

Missed Opportunities for HIV Screening in Pharmacies and Retail Clinics

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SUMMARY

In the wake of new recommendations to offer HIV screening to everyone aged 13-64 years and to start all people living with HIV/AIDS on highly active antiretroviral therapy (HAART) regardless of CD4 count, the need to generate widespread, scalable HIV screening programs is greater than ever. Nearly 50,000 new HIV infections occur in the United States each year, and the Centers for Disease Control and Prevention estimates that approximately half of these new infections are transmitted by individuals who are unaware of their HIV serostatus. Numerous barriers to screening exist, including the lack of primary care for many at-risk patients, expense of screening in traditional settings, and need for repeat testing in high-risk populations. With their relative accessibility and affordability, community pharmacies and retail clinics within those pharmacies are practical and appealing venues for expanded HIV screening. For widespread pharmacy-based testing to become a reality, policymakers and corporate pharmacy leadership would need to develop innovative solutions to the existing time pressures of pharmacists' behind-the-counter functions and absence of reimbursement for direct patient care services. Pharmacists nationwide should also receive training to assist with risk reduction counseling and linkage to care for customers purchasing the new over-the-counter HIV test.

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More than 1.1 million people in the United States are living with the human immunodeficiency virus (HIV), but over 20% are unaware of their infection.¹ Those who are unaware of their serostatus transmit half of the 50,000 new infections annually,²⁻⁴ and people living with HIV/AIDS (PLWH) who are aware they are positive are much less likely to spread the infection through high-risk behaviors.³⁻⁵ Serostatus awareness is essential to the "treatment as prevention" public health strategy, since diagnosis is the first step towards treatment. The landmark HIV Prevention Trials Network (HPTN) 052 study demonstrated a 96% relative reduction in HIV transmission from patients on highly active antiretroviral therapy (HAART),⁶ further underscoring the importance of early identification of positive serostatus. Therefore, the Centers for Disease Control and Prevention (CDC) recommends routine opt-out HIV testing for everyone aged 13-64 years regardless of risk factors⁷ and annual screening of high-risk persons.⁸ In April 2013, the U.S. Preventive Services Task Force (USPSTF) issued a grade "A" recommendation to screen everyone aged 15-65 for HIV,⁹ further strengthening the need for expansion of existing testing programs.

In 2010, the White House issued the National HIV/AIDS Strategy (NHAS), a roadmap to decrease HIV incidence by 25% through reducing transmission by 30% and increasing the percentage of PLWH who are serostatus aware from 79% to 90%.¹⁰ In addition to reducing HIV transmission, earlier identification of PLWH improves clinical outcomes^{4,11,12} and lowers overall health care costs.¹³ Achievement of NHAS goals could result in savings of \$48 billion by 2020.^{14,15} The Patient Protection and Affordable Care Act of 2010 (ACA) may help to meet NHAS goals by increasing health care access of high-risk groups, such as young minority men, through the expansion of Medicaid and through no cost sharing policies for HIV testing.⁴ However, the NHAS is projected to fall short of its stated goals without substantial and immediate expansion of diagnostic and preventive services.¹⁵

HIV testing has long been conducted in primary care and sexually transmitted disease (STD) clinics and is increasingly provided in emergency departments and urgent care centers.^{16,17} However, these venues fail to reach a significant proportion of the population aged 13-64 years. For those high-risk patients who have received prior testing in a traditional clinical setting, many face the obstacle of needing repeat testing annually, as per CDC recommendations.⁸ To address these gaps, in 2011 the CDC rolled out a new strategy for "High Impact Prevention," with an Expanded Testing Initiative (ETI) that focuses on cost-effective, scalable models for widespread HIV testing.¹⁸

Many community-based organizations, such as family planning clinics, substance abuse treatment programs, field-based testing campaigns, and mobile STD clinics, are committed to actively seeking out high-risk populations to offer HIV testing in line with ETI goals.^{17,19} In the summary of ETI results from 2007-2010, nonclinical settings, including community-based organizations that targeted high-risk populations, reported the highest percentage of positive results of any of the testing venues.¹⁷ While these targeted testing approaches will continue to be an important part of HIV prevention strategies, they do not provide a model of HIV testing that is readily scalable for the population at large.

With thousands of locations nationwide, pharmacies and retail clinics, such as CVS's MinuteClinic, Walgreens' Healthcare Clinic, Target Clinic, The Clinic at Wal-Mart, and Rite Aid's NowClinic, are well positioned to become rapidly scalable venues for HIV screening. Although retail clinics offer

a wide array of basic health examinations, vaccinations, and laboratory testing, HIV testing has not been adopted in this setting, even though most insurers reimburse for the test. While retail clinics are still growing in number, they are not yet operational in every state,²⁰ and they have relatively poor penetration into lower-income areas.^{21,22} Community pharmacies, on the other hand, are easily accessible by most of the American public²³ and already offer some direct patient care and such public health services as vaccinations.^{24,25} However, the current reimbursement structure for pharmacists does not afford the time or financial incentives needed to launch widespread pharmacist-led HIV testing. Over-the-counter tests are available at both pharmacies and retail clinics but may be cost prohibitive to many high-risk customers,^{26,27} and the current sales model misses the opportunity to engage providers at these locations in actively counseling consumers and linking patients who test positive into care.

■ Retail Clinic-Based Testing

Since their inception in 2000, retail clinics have exploded onto the health care scene, growing from only 300 locations in 2007 to more than 1,450 sites, with nearly 6 million visits annually.^{20,28} This model relies upon midlevel providers, often nurse practitioners or physician assistants, who are overseen by a licensed physician. Nearly all of these retail clinics are housed within commercial pharmacies, grocery stores, or “big-box” retail stores and are 200-500 square feet on average with 1 or 2 exam rooms.²⁹ Visits last 15-25 minutes and diagnostic and therapeutic services are covered by most major insurers, including Medicare and Medicaid.²⁹ Some insurers even waive the copayment to encourage use of retail clinics services,^{30,31} since they cost \$78 on average, which is less than most primary care and emergency department visits.³² A 2008 study found that an average visit to MinuteClinic costs \$51 less than an urgent care visit, \$55 less than a primary care physician visit, and \$279 less than an emergency department visit.³³

With slogans such as MinuteClinic’s “You’re sick, we’re quick,” these convenient care clinics advertise no long wait times and no need for an appointment. A survey of retail clinic patients found that 44% of visits were on the weekend or during weekday hours when most physician offices are closed.²⁸ As of 2009, 13.4% and 35.8% of the U.S. population lived within a 5- to 10-minute drive of such a clinic, respectively.³² Patients cite the short distance from home, reasonable and transparent pricing, and little or no wait time as primary incentives to seek care at retail clinics.³⁴ The retail clinic market is poised to grow even further with the expansion of coverage to young and lower-income patients under the ACA.³⁵ These clinics continue to grow not only in number,^{20,28,35,36} but also in scope, with Walgreens beginning to offer chronic disease management for conditions such as asthma, diabetes, and high cholesterol.^{37,38}

FIGURE 1 Services Currently Available at Retail Clinics

Vaccinations
Influenza
Tetanus and diphtheria (Td)
Tetanus/diphtheria/pertussis (Tdap)
Pneumonia (pneumococcal)
Shingles (herpes zoster)
Chickenpox (varicella)
Hepatitis A
Hepatitis B
Human papillomavirus (HPV)
Measles, mumps, rubella (MMR)
Meningitis (meningococcal)
Polio (IPV)
Physical Exams
Sports physicals
School physicals
Administrative physicals
Medicare wellness physicals
Health Screening
Blood pressure screening
Cholesterol screening
Diabetes screening
PPD/tuberculosis testing
Weight loss program
Diagnostic Tests (As Part of Exam)
Influenza A & B
Blood glucose
Lipid panel
Mononucleosis
Pregnancy (urine)
Strep throat
Urinalysis

Note: This is a representative sample from the MinuteClinic website’s list of services.⁹²

Retail clinics provide a host of primary care services à la carte (Figure 1).^{28,39} Considering the USPSTF and CDC recommendations for routine opt-out testing for most adults, HIV testing remains conspicuously absent from retail clinics’ list of services. The omission of HIV testing in this setting stands in stark contrast to retail clinics’ developing image as venues for basic primary care. As of September 2010, New York state law requires that clinicians offer HIV testing to everyone aged 13-64 years who is receiving hospital or primary care services from a physician, physician assistant, nurse practitioner, or midwife, including at retail clinic locations.⁴⁰ However, of the more than 1,450 retail clinics in the United States,²⁰ none offer retail clinic provider-led HIV testing in spite of being centers for basic primary care services.

Retail clinics are missing a significant business and public health opportunity for expanded HIV testing that could be rapidly integrated into existing services at hundreds of locations nationwide. With their relatively affordable and accessible business model, these convenient care clinics are well positioned to offer HIV testing for the “now” generation. Retail clinics already service a large cohort of young patients,

the majority of whom lack a primary care physician.^{28,41} The no-appointment, no-wait model could allow patients to come in for an HIV test as partners, which may be difficult to arrange in traditional primary care settings. The convenience of these clinics may also facilitate repeat annual screening for patients in high-risk groups.

While retail clinics are promising venues for expanded HIV testing programs, they do not overcome all of the financial and logistical obstacles that stand in the way of achieving NHAS goals. Although the costs of an average retail clinic visit are less than that of a primary care or emergency department visit,⁴² the fact that these costs are out-of-pocket expenditures may still make them cost prohibitive to many uninsured patients. When retail clinics first entered the health care scene, there was hope that these institutions could improve care for uninsured, underinsured, and marginalized populations without access to primary care.⁴³⁻⁴⁵ However, a 2010 study found that populations in retail clinic catchment areas have a higher median income, better education, and lower likelihood of being uninsured.²¹ Approximately 70% of patients visiting retail clinics are insured, although the majority report having no primary care physician.²⁸ An analysis of U.S. Census and Health Resources and Services Administration data revealed that retail clinics were in areas with a lower percentage of African American patients, lower poverty rates, higher median income, and lower likelihood of being medically underserved.²² In addition to having poor penetration into disenfranchised communities,²⁰ retail clinics currently only operate in 39 states. However, as the network of retail clinics grows around the United States, corporate pharmacies should consider further expansion into marginalized communities, particularly with expanded coverage of lower-income patients under the ACA.³⁵

■ Pharmacy-Based Testing

With convenient locations in most neighborhoods in the United States,²³ pharmacies represent another missed opportunity for expanded HIV testing. Pharmacists are highly trained and underutilized health resources who are all too often limited to “behind-the-counter” functions. However, in recent years, there has been a shift in the practice of community pharmacists from drug dispensers to active members of managed care teams.⁴⁶ At the community level, pharmacists are engaged in immunization delivery,^{47,48} smoking cessation,^{49,50} osteoporosis screening,^{51,52} syringe exchange/sales programs,^{53,54} wellness counseling,⁵⁵ diabetes and cardiovascular disease screening,⁵⁶ HIV medication therapy management,^{57,58} and HAART adherence counseling.^{24,25,59-63} Surveys in New York and Rhode Island suggest that the majority of pharmacists would also be willing to act as providers of HIV testing.^{25,54,64}

Pharmacists are already engaged in serving PLWH at HIV specialty pharmacy locations. Walgreens certifies over 500 of its pharmacies as HIV Centers of Excellence.⁶⁵ Providers at

each of these locations have undergone specialized cultural and clinical training relating to HIV/AIDS care.⁶⁵ According to Walgreens’ website, pharmacists counsel patients on HAART side effects, send refill reminders to promote adherence, and even help connect patients with HIV/AIDS financial support programs in the community.⁶ In spite of their focus on HIV care, HIV screening is not routinely offered at any of the Centers of Excellence.

Several pilot programs are assessing the feasibility of pharmacy-based HIV testing. In a pilot program of pharmacist-led HIV testing in 20 community pharmacies in Spain, investigators surveyed 806 participants, over half of whom had never been tested previously.⁶⁶ Customers reported that the convenience and accessibility of community pharmacies were significant motivators in their decision to receive the test.⁶⁶ In another study, investigators coordinated counselor-led HIV rapid testing of 2,030 individuals in 5 community pharmacies in high HIV-prevalence areas in New York.⁶⁷ Of pharmacy customers who were approached, 72.9% agreed to the free HIV test, and 98.6% of participants reported that testing in the pharmacy setting was “easy.”⁶⁷ In the United States, for the 3 days leading up to the 2011 National HIV Testing Day, the CDC partnered with Walgreens to offer free HIV testing at 22 stores, ultimately screening over 900 customers.⁶⁸ While limited in their scope, these pilot studies validate the feasibility of a pharmacy-based testing model.

In June 2012, the CDC announced a larger pilot program for pharmacy and retail clinic-based HIV testing as an extension of the Expanded Testing Initiative.^{17,69} As Jonathan Mermin, MD, director of the CDC’s Division of HIV/AIDS Prevention stated, “Our goal is to make HIV screening as routine as a blood pressure check.”⁶⁹ Under this 2-year program, pharmacists and retail clinic providers at 12 urban and 12 rural pharmacies will administer HIV testing, offer counseling, and link patients with positive results to HIV care.⁷⁰ Following the pilot program, the CDC plans to develop a toolkit that pharmacists and retail clinic providers can use to implement HIV testing nationwide.⁶⁹ With sufficient corporate support, this pharmacy-based HIV testing approach could be rapidly scalable, potentially jumpstarting nationwide screening efforts enough to meet the 2015 NHAS targets.

Although pharmacy-based HIV testing removes many accessibility barriers, several political, financial, and logistical obstacles need to be addressed for this model to become an effective contributor to nationwide screening initiatives. One of the biggest challenges is the lack of framework for pharmacist reimbursement for HIV testing and counseling⁶² in an already time-limited practice setting.⁷¹ Some reimbursement mechanisms for direct patient care services are in place via pharmacist-specific Current Procedural Terminology codes for medication therapy management,^{58,72} but these codes do not cover preventive testing and counseling. Legal definitions

of pharmacists as health care providers also vary state to state and impact potential compensation for health counseling and screening. In some states, pharmacists are considered part of the care provider continuum with nurse practitioners and physician assistants, while in other states, they are not legally recognized as providers of direct patient care. The U.S. Surgeon General supports recognition of pharmacists as providers who are active members of a health management team.⁷³ The legal role of pharmacists in direct patient care needs to be clarified on a federal level prior to the development of standardized reimbursement for counseling and testing.⁵⁷

Another concern of the pharmacy-based testing model is the ability to offer pre- and posttest counseling because many pharmacies without retail clinics lack the confidential space for such discussions.^{54,74} In addition to treatment and preventive counseling for patients who test positive, HIV-uninfected persons may benefit from risk reduction counseling.^{64,74,75} Widespread expansion of pharmacist-led HIV testing would therefore require specialized training in cultural sensitivity, sexual history taking, and risk reduction counseling.⁷⁴ Pharmacists at HIV specialty pharmacies around the United States already receive this targeted training,⁶⁵ but widespread expansion into this setting may be better supported by universal integration of HIV counseling instruction into pharmacy school curricula.

Over-the-Counter Testing

In July 2012, the U.S. Food and Drug Administration (FDA) approved the first over-the-counter (OTC) rapid HIV test, OraQuick, which uses an oral sample to generate results in approximately 20 minutes.⁷⁶ With a sensitivity of 92% and specificity of 99.98%,⁷⁷ this OTC test offers a fairly reliable option for HIV testing in the privacy of the patient's home. Although this OTC test lacks the live pre- and posttest counseling that is available in traditional settings, the manufacturer offers a 24/7 phone support center to assist with patient counseling and linkage to care.⁷⁶ According to the Monte Carlo model that influenced the FDA's decision to approve the OTC rapid test, an estimated 2.8 million people will use the test within the first year.⁷⁸

Several higher-prevalence populations, particularly young people, men who have sex with men (MSM), and minorities, have voiced significant interest in the OTC test.^{26,79-81} In an online survey of 5,908 MSM in France, 86.5% of participants expressed interest in purchasing the rapid test, citing convenience, privacy, and rapidity as its most appealing characteristics.⁷⁹ OTC testing may also facilitate repeat testing for high-risk individuals as recommended by the CDC.^{8,78} In a study of MSM in Seattle, Washington, participants reported that they would be more likely to repeat testing if OTC tests were available and financially feasible.²⁷ However, in this study, only 26% of the respondents were willing to pay up to \$40, the market

price of the OraQuick test.²⁷ Given the association between poverty and increased HIV prevalence,^{82,83} the value of the test may be intimately related to its cost and financial accessibility to lower-income consumers.⁸⁴

While this OTC test broadens patients' options by bringing HIV testing to the privacy of their own homes, it is meant to supplement and not substitute for testing in traditional venues.⁸⁵ The oral swab is less sensitive than existing blood tests and will miss 1 in 12 seropositive patients tested.⁷⁷ A negative test may be misleading in the case of a very recent exposure, providing false reassurance during the window period between infection and seroconversion 4 to 6 weeks later. False positives are also possible, so a confirmatory western blot is recommended. OTC kits, therefore, do not obviate the need for safety net testing programs. Rather, these programs are more necessary than ever to confirm home test results for marginalized populations⁸⁶ and offer additional counseling regardless of serostatus.

Connection to care also remains a significant challenge with the at-home test. Only 69%-77% of newly diagnosed patients receive linkage to primary HIV care in current provider-led testing venues.^{87,88} Although the OTC test kits advertise 24/7 phone counseling and contact information for providers in the area, there is still concern that patient initiative and indirect provider referrals will be significant barriers to engaging in care.^{46,78,86} In a study of referral techniques, patients who received an active referral to HIV care through a case manager were significantly more likely to successfully link to care than those who were passively referred to local clinics.⁸⁹ However, in OraSure Technologies' marketing research trials, 96% of participants who tested positive responded that they were at least "highly likely" to contact their doctor regarding the results.⁹⁰

Community pharmacists may be uniquely situated to facilitate the critical link to HIV care. However, existing time constraints in the community pharmacy setting and lack of reimbursement structure stand in the way of this potential opportunity for coordination of care. Pharmacists already offer counseling regarding other OTC tests for pregnancy, yeast infections, urinary tract infections, cholesterol, and diabetes.⁴⁶ In a survey of community pharmacists, many participants identified an opportunity to provide patients counseling at the point of sale of the OTC test, whether the test is located in front of or behind the counter.⁴⁶ Several of those surveyed also suggested that the pharmacist could play an active role in linkage to care for patients who took the test within the pharmacy.⁴⁶ Concurrent with the FDA's approval of OraQuick, the CDC launched a pilot program at 24 community pharmacies to train pharmacists in how to provide pre- and posttest counseling to customers taking the OTC test.⁹¹ However, with growing opportunities for HIV testing in pharmacies, both in front of and behind the counter, practice in HIV counseling should be incorporated into every new pharmacist's training.

Conclusions

Recent developments—including the advent of rapid testing, expansion of routine HIV screening to everyone aged 13-64 years regardless of risk, expanded coverage under the ACA, and new recommendations to start all PLWH on HAART—have changed the landscape of HIV prevention.⁷ However, in order to meet the NHAS goals, providers and policymakers need to look for HIV screening opportunities beyond traditional clinical settings. The birth of the retail clinic has heralded in an age of “on demand” medicine. As a business model, retail clinics are a reminder that patients are customers to whom medical services are aggressively marketed for their convenience, accessibility, and affordability. However, the absence of HIV testing at retail clinics contradicts their stance as sites of basic primary care. In New York, the absence of HIV testing at retail clinics is in clear violation of current state law.⁴⁰ With improved corporate leadership, retail chains could deploy widespread HIV testing at the more than 1,400 clinics nationwide, rapidly expanding HIV testing initiatives.

With expanded HIV testing recommendations and the increasing promise of “treatment as prevention,” it is more important than ever to develop patient-centered, financially sustainable solutions to HIV screening barriers. Expanding testing options in community-based facilities such as community pharmacies empowers patients by giving them the ability to get tested on their own time in the setting of their choice. Offering a broader array of HIV testing sites spanning from primary care clinics to urgent care centers to retail clinics, commercial pharmacies, and OTC kits increases the likelihood that patients will “opt-in” to testing.

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