Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-04925-469

Evaluation of Human Immunodeficiency Virus Screening in Veterans Health Administration Outpatient Clinics

February 28, 2017

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted a systematic review in FY 2015 of the Veterans Health Administration's outpatient clinics, including the Community Based Outpatient Clinics, to evaluate for compliance with selected Veterans Health Administration requirements regarding human immunodeficiency virus (HIV) screening.

The objectives were to determine whether outpatient clinics complied with the requirements to:

- Identify an HIV Lead Clinician to facilitate HIV-related communications and reporting.
- Establish local policies and procedures to facilitate HIV testing and notification of test results, minimize excessive testing, and communicate confirmed positive HIV test results to appropriate providers.
- Provide HIV screening as part of routine medical care.
- Document informed consent for HIV testing.

We performed this focused review at 56 VA facilities. Our initial electronic health records sample consisted of 1,990 outpatients who met the criteria for review.

We estimated that 96.3 percent (95% CI: 88.96–98.85) of the Veterans Health Administration facilities identified a Lead HIV Clinician and 92.6 percent (95% CI: 84.09–96.75) of Veterans Health Administration facilities established policies, procedures, and guidelines for HIV screening. Additionally, 83.6 percent (95% CI: 73.06–90.60) of those facilities required HIV screening as a routine component of care.

We estimated that clinicians offered screening to 66.4 percent (95% CI: 64.32–68.48) of outpatients during August 1, 2009 through March 31, 2014, and an additional 4.6 percent (95% CI: 3.78–5.64) of outpatients were offered screening prior to August 1, 2009. We did not find documentation of the offer of screening in 28.9 percent (95% CI: 26.99–30.98) of electronic health records.

We estimated that clinicians documented oral informed consent in 75.1 percent (95% CI: 71.28–78.64) and written informed consent in 6.6 percent (95% CI: 4.77–9.05) of records for outpatients screened for HIV. We also estimated that informed consent was not documented in 18.3 percent (95% CI: 15.20–21.79) of records for outpatients screened for HIV.

We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers ensure that:

- Clinical staff offer HIV screening as part of routine medical care and that managers monitor for compliance.
- Clinicians document informed consent for HIV testing and that managers monitor for compliance.

Comments

The Under Secretary for Health concurred with the findings and recommendations. (See Appendix B, pages 11–14, for the full text of the comments.) The implementation plans are acceptable, and we will follow up until all actions are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a systematic review of the Veterans Health Administration's (VHA) community based outpatient clinics (CBOCs) and other outpatient clinics (OOCs) to evaluate for compliance with selected VHA requirements regarding human immunodeficiency virus (HIV) screening.

The objectives were to determine whether CBOCs and OOCs complied with the requirements to:

- Identify an HIV Lead Clinician to facilitate HIV-related communications and reporting.
- Establish local policies and procedures to facilitate HIV testing and notification of test results, minimize excessive screening, and communicate confirmed positive HIV test results to appropriate providers.
- Provide HIV screening as part of routine medical care.
- Document informed consent for HIV screening.

Background

The Centers for Disease Control and Prevention estimates that approximately 15.8 percent of the estimated 1.1 million people in the United States living with HIV are unaware of their HIV status.[1] The prevalence range for undocumented HIV infection in VHA has been found to range from 0.1–2.8 percent among outpatients.[2] With over 6 million unique active patients,[3] there may be thousands of veterans with undiagnosed HIV infection.

Increased survival among patients with HIV disease in the United States is achieved only for those who are identified early and receive appropriate care.[4] Substantial data suggests that routine HIV screening is a cost-effective intervention.[5]

In 2008, VHA required each Facility Director to appoint an HIV Lead Clinician so that a principal point of contact is established for communicating and reporting on HIV-related

[1] Centers for Disease Control and Prevention. HIV Screening. Standard Care. *Statistics Basics Fact Sheet,* November 2013. http://www.cdc.gov/actagainstaids/campaigns/hssc/index.html. Accessed February 19, 2016.
[2] Owens, DK, Sundaram, V, Lazzeroni LC, et al. Prevalence of HIV Infection Among Inpatients and Outpatients in Department of Veterans Affairs Health Care Systems: Implications for Screening Programs for HIV. American Journal of Public Health 2007; 97(12):2173-8.
[3] VHA Support Service Center. Accessed January 6, 2016.
[4] Walensky, RP, Freedberg, KA, Weinstein, MC, Paltiel, AD. Cost-Effectiveness of HIV Testing and Treatment in the United States. CID 2007:45 (Suppl 4), S248-S254.
[5] Ibid.

issues. The HIV Lead Clinician must be a provider committed to excellence in the diagnosis and care of HIV-infected veterans.[6]

In August 2009, VHA issued a policy requiring the provision of HIV screening as part of routine medical care.[7] The Facility Director became responsible for establishing local policies and procedures to facilitate HIV screening and minimize the risk of unwarranted or excessive screening. Although VHA policy also provides guidance on when to utilize risk-based screening, VHA has provided criteria which limit its potential use at facilities.[8] Current VHA Clinical Preventive Services Guidance recommends universal HIV screening in all adults, ages 18 years and older, at least once.[9]

Additionally, VHA took steps to improve processes related to HIV screening. First, VHA issued a separate policy eliminating the requirement for written consent for HIV testing and allowing documented oral consent.[10] VHA also published recommendations on the use of rapid HIV tests for patients who undergo HIV testing.[11]

Rapid HIV tests rely on oral fluid (for example, saliva) or whole blood obtained from venipuncture or finger stick. Rapid HIV tests have been used nationally in clinical and non-clinical health care settings with accuracy and ease and to help expand access and availability of HIV testing. Rapid tests have also benefited patients by simplifying the results notification process. Although positive rapid HIV test results are considered preliminary and must be confirmed by laboratory testing, negative rapid HIV test results are considered conclusive. For informational purposes, we assessed which rapid HIV tests are used at VA Medical Centers (VAMC) and how VAMCs classified the urgency of positive HIV test results since the timely communication of test results is essential to the provision of quality care.

Scope and Methodology

Scope. The Office of Healthcare Inspections conducted this evaluation during CBOC/OOC reviews performed in fiscal year 2015. We performed this focused review at 56 VAMCs and randomly selected 40 outpatients (or all outpatients if fewer than 40 were available) per facility to assess for the objectives.

Our initial electronic health records (EHR) sample consisted of 1,990 outpatients who met the following criteria:

[6] VHA Directive 2008-082, *National HIV Program*, December 5, 2008, p.3.
[7] VHA Directive 2009-036, *Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities*, August 14, 2009, p. 2.
[8] Ibid, p. 4.
[9] VHA National Center for Health Promotion and Disease Prevention (NCP), *Screening for HIV,* http://vaww.prevention.va.gov/Screening_for_HIV.asp. Accessed February 19, 2016.
[10] VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, p.1 and 7.
[11] Under Secretary for Health's Information Letter, *Use of Rapid Tests for Routine Human Immunodeficiency Virus (HIV) Screening*, February 16, 2010.

- Had at least one outpatient visit at the parent facility's CBOCs or OOCs (excluding Emergency Department and Urgent Care Clinic visits) within a 12-month period during April 1, 2013, through March 31, 2014.[12]
- Had an outpatient visit in fiscal year 2012.
- Did not receive a diagnosis or treatment for HIV 6 months prior to the study period.
- Did not receive hospice or palliative care 6 months prior to or during the study period.

Methodology. We reviewed facility self-assessments, policies, procedures, and guidelines to assess for administrative controls over the HIV screening process as required by VHA policy. We also evaluated EHRs to determine if the selected review elements were documented according to the applicable VHA policies. We determined the number of outpatients offered screening or screened between August 1, 2009, the VHA policy implementation date,[13] and March 31, 2014, the end of our study period. For the sampled outpatients not offered screening or not screened during that timeframe, we assessed if the offer for screening or the actual screening occurred prior to August 1, 2009. We then validated the findings with key managers and staff.

We used a two-stage complex probability sample design to select outpatients from the study population for the EHR reviews. In the first stage of sampling, we statistically randomly selected 56 VAMCs stratified by the 12 catchment areas of the OIG's Office of Healthcare Inspections regional offices. Then we compiled a list of eligible outpatients who were assigned to the parent facility for each of the selected 56 VAMCs.

In the second stage of sampling, we randomly selected 40 outpatients from each of the 56 patient lists for our EHR reviews. If a VAMC had fewer than 40 eligible outpatients who met the criteria for the focused review, we reviewed all of the outpatients on the list.

Statistical Analysis. We estimated the VHA compliance for each of the review elements, taking into account the complexity of our multi-stage sample design. We used Horvitz-Thompson sampling weights (reciprocal of sampling probabilities) to account for unequal probability sampling and the Taylor expansion method to obtain the sampling errors for the estimates. We considered a VAMC compliant with policy if at least 90 percent of its eligible outpatients met HIV screening requirements.

We presented 95 percent confidence intervals (95% CI) for the estimates of the true values (parameters) of the study population. A confidence interval gives an estimated range of values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95% CI indicates that among all possible samples that we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals.

[12] Emergency Department and Urgent Care Clinic visits were excluded.
[13] VHA Directive 2009-036, p. 1.

Percentages can only take non-negative values from 0 to 100, but their logits can have unrestricted range so that the normal approximation can be used. Thus, we calculated the confidence intervals for percentages on the logit scale and then transformed them back to the original scale to ensure that the calculated confidence intervals contained only the proper range of 0 to 100 percent. All data analyses were performed using SAS statistical software, version 9.4 (TS1M0), SAS Institute, Inc. (Cary, North Carolina).

The Office of Healthcare Inspections conducted this evaluation during CBOC/OOC reviews beginning October 1, 2014, through September 30, 2015. Facility-specific review results were reported in 56 CBOC/OOC reports. For this summary report, we aggregated and analyzed the data collected from these individual facility evaluations.

We conducted this inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Identification of an HIV Lead Clinician

We estimated that 96.3 percent of VHA facilities identified a Lead HIV Clinician, and 95 percent of the time, the true compliance rate is between 88.96 and 98.85 percent. Thus the compliance rate was not statistically significantly below the 90 percent benchmark.

Issue 2: Establishment of Local Policies and Procedures

We estimated that 92.6 percent (95% CI: 84.09–96.75) of VHA facilities established local policies, procedures, and guidelines for HIV screening. Additionally, we estimated that 83.6 percent (95% CI: 73.06–90.60) of those facilities required HIV screening as a routine component of care. The compliance rate was not statistically significantly below the 90 percent benchmark.

We also estimated that 90.9 percent (95% CI: 83.10–95.30) of VHA facilities had policies, procedures, and guidelines related to the communication of HIV test results. For informational purposes, Table 1 below displays the facilities' designations for positive HIV results.

Table 1. Facility Designations for Positive HIV Test Results

Reported Designations for Positive HIV Test Results	Number of Facilities With HIV Policies or Procedures n=51	Estimated VA Compliance 95 Percent Confidence Interval Limits		
		Percent	Lower	Upper
Abnormal	20	38.5	28.43	49.72
Not defined	18	35.4	26.20	45.82
Critical	7	13.8	7.61	23.88
Emergent	6	12.2	7.19	20.03

Source: CBOC/OOC cyclical inspections conducted during FY 2015 (Appendix A).

Issue 3: Rapid Tests

We estimated that 33.1 percent (95% CI: 24.20–43.39) of VHA facilities offered HIV rapid tests. For informational purposes, Table 2 below displays the types of HIV Rapid Tests used by the facilities.

Table 2. Types of HIV Rapid Tests

HIV Rapid Test Types	Number of Facilities n=18	Estimated VA Usage 95 Percent Confidence Interval Limits		
		Percent	Lower	Upper
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test®	12	66.8	49.59	80.38
Uni-Gold Recombigen HIV®	3	16.4	7.30	32.93
Clearview HIV ½ STAT-PAK®	2	10.9	3.46	29.57
Clearview COMPLETE HIV 1/2®	1	5.9	1.13	25.59

Source: CBOC/OOC cyclical inspections conducted during FY 2015 (Appendix A).

Issue 4: HIV Screening as Part of Routine Medical Care

We estimated that clinicians documented the offer of HIV screening during the study period in 66.4 percent (95% CI: 64.32–68.48) of EHRs reviewed. Additionally, we estimated that clinicians documented the offer of HIV screening in 4.6 percent (95% CI: 3.78–5.64) of EHRs prior to August 1, 2009.[14] We did not find documentation of the offer of screening in 28.9 percent (95% CI: 26.99–30.98) of EHRs. The compliance rate was statistically significantly below the 90 percent benchmark. Table 3 below displays the data analysis results for the documentation of the offer of HIV screening.

Table 3. Offer of HIV Screening

Offer of HIV Screening	Number of Sampled Records n=1,990	Estimated VA Compliance 95 Percent Confidence Interval Limits		
		Percent	Lower	Upper
Between August 1, 2009 – March 31, 2014	1,322	66.4	64.32	68.48
No documentation of screening	576	28.9	26.99	30.98
Prior to August 1, 2009	92	4.6	3.78	5.64

Source: CBOC/OOC cyclical inspections conducted during FY 2015 (Appendix A).

[14] VHA Directive 2009-036, p. 4.

Issue 5: Documentation of Informed Consent

We estimated that clinicians documented oral informed consent in 75.1 percent (95% CI: 71.28–78.64) and written informed consent in 6.6 percent (95% CI: 4.77–9.05) of EHRs. We estimated that informed consent was not documented for testing that occurred in 18.3 percent (95% CI: 15.20–21.79) of EHRs. The compliance rate was statistically significantly below the 90 percent benchmark. Table 4 below displays the data analysis results for the documentation of consent for HIV testing.

Table 4. Documentation of Consent for HIV Testing

Consent for HIV Testing	Number of Records n=531	Estimated VA Compliance 95 Percent Confidence Interval Limits		
		Percent	Lower	Upper
Oral consent was documented prior to testing	399	75.1	71.28	78.64
Written consent was documented prior to testing	35	6.6	4.77	9.05
Consent was not documented	97	18.3	15.20	21.79

Source: CBOC/OOC cyclical inspections conducted during FY 2015 (Appendix A).

Conclusions

We estimated that the identification of a Lead HIV Clinician was found at 96.3 percent (95% CI: 88.96–98.85) of VHA facilities. We also estimated that local policies and procedures were established at 92.6 percent (95% CI: 84.09–96.75) of VHA facilities, and 83.6 percent (95% CI: 73.06–90.60) of VHA facilities required HIV screening as a component of routine care.

We estimated that 90.9 percent (95% CI: 83.10–95.30) of the VHA facilities had policies, procedures, and guidelines related to the communication of HIV test results; however, the classification of positive results varied. Additionally, for informational purposes, we estimated that 33.1 percent (95% CI: 24.20–43.39) of VHA facilities offered HIV rapid tests.

We estimated that clinicians did not offer HIV screening to 28.9 percent (95% CI: 26.99–30.98) of the outpatients reviewed, as documented in the EHRs. We estimated that informed consent was not documented for testing that occurred in 18.3 percent (95% CI: 15.20–21.79) of EHRs. These compliance rates were statistically significantly below the 90 percent benchmark.

Recommendations

1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinical staff offer HIV screening as part of routine medical care and that managers monitor compliance.

2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians document informed consent for HIV testing and that managers monitor for compliance.

Parent Facilities Reviewed

Names	Locations
Samuel S. Stratton VA Medical Center	Albany, NY
Alaska VA Healthcare System	Anchorage, AK
VA Ann Arbor Healthcare System	Ann Arbor, MI
Charles George VA Medical Center	Asheville, NC
VA Maine Healthcare System	Augusta, ME
Battle Creek VA Medical Center	Battle Creek, MI
Beckley VA Medical Center	Beckley, WV
Edith Nourse Rogers Memorial Veterans Hospital	Bedford, MA
Gulf Coast Veterans Health Care System	Biloxi, MS
VA Boston Healthcare System	Boston, MA
Ralph H. Johnson VA Medical Center	Charleston, SC
Chillicothe VA Medical Center	Chillicothe, OH
Cincinnati VA Medical Center	Cincinnati, OH
Louis A. Johnson VA Medical Center	Clarksburg, WV
William Jennings Bryan Dorn VA Medical Center	Columbia, SC
VA North Texas Health Care System	Dallas, TX
VA Illiana Health Care System	Danville, IL
Dayton VA Medical Center	Dayton, OH
Durham VA Medical Center	Durham, NC
VA New Jersey Health Care System	East Orange, NJ
Erie VA Medical Center	Erie, PA
Veterans Health Care System of the Ozarks	Fayetteville, AR
North Florida/South Georgia Veterans Health System	Gainesville, FL
VA Pacific Islands Health Care System	Honolulu, HI
Iowa City VA Health Care System	Iowa City, IA
G.V. (Sonny) Montgomery VA Medical Center	Jackson, MS
VA Southern Nevada Healthcare System	North Las Vegas, NV
VA Central Western Massachusetts Healthcare System	Leeds, MA
Central Arkansas Veterans Healthcare System	Little Rock, AR
Robley Rex VA Medical Center	Louisville, KY
William S. Middleton Memorial Veterans Hospital	Madison, WI
Manchester VA Medical Center	Manchester, NH
Marion VA Medical Center	Marion, IL

Martinsburg VA Medical Center	Martinsburg, WV
Memphis VA Medical Center	Memphis, TN
VA Hudson Valley Health Care System	Montrose, NY
Captain James A. Lovell Federal Health Care Center	North Chicago, IL
Northport VA Medical Center	Northport, NY
Oklahoma City VA Health Care System	Oklahoma City, OK
VA Nebraska-Western Iowa Health Care System	Omaha, NE
VA Palo Alto Health Care System	Palo Alto, CA
Phoenix VA Health Care System	Phoenix, AZ
VA Pittsburgh Healthcare System	Pittsburgh, PA
John J. Pershing VA Medical Center	Poplar Bluff, MO
VA Sierra Nevada Health Care System	Reno, NV
VA Roseburg Healthcare System	Roseburg, OR
Salem VA Medical Center	Salem, VA
VA San Diego Healthcare System	San Diego, CA
San Francisco VA Health Care System	San Francisco, CA
VA Puget Sound Health Care System	Seattle, WA
Mann-Grandstaff VA Medical Center	Spokane, WA
St. Cloud VA Health Care System	St. Cloud, MN
VA St. Louis Health Care System	St. Louis, MO
Central Texas Veterans Health Care System	Temple, TX
Tomah VA Medical Center	Tomah, WI
West Palm Beach VA Medical Center	West Palm Beach, FL

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: September 16, 2016

From: Under Secretary for Health (10)

Subject: Office of Inspector General (OIG) Draft Report, Community Based Outpatient Clinics (CBOC) Summary Report: Evaluation of Human Immunodeficiency Virus Screening in Veterans Health Administration Outpatient Clinics (Project No. 2015-04925-HI-0643) (VAIQ 7711023)

To: Assistant Inspector General for Health Inspections (54)

1. Thank you for the opportunity to review and comment on the draft report, Evaluation of Human Immunodeficiency Virus Screening in VHA Outpatient Clinics. The Veterans Health Administration (VHA) is strongly committed to developing long-term solutions that mitigate risks to the timeliness, cost-effectiveness, quality and safety of the Department of Veterans Affairs (VA) health care system. VHA is using the input from VA's Office of Inspector General, and other advisory groups to identify root causes and to develop critical actions. As VHA implements corrective measures, we will ensure our actions are meeting the intent of the recommendations. VHA is dedicated to sustained improvement in the high risk areas.

2. The recommendations in this report apply to GAO high risk areas 1 and 4. VHA's actions will serve to address ambiguous policies, inconsistent processes, and inadequate training for VA staff.

3. I have reviewed the draft report, and provide the attached action plan to address the report's recommendations (2).

4. If you have any questions, please email Karen M. Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

David J. Shulkin, M.D.

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, CBOC Summary Report – Evaluation of Human Immunodeficiency Virus Screening in VHA Outpatient Clinics

Date of Draft Report: June 14, 2016

Recommendations/ Actions	Status	Completion Date

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinical staff offer HIV screening as part of routine medical care and that managers monitor for compliance.

VHA Comments: Concur in principle

VHA Response:

During our review of this report and recommendations, VHA finds that our national policy may need updating because it was published 7 years ago, and the environment of Human Immunodeficiency Virus (HIV) care has continued to change during that timeframe. Rather than reinforcing old policy requirements, VHA's Office of the Deputy Under Secretary for Health for Policy and Services will convene an interdisciplinary workgroup to evaluate current Center for Disease Control recommendations, policy implementation goals, evidence of benefit to offering screening, and the impact of potential compliance monitor options on access to care. If, after review, the workgroup finds the preponderance of evidence does not demonstrate improvement in HIV outcomes from offering screening, then VHA will consider the impact of the increase in time practitioners spend documenting that they offered screening on access to care. If there is insufficient evidence to support adding another mandatory national clinical reminder to the electronic health record, VHA may opt against using public resources for a purpose that has not demonstrated health benefit to Veterans. Similarly, if the increased time required for additional documentation in the medical record negatively impacts access to care, VA may opt against added documentation and monitoring requirements in favor of getting care to more Veterans.

At completion of this action plan, VHA will provide OIG with:

1. An approved report of the findings and recommendations of the workgroup, and

2. An approved plan for implementation of any of the workgroup's recommendations that require action.

Status: In Process

Target Completion Date: December 2016

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians document informed consent for HIV testing and that managers monitor for compliance.

VHA Comments: Concur

VHA Response:

In 2009, VHA Handbook 1004.01 eliminated the signature consent requirement for HIV testing. The revised Handbook requires practitioners to document the patient or surrogate's oral informed consent for HIV testing in the record. The National Center for Ethics in Health Care (NCEHC) and the Office of Informatics and Analytics in collaboration with the HIV, Hepatitis, and Public Health Pathogens Programs (HHPHP) in the Office of Patient Care Services (PCS), designed an External Peer Review Program (EPRP) study to review consent procedures for HIV testing. EPRP data extractions in FY 2013, 2014 and 2015 show steady improvement in documentation of oral consent in outpatient settings. This study was repeated nationally in August 2016.

At completion of this action plan, VHA will provide OIG with the FY 2016 EPRP results

Status: In Process

Target Completion Date: February 2017

OIG Contact and Staff Acknowledgments

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