screening more than doubled HIV screening rates at a diverse pediatric practice (Mullins, et al., 2010). Miller, et al., focused on new HIV diagnosis rates in universal versus targeted screening efforts across several U.S. states. While targeted screening reached more at-risk sexual minority youth, the combination of universal and targeted screening most improved HIV screening rates and discovery of new diagnoses (Miller, et al., 2017).

Another intervention identified by this review was a provider report card on HIV screening rates. Luu, et al., 2021 examined the introduction of a quarterly provider report card at a large California health system, which modestly increased HIV screening rates (Luu, et al., 2021).

Several studies examined the use of electronic medical record (EMR) alerts or clinical decision support tools to increase HIV screening rates. This intervention was often not limited to only adolescent patients; thus, the studies included adults through age 65 in most cases. All five identified studies showed improvements in HIV screening rates with the introduction of an EMR

The final intervention identified was video game programs targeted at adolescents and young adults. These interventions remain novel, and both studies were able to demonstrate acceptability of the intervention to the adolescent populations and increases in HIV testing knowledge, but neither showed the direct impact of the interventions on HIV screening rates (Pendergrass, et al., 2020; Wilbourn, et al., 2020). According to the primary investigator of the Pendergrass study, the COVID-19 pandemic interrupted ongoing research into whether these gaming interventions improved HIV testing rates in school-based health clinics.

Several national guidelines support universal HIV screening. The CDC recommends HIV screening for all persons 13 to 64 years of age at least once regardless of risk factors and recommends screening for younger or older persons if risk factors for HIV are present (CDC, 2006). The American College of Obstetricians and Gynecologists (ACOG) issued a statement in support of the CDC guidelines (ACOG, 2008). The USPSTF also issued a grade A recommendation to universal HIV screening for all persons 15 to 65 years of age at least once in 2013 (USPSTF, 2019). The American Academy of Family Physicians (AAFP) issued a statement in support of universal HIV screening in accordance with the USPSTF guidelines for persons 15 to 65 years old (AAFP, 2019). The American Academy of Pediatrics also recommends universal HIV screening for all persons 16 to 18 years of age when HIV local prevalence is greater than 0.1% (AAP, 2013). In the U.S. healthcare system, universal HIV screening is a well-accepted standard of care. Best practices for implementation of universal HIV screening are not included in these guidelines.
Of the six interventions found to be effective, point-of-care HIV testing was selected for implementation because it demonstrated large gains in HIV screening rates in clinical sites with populations similar to the project site. Additionally, point-of-care HIV testing was shown to be preferred over laboratory-based testing by adolescent and young adult populations (Haines, et al., 2011; Schwandt, et al., 2012). Finally, HIV point-of-care testing complemented already existing clinical workflows at the project site such as standing orders for HIV testing. Therefore, the purpose of this quality improvement project was to develop and implement an HIV point-of-care testing protocol in adolescent primary care.

**Rationale**

The Chronic Care Model (CCM) guided this quality improvement project. The CCM focuses on assembling resources to improve care of chronic diseases within a healthcare system (Wagner, E. H., 1998). Recently, researchers applied the CCM to improve HIV management, HIV prevention, and HIV testing (Goetz, et al., 2008; ElZarrad, et al., 2012). The CCM focuses on six elements of the health care system to optimize chronic disease care: the health system, the community, self-management support, delivery system design, decision support, and clinical information systems (Wagner, E. H., 1998). This project utilized these six elements as follows.

**The health system.** The project lead recruited stakeholders within the organization to assist in systems level changes. A specific aim of the project was to gain support from management and clinical staff for the new point-of-care HIV testing protocol. Developing the protocol required assistance from clinic operations staff, billing staff, medical record staff, and the medical directors. Implementing successfully required support from clinical staff including providers, nurses and medical assistants.
The community. The project lead partnered with the R.I. Department of Health in securing funding for this project and the HIV point-of-care test kits. The project lead completed applications for funding from the New England AIDS Education and Training Centers.

Self-management support. Patients engaged in shared decision-making regarding HIV screening. The project lead developed standardized patient education materials and ensured patient access to counseling in the HIV point-of-care testing protocol. This empowered patients with knowledge of HIV screening and safe sex practices.

Delivery system design. Standing orders for HIV screening implemented by nurses and medical assistants free up providers from this task and allowed support staff to practice to the top of their training and abilities. Workflows were developed with input from clinic staff to determine best practices for this new protocol.

Decision support. This project educated staff on evidence-based guidelines for HIV screening and why universal HIV screening improves care. This training motivated staff to offer more screenings to patients.

Clinical information systems. This project emphasized existing electronic medical record alerts and disseminated provider HIV screening dashboards quarterly. The project lead retrieved a list of patients who have yet to receive HIV screening from electronic health records data and outreached those patients for appointments to complete HIV screenings.

The process of change for this quality improvement project was guided by Lewin’s Change Theory (Wagner, J., 2018). This theory is a three-step model of change: unfreezing, change, and refreezing. In the first step, unfreezing, the organization prepares for the change. The second step, change, is when the change process is implemented. The third step, refreezing,
is when the organization solidifies the new processes (Wagner, J., 2018). Lewin’s change model also identifies driving and restraining forces that influence the change process. For this project, a force field analysis diagram identified these driving and restraining factors, Appendix B, and is discussed in detail in the Context portion of this proposal.

**Specific Aims**

The purpose of this project was to improve HIV screening rates for adolescents and young adults at a large FQHC in Providence, R.I. and demonstrate that universal HIV screening was achievable in this patient population. The overarching aim was to develop, implement and evaluate a HIV point-of-care testing protocol for patients 15-25 years of age. Sub aims were the following:

- Leadership, clinical staff and the project lead will co-create the new HIV point-of-care testing protocol.
- 95% of the family medicine clinic staff will complete training for the HIV point-of-care testing protocol.
- 95% of eligible patients will be offered HIV point-of-care testing during the 12-week project period.
- 95% of eligible patients will be counseled and educated on HIV screening and prevention.
- 95% of patients who consent to HIV screening will complete HIV point-of-care testing.
- 95% of patients with preliminary positive results will complete counseling, confirmatory testing, and linkage to care.
- Staff will express support for the final protocol.
Methods

The Plan-Do-Study-Act (PDSA) cycle improvement model guided the development, implementation, and evaluation of the new protocol for HIV point-of-care testing. PDSA cycles consist of four items. The “plan” phase includes project planning and preparation for a change. The “do” phase implements the change, often in small increments. The “study” phase is assessment of the steps taken. The “act” phase is adjusting the process with the information gained. The cycle is then repeated until an acceptable process is developed (Institute for Healthcare Improvement, 2020). The PDSA cycles took place weeks 2, 4, 8 and 12 to garner feedback from stakeholders and clinical staff.

Context

The project was implemented in a large federally qualified health center (FQHC) in Providence, R.I. This urban FQHC consisted of 9 primary care clinics, various specialty clinics and 2 urgent care centers. This clinic serves a well-established panel of patients from the South Providence area. The most prevalent primary language for this patient population was Spanish, followed by English, Portuguese, and French Creole. Patients in the 15-25 years of age cohort were often first- or second-generation immigrants. Health literacy for this population was impacted by language barriers, low education levels, and lack of clinic time to provide extended health counseling. Patients in the target age cohort were often living with parents or guardians who accompanied patients to visits.

A microsystem map assisted in describing the context of the adolescent or young adult patient in the clinical microsystem of the primary care FQHC (Appendix C). This microsystem map displays those who influence the adolescent or young adult patient’s health outcomes, specifically sexual health and HIV screenings. For this project, providers, nurses, and medical
assistants were the focus of this system change and are highlighted in blue. These stakeholders influenced the patient’s sexual health outcomes by providing access to confidential screenings and patient education. Other factors that influenced the patient’s health outcomes include parents or guardians, the internet, school, and peers. These other actors influenced the patient’s health literacy, acceptance of screenings, and financial support.

The clinical staff at this site consisted of 14 provider teams across four specialties: family medicine, pediatrics, OB/GYN, and internal medicine. Each provider team consisted of one provider, one registered nurse, and one medical assistant. Patients were assigned to a primary care provider and regularly seen by that provider for care. Occasionally, patients were scheduled with other providers depending on scheduling availability. Laboratory services were co-located on the first floor of the clinic. A social worker was available on-site as part of the integrated behavioral health team. One provider HIV specialist was also located on-site in the family medicine department and served as the project lead for this quality improvement project. The project was sited in the family medicine department.

Existing workflows regarding sexual health counseling and HIV screening for patients 15-25 years of age included a standing order for nurses and medical assistants to offer universal HIV screening via laboratory-based testing. Providers conducted sexual health counseling during annual physical exams or annual well child visits. For minor patients, parents or guardians were asked to exit the exam room near the end of the visit so that sexual health counseling would be conducted with the patient privately. Handouts for these counseling sessions were not standardized at the practice. The provider educated the patient and offered HIV and STI testing during this counseling time. If a patient consented to testing, the provider ordered laboratory-based testing, which required the patient to exit the exam room, take a paper order slip to the lab
area on the first floor of the clinic, and check-in for phlebotomy. The patient then waited to be called by the phlebotomist for a blood draw and urine sample to be collected. The patient’s parent or guardian would accompany the patient to the laboratory area and must wait with the patient until the samples are collected. For negative results, the patient was called a few days later or could review results on the online patient portal. Patients with positive HIV results were called to come into clinic and results were delivered in-person by the provider. Linkage to care and HIV counseling was conducted by the provider at that time with utilization of the integrated behavioral health team as needed.

A cause-and-effect fishbone diagram was constructed to illustrate the challenges contributing to low HIV screening rates in this population (Appendix D). As the fishbone diagram illustrates, adolescent and young adult patients in this population faced unique barriers to completing HIV screening including stigma, confidentiality concerns, low health literacy, low perceived risk, lack of reimbursement to the clinic for HIV screenings, and lack of clinic time for counseling. This project aimed to mitigate two barriers specifically: confidentiality concerns and low health literacy. Confidentiality concerns encompasses disclosure of testing activities, and disclosure of confidential medical history. Minor patients expressed concern that HIV or sexually transmitted infection (STI) testing billed to a parent’s insurance plan would be revealed to the parent by the insurance company. Patients under the age of 18 were required to attend medical visits with their parent or guardian present, making confidential testing more challenging when a parent accompanied a patient for laboratory-based screenings. Finally, minor patients worried that information in their medical record could be disclosed to a parent or guardian such as HIV testing or reported sexual activity.
Another contributor to low HIV screening rates in this population was low health literacy. Most patients reported a low perceived risk of HIV and many patients misunderstood how HIV is spread, for example assuming only men who have sex with men (MSM) can become infected. Other patients were unaware of ways to prevent HIV infection such as barrier use, pre-exposure prophylaxis (PrEP), or post-exposure prophylaxis (PEP). This quality improvement project focused on confronting these two barriers to HIV screening.

A force field analysis mapped the factors at the clinical site that drove or restrained implementation of the project (Appendix B). Driving forces for this change included evidence-based research and national guidelines supporting universal HIV screening. Community partners were a driving force for this project as the Rhode Island Department of Health coordinated funding and technical support for the HIV point-of-care test kits. The clinic management team was in support of the project as it aligned with goals of increasing HIV screening rates which were reported to the U.S. Health Resources and Services Administration (HRSA) annually as a measure of clinical quality of care. Finally, a site champion was available to plan and implement the project.

Forces that had the potential to restrain this project were cost issues surrounding insurance reimbursement, the need to develop staff trainings, and the time needed to develop the protocol. Potential forces that could have restrained the project were if HIV point-of-care testing slowed clinic workflows. Patient factors such as low health literacy and confidentiality concerns could have resulted in patients declining the screening test. Potential driving forces for the project included that the testing was acceptable to patients and staff. A final potential driving force would be demonstration of improved HIV screening rates, which was in line with organizational goals.
Intervention

Description of the Protocol

The focus of this project was implementation of an HIV point-of-care testing protocol and has been summarized in a process workflow (full size model available in Appendix E). This workflow built on established clinic workflows for sexual health counseling for minors, as described in the context section.

Eligible participants were defined as patients presenting for in-person appointments at the project clinic, between 15-25 years of age, without prior diagnosis of HIV, and without prior HIV screening documented in the electronic medical record. All visit types were included such as well child visits, follow-up visits, nurse visits, and sick visits. In accordance with state and federal guidelines, parental consent was not needed for this HIV point-of-care test. The protocol is described in detail in Figure 1 below.

![Figure 1: Process Flow HIV POCT](image-url)
As illustrated in Figure 1, the universal screening protocol was triggered when the patient was roomed. A nurse or medical assistant initiated the protocol by rooming the patient without parent or guardian present and offering the HIV point-of-care screening test as an opt-out routine test. The nurse or medical assistant provided an HIV screening handout with basic information regarding the test and a patient education handout on how to prevent HIV (Appendix F and G). The HIV screening handout included information on HIV screening, types of HIV tests, confidentiality of testing, and what the results mean. The HIV Prevention handout was from the CDC and includes ways to prevent HIV infection including information on PrEP and PEP, condoms, limiting sexual partners, changing sexual habits to limit exposure, etc. If the patient consented verbally, the HIV point-of-care test sample was collected by the nurse or medical assistant. Depending on patient preference the sample collected was either an oral swab, which was self-collected by the patient with vigorous gum scrubbing, or a fingerstick blood sample, which was done by medical staff. The sample was taken to the point-of-care testing area where the test was conducted by the nurse or medical assistant. All point-of-care tests were run in a specific room reserved for this purpose in the family medicine department. A manual log of each test conducted, and the test result was kept in this area and completed by staff to track test kit utilization at the clinic (see Appendix H). This log was updated daily with any missed opportunities for HIV screenings via chart review by the project lead.

This project used the OraQuick ADVANCE ® Rapid HIV-1/2 Antibody test kit which delivers results in 20 minutes and is approved by the Federal Drug Administration (FDA) under the clinical laboratory improvement amendments (CLIA) as a waived test, meaning it is approved for use in the clinic by trained medical staff. This test kit has high sensitivity of 99.3%
(95% Confidence Interval, 98.4-99.7%) for oral fluid samples in confirmed HIV-1 infected persons, and high sensitivity of 99.6% (95% C.I., 98.5-99.9%) for fingerstick samples in confirmed HIV-1 infected persons (OraSure Technologies, 2004). The specificity of the test kit is 99.8% (C.I. 95%, 99.6-99.9%) for oral fluid samples in confirmed HIV-1 non-infected persons, and specificity is 100% (95% C.I., 99.7-100%) for fingerstick samples in confirmed HIV-1 non-infected persons (OraSure Technologies, 2004). The test is not validated for patients under 12 years of age.

If a patient declined testing, the provider would enter the exam room to reinforce the importance of screening and encourage HIV screening once more. If the patient consented, sampling was then conducted by the nurse or medical assistant. If patient still declined, no testing was conducted, but the provider would provide safe sex counseling after which the parent or guardian entered the exam room for the clinic visit. Declined screenings were entered in the Manual log with reason for declination.

For patients who agreed to testing, while the visit ensued, the nurse or medical assistant would ascertain the result of the HIV point-of-care test, enter it into the electronic medical record, and alert the provider via secure messaging. If the patient tested negative, the provider would ask the parent or guardian to exit at the end of the visit, and the provider would then inform the patient about the result and provide them with accompanying safe sex counseling. All visits with HIV point-of-care testing completed were marked as confidential by the provider in the electronic medical record. At the conclusion of the counseling, the patient exited to meet the parent or guardian in the waiting room.

If an HIV point-of-care test result was preliminary positive, the HIV point-of-care testing protocol outlined next steps for the clinic team (see Appendix I). This included utilizing the
integrated behavioral health team, ordering follow up confirmatory testing, scheduling a follow up visit, delivering confirmatory results in-person, and linkage to HIV care if needed. Training for providers would include navigating delivery of positive results to patients in a sensitive and culturally appropriate manner. The integrated behavioral health teams would also undergo training regarding delivery of positive results in order to best support these patients at the results visits. Positive results were tracked in the Manual Log along with confirmatory testing and linkage to care.

**Implementing the Protocol**

This quality improvement project included pre-implementation planning actions such as collaboration with clinical operations staff on the protocol, sourcing supplies, creating patient education materials, and developing staff trainings. The pre-implementation stage of this change was the unfreezing step of Lewin’s change theory when the organization prepared for the change.

In preparation for the project, clinical operations staff collaborated with the project lead to establish clinical workflows, source needed materials, and edit the electronic medical record to allow documentation of the test. Operations staff updated a standing order for nurses and medical assistants to offer HIV screening to patients to include HIV point-of-care testing. Operations confirmed HIV point-of-care testing was included in the clinic’s CLIA-waiver contracts and under the malpractice insurance group plan. The project lead sourced the point-of-care test kits via the R.I. Department of Health after securing funding through the New England AIDS Education and Training Centers grant. The initial funding included 200 test kits for the 12-week project period. The project lead developed two patient education materials in collaboration with clinical staff: one tri-fold pamphlet on HIV screening and testing and a second pamphlet on safe
sexual practices to prevent HIV. These educational materials were made available to the patient via a scannable QR code using the patient’s phone to improve confidentiality and to ensure access to the materials after the visit.

The project lead and operations staff collaborated to create appropriate staff training on the protocol. Once staff training commenced, the project entered the change phase of Lewin’s change model. Nurses and medical assistants were educated on universal HIV screening and the new HIV point-of-care testing protocol via asynchronous learning modules. A one hour in-person training was scheduled for staff to complete a competency evaluation during which medical assistants and nurses demonstrated how to correctly complete the HIV point-of-care test. Providers were trained on universal HIV screening, delivering HIV results to patients, and HIV linkage to care. The project lead was available to staff during training to answer questions. Attendance at training and competency evaluations were recorded in the training attendance log (Appendix J). A staff survey was completed to assess staff support for the protocol (Appendix K). This survey was tested for face validity by the project lead and collaborating operations staff. A complete description of this survey is included in the Analysis section of this proposal.

After implementation of the protocol, or unfreezing step in Lewin’s change theory, the project lead met with clinical staff at weeks 2, 4, 8 and 12 to provide project updates and to collect feedback on process. These check-ins also served to repeat the steps of Lewin’s change model to introduce improvements in the process periodically. Staff suggestions and opinions guided updates to the process. At the end of the project period, week 12, a final staff survey was conducted to assess feasibility, value added to care, and staff support for the protocol (Appendix L). A complete description of this survey is included in the Analysis section of this proposal.

**Evaluation of the Intervention**
Evaluation of the project centered on improvement in the HIV screening process and assessing staff support for the protocol. A Logic model demonstrating project outputs and outcomes is in Appendix M. Improving the HIV screening process will result in more completed HIV screenings, which in time will improve HIV screening rates for the target population. Improved HIV screening rates will identify new HIV diagnoses faster, limiting the spread of HIV and thereby decreasing the number of new HIV diagnoses in the long term. The process improvement was evaluated by comparing pre-project HIV screening data with post-implementation HIV screening data. Data regarding HIV screening at the target site was collected for 4 weeks prior to implementation to establish a baseline and the data log is attached as Appendix N. The data log of patient screenings was reviewed on an ongoing basis to determine improvement points in the process during the project period. Final HIV screening data was compared to baseline to demonstrate improvement in the HIV screening process.

Staff support for the protocol was evaluated via staff survey post-training and at the end of the 12-week project. These surveys measured staff support by assessing the efficacy of the training, staff buy-in, and feasibility of the process. The surveys are attached as Appendices L & M with further discussion of them in the Measures and Analysis section of this proposal. The project lead conducted informal staff check-ins at weeks 2, 4, 8, and 12 to determine improvements to the protocol via PDSA cycles.

**Measures and Analysis**

This quality improvement project defined success via satisfaction of the project’s specific aims, summarized in Table 1: Measures Table.
The first aim was to develop the HIV point-of-care testing protocol collaboratively between project lead, operations staff, and clinical staff. This aim would be satisfied if the protocol is ready for implementation at the start of the project period including completing staff trainings, sourcing all needed materials, creating patient education handouts, and editing the electronic medical record for documentation. Analysis was qualitative reporting of anecdotal evidence drawn from meeting minutes, training logs, patient handouts and the electronic medical record.

A second aim was that 95% of clinical staff would complete training in the new protocol. This would be measured by the staff attendance tracked on the training attendance log (Appendix J). The training would be made available by asynchronous modules followed by a 1 hour in-person competency evaluation during which nurses and medical assistants would correctly demonstrate sampling, conducting, and documenting the test. A post-training staff survey was completed to assess staff acceptance of the protocol via three measures: efficacy of the training,
staff confidence in conducting screening, and staff perception of value-added to patient care. The staff training survey can be found in Appendix K. Questions 1, 2, 3, and 4 measured the effectiveness of the training in delivering knowledge and preparing staff to conduct HIV point-of-care testing in clinic. Question 5 measured staff buy-in by measuring perception of value of the new process.

The next three aims reflected this project’s goal to achieve universal HIV screening in adolescents and young adults and was tracked via the manual log and data log. The goal was that 95% of eligible patients would be offered HIV screening during the project period; 95% of eligible patients would receive counseling; and 95% of those patients who consented to testing would complete HIV testing. Collection of this data would be done via chart review of the electronic medical record and validated by comparison to the manual log of HIV point-of-care tests conducted. Eligible patients were defined as 15 to 25 years of age, presenting for an in-person appointment, without prior HIV diagnosis, and with no prior HIV screening documented in the electronic medical record. This definition is in accordance with the Uniform Data System (UDS) standard described by Health Resources and Services Administration (HRSA) and in line with universal HIV screening guidelines defined by the USPSTF that all persons 15 to 65 years of age be tested for HIV once in their lifetime (UDS, 2021; USPSTF, 2019). This measure excluded any patients already diagnosed with HIV because it is clinically unnecessary to HIV screen patients already diagnosed with HIV. This measure was selected because it is universally applied to FQHC clinics across the U.S. and is tracked in the clinic’s electronic medical record for quality purposes.

Patients were considered successfully counseled if they received both patient education handouts at the time of the visit. Providers were encouraged to conduct sexual health counseling
in addition to the education handouts, although there was not a standard way for providers to
document sexual health counseling in the chart. Thus, provider delivered counseling was not
measured in this project, though it was implied because providers delivered the test results to
patients verbally.

Missed screenings were defined as an eligible patient who was not offered HIV screening
on the day of an in-person visit. Declined screenings were defined as patients who were offered
HIV screening and declined the testing with a reason for declination documented in the manual
log. Declined screenings could still complete counseling if both educational handouts were
provided to the patient at the visit.

Completed screenings were defined as eligible patients who consented to testing,
underwent HIV testing, and received results from a provider. Ideally, patients who completed
screenings received education handouts. If handouts were not provided, a screening was still
defined as completed if the test was conducted and results were delivered to the patient.
Frequencies and proportions of completed screenings in relation to eligible patients were
calculated at baseline and weekly and plotted on a run chart. Change score and percentage
improvement were calculated at weeks 4, 8, and 12. Qualitative methods were used to track
reasons for declined screenings and to identify themes which emerge related to declined
screenings.

Another aim of the project was that 95% of patients with positive test results would
receive counseling (this is separate from patient handouts and specific to a positive result),
confirmatory testing, and linkage to HIV care. Patients with positive HIV results were tracked in
the manual log. The project lead would track completion of confirmatory testing and linkage to
care outcomes via manual chart review. The frequency and proportion of patients counseled in relation to the number of eligible patients was calculated.

A final aim was that staff would report support for the protocol. Staff support was measured via survey at the end of the 12-week project period and is attached as Appendix L. This survey adopted a Likert score and focused on staff buy-in and protocol feasibility. Questions 1, 2, and 4 measured staff buy-in of the new protocol. Questions 3 and 5 measured feasibility of the process in clinical practice. This aim would be satisfied if the majority of staff (>50%) responded favorably (rating agree or strongly agree) to the buy-in and feasibility questions contained in this survey.

**Ethical Considerations**

Introducing HIV point-of-care testing for a specific age cohort and not universally across all patients could have presented an ethical issue; however, this age group was identified as the group to start with because they experienced the lowest HIV screening rates at the target site. Adolescents and young adult patients also had unique concerns regarding confidentiality which HIV point-of-care testing alleviated. Therefore, the focus on adolescents was appropriate and not discriminatory.

The project site did have an ethics/research review board and value-based care committee. The project lead presented the project proposal to the value-based care committee with no conflicts identified and support expressed by the committee members. Project lead also contacted the medical director, a member of the ethical review board, who concurred that as a quality improvement project this was exempted from IRB approval and could move forward as planned without further review from the site ethics board.
Ethics clarification was also sought at University of Massachusetts Boston. The project or innovation proposed was quality improvement and does not meet the definition of human subjects research because it was not designed to generate generalizable findings but rather to provide immediate and continuous improvement feedback in the local setting in which the project was being carried out. The University of Massachusetts Boston IRB had determined that quality improvement projects did not need to be reviewed by the IRB. Appendix O is the Clinical Quality Improvement Checklist from the University of Massachusetts Boston IRB which demonstrated that this project was quality improvement and did not involve human subjects.

Results

The HIV point-of-care testing protocol was finalized May 24, 2022 with approval from all relevant parties including operations staff, clinic management, medical directors, and the value-based care committee meeting the goals of sub-aim 1. There was a delay in delivery of the HIV point-of-care test kits, and implementation was on hold until the kits were delivered.

Staff Training and Preparedness

The family medicine staff training was conducted on July 6, 2022 with 12 out of 13 staff members in attendance. The final staff member was trained the following week; meeting and exceeding the goal that 95% of the staff would be trained (sub-aim 2). The post-training staff survey was completed by 9 staff members and indicated staff support for the protocol and preparedness to implement the project. The project start date for implementing the protocol in the clinic and data collection was July 11, 2022.

Regular check-ins with staff were conducted including presentation of relevant data and opportunities to identify what was working well and what needed to be modified. At the 2-week
check-in, staff suggested that patient education handouts be laminated and re-used since patients were not taking the handouts with them after the visit. This change was introduced and laminated handouts were developed and used. At the 8-week check-in, the project lead noted that patient education and counseling was not being recorded in the electronic medical record. Retraining was conducted with medical assistants to address this issue. At the 12-week check-in, project lead distributed the final staff survey with 9 out of 13 staff completing this final survey.

The aims, measures and results of this project are summarized here below in Table 2:

**Table 2: Aims, Measures, and Results**

<table>
<thead>
<tr>
<th>Aims or Objectives</th>
<th>How to Operationalize/Measure</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop HIV point-of-care testing protocol with consensus from management and staff</td>
<td>Review of meeting minutes, staff training materials, patient education materials, electronic medical record updates, availability of test kits, and supplies</td>
<td>Protocol developed and implemented</td>
</tr>
<tr>
<td>95% of clinic staff at project site will be trained on the protocol</td>
<td>Document in staff attendance, conduct post-training staff survey to measure training efficacy and staff buy-in</td>
<td>13/13 (100%) Survey results demonstrate training effective, staff buy-in present Satisfied sub-aim</td>
</tr>
<tr>
<td>95% of eligible patients will be offered screening in 12-week project</td>
<td>Data log to record the number of eligible visits, missed screenings, and declined screenings with reasons for decline</td>
<td>49/69 (71%) Less than 95% goal</td>
</tr>
<tr>
<td>95% of eligible patients will receive counseling in 12-week project</td>
<td>Data log to record the number of eligible visits, and if counseling provided to patient</td>
<td>27/69 (39.1%) Less than 95% goal</td>
</tr>
<tr>
<td>95% of patients who consent to screening will complete HIV screening</td>
<td>Data log to record the number of eligible visits, offered screenings, and completed screenings</td>
<td>40/44 (91%) Less than 95% goal</td>
</tr>
<tr>
<td>95% of patients with preliminary positive results will get counseling, confirmatory testing, and linkage to HIV care</td>
<td>Data log to record all positive results, counseling, confirmatory testing, and linkage to care outcomes</td>
<td>Not applicable, no positive results</td>
</tr>
<tr>
<td>Staff will express support of the protocol</td>
<td>Conduct staff survey at the end of project period to measure staff buy-in, feasibility, and value-added to care</td>
<td>Majority of staff with positive final survey responses Sub-aim satisfied</td>
</tr>
</tbody>
</table>
The staff training survey to assess staff preparedness and staff support for the project was completed by 69% of clinic staff. Mean scores were calculated based on a 5-point Likert scale (1 Strongly Disagree, 2 Disagree, 3 Neutral, 4 Agree, 5 Strongly Agree) and categorized into positive response (score 4, 5) or negative response (score 1,2,3). Aggregated frequency and proportion of positive responses were calculated. All survey questions gained a positive response from the majority of staff, or greater than 50%. Generally, this data indicates the training was effective and staff believed the project would add value to patient care. The survey response data is summarized in the graph below, Figure 2.

![Post-Training Survey Responses](image)

**Demographic Data**

The demographic characteristic of the pre-project and project eligible patients are summarized in Table 3: Demographic Data, below. This table demonstrates that the pre-project cohort of patients and the project cohort of patients were similar in age, geographic residence, and Hispanic ethnicity. The mean age was 21.5 years of age in pre-project cohort and 19.9 years of age in project cohort. In both cohorts, most patients lived in Providence zip codes (87.5% pre-project; 92.8% project). There was a high proportion of patients identifying as Hispanic or Latino.
(70.8% in pre-project; 84.1% project). There was variation between the two cohorts in gender identity and race demographics. Pre-project patients were more likely to be male (45.8% pre-project; 36.2% project), and race categories varied as seen below.

<table>
<thead>
<tr>
<th>Demographic Data</th>
<th>Pre-Project, 4 weeks</th>
<th>Project, 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg Age (years)</td>
<td>21.5</td>
<td>19.9</td>
</tr>
<tr>
<td>Gender Identity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11 (45.8%)</td>
<td>25 (36.2%)</td>
</tr>
<tr>
<td>Female</td>
<td>12 (50%)</td>
<td>44 (63.8%)</td>
</tr>
<tr>
<td>Transgender</td>
<td>1 (4.2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refused/Unreported</td>
<td>15 (62.5%)</td>
<td>38 (55.1%)</td>
</tr>
<tr>
<td>White</td>
<td>4 (16.7%)</td>
<td>20 (29.0%)</td>
</tr>
<tr>
<td>African American</td>
<td>1 (4.2%)</td>
<td>6 (8.7%)</td>
</tr>
<tr>
<td>More Than 1 Race</td>
<td>4 (16.7%)</td>
<td>4 (5.8%)</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0%)</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latinx/Hispanic</td>
<td>17 (70.8%)</td>
<td>58 (84.1%)</td>
</tr>
<tr>
<td>Non-Latinx/Hispanic</td>
<td>6 (25.0%)</td>
<td>6 (8.7%)</td>
</tr>
<tr>
<td>Providence Zip Code</td>
<td>21 (87.5%)</td>
<td>64 (92.8%)</td>
</tr>
</tbody>
</table>

**HIV Screening Outcomes**

The goal was to offer HIV screening to 95% of eligible patients during the 12-week project. Data was tracked on a manual log (Appendix H) and in the electronic medical record. Pre-project (baseline) proportion of patients who were offered screening was also abstracted from the electronic medical record over a 4-week period for comparison as a baseline. The pre-project data showed that the clinic staff offered 58.3% of eligible patients HIV screening. The data compiled during the project showed staff offered HIV screening to 71.0% of eligible
patients. This result does not satisfy the project’s goal of 95% but does demonstrate a 22% improvement from baseline.

A further aim of the project was to offer patient education and counseling to 95% of eligible patients. Prior to the project, the clinic staff did not have standard documentation for HIV counseling and education in the electronic medical record. Data compiled during the project showed 39.1% of patients received education and counseling as documented in the medical record. Documentation that patients were offered education and counseling relied on staff to document a checkbox in the medical record that counseling was provided to the patient. At the week 8 staff check-in, it was determined that staff were not documenting the counseling and education even when appropriately provided. After retraining, the counseling and education documentation did improve. The project goal of reaching 95% of eligible patients with counseling, sub-aim 4, was not met.

A project aim was for 95% of patients who consented to HIV screening, to complete HIV testing. For patients who consented to be screened the proportion of completed screenings increased from baseline to post-project 77% vs. 91% respectively. While this did not meet the goal for 95% of consented patients to have completed testing, it did represent a 14% improvement which has important clinical significance.

Another project aim was for 95% of patients with positive HIV results to receive counseling, confirmatory testing, and linkage to care. In pre-project data, there were no instances of positive HIV results. In the project data, there were also no instances of positive HIV results. This sub-aim lacked sufficient data for analysis.
Qualitative data regarding declined screenings were also collected with the two most common reasons for declining screening were due to parent or guardian presence or patient did not complete laboratory testing as ordered. Other documented reasons for declining screening included not feeling it was needed or not being at risk for HIV infection.

**Impact on HIV Screening Rates**

The HIV screening rate was analyzed via the HIV screening care cascade comparing pre-project data with project data, as seen below in Figure 3.

![Figure 3: HIV Screening Care Cascade](image)

Figure 3 shows the protocol decreased rates of missed screenings and increased rates of offered HIV screenings to eligible patients. There was also decreased rates of declined screenings, and
an increase in completed counseling regarding HIV screening. The completed screenings of all patients who consented to screening increased from 77% to 91%.

Additionally, completed HIV screening rates of all eligible patients were calculated weekly to determine if the project had a positive impact. This measure differs from the sub-aim to complete screenings for 95% of patients who consent because the denominator here is for all eligible patients, not just those that consent to testing. The rate of completed HIV screenings is graphed below in Figure 4, and a trend line was determined. Weeks 1-4 represent pre-project data and weeks 5-16 represent project data. This graph demonstrates that as staff became more familiar and comfortable with the project, the screening rate increased.

Two data points to note in Figure 4 were weeks labeled 9 and 10, during which the project lead and several staff were out sick. The covering staff members during that time had not been trained on the project protocol and could not offer HIV point-of-care testing to patients during those weeks.
Staff Satisfaction with the Protocol

A final aim for this project was that the majority of staff (greater than 50%) would express support for the protocol at the completion of the project. At the conclusion of the project (week 12) the staff satisfaction survey (Appendix L) was deployed and completed by 69% of the staff.

![Post-Project Survey](image)

As illustrated in Figure 5, survey responses were very positive. Staff responses to every question exceeded the goal that 50% of respondents would rate the project positively. Staff selected the highest positive responses regarding satisfaction with the workflow (question 2), value added to care (question 4), and desire to continue offering the testing to patients (question 5). Question #1 had the lowest proportion of positive responses, 78% of staff, while still meeting the goal of 50%: “I was asked to give my input to improve the HIV point-of-care workflow.” 89% of staff responded positively for the feasibility question, 3: “There is enough time to complete the HIV point-of-care test in clinic.” The post-project survey data is summarized in the graph below, Figure 4.

Discussion
Summary

Introducing an HIV point-of-care testing protocol in adolescent primary care improved HIV screening rates in a diverse adolescent and young adult population over a 12-week period. The project demonstrated several strengths and weaknesses.

A strength of this project was that the protocol demonstrated improved HIV screening in a population that commonly experiences barriers to completing HIV screening. Of the three clinical sub-aims with goals of hitting 95%, none achieved that target. The 95% goal was chosen based on the CDC guidelines for universal HIV screening when selecting goals for the project. Universal screening implies that reaching 100% of patients was a potential goal for this project. In addition, the benchmarks set by the Joint United Nations Programme on HIV/AIDS (UNAIDS) 2030 targets to end the HIV epidemic were set at 95% (UNAIDS, 2015). Choosing this benchmark was a lofty goal for a 12-week project, but there were limited studies to suggest what a realistic goal might be for this timeframe in this setting. Overall, the protocol demonstrated improvements in completed screening rates and the screening rates improved over time. This suggests that given more time the aspirational 95% benchmark might be attained.

The project succeeded in identifying barriers to HIV screening for this patient population. Qualitative data collection showed the top two reasons patients declined HIV screenings were not completing the ordered bloodwork at the laboratory and declining because a parent or guardian was with them that day. The protocol attempted to address these barriers; however, even when roomed alone, some patients were uncomfortable conducting HIV testing with a parent or guardian in the waiting room. Minor patients were required to bring a guardian with them to all visits due to clinic and state policies.
Another project strength was that staff saw value in the protocol and supported continuing the pathway past project completion. Continuation of the protocol is dependent on fostering staff support and understanding perceived challenges and barriers. A weakness noted by staff in the final survey was that the time to complete the screening was disruptive to clinic workflow. The clinic is often short on examination room space and staff reported having to wait for the point-of-care result often led to teams running behind schedule. The limited time allotted per patient appointment is unlikely to change, however, the clinic could explore alternative HIV test kits that offer faster results (15 minutes versus 20 minutes). Other alternative venues for adolescent point-of-care testing may offer better access to patients when a parent is not present. Examples might include school-based health centers or collegiate student health facilities. These clinics often care for adolescent or young adult patients without a parent or guardian present, allowing for more confidentiality in the screening process.

A significant issue uncovered by this project was that reimbursement from payors would not cover the cost of the point-of-care test kits. After project implementation it was discovered that the allowable costs for HIV point-of-care screening ranged from $0 to $12. Given that the test kits and supplies cost approximately $14.50 per test excluding costs of staff time to conduct testing, continuation of the protocol without dedicated funding would be financially impossible. Continuation of the project would require organizational and policy support to improve reimbursement from payors.

**Interpretation**

Implementation of a point-of-care HIV testing pathway for adolescents at the site resulted in a 16.3% improvement in rates of completed HIV screenings over the 12 weeks of the project. This outcome is comparable to other published research on HIV point-of-care testing in
adolescent populations. Smith, J., et al. (2020) demonstrated an 18.5% improvement in adolescent HIV screening rates after introducing HIV point-of-care testing over a 12-month period. A large quality improvement project published by Arrington-Sanders, R., et al. (2018) also demonstrated increased pediatric and adolescent screening rates from 29.6% to 82.7% over a 12-month period via introduction of HIV point-of-care testing and system level changes. Mullins, T.L.K., et al. (2010) also demonstrated a 16.9% increase in adolescent HIV screening rates after introduction of HIV point-of-care testing and cited adolescent preference for less invasive sampling and rapid results. It is interesting to note that the studies cited above were carried out over 12 months. Given that our project was only 12 weeks, and that there was an increased rate of screening over the 12 weeks, if the project continued for 12 months we might have seen even greater improvement.

A review of the data showed that in pre-project period, 23.1% of HIV testing orders were not completed by the patient (3 out of 10). Comparatively, project period data showed only 8.2% of all HIV testing orders were not completed by the patient (4 out of 49). All of the HIV point-of-care tests ordered were resulted, most likely because the test result was ready in 20 minutes and typical clinic appointments can last that long or longer. This finding was in line with a 2008 Veteran’s Affairs study, Anaya, H., et al., that showed HIV point-of-care testing improved receipt of results compared to laboratory-based HIV testing.

Staff support for the protocol was demonstrated in both staff surveys; however, some staff questioned the feasibility of the protocol during PDSA cycle huddles and in the final staff survey. Staff cited the time to complete the counseling and testing as problematic in a busy family medicine clinic. During the project, the project lead also noted that counseling was not documented on all patients even when completed. Staff reported documentation fatigue or
simply forgetting to check that box in the electronic medical record. Thus, the data regarding how much counseling was completed during the project was likely under-reported. More importantly, the staff exhibited signs that this protocol may not be feasible in the time constraints and staffing constraints of the clinic. The limited amount of time allotted for patients in the clinic posed a tradeoff: as more time was spent on HIV and STI prevention counseling, less time was available for other types of counseling, patient questions, or provider time with patient.

**Challenges**

This project encountered several challenges. The project focused solely on patients who had not been screened for HIV previously in the clinic’s electronic medical record. The family medicine department had achieved high universal HIV screening rates prior to project implementation as 70-90% of patient panels had completed screening depending on assigned provider (this percentage includes all patients 15-65 years of age on a provider’s panel). This introduces some bias in that the patients eligible to be entered onto the project pathway may be more likely to have declined HIV screenings in the past.

During weeks 9 and 10 of the project, several regular staff members were absent due to illness. The covering staff were not trained in the protocol and thus, the project collection for those weeks demonstrated decreased HIV screening rates. The data was included in the project analysis as this quality improvement project reflects the challenges of introducing process change in modern healthcare settings.

Staff reported the time to complete the screening test negatively impacted clinic workflows. The feasibility of continuing to offer this testing in a busy primary care clinic without considering any workflow adaptations is questionable.
Conclusions

HIV point-of-care testing improves HIV screening rates in adolescent and young adult patients in a primary care setting. This protocol offers a more confidential HIV screening process to young adults and adolescents, overcoming barriers to testing.

The specific HIV screening goals of this project, 95-95-95%, were not met. Expanded training to include covering staff members will help improve screening rates as the clinic continues the protocol. Staff re-training on the importance of the patient education element demonstrated improvements in the process and can be reiterated.

Future PDSA cycles of this pathway should address clinic time constraints and investigate if there are ways to streamline the process or if faster point-of-care tests are available and should be carried out over a longer timeframe. Future projects will also need to explore ways to cover the costs of HIV point-of-care testing. Advocacy to cover HIV point-of-care testing as a USPSTF preventative service for adolescents and young adults to improve access to HIV screening for this population is needed at the organization, insurer, and government level.

Adopting HIV point-of-care testing in health centers that can offer testing to adolescent and young adult patients without parents present, such as school-based clinics or college health centers, should also be considered as future areas of study.

Funding

Funding for test kits from the Rhode Island Department of Health via New England AIDS and Education Training Centers grant.
Acknowledgements

Many sleepless nights contributed to the culmination of this project. I express sincere thanks to my Scholarly Project Committee Members, Dr. Eileen Stuat-Shor, Dr. Elizabeth Russet, and Manuela Pires Tambollio, for their guidance and assistance with this project. Many thanks to my peer writing partner, Peguy Sylvain, for preserving through with me. To my dear husband, who watched our kids for countless hours so that this important work would get done: you always wanted to marry a doctor, Andrew.

I acknowledge and give thanks to all the mentors over my nursing career, who helped shape my nursing brain in ways I did not yet understand. And lastly, to the patients who inspired me and continue to motivate me to do better- thank you for your trust.
### Appendix A: Table 3.
Evidence Summary Table:

<table>
<thead>
<tr>
<th>Studies</th>
<th>Intervention</th>
<th>Significant Findings and Outcome</th>
<th>Level and Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Anaya, et al. (2008)</td>
<td>Point-of-Care HIV Testing</td>
<td>A. Rapid HIV testing resulted in more receipt of results than traditional testing. B. Used Certified Health Educators for patient teaching and rapid HIV testing, resulting in HIV screening rate increase from 29.6% to 82.7%. C. Clinic site that introduced rapid HIV testing saw 618% increase in HIV screening tests and 600% increase in positive HIV results. D. Rapid HIV testing increased HIV screening rates from 27.7% to 44.6% in 12-month period. E. Rapid HIV testing project increased pediatric HIV screening from 4.55% to 41.5%.</td>
<td>A. I/A, N= 251 Aged 18-65yo Veteran population B. II/A, N= 4,433 Aged 13-25yo 94.1% African American C. II/B, N= 22,658 Aged 13-65 63% African American D. II/A, N= 9,491 Aged 13-22yo (17.5yo avg) 69.4% African American E. II/A, N= 2,394 Aged 15-21yo 45.6% Hispanic</td>
</tr>
<tr>
<td>B. Arrington-Sanders, et al. (2018)</td>
<td>Nurse-led protocol</td>
<td>A. Nurse-led protocol arm accomplished more HIV screening than control arm. C. Nurse-led rapid HIV testing saw 618% increase in HIV screening tests and 600% increase in positive HIV results. E. Nurse-led rapid HIV testing increased pediatric HIV screening from 4.55% to 41.5%.</td>
<td>A. I/A, N= 251 C. II/B, N= 22,658 E. II/A, N= 2,394</td>
</tr>
<tr>
<td>C. Crumby, et al. (2016)</td>
<td>Nurse-led protocol</td>
<td>A. Nurse-led protocol arm accomplished more HIV screening than control arm.</td>
<td>A. I/A, N= 251</td>
</tr>
<tr>
<td>D. Mullins, et al. (2010)</td>
<td>Universal vs. Targeted screening</td>
<td>D. New universal screening guidelines increased HIV screening rates from 12.6% to 27.7%. F. Targeted screening reached more sexual minority males of color (39.8%) than universal screening (3.6%). A combination approach reaches the most sexual minority males of color.</td>
<td>D. II/A, N= 9,491 F. II/A, N= 3,301 Aged 13-24yo</td>
</tr>
<tr>
<td>E. Smith, et al. (2021)</td>
<td>Nurse-led protocol</td>
<td>A. Nurse-led protocol arm accomplished more HIV screening than control arm. C. Nurse-led rapid HIV testing saw 618% increase in HIV screening tests and 600% increase in positive HIV results. E. Nurse-led rapid HIV testing increased pediatric HIV screening from 4.55% to 41.5%.</td>
<td>A. I/A, N= 251 C. II/B, N= 22,658 E. II/A, N= 2,394</td>
</tr>
<tr>
<td>Provider Report Card</td>
<td>G. Quarterly provider report cards correlated with modest increase in HIV screening rates after 1 year.</td>
<td>G. II/B, N= 19,008 California primary care center</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>H. Avery, et al. (2014)</td>
<td></td>
<td>H. EMR alert increased HIV screening rates for six sequential quarters at community health system.</td>
<td></td>
</tr>
<tr>
<td>K. Tapp, et al. (2020)</td>
<td></td>
<td>K. EMR alert for HIV and Hepatitis C resulted in higher screening rates.</td>
<td></td>
</tr>
<tr>
<td>L. Pendergrass, et al. (2020)</td>
<td>Video Game Intervention</td>
<td>L. Video game intervention increased HIV testing knowledge in at risk youth.</td>
<td></td>
</tr>
<tr>
<td>M. Wilbourn, et al. (2020)</td>
<td></td>
<td>M. Video game intervention acceptable to youth and showed increase in HIV knowledge and testing.</td>
<td></td>
</tr>
</tbody>
</table>

Appendix B: Force Field Analysis

Current driving forces
- Local Health Department support
- Management support
- HIV site champion to spearhead

Current restraining forces
- Costs and lack of insurance reimbursement
- Staff training needed
- Time to develop new protocol and workflows

Potential driving forces
- Acceptable to patients
- Staff support for project
- Improved screening process

Potential restraining forces
- Patient low health literacy
- Time to conduct testing in clinic slowing clinic workflow
- Confidentiality concerns for patients

New Point-of-Care HIV testing protocol
Appendix C: Microsystem Analysis.

**Clinical Microsystem:** Primary Care FQHC in Providence, R.I.
**Subpopulation:** Adolescent and young adult patients

**Specific Healthcare Needs:**
1. Well child visits and annual physical exams
2. Sexual health history
3. HIV and STI screenings
4. Safe sex counseling
5. Confidentiality
6. Access to prevention services (PrEP, PEP)

**Improvement Ideas:** Introduce HIV point-of-care testing to improve confidentiality of HIV screening process and acceptability to adolescent patients. Include standing orders for testing to be opt-out and conducted by nurses or medical assistants during rooming of patients. Ensure safe sex counseling through staff training and standardized patient handouts to improve patient health literacy. Educate providers on confirming preliminary positive results and linkage to care.
Appendix D: Fishbone Diagram
Appendix E: Process flow chart. Point-of-Care Testing Protocol
Appendix F: HIV Screening Handout (front and back)

The worst HIV status is: unknown.

Expect the Test
PCHC follows CDC guidelines to offer HIV screening to all patients.

Get Tested.
PCHC Englewood Clinic - 365 Putnam Avenue, Providence, R.I. 02905
(401) 415-9000
PCHC Express Clinic - 31 Rowood Street, Providence, R.I. 02909
(401) 415-9000

Routine HIV Screening
The CDC recommends testing all patients 13-65 years of age for HIV in all healthcare settings regardless of sexual activity.

An HIV screening test will be done at this visit unless you decline.

This screening is covered by insurance.

Testing and results will be kept private and confidential.

If you are under 18 years old, you can be tested even without a parent or guardian present. Testing and results are private to you.

What is HIV?
HIV or Human Immunodeficiency Virus is an infection that attacks the immune system.

HIV can be transmitted through sexual contact, needle-sticks, blood transfusion, organ transplant, breastfeeding or at birth.

HIV testing will detect if you have HIV 3-4 weeks after being exposed.

Types of HIV Tests:

Rapid Point-of-Care HIV Test
A rapid HIV test can be done with a gum swab or fingerstick and takes 20 minutes for results. Results will be given to you the same day at the end of your visit.

Laboratory-based HIV Test
Laboratory-based HIV tests are done with a blood draw that is sent to the lab. Results are posted in the patient portal 2-4 days later.

HIV Test Results

What if I test negative?
If your HIV test is negative, you are unlikely to have an HIV infection.

If you were infected with HIV in the past month, your HIV test might not be positive yet. Repeat testing in 4 weeks to be sure you are negative for HIV.

What if I test positive?
Your results will be delivered to you in person and in private. Our staff and providers will link you to HIV care and services and conduct further follow up testing at that time.

When was your last HIV Test?

Example of OraQuick ADVANCE Rapid HIV Test
Appendix G: CDC HIV Prevention Handout

SAFER SEX 101 FOR HIV

There are now many tools to help prevent HIV. Here’s how to reduce your chance of getting or transmitting HIV through sex.

UNDERSTAND THE RISKS

Some kinds of sex are riskier than others for getting or transmitting the virus.

- Anal sex is when the penis is put inside the anus, and it is the riskiest kind of sex for getting or transmitting HIV. Being the bottom or having your partner’s penis inside you is much riskier than being the top or putting your penis inside your partner.

- Vaginal sex is when the penis is put inside the vagina. Either partner can get HIV during vaginal sex, though it isn’t as risky as anal sex.

- Oral sex is when the mouth touches the penis, vagina, or anus. There is little to no risk of getting or transmitting HIV from oral sex.

- You can’t get or transmit HIV from sexual activities that don’t involve contact with body fluids (e.g., touching).

The only way to know your HIV status is to get tested. Knowing your status can give you important information and help you make good decisions to prevent getting or transmitting HIV.

REDUCE YOUR RISK

There are a number of ways you can reduce the risk of getting or transmitting HIV.

- If you have HIV, take HIV medicine, called antiretroviral therapy (ART), as prescribed. Taking HIV medicine as prescribed can make your viral load (amount of virus in your blood) undetectable. If you stay undetectable, you can stay healthy and have effectively no risk of transmitting HIV to your sex partner.

- If you are at risk for HIV, take medicine to prevent HIV called pre-exposure prophylaxis (PrEP). When taken as prescribed, PrEP is highly effective for preventing HIV from sex.

- Take antiretroviral medicine, called post-exposure prophylaxis (PEP), if you think you have been exposed to HIV in the last 72 hours and are not on PrEP.

The more of these actions you take, the safer you can be.

For more information, please visit www.cdc.gov/hiv.
# Appendix H: Manual Log

## Manual Log – HIV Point-of-Care Tests

<table>
<thead>
<tr>
<th>Patient MRN:</th>
<th>Date &amp; Initials</th>
<th>Sample Type</th>
<th>First Screening?</th>
<th>Result</th>
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□ Oral
□ Fingerstick
□ Yes
□ No
□ Nonreactive
□ Reactive
Appendix I: Process flow chart for Preliminary Positive HIV Point-of-Care result
Appendix J: Training Attendance Log

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Attended</th>
<th>Competency Completed</th>
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</table>
Appendix K: Staff Training Survey

**HIV Point-of-Care Test Training Survey**

This survey does not require your name and will be kept anonymous. Thank you for your time in completing it.

* Required

1. I understand my role in the HIV Point-of-Care Test workflow and what is expected of me. *

   Mark only one oval.
   
   1 2 3 4 5
   
   Strongly Disagree ☐ ☐ ☐ ☐ ☐ Strongly Agree

2. I feel ready to complete the HIV Point-of-Care Test in clinic. *

   Mark only one oval.
   
   1 2 3 4 5
   
   Strongly Disagree ☐ ☐ ☐ ☐ ☐ Strongly Agree

3. I feel confident offering patients education handouts and counseling related to the HIV Point-of-Care Test. *

   Mark only one oval.
   
   1 2 3 4 5
   
   Strongly Disagree ☐ ☐ ☐ ☐ ☐ Strongly Agree

4. After this training, I gained new knowledge regarding HIV screening. *

   Mark only one oval.
   
   1 2 3 4 5
   
   Strongly Disagree ☐ ☐ ☐ ☐ ☐ Strongly Agree

5. I believe the HIV Point-of-Care Test adds value to our patient care. *

   Mark only one oval.
   
   1 2 3 4 5
   
   Strongly Disagree ☐ ☐ ☐ ☐ ☐ Strongly Agree

6. Any suggestions to improve this training or process? *

   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
Appendix L: Final Staff Survey

HIV Point-of-Care Test Final Survey
This survey does not require your name and will be kept anonymous. Thank you for your time in completing it.

* Required

1. I was asked to give my input to improve the HIV Point-of-Care Test workflow. *
   Mark only one oval.
   
   1  2  3  4  5
   Strongly Disagree □ □ □ □ □ Strongly Agree

2. I am satisfied with the workflow for the HIV Point-of-Care Test. *
   Mark only one oval.
   
   1  2  3  4  5
   Strongly Disagree □ □ □ □ □ Strongly Agree

3. There is enough time to complete the HIV Point-of-Care Test in clinic. *
   Mark only one oval.
   
   1  2  3  4  5
   Strongly Disagree □ □ □ □ □ Strongly Agree

4. I believe the HIV Point-of-Care Test adds value to our patient care. *
   Mark only one oval.
   
   1  2  3  4  5
   Strongly Disagree □ □ □ □ □ Strongly Agree

5. I would like to continue offering HIV Point-of-Care Testing to our patients. *
   Mark only one oval.
   
   1  2  3  4  5
   Strongly Disagree □ □ □ □ □ Strongly Agree

6. Any suggestions to improve this process? *

   □ □ □ □ □ □ □ □ □ □ □ □
Appendix M: Logic Model

Logic Model - HIV Point-of-care testing protocol

Problem: At an urban FQHC, HIV screening rates are lowest in adolescents and young adults. This patient population experiences confidentiality and health literacy barriers to completing HIV screening. Current screening practices do not overcome these barriers.

Goal: To improve HIV screening rates in adolescent and young adults in a primary care setting by developing a HIV Point-of-care testing protocol.

Resources
- Clinical Staff
- Operations staff
- Leadership
- Project Lead
- Electronic Medical Record
- RIDDH Funding

Activities
- Develop HIV Point-of-care protocol
- Standardize Patient Education materials
- Develop and implement staff training and competency evaluation
- Order test kits and materials
- Create electronic medical record documentation

Outputs
- Finalize HIV Point-of-care protocol
- Demonstrate improved process for universal HIV screening in adolescents and young adults
- Staff satisfaction with new protocol

Outcomes
- Short-Term: Complete more HIV screenings in adolescents and young adults. Improve patient health literacy.
- Intermediate: Increase HIV screening rates in target population.
- Long-Term: Decrease in new HIV diagnoses.

Rationale and Assumptions:
- Low HIV screening rates contribute to delayed HIV diagnosis, increased spread of HIV, and increased morbidity at diagnosis.
- Adolescents and young adults find HIV Point-of-care testing more acceptable than laboratory-based testing.
## HIV POCT Data Tracking

<table>
<thead>
<tr>
<th>Patient MRN</th>
<th>Patient Code</th>
<th>Date</th>
<th>Missed Screen</th>
<th>Declines/Reason</th>
<th>Counselled</th>
<th>Sample Type</th>
<th>First Screen</th>
<th>Result</th>
<th>Follow up Positive</th>
<th>Gender</th>
<th>Age</th>
<th>Race</th>
<th>Ethnicity</th>
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# Appendix O: IRB Determination of Clinical Quality Improvement

## CLINICAL QUALITY IMPROVEMENT CHECKLIST

<table>
<thead>
<tr>
<th>Date: 03/28/2022</th>
<th>Project Leader: Jennifer Belfry</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Title</strong>: Introduction of Rapid HIV Testing at Providence Community Health Centers</td>
<td></td>
</tr>
<tr>
<td><strong>Institution where the project will be conducted</strong>: Providence Community Health Centers, Prairie Avenue Clinic, Family Medicine Department</td>
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**Instructions:** Answer **YES** or **NO** to each of the following statements about QI projects.

<table>
<thead>
<tr>
<th>Statement</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>The specific aim is to improve the process or deliver of care with established/accepted practice standards, or to implement change according to mandates of the health facilities’ Quality Improvement programs. There is no intention of using the data for research purposes.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>The project is <strong>NOT</strong> designed to answer a research question or test a hypothesis and is <strong>NOT</strong> intended to develop or contribute to generalizable knowledge.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>The project does <strong>NOT</strong> follow a research design (e.g. hypothesis testing or group comparison [randomization, control groups, prospective comparison groups, cross-sectional, case control]). The project does <strong>NOT</strong> follow a protocol that overrides clinical decision-making.</td>
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<tr>
<td>The project involves implementation of established and tested practice standards (evidence-based practice) and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does <strong>NOT</strong> develop paradigms or untested methods or new untested standards.</td>
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<tr>
<td>The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does <strong>NOT</strong> seek to test an intervention that is beyond current science and experience.</td>
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<tr>
<td>The project has been discussed with the QA/QI department where the project will be conducted and involves staff who are working at or patients/clients/individuals who are seen at the facility where the project will be carried out.</td>
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</tr>
<tr>
<td>The project has <strong>NO</strong> funding from federal agencies or research-focused organizations, and is not receiving funding for implementation research.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>The clinical practice unit (hospital, clinic, division, or care group) agrees that this is a QI project that will be implemented to improve the process or delivery of care.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>The project leader/DNP student has discussed and reviewed the checklist with the project Clinical Faculty. The project leader/DNP student will <strong>NOT</strong> refer to the project as research in any written or oral presentations or publications.</td>
<td></td>
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</table>

**ANSWER KEY:** If the answer to **ALL** of these questions is **YES**, the activity can be considered a Clinical Quality Improvement activity that does not meet the definition of human research. UMB IRB review is not required. Keep a dated copy of the checklist in your files. If the answer to **ANY** of these questions is **NO**, the project must be submitted to the IRB for review.

---

Quality Improvement Project Checklist  
Version Date: August 13, 2018
References


Bisexual, and Other Men Who Have Sex with Men and Transgender Women. AIDS and Behavior, 22(2), 522–530. <https://doi.org/10.1007/s10461-017-2005-1>


rates in a Midwest primary care practice using an electronic clinical decision support system: A quality improvement study. *BMC Medical Informatics and Decision Making, 16*, 76.


https://doi.org/10.1001/archpediatrics.2010.161


https://doi.org/10.21037/mhealth.2020.01.05

https://health.ri.gov/publications/surveillance/2019/HIVSTD.pdf


https://doi.org/10.1016/j.pmedr.2019.101036


https://doi.org/10.1001/jama.2019.6587


Retrieved from: [https://ourspace.uregina.ca/handle/102](https://ourspace.uregina.ca/handle/102)

Wilbourn, B., Howell, T. H., Castel, A. D., D’Angelo, L., Trexler, C., Carr, R., & Greenberg, D. (2020). Development, Refinement, and Acceptability of Digital Gaming to Improve HIV Testing Among Adolescents and Young Adults at Risk for HIV. *Games for Health Journal, 9*(1), 53–63. [https://doi.org/10.1089/g4h.2018.0162](https://doi.org/10.1089/g4h.2018.0162)