

## RESEARCH AND PRACTICE

# Missed opportunities for diagnosing HIV via routine screening in an inner-city primary care clinic

Abigail Hankin, MD, MPH<sup>1</sup>, Sara Turbow, MD, MPH<sup>1</sup>, Jennifer Spicer, MD, MPH<sup>1</sup>, Heather Freiman, MSPH, MA<sup>1</sup>, Bijal Shah, MD<sup>2</sup>, and Natasha Travis, MD<sup>1</sup>

<sup>1</sup>Department of Medicine, School of Medicine, Emory University, Atlanta, GA; <sup>2</sup>Department of Emergency Medicine, School of Medicine, Emory University, Atlanta, GA

### ABSTRACT

**Background:** Although routine, opt-out HIV screening has been recommended for nearly a decade, clinical practice has not kept pace. Here, we examine missed opportunities for HIV screening among patients newly diagnosed with HIV via a routine non-targeted opt-out HIV screening program in a primary care clinic at an inner-city safety-net hospital.

**Methods:** Select demographic and clinical data were analyzed for all persons with a new HIV diagnosis between July 9, 2013 and August 31, 2015. Retrospective reviews of medical records were performed to identify missed opportunities for HIV screening in the year prior to HIV diagnosis.

**Results:** Among 6,582 patients tested for HIV as part of the screening program, 27 patients had a new HIV diagnosis (0.41%). In the year prior to diagnosis, 19 (70%) of these had contact with the healthcare system but were not tested for HIV. At the visit associated with the new HIV diagnosis, 70% of patients did not present with an indication for risk-based HIV screening or symptoms potentially associated with HIV-related infections.

**Conclusions:** Despite CDC recommendations for routine, non-targeted, opt-out HIV screening in all healthcare settings, 70% of patients newly diagnosed with HIV via routine screening in a primary care clinic had contact with the healthcare system in the year prior to the new HIV diagnosis but were not tested for HIV. These findings highlight the importance of routine, non-targeted screening to identify patients with HIV as well as continued provider and patient education about the value of routine HIV screening.

**Keywords:** HIV screening, primary care, opt-out screening, routine screening

### INTRODUCTION

Advances in HIV treatment have resulted in dramatic decreases in morbidity and mortality for persons living with HIV. However, the estimated number of new HIV infections in the United States (US) has remained virtually unchanged since the early 1990s, with approximately 50,000 new infections each year (Moore, 2011). A factor believed to contribute to the steady rate of new infections is that nearly one of every five Americans living with HIV is not aware of his/her infection (Batey, 2012).

In 2006, in an effort to decrease the proportion of patients who are HIV-infected but not diagnosed, the Centers for Disease Control and Prevention (CDC) issued recommendations for one-time routine HIV screening in all healthcare settings for patients aged 13 to 64 using verbal opt-out consent (Branson, 2006). The CDC recommended against the use of separate written consent or mandatory pre-test counseling.

Clinical practice has not evolved to meet the changing recommendations by the CDC (Cohan, 2009; CDC, 2010; Brennan, 2013), and there are continuing gaps in knowledge among trainees and physicians that lead to incomplete

adherence to the CDC screening guidelines (Mohajer, 2012; Jain, 2009; Berkenblit, 2012). Additionally, there may be insufficient time or competing priorities that act as barriers to following the recommendations for routine screening (Burke, 2007; Korthuis, 2011). Nearly 10 years after publication of the revised CDC HIV screening recommendations, this lack of adherence to the guidelines creates delays between HIV infection and diagnosis and may increase the likelihood that healthcare providers will diagnose the disease late in its course (Samet, 2011).

The goal of this research was to determine if missed opportunities for routine screening still persist, to characterize the nature of patient complaints associated with a missed opportunity to test, to assess the clinical status of these newly diagnosed patients, and to determine if patients became effectively linked to care.

### METHODS

In July 2013, a resident-based primary care clinic (PCC) of an inner-city safety-net hospital located in an area of high HIV prevalence in the southeastern US implemented a routine, non-targeted, opt-out HIV screening program in collaboration with the nursing and physician leadership of

the clinic. The program put into effect the CDC recommendations and the updated U.S. Preventive Services Task Force (USPSTF) guidelines (Moyer, 2013). An equivalent screening program began simultaneously in the hospital's emergency department (ED) and no program existed in the inpatient setting (not clear).

Each year, there are approximately 53,000 visits to this PCC, representing approximately 23,000 distinct patients, most of whom are African American (91.0%) and female (59.0%). Patients seen in this clinic are primarily adults (mean age 55.1 years), and 41.7% are uninsured/self-pay. Among patients with insurance coverage, Medicare (28.6%) and Medicaid (16.6%) are the most common insurance sources.

As part of the patient's triage, a nurse or clinical assistant completed an HIV test eligibility assessment tool embedded in the electronic medical record (EMR). Patients were ineligible for the test offer if they already HIV-positive, were cognitively unable to decline testing, or had a negative HIV test recorded in the EMR within the last six months. Eligible patients were offered tests to using opt-out language. For patients who did not decline, the nurse or assistant notified the physician or provider to place the order and instructed the patient to visit the hospital's outpatient laboratory for a blood draw after completion of his/her examination.

The clinical laboratory of the hospital accomplished the HIV testing. From July 2013 through February 2015, a 3<sup>rd</sup> generation HIV EIA test (VITROS<sup>®</sup> Immunodiagnostic Product Anti HIV 1/2 Reagent Pack, Ortho Diagnostics, Rochester, NY) was used; the laboratory has since switched to a 4<sup>th</sup> generation test (ARCHITECT HIV Ag/Ab Combo assay, Architect i2000sr, Abbott Laboratories, Germany). For all reactive HIV screens ("preliminary positive"), the laboratory performed a reflex confirmatory Western Blot (HIV-1, BioRad<sup>™</sup>, Foster City, CA). For patients with a positive test result, the team confirmed new diagnoses via patient self-report or hospital EMR review. The program's medical social workers consulted the patient's primary care physician to disclose the test result, initiate a blood draw for a CD4 count, and link the patient to HIV-related medical care and social support services.

### Medical Record Review

Patients were included in medical record review and analyses if they visited the PCC from July 9, 2013 through August 31, 2015, completed an HIV screen during this time, and had been newly diagnosed with HIV infection. Two

physicians (JS & ST) performed medical record reviews and data extraction.

Hospital admissions, PCC appointments, and visits to the ED in the year prior to diagnosis were reviewed. For the most proximal visit of each type, the patient's chief complaint and visit or admission diagnosis were recorded. Similar information was collected for the visit when the positive HIV screen was ordered. Additionally, the total count of each visit type in the year prior to diagnosis was collected.

Demographic factors, including age at diagnosis, sex, and race/ethnicity, were extracted from automated EMR data reports received by the program. Test result data, including HIV EIA or Ag/Ab, Western blot, and CD4 count at diagnosis were abstracted from the laboratory results in the EMR. Data related to linkage to care data were abstracted from the program's internal database. A patient was considered linked to care if they had, in the EMR, documentation of a follow-up visit with an HIV care provider or via conversations with the patient's HIV care provider.

### Data Analysis

All data were stored in secure password-protected databases (Microsoft Excel, 2010 and REDCap) (Harris, 2009) on a password protected computer and were analyzed using SAS<sup>®</sup> version 9.3 (SAS, 2012). Standard descriptive statistics were used for patient demographics, CD4 counts, and variables relating to patient visits to the healthcare system in the year prior to diagnosis with HIV infection and linkage to care with an HIV provider.

The university institutional review board and hospital and the hospital research oversight committee approve the program protocol.

## RESULTS

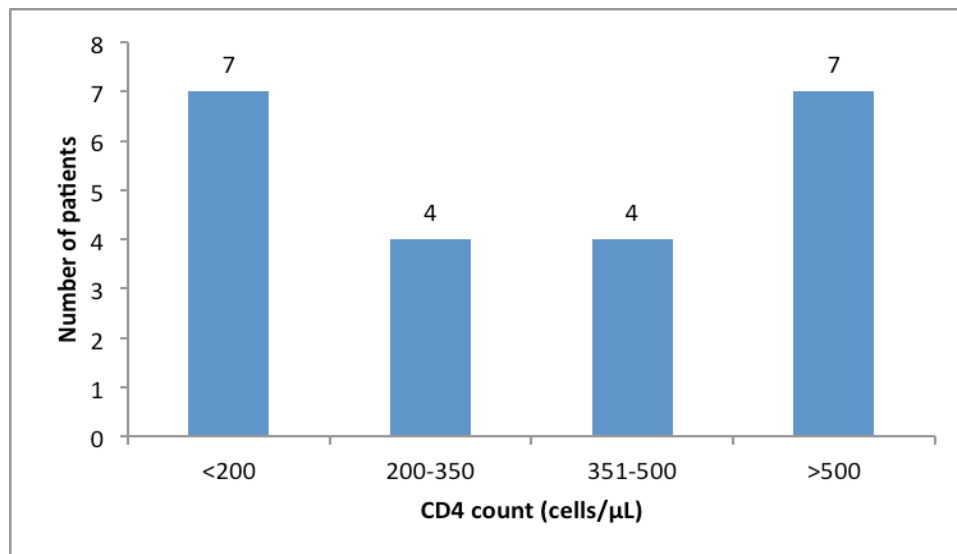
In the two years after implementation of the routine HIV screening program in the PCC, 6,582 patients were tested, and physicians diagnosed 27 with HIV (0.41%). Among these patients, 55.0% (n=15) were male and 96.3% (n=26) were African American (Table 1). Patients also covered a wide age range; in this cohort, the oldest patient diagnosed was 67 years old. Twenty-two patients (81.5%) had initial CD4 counts available. Among these, the median CD4 count at diagnosis was 332 cells/ $\mu$ L (range 5-968 cells/ $\mu$ L); one-third (n=7) had an initial CD4 count below 200 cells/ $\mu$ L (Table 1, Figure 1).

**Table 1. Characteristics, initial CD4 count, and prior visits of persons newly diagnosed with HIV**

	<b>New positives (n=27)</b>
<b>Demographic Characteristics</b>	
Age, Median (range)	44 years (22-67 years)
<b>Sex</b>	
Male	55% (n=15)
Female	45% (n=12)
<b>Race</b>	
White	4% (n=1)
Black	96% (n=26)
<b>Ethnicity</b>	
Hispanic	4% (n=1)
Not Hispanic	93% (n=25)
Unknown	4% (n=1)
<b>CD4 count at diagnosis</b>	
<200 cells/ $\mu$ L	26% (n=7)
$\geq$ 200 cells/ $\mu$ L	56% (n=15)
Not available	19% (n=5)
Median CD4 count (range)*	332 cells/ $\mu$ L (5-968 cells/ $\mu$ L)
<b>Prior visits of persons testing newly positive</b>	
At least one visit in the year prior to diagnosis	70% (n=19)
Median visits among patients with at least one visit (range)	2 (1-9 visits)
<b>Location of visits in year prior to diagnosis</b>	
PCC-only	58% (n=11)
ED-only	16% (n=3)
Inpatient-only	5% (n=1)
PCC and ED	5% (n=1)
PCC and Inpatient	5% (n=1)
PCC, ED, and Inpatient	11% (n=2)

\*Among 22 patients with a CD4 count available in the EMR

**Figure 1. Initial CD4 count at new HIV diagnosis\***



\*Among 22 patients with an initial CD4 count available in the EMR

In the year prior to their HIV diagnosis, 70% of patients (n=19) had contact with the healthcare system. Cumulatively, these patients had 62 total encounters prior to diagnosis. The most frequent form of contact was PCC visits: 14 patients were seen in the PCC at least once in the year before new HIV diagnosis (range: 1-7, median = 2). Of the remaining patients with healthcare system contact in the year prior to diagnosis, four were seen in the ED and one was admitted to the hospital (inpatient). Of note, in the year prior to diagnosis, one patient had six visits to the healthcare system without being offered HIV testing. These included three PCC visits, two ED visits, and one hospital admission.

Offers of HIV testing at prior visits occurred most frequently in the PCC. Six patients were offered HIV screening at PCC visits prior to diagnosis. Five did not decline a test, but only one patient completed the test. Half of the patients who did not decline HIV screening at the prior PCC visit had a test ordered, but did not go to the laboratory for testing, and, for one patient who did not decline, a test order was never placed. Documentation of test offers in the inpatient and ED settings was poor, with only one test offer documented in each of those settings among this population.

During the positive-test visit, i.e., the visit at which the test ordered in the PCC resulted positive, 19 of 27 patients (70%) did not present with an indication for risk-based HIV screening or symptoms potentially associated with HIV-related infections. Among these 19 patients, the primary complaints discussed at the positive-test visits included hypertension, diabetes, obesity, and depression. Among the remaining eight patients with potentially HIV-related complaints at this positive-test visit, two were seen for testing for sexually transmitted infections, two for other genital complaints, two for rash, one for fatigue, and one for lymphadenopathy.

Of these 27 patients, those with an initial CD4 count less than < 200 cells/ $\mu$ L at diagnosis had a slightly higher mean number of PCC visits in the year prior to diagnosis relative to patients with higher CD4 counts (1.86 $\pm$ 2.9 visits vs. 1.4 $\pm$ 1.4visits, p=0.62). Of the 27 patients, 23 were linked to HIV care.

## DISCUSSION

The goal was to identify and characterize missed opportunities for HIV diagnosis among a population of patients later identified as HIV-positive after initiation of a routine, non-targeted, opt-out HIV screening program in a hospital PCC. After implementation of this screening in July 2013, physicians diagnosed 27 patients with new cases of HIV, 70% of whom had contact with the healthcare system in the year prior to diagnosis. Most of these contacts were in the outpatient setting, and most patients presented for complaints unrelated to their HIV infection. These findings highlight the value of routine HIV screening for all patients. This analysis also reinforces the need for education of providers on the benefits of non-risk based screening and to obligation to encourage patients to take the test regardless of perceived risk factors. Of patients identified as newly HIV-

positive, 70% did not present with symptoms potentially associated with opportunistic infections. Additionally, routine HIV screening should not be limited to primary care physicians. Specialists saw several patients in the year prior to diagnosis; they admitted two to surgical services (inpatient) for lymphadenopathy, a common symptom of HIV, but did not screen them for HIV. Providers across all specialties should strive to make non-targeted HIV screening a routine part of their care.

In the PCC setting, missed opportunities for HIV screening occurred at each level of the process: patient, system, and provider. As part of the routine HIV screening program, triage personnel completed the EMR-based HIV test offer eligibility assessment at all visits and offered opt-out testing for eligible patients. Patients frequently refuse testing, most likely out of stigma or fear, or because of the way the test offer is worded (Branson, 2006). Education and counseling can correct this patient-level issue; in a busy PCC, unfortunately, finding time to complete these tasks is challenging. When patients do not decline the test, triage personnel must ask the provider to order the test, as they are not able to do so themselves. Despite reminders, providers may forget to order the test – as was demonstrated for one patient in this analysis. This represents a systems- and provider-level issue. Additionally, missed HIV diagnoses may be secondary to provider lack of knowledge of screening recommendations. Despite efforts to disseminate the 2006 CDC recommendations for HIV screening to physicians and trainees, many internal medicine and emergency medicine residents are unaware of the change in guidelines (Mohajer, 2012; Jain, 2009). Also, at the institution, once the physician places the HIV test order and the PCC visit is complete, patients must go to a different location within the hospital for laboratory services. Attending a separate laboratory can be challenging for patients. Such a requirement apparently resulted in delayed HIV diagnosis for five patients reviewed in this analysis. Interventions at the patient, provider, and system level are underway to correct these problems and avoid future missed and delayed diagnoses.

Nationally, infectious disease specialist or HIV primary care provider have seen at least once and have tested about 60% of persons living with HIV (Nakao, 2014). Among patients in the present analysis, 85% s had document linkage to care documented. This result warrants further investigation into the outcomes for these patients, including establishing the percent receiving regular HIV care and the percent achieving viral suppression. Of additional interest are qualitative investigation and counseling interventions with the patients who refused linkage to care. Although only one patient included here refused linkage services, clinicians and public health experts should consider this group.

Strengths of this analysis include the ability to “look back in time” at the patient’s clinical history prior to a new HIV diagnosis. For some patients, there were documented missed opportunities for earlier detection.

This analysis, like all retrospective chart reviews, is only as sound as the documentation available and is limited to

information included within the EMR. In this context, this limitation is most apparent in documentation of test offers and refusal reasons in the year prior to a new HIV diagnosis. In the PCC setting, whether a test was offered or not was documented approximately two-thirds of the time, and the reason for a test not being offered or being refused was documented even less frequently. The absence of documentation of this information prevents improvement of performance.

### IMPLICATIONS FOR PUBLIC HEALTH

In this analysis, most patients newly diagnosed with HIV infection via a PCC-based routine HIV screening program visited the healthcare system at least once within the year before new HIV diagnosis. At visits before this diagnosis, healthcare personnel did not order tests, perhaps for reasons related to the patient, provider, and/or healthcare system. On the day of a new HIV diagnosis, physicians saw almost all of the patients for a complaint not related to HIV risk factors and a provider utilizing a risk-based screening protocol would not have tested them. This finding highlights the value of routine, non-risk based HIV screening in the PCC setting. Implementation of such screening for all patients in the PCC setting can make it easier for providers to offer and order an HIV test, decrease patients' fear associated with HIV screening, and reduce the stigma of HIV.

### Acknowledgement

The program described herein received partial funding support by a grant from Gilead Sciences, Inc. (FOCUS Program: <http://www.gilead.com/responsibility/hiv-focus-program>)

### References

Batey D.S., Hogan V.L., Cantor R., Hamlin C.M., Ross-Davis K., Nevin C., et al. (2012). Short communication routine HIV testing in the emergency department: Assessment of patient perceptions. *AIDS Research and Human Retroviruses*, 28 (4), :352-6.

Branson B.M., Handsfield H.H., Lampe M.A., Janssen R.S., Taylor A.W., Lyss S.B., et al. (2006). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *Morbidity and Mortality Weekly Report Recommendation*, 55 (Rr-14),1-17, quiz CE1-4.

Berkenblit G.V., Sosman J.M., Bass M., Gebrekristos H.T., Cofrancesco J., Jr., Sullivan L.E., et al. (2012) Factors affecting clinician educator encouragement of routine HIV testing among trainees. *Journal of General Internal Medicine*, 27(7), 839-44.

Brennan M.B., Kolehmainen C., Barocas J., Isaac C., Crnich C.J., Sosman J.M., et al. (2013). Barriers and facilitators of universal HIV screening among internal medicine residents HIV testing attitudes and practices among clinicians in the era of updated Centers for Disease Control and Prevention recommendations. *World Medical Journal*, 112(5),199-205.

Burke R.C., Sepkowitz K.A., Bernstein K.T., Karpati A.M., Myers J.E., Tsoi B.W., et al. (2007). Why don't physicians test for HIV? A review of the US literature. *AIDS*, 21(12), 1617-24

Centers for Disease Control and Prevention. (2010). Vital signs: HIV testing and diagnosis among adults--United States, 2001-2009. *Morbidity and Mortality Weekly Report*, 59 (47), 1550-5.

Centers for Disease Control and Prevention (2013). Linkage to and Retention in HIV Medical Care [Website]. Retrieved from <http://www.cdc.gov/hiv/prevention/programs/pwp/linkage.html>

Cohan D., Gomez E., Dowling T., Zetola N., Kaplan B., Klausner J.D.. (2009). HIV testing attitudes and practices among clinicians in the era of updated Centers for Disease Control and Prevention recommendations. *Journal of the Acquired Immune Deficiency Syndrome*, 50(1), 114-6.

Harris P.A., Taylor R., Thielke R., Payne J., Gonzalez N. & Conde J.G. (2009). Research electronic data capture (REDCap)-a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics* 42(2), 377-81.

Jain C.L., Wyatt C.M., Burke R., Sepkowitz K. & Begier E.M. (2009). Knowledge of the Centers for Disease Control and Prevention's 2006 routine HIV testing recommendations among New York City internal medicine residents. *AIDS Patient Care and Sexually Transmitted Diseases*, 23 (3), 167-76.

Korthuis P.T., Berkenblit G.V., Sullivan L.E., Cofrancesco J., Jr., Cook R.L., Bass M., et al. (2011). General internists' beliefs, behaviors, and perceived barriers to routine HIV screening in primary care. *AIDS Education and Prevention*, 23(3 Suppl), 70-83.

Mohajer M.A., Lyons M., King E., Pratt J., Fichtenbaum C.J. (2012) Internal medicine and emergency medicine physicians lack accurate knowledge of current CDC HIV testing recommendations and infrequently offer HIV testing. *Journal of the International Association of Physicians in AIDS Care*, 11J (2), 101-8.

Moore R.D. (2011). Epidemiology of HIV infection in the United States: Implications for linkage to care. *Clinical Infectious Diseases*, 5(52 Suppl 2), S208-13.

Moyer V.A. (2013). Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine*, 159 (1), 51-60.

Nakao J.H., Wiener D.E., Newman D.H., Sharp V.L. & Egan D.J (2014). Falling through the cracks? Missed opportunities for earlier HIV diagnosis in a New York City Hospital. *International Journal of STD & AIDS*, 25(12), 887-93.

Prevention CfDca. (2010). Vital signs: HIV testing and diagnosis among adults--United States, 2001-2009. *Morbidity and Mortality Weekly Report*, 59 (47), 1550-5.

Samet J.H., Freedberg K.A., Savetsky J.B., Sullivan L.M. & Stein M.D. (2011). Understanding delay to medical care for HIV infection: The long-term non-presenter. *AIDS*, 15 (1), 77-85.

SAS statistical software. The data analysis for this paper was generated using SAS software, Version 9.3 of the SAS System for PC. Copyright © 2012 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.