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**OFFICE OF
INSPECTOR GENERAL**

**HIV TESTING IN
HRSA-FUNDED
HEALTH CENTER SITES**



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EXECUTIVE SUMMARY: HIV Testing in HRSA-Funded Health Center Sites OEI-06-10-00290

WHY WE DID THIS STUDY

Health center sites funded by the Health Resources and Services Administration (HRSA) provide primary health care to millions of patients each year and are critical to efforts to test patients for human immunodeficiency virus (HIV) and reduce its spread. Since 2006, the Centers for Disease Control and Prevention (CDC) has recommended routine HIV testing—i.e., that patients be tested as a routine part of care and be told they will be tested unless they decline. This approach aims to expand testing to a wider patient population and increase testing rates. We did this study to determine the extent to which HRSA-funded sites adopted four practices that CDC recommended: (1) routine HIV testing of all patients 13–64 years of age; (2) not requiring prevention counseling for all patients; (3) gaining patient consent for the HIV test in the same way as for other screening and diagnostic tests; and (4) providing HIV tests as standard, opt-out tests.

HOW WE DID THIS STUDY

We analyzed survey responses from 324 HRSA-funded sites; the results are projectable to the estimated population of 5,275 sites that provide primary care. We determined the extent to which sites adopted the four practices and how Federal recommendations influenced their written HIV testing policies. We also asked sites to describe factors that affected their adoption of these practices and their provision of HIV testing.

WHAT WE FOUND

Health center sites have not fully adopted all four practices recommended by CDC for routine HIV testing. Regarding whom to test, for which CDC's recommendation varies according to the circumstances of individual health care providers, 20 percent of sites reported testing all patients 13–64 years of age; 1 percent tested all adults, but not teens; and 55 percent targeted testing to high-risk patients. Regarding the other three practices, 29 percent adopted the practice regarding prevention counseling; 27 percent adopted the practice regarding gaining patient consent for the HIV test; and 15 percent adopted the practice regarding providing HIV tests as standard, opt-out tests. Most sites had written HIV testing policies that were influenced by the recommendation. Factors that affected adoption of the practices and affected HIV testing at sites included the financial resources of sites and patients, existence of partnerships with other community organizations, patient and staff perceptions about patient risk of contracting HIV, and patient discomfort associated with HIV testing.

WHAT WE RECOMMEND

We recommend that HRSA require grantees to establish and report to HRSA two HIV testing metrics: prevalence and positivity, as follows: (1) grantees should establish and report the prevalence of undiagnosed HIV among their patient populations, and (2) grantees should report HIV positivity (the proportion of patients who test positive among all those tested). We also recommend that HRSA continue to provide guidance and education to grantees and sites regarding the CDC-recommended practices and HIV testing. HRSA concurred with our recommendations and described its activities to improve HIV testing in sites.

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OBJECTIVES

1. To determine the extent to which health center sites funded by the Health Resources and Services Administration (HRSA) adopted practices recommended by the Centers for Disease Control and Prevention (CDC) for routine testing for human immunodeficiency virus (HIV).
2. To determine the extent to which Federal recommendations for HIV testing influenced health center sites' written HIV testing policies.
3. To describe factors that affected adoption of the practices and affected HIV testing in health center sites.

BACKGROUND

HIV Epidemic

HIV is the virus that causes acquired immune deficiency syndrome (AIDS). In June 2012, CDC estimated that 1.2 million people in the United States were living with HIV.¹ According to CDC, nearly one in five of those people does not know his or her HIV status.² Traditionally, groups at high risk for HIV included men who have sex with men, those who have unprotected sex with people who have HIV, and those who share injection drug needles.³ However, according to CDC, the HIV epidemic has spread beyond these traditional high-risk groups. CDC states, "Since the 1980s, the demographics of the HIV epidemic in the U.S. have changed; increasing proportions of infected persons are aged [less than] 20 years, women, members of racial or ethnic minority populations, persons who reside outside metropolitan areas, and heterosexual men and women who frequently are unaware that they are at risk for HIV."⁴ The changes in the populations affected by HIV are such

¹ CDC, "Monitoring Selected National HIV Prevention and Care Objectives By Using HIV Surveillance Data—United States and 6 U.S. Dependent Areas—2010." *HIV Surveillance Supplemental Report*. June 2012. Accessed at http://www.cdc.gov/hiv/surveillance/resources/reports/2010supp_vol17no3/pdf/hssr_vol17_no_3.pdf on September 6, 2012.

² CDC, *HIV in the United States*. March 2012. Accessed at http://www.cdc.gov/hiv/resources/factsheets/PDF/HIV_at_a_glance.pdf on September 5, 2012.

³ CDC, *HIV Prevalence Among Selected Populations: High Risk Populations*. Accessed at http://www.cdc.gov/hiv/topics/testing/resources/reports/hiv_prevalence/high-risk.htm on April 25, 2012.

⁴ CDC, "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings," *Morbidity and Mortality Weekly Report*, September 22, 2006. Accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> on June 19, 2012.

that CDC no longer considers a traditional high-risk designation as the key determinant for who should receive an HIV test.

CDC's Recommendation for Routine HIV Testing

CDC's recommendations regarding HIV testing have changed in recent years. Prior to 2005, CDC recommended a focused approach to HIV testing, including targeting high-risk groups, offering prevention counseling for all patients, and gaining patient consent for tests through HIV-specific consent forms. In 2005, CDC released recommendations to certain settings and populations, including correctional facilities, emergency rooms, and obstetric patients (i.e., pregnant women). The new recommendations called for routine testing of patients in these settings and groups, a departure from CDC's prior guidance.

In 2006, CDC significantly changed its recommended approach for how primary care providers should provide HIV tests, releasing a new recommendation to expand routine testing to all health care settings. CDC recommended that HIV testing be based, in part, on prevalence of undiagnosed HIV in the patient population, rather than on patient risk factors, and encouraged adopting four specific practices:

- testing all patients aged 13–64 unless the patient has previously been tested for HIV or the prevalence of undiagnosed HIV is less than 0.1 percent, in which case routine testing is no longer warranted;
- not requiring prevention counseling for all patients;
- gaining patient consent for the HIV test in the same way as for other screening and diagnostic tests—i.e., not requiring separate consent; and
- providing HIV tests as standard, opt-out tests.⁵

CDC recommended these practices to expand HIV testing to a wider patient population, reduce the stigma that surrounds testing, and increase the number of people who know their status. CDC cited research indicating that those who know they have HIV are less likely to transmit the virus for two reasons: first, the majority of patients who learn they have HIV substantially reduce sexual behaviors that may transmit the virus, and second, patients who know they have HIV typically begin medications that combat HIV, which lowers the amount of the virus in

⁵ CDC, "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings," *Morbidity and Mortality Weekly Report*, September 22, 2006. Accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> on June 19, 2012.

their bodies and consequently reduces their risk of transmitting HIV to others.⁶ See Appendix A for full text of the 2006 CDC recommendation.

Determining Whom to Test. Providers have historically targeted HIV tests specifically to high-risk patients. Targeted testing focuses on populations that engage in high-risk behaviors, such as intravenous drug use and certain sexual activities. Because HIV has reached a broader population, CDC now recommends that primary care providers test all patients aged 13–64, with two exceptions. First, CDC notes that if the patient has previously been tested, HIV tests should be offered at clinician’s discretion. Second, CDC notes that if the prevalence of undiagnosed HIV infections in the patient population is known to be less than 0.1 percent, routine testing would no longer be recommended.⁷ According to the American College of Physicians and the HIV Medicine Association, a provider would need to test approximately 4,000 patients to establish a prevalence of undiagnosed HIV infection of less than 0.1 percent.⁸

Providing Prevention Counseling. CDC formerly encouraged—and some States required—providers to give all patients prevention counseling before administering an HIV test.^{9, 10} During such counseling, providers gave patients information about risk factors and how to prevent transmission of HIV; some providers offered personalized risk assessments.¹¹ CDC now recommends that prevention counseling not be required as a part of HIV testing. CDC cited research that found that providers perceived prevention counseling to be prohibitively time consuming, especially in busy health care settings, and that counseling

⁶ CDC, “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings,” *Morbidity and Mortality Weekly Report*, September 22, 2006. Accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> on June 19, 2010.

⁷ Ibid.

⁸ A. Qaseem; V. Snow; P. Shekelle; R. Hopkins, Jr.; and D. Owens. “Screening for HIV in Health Care Settings: A Guidance Statement From the American College of Physicians and HIV Medicine Association.” *Annals of Internal Medicine*. January 20, 2009. Accessed at <http://annals.org/article.aspx?volume=150&issue=2&page=125> on September 5, 2012.

⁹ CDC, “Technical Guidance on HIV Counseling,” *Morbidity and Mortality Weekly Report*, January 15, 1993. Accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00020645.htm> on June 19, 2012.

¹⁰ S. Neff and R. Goldschmidt, *Compendium of State HIV Testing Laws*. September 2011. Accessed at <http://www.nccc.ucsf.edu/docs/QRG.pdf> on May 17, 2012.

¹¹ CDC, *HIV Counseling with Rapid Tests*. Accessed at http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt_counseling.htm on June 14, 2012.

may limit testing because some individual providers are uncomfortable discussing patients' behaviors and risk factors.

Gaining Patient Consent. CDC previously recommended gaining patient consent for HIV tests separately from consent for other medical care; this separate consent was thought to ensure that patients would be better informed about HIV tests and that the tests would be voluntary. CDC now recommends that providers offer information about HIV and obtain consent for HIV tests in the same way as for other screening and diagnostic tests, which is expected to reduce the stigma associated with HIV testing and to increase the likelihood that patients will be tested. CDC specifically states that a separate consent form should not be required and is not recommended. In changing the recommended practice, CDC cited a study of pregnant patients in which the use of HIV-specific consent forms reduced testing rates.¹²

Offering Tests on an Opt-out Basis. Historically, providers presented HIV testing to patients as an elective medical test, asking whether they wanted the test. This practice is known as opt-in testing. CDC now recommends that providers present HIV tests as a standard practice for all patients unless a patient specifically declines. This practice is known as opt-out testing. CDC cites research indicating that making HIV tests standard can increase the number of people who know their HIV status, identify HIV-infected persons earlier in the disease's development, reduce stigma associated with HIV testing, and lead to increased acceptance of HIV testing as a standard of care.

Other Federal and State Guidelines

Other entities, such as a Federal task force and some States, have requirements or recommendations that conflict with some CDC-recommended practices. For example, the United States Preventive Services Task Force (USPSTF)—an independent body that provides guidance on many health care matters—currently recommends targeted HIV testing for high-risk groups, but released draft recommendations for widespread screening in November 2012.¹³ Additionally, research

¹² CDC, "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings," *Morbidity and Mortality Weekly Report*, September 22, 2006. Accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> on June 19, 2010.

¹³ USPSTF, *Screening for HIV*. April 2007. Accessed at <http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm> on September 5, 2012. The USPSTF released draft recommendations on the topic November 20, 2012, recommending that clinicians screen patients ages 15 to 65 years for HIV infection.

indicates that as late as 2011, four States had laws requiring that patients sign a separate written consent form specifically for an HIV test.

HRSA-Funded Health Center Sites

HRSA funds grantees that administer four different types of health centers: community health, migrant health, health care for the homeless, and public housing primary care, collectively referred to as “health center sites.” Such health center sites provide primary health care to millions of patients each year and are critical to efforts to increase HIV testing. Health center sites provide access to health care services for people who are uninsured or publicly insured; geographically isolated; or otherwise medically vulnerable, including populations that are disproportionately affected by HIV, such as homeless persons, African Americans, and Hispanics/Latinos.^{14, 15, 16, 17, 18, 19}

During 2011, health center sites provided services to more than 17 million patients.²⁰ The American Recovery and Reinvestment Act of 2009 (ARRA) and the Patient Protection and Affordable Care Act of 2010 (ACA) increased health center funding.^{21, 22} Estimates indicate that combined, these additional funds will enable health centers to greatly increase the number of patients served.^{23, 24}

¹⁴ National Alliance to End Homelessness (NAEH), *Fact Sheet: Homelessness and HIV/AIDS*. Accessed at <http://www.endhomelessness.org/content/article/detail/1073> on June 12, 2012.

¹⁵ United States Census Bureau, *State and County Quick Facts*. Accessed at <http://quickfacts.census.gov/qfd/states/00000.html> on June 12, 2012.

¹⁶ NACHC, *America’s Health Centers* (fact sheet). Accessed at <http://www.nachc.com/client/documents/America's%20Health%20Centers%20Fact%20Sheet%20August%202011.pdf> on June 12, 2012.

¹⁷ CDC, *HIV/AIDS Among African Americans*. Accessed at <http://www.cdc.gov/hiv/topics/aa/resources/factsheets/aa.htm> on June 12, 2012.

¹⁸ CDC, *HIV/AIDS Among Hispanics/Latinos*. Accessed at <http://www.cdc.gov/hiv/hispanics/resources/factsheets/hispanic.htm> on June 12, 2012.

¹⁹ HRSA, *About HRSA*, Accessed at <http://www.hrsa.gov/about/index.html> on June 19, 2012.

²⁰ Office of Inspector General discussion with HRSA officials, June 26, 2012.

²¹ ARRA, P.L. 111-5, Division A, Title VIII. In 2009, Congress appropriated a one-time direct investment of \$2 billion in supplemental funding specifically for health centers.

²² ACA, P.L. 111-148 § 10503, Public Health Service Act § 330. The ACA created the Community Health Centers Trust Fund and appropriated \$11 billion in funding over 5 years for the health center program.

²³ NACHC, *Community Health Centers and Health Reform*. Accessed at <http://www.nachc.com/client/Summary%20of%20Final%20Health%20Reform%20Package.pdf> on June 12, 2012.

²⁴ U.S. Department of Health and Human Services (HHS), *Fiscal Year 2013, Budget in Brief*. Accessed at <http://www.hhs.gov/budget/budget-brief-fy2013.pdf> on September 27, 2012.

HIV Testing in Health Center Sites

The rates of HIV testing reported by health center sites have increased slightly in recent years. In 2006, CDC found that HIV tests conducted in community clinics (which include HRSA-funded health center sites examined in this report) diagnosed 21 percent of all new HIV infections, yet only 5 percent of community clinic patients were tested that year.²⁵ In 2011, 5 years after CDC released its recommendation for routine HIV testing, HRSA reported slightly higher annual testing rates. Specifically, in 2011, 7.4 percent of health center grantee patients aged 13–64 years—the age group that CDC recommends for routine HIV testing—received HIV tests at health center sites, up from 5.8 percent in 2010.²⁶

Federal regulations do not require HRSA-funded health centers to offer HIV tests at each site. Rather, HRSA requires that a grantee either offer HIV testing in some or all of its health center sites or refer patients to other health care providers for HIV tests. Additionally, HRSA requires each grantee to report into the Uniform Data System (UDS) the number of HIV tests provided in its health center sites each year.²⁷ HRSA also requires those grantees that receive funding through the Ryan White HIV/AIDS Program (about 14 percent of health center grantees) to track certain performance measures regarding HIV testing and care.²⁸ However, this requirement does not cover health center grantees that do not receive such funding. Additionally, HRSA has indicated plans to require that grantees report HIV positivity, which is one of the core indicators for

²⁵ The Forum for Collaborative HIV Research, *Metrics and Evaluation Measures for Monitoring the Implementation of Routine HIV Testing in the U.S.*, April 23, 2009. Accessed at http://www.hivforum.org/storage/hivforum/documents/metrics/hiv_testing_metrics_report_12.14.09.pdf on May 23, 2012.

²⁶ Office of Inspector General Staff discussion with HRSA officials, June 26, 2012. Patients may have also received HIV tests before or after the 2011 time period included in this 7.4-percent statistic or may have received HIV tests in other health care settings.

²⁷ HRSA, *Health Center Data*. Accessed at <http://bphc.hrsa.gov/healthcenterdatastatistics/reporting/index.html> on May 3, 2012.

²⁸ HRSA, *HAB [HIV/AIDS Bureau], HIV Performance Measures*. Accessed at <http://hab.hrsa.gov/deliverhivaidscares/habperformmeasures.html> on May 17, 2012. The Ryan White HIV/AIDS Program provides HIV-related services to people who do not have the financial resources or sufficient health care coverage for coping with the disease.

monitoring HHS-funded HIV prevention, treatment, and care services.^{29, 30}

HRSA has promoted the CDC recommendation for routine HIV testing as well as other initiatives that encourage HIV testing. In September 2010, HRSA released a Program Assistance Letter summarizing current CDC-recommended practices for HIV testing and providing additional resources for health centers that seek to increase HIV testing. In January 2011, HRSA hosted a technical assistance call with health center grantees to discuss the Office of National AIDS Policy's (ONAP) National HIV/AIDS Strategy and HRSA's plans to enhance HIV care at health center sites.³¹

Some HRSA-funded health centers receive HIV-related guidance and funding from other organizations. For example, NACHC provides health centers with guidance on routine HIV testing.³² Additionally, health centers may receive special funding for HIV testing under CDC's Expanded HIV Testing for Disproportionately Affected Populations Initiative; the Enhanced Comprehensive HIV Prevention Plan (ECHPP), a project that supports HIV services for health centers in the 12 cities most affected by the HIV epidemic; and the Ryan White HIV Program for early intervention services, which include HIV testing.^{33, 34, 35}

METHODOLOGY

Scope

This report provides information about HIV testing practices at HRSA-funded health center sites as reported in 2011. We examined the health center sites' adoption of the four testing-related practices specified in CDC's 2006 recommendation for routine HIV testing, the reported

²⁹ HIV positivity is the number of positive HIV tests divided by the number of all HIV tests administered.

³⁰ The White House Office of National AIDS Policy Blog. *Secretary Sebelius Approves Indicators for Monitoring HHS-Funded HIV Services*. Accessed at <http://blog.aids.gov/2012/08/secretary-sebelius-approves-indicators-for-monitoring-hhs-funded-hiv-services.html> on September 18, 2012.

³¹ ONAP, *National HIV/AIDS Strategy for the United States*, July 2010. Accessed at www.whitehouse.gov on May 17, 2011.

³² NACHC, *HIV Screening Model for Primary Care*. Accessed at <http://www.nachc.com/hivmodel.cfm> on May 16, 2012.

³³ The 12 ECHPP cities are Atlanta; Baltimore; Chicago; Dallas; Houston; Los Angeles; Miami; New York City; Philadelphia; San Francisco; San Juan; and Washington, D.C.

³⁴ CDC, Funding Opportunity Announcement PS10-10138: *Expanded HIV Testing for Disproportionately Affected Populations*. Accessed at <http://www.cdc.gov/hiv/topics/funding/ps10-10138/index.htm> on May 16, 2012.

³⁵ HRSA, *The Ryan White HIV/AIDS Program, Part C*. Accessed at <http://hab.hrsa.gov/livinghistory/programs/Part-C.htm> on May 16, 2012.

influence of Federal recommendations on health center sites' written HIV testing policies and practices, and factors that affected the adoption of the practices and affected HIV testing. The health center site responses regarding testing practices are projectable to all HRSA-funded health center sites providing primary care in 2010.

Sample

HRSA data indicate that 8,144 health center sites received funding in November 2010. We selected a simple random sample of 500 health center sites from these.

Data Collection

To determine the extent to which HRSA-funded health center sites that provide primary care adopted the CDC-recommended practices for routine HIV testing, we surveyed 500 health center sites about their HIV testing practices during May–November 2011. During data collection, we excluded 149 of the 500 sampled health center sites because they did not provide primary care, they were no longer in operation, or their associated health center grantees did not respond to our inquiries. For example, some health center sites provided only dental or gynecological services and other health center sites had closed. We received responses from 324 of the eligible 351 health center sites, a 92-percent response rate. To encourage responses, we sent emails and postcards to health center sites and made a minimum of three phone calls. The study results are projectable to the estimated population of 5,275 HRSA-funded health center sites that provide primary health care.

Data Analysis

We analyzed survey responses to determine HRSA-funded health center sites' HIV testing practices. We used the following criteria to calculate adoption rates for each of the four CDC-recommended practices for routine HIV testing:

Determining Whom To Test. On the basis of the wording of the CDC recommendation regarding determining which patients to offer HIV tests, we categorized health center sites into three groups:

- 1) The first group consists of health center sites that provided HIV tests only to patients who requested a test and/or patients who showed symptoms of HIV. This group is too limited to be aligned with the CDC recommendation for routine testing.
- 2) We identified a second group of health center sites that offered tests to patients with certain risk factors, which CDC recommends is appropriate only for patients who have previously been tested for HIV and in health care facilities that have established a prevalence

of undiagnosed HIV of less than 0.1 percent among their patient populations.

- 3) The third group consists of health center sites that tested all patients 13–64 years of age, without taking into account patient-specific risk factors. CDC recommends that most health care facilities follow this testing pattern.

Providing Prevention Counseling. Regarding prevention counseling, we considered all health center site responses to be in alignment with the CDC recommendation unless the health center site indicated that it provided prevention counseling to all patients, which CDC specifically does not recommend.

Gaining Patient Consent. Regarding gaining patient consent, we considered all health center site responses to be in alignment with the CDC recommendation unless the health center site indicated that it used a separate written consent form, which CDC specifically does not recommend.

Offering Tests on an Opt-out Basis. Regarding offering tests on an opt-out basis, we considered all health center site responses to be in alignment with the CDC recommendation unless the health center site indicated that it required some or all patients to specifically indicate that they wanted an HIV test, which CDC refers to as “opt-in” testing.

We also determined whether health center sites had written HIV testing policies and examined factors that affected the adoption of each recommended practice, such as whether health center sites received funding specific to HIV testing or partnered with other organizations in the community. See Appendix B for estimates and confidence intervals.

Limitations

We did not verify the accuracy of the information provided by health center sites. However, we attempted to identify inconsistencies, unclear responses, abbreviated responses, and indications that the respondent may have misunderstood the question. We resolved these issues when possible and in some cases followed up with respondents to clarify. Additionally, respondents often described patient perceptions and behaviors. However, we did not verify with patients that the respondents’ descriptions of their perceptions or behaviors were accurate.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Health center sites have not fully adopted all four CDC-recommended practices.

Ninety percent of HRSA-funded health center sites offered HIV testing but had not fully adopted all four of CDC's recommended practices. The remaining 10 percent, which did not offer HIV testing, typically referred patients to other providers, such as local health departments, for HIV tests.

Determining Whom To Test. Twenty percent of health center sites that offered HIV tests reported testing all patients 13–64 years of age. CDC recommends this approach in health center sites that have not established a prevalence of undiagnosed HIV of less than 0.1 percent in their patient populations and for patients not previously tested for HIV. An additional 1 percent reported testing all adults, but not teens. Fifty-five percent targeted high-risk patients, such as those with histories of injection drug use. This approach aligns with the USPSTF recommendation and is consistent with the CDC-recommended practice if patients have previously been tested for HIV or if health center sites have established a prevalence of undiagnosed HIV of less than 0.1 percent in their patient populations. However, few health center sites in our sample reported testing enough patients to establish their prevalence of undiagnosed HIV.³⁶ The remaining 24 percent of sites offered HIV tests only when patients requested a test or had symptoms of HIV or took some other approach.

Health center sites that reported testing all patients aged 13–64 also reported additional practices that suggest they have a greater focus on HIV prevention and care than other health center sites. For example, these health center sites were more likely to report that they have written HIV testing policies regarding who should receive an HIV test.³⁷ They were

³⁶ Many health center sites in this group likely are not aligned with this CDC-recommended practice because they have not tested enough patients to establish a prevalence of undiagnosed HIV of less than 0.1 percent in their patient populations. CDC recommends this practice if the HIV-positive diagnostic yield is less than 1 per 1,000 patients tested. In our sample, 216 health center sites reported the number of HIV tests they had conducted; only 15 had performed at least 1,000 tests during our review period.

³⁷ Sixty-six percent of health center sites that tested all patients 13–64 years of age had written HIV testing policies, whereas only 38 percent of health center sites that did not test all such patients had written HIV testing policies. This difference is statistically significant ($p < 0.0001$). The 95-percent confidence interval for the 66-percent estimate is 54.0–78.2 percent.

also more likely than other health center sites to report offering care to patients already infected with HIV.³⁸

Providing Prevention Counseling. Twenty-nine percent of health center sites that offered HIV testing adopted the CDC recommendation of not requiring prevention counseling for every patient. The remaining 71 percent provided prevention counseling to all patients either before or after their HIV tests. CDC recommends that prevention counseling not be required as a part of HIV screening programs. A goal of this recommended practice is to reduce counseling time and thereby reduce the time required to provide HIV tests in busy health care settings. Accordingly, providers in health center sites that encourage providers to determine appropriate prevention counseling spent less time providing counseling to patients than providers in other health center sites.³⁹

Gaining Patient Consent. Twenty-seven percent of health center sites that offered HIV testing gained consent for such tests in the same way as for other screening and diagnostic tests, a practice that CDC recommends to reduce the stigma associated with HIV tests. The remaining 73 percent used a separate form to gain consent for HIV tests as either one method for gaining consent (54 percent) or as the only method for gaining consent (19 percent). CDC recommends that providers gain patient consent for an HIV test through general consent for medical care, regardless of whether consent is written or verbal, and specifies that it does not recommend a separate consent form for HIV testing.

Offering Tests on an Opt-out Basis. Fifteen percent of health center sites that offered HIV testing provided HIV tests as standard, opt-out tests. The remaining 85 percent did not adopt opt-out HIV testing. Specifically, 49 percent offered only opt-in testing, which required patients to indicate that they wanted an HIV test. The other 36 percent offered HIV testing using a combination of the two approaches, allowing individual providers to determine whether to provide HIV testing on an opt-in or opt-out basis. Health center sites that offered HIV tests as standard, opt-out tests were

³⁸ Fifty-four percent of health center sites that tested all patients 13–64 years of age provided HIV care, whereas 23 percent of health center sites that did not test all such patients provided HIV care. This difference is statistically significant ($p < 0.0001$). The 95-percent confidence interval for the 54-percent estimate is 41.6–66.9 percent.

³⁹ Of health center sites that did not require prevention counseling for all patients, 25 percent reported that providers spent 5 minutes or more counseling patients. By comparison, 57 percent of health center sites that provided prevention counseling to all patients before or after an HIV test also reported that providers spent 5 minutes or more counseling patients. This difference is statistically significant ($p < 0.0001$).

more likely than other health center sites to report increases in HIV testing over the last 5 years.⁴⁰

The CDC recommendation influenced most health center sites' written HIV testing policies

Most health center sites—76 percent—reported having written HIV testing policies. Their written policies covered topics such as gaining consent, prevention counseling, and patients who should be tested.⁴¹ Even though health center sites had not fully adopted all four CDC-recommended practices, 84 percent reported that CDC's recommendation influenced their written HIV testing policies. Ninety percent reported updating their policies since 2006, the year CDC released its routine testing recommendation. Health center sites with written HIV testing policies reported that their policies were also influenced by Federal recommendations issued by the USPSTF (15 percent) and by other organizations, including the American Medical Association (7 percent) and the World Health Organization (2 percent).

Health center sites reported that financial resources and other factors affected adoption of the CDC-recommended practices and affected HIV testing

Health center sites reported factors that affected their adoption of the CDC-recommended practices and that more generally affected their HIV testing.

Financial resources. Forty-three percent of health center sites reported that they received funding specifically for HIV testing, from sources such as CDC and the Ryan White program. Health center sites that received funding for HIV testing were more likely to adopt two of the four CDC-recommended practices for HIV testing. These health center sites were more likely to adopt the practice of testing all patients 13–64 years of

⁴⁰ Seventy-two percent of health center sites that offered opt-out HIV tests reported that HIV testing had increased over the past 5 years. In comparison, 48 percent of other health center sites reported increased testing over the past 5 years. This difference is statistically significant ($p < 0.0001$). The 95-percent confidence interval for the 72-percent estimate is 58.6–85.6 percent.

⁴¹ The remaining 24 percent of health center sites reported that they did not have written policies or other written guidance regarding HIV testing.

age and to offer tests on an opt-out basis than those that did not receive HIV-specific funding.^{42, 43}

Further, health center sites also reported that lack of resources on the part of both patients and health center sites limited HIV testing. For example, 32 percent of health center sites reported that they can offer only a limited number of free or reduced-cost tests, and 24 percent reported that patients often could not afford to pay for testing themselves. Respondents from one health center site reported that patients who were not eligible for free HIV tests were unlikely to pay for tests, and respondents from another health center site reported that patients had difficulty paying even the small office visit fee, let alone an additional testing fee.

Existence of Partnerships. Forty-three percent of health center sites reported working with other organizations in their communities to combat HIV. This activity was associated with the practice of testing all patients aged 13–64.⁴⁴ Partner organizations worked with health center sites on efforts such as providing testing, increasing community awareness of HIV, improving community planning for HIV prevention, and reducing HIV transmission in the community. Health center sites reported partnering with other organizations including State and local health departments, local Ryan White programs, universities, churches, and homeless clinics on yearly events, such as National HIV Testing Day, and at seasonal events, such as local health fairs, as well as on collaborating on long-term planning through HIV reduction task forces and consortiums.

Perception of Risk. Health center sites reported that patient and staff perception of low patient risk for HIV limited HIV testing. Although some patients may accurately perceive themselves to be at low risk, the

⁴² Sixty-eight percent of health center sites that tested all patients aged 13–64 also reported that they received funding specifically for HIV testing. In comparison, 37 percent of health center sites that did not test all such patients received funding. This difference was statistically significant ($p < 0.0001$). The 95-percent confidence interval for the 68-percent estimate is 55.9–79.7 percent.

⁴³ Health center sites that offered HIV testing on an opt-out basis reported receiving funding specifically for HIV testing, a resource that may allow for greater adoption of this recommended practice. Specifically, 63 percent of health center sites that offered tests on an opt-out basis received HIV-specific funds. In comparison, 40 percent of health center sites that required patients to request an HIV test also received HIV-specific funds. This difference was statistically significant ($p < 0.0001$). The 95-percent confidence interval for the 63-percent estimate is 48.2–77.4 percent.

⁴⁴ Sixty-one percent of health center sites that tested all patients 13–64 years of age also partnered with organizations in their communities to promote HIV awareness. In comparison, 40 percent of health center sites that did not test all such patients partnered with others in their communities. This difference was statistically significant ($p < 0.0001$). The 95-percent confidence interval for the 61-percent estimate is 48.6–73.4 percent.

HIV epidemic has broadened and patients not considered high risk may still be infected. However, 60 percent of health center sites reported that they believed their patients did not perceive themselves to be at risk, and most of these health center sites also reported that their staffs did not perceive the centers' patient populations to be at high risk. Health center sites that do not perceive their patient populations to be at high risk may not believe that routine testing is appropriate. In many cases, health center site respondents attributed staff and patient perception of HIV risk to a lack of education about HIV and lack of awareness that the effectiveness of testing on the basis of patient risk factors has diminished.

Patient comfort. Health center sites also reported that they perceive patients as being uncomfortable requesting an HIV test or receiving test results. Specifically, 38 percent of health center sites reported that patients were not comfortable requesting an HIV test and that this limited testing in the health center sites. Respondents from several health center sites explained that patients often appeared concerned that their requests for HIV testing or their test results would not remain confidential. For example, respondents from a health center site in a small community reported that patients might be inhibited from discussing HIV testing because the office staff know most people in the community. Another 20 percent of health center sites reported that patients were not willing to wait or return for HIV test results. Several health center sites reported that patients do not wait or return because they are afraid to learn that they may be infected. For example, respondents from one health center site reported that some patients would rather not know their HIV status and that they were likely unaware of the treatments available and the extended life expectancy once treatment begins.

CONCLUSION AND RECOMMENDATIONS

HRSA-funded health center sites provide primary health care to millions of patients each year and are critical to efforts to test patients and reduce the spread of HIV. CDC estimates that one in five people in the United States who are living with HIV do not know their HIV status and, therefore, are more likely to transmit the disease to others. CDC recommends that health care facilities determine their HIV testing approaches on the basis of data and evidence about the prevalence of undiagnosed HIV in the patient population. CDC also recommends four key practices for HIV testing.

Health center sites have not fully adopted all four of CDC's recommended practices. Most had written HIV testing policies influenced by CDC's routine testing recommendation. Health center sites reported that several factors influenced their adoption of the recommended practices and affected their HIV testing, such as financial resources, existence of partnerships with others in their communities, patient and staff perception of patient risk of contracting HIV, and patient comfort in requesting tests and hearing test results.

We recommend that HRSA:

Require health center grantees to establish and report to HRSA two relevant HIV testing metrics: prevalence and positivity

CDC recommends HIV testing that is based, in part, on prevalence of undiagnosed HIV in the patient population. HRSA should require health center grantees to determine the prevalence of undiagnosed HIV in their patient populations and report this to HRSA. Additionally, recognizing that some grantees will establish prevalence more quickly than others, HRSA should require grantees to report to it regarding their progress toward establishing prevalence. CDC indicates that once a grantee tests enough patients to establish a prevalence of less than 0.1 percent, routine testing is no longer warranted. However, few health center sites in our sample reported testing enough patients to establish their prevalence of undiagnosed HIV, suggesting that a HRSA requirement is needed to make progress toward identifying which health center sites should routinely perform HIV tests.

As health center grantees work toward establishing the prevalence of undiagnosed HIV in their patient populations, they should also report to HRSA their HIV positivity—the number of positive HIV tests divided by the number of all HIV tests administered. HRSA already requires each grantee to enter into the UDS the number of HIV tests provided in the grantee's health center sites each year. However, HRSA does not collect

information about how many of those HIV tests resulted in HIV-positive diagnoses. Recently, HHS released seven core indicators for monitoring HHS-funded HIV prevention, treatment, and care, including HIV positivity. Required reporting of HIV positivity would align data collection by HRSA health center grantees with that of other HHS-funded HIV programs and services. Further, required reporting would raise awareness of HIV testing among health center sites that are critical to reducing the spread of HIV.

Provide additional guidance and education regarding the CDC-recommended practices and HIV testing

HRSA provided guidance regarding the CDC-recommended practices through AIDS Education and Training Centers and a Program Assistance Letter and provided education about HIV testing through a technical assistance call with health center grantees. However, our findings suggest that more guidance and education regarding these practices and HIV testing is needed. HRSA could provide guidance and education by making additional technical assistance calls, issuing program assistance letters, and offering additional training sessions and educational opportunities to health center grantees and sites. Guidance should include methods for establishing prevalence and for determining HIV positivity. The guidance should include strategies regarding how to incorporate the recommended practices into written HIV testing policies and into primary care services. HRSA guidance should also encourage health center sites to partner with other organizations in their communities and to raise awareness among patients and staff about patient risk for HIV infection.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

HRSA concurred with our recommendations and described past and current activities to improve HIV testing in health centers. Regarding the first recommendation to establish and report metrics for HIV testing, HRSA stated that it will begin collecting HIV positivity rates as part of health centers' annual UDS reports. HRSA also stated that it will work with CDC to assess HIV prevalence rates in health center service areas. Regarding the second recommendation to provide additional guidance and education, HRSA stated it that it will continue to support health centers by developing new resources and enhancing existing resources.

We did not make any changes to the report on the basis of HRSA's comments. For the full text of HRSA's comments, see Appendix C.

APPENDIX A

Centers for Disease Control and Prevention's Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings⁴⁵

Recommendations for Adults and Adolescents

CDC recommends that diagnostic HIV testing and opt out HIV screening be a part of routine clinical care in all health-care settings while also preserving the patient's option to decline HIV testing and ensuring a provider-patient relationship conducive to optimal clinical and preventive care. The recommendations are intended for providers in all health-care settings, including hospital EDs [emergency departments], urgent-care clinics, inpatient services, STD [sexually transmitted disease] clinics or other venues offering clinical STD services, tuberculosis (TB) clinics, substance abuse treatment clinics, other public health clinics, community clinics, correctional health-care facilities, and primary care settings. The guidelines address HIV testing in health-care settings only; they do not modify existing guidelines concerning HIV counseling, testing, and referral for persons at high risk for HIV who seek or receive HIV testing in nonclinical settings (e.g., community based organizations, outreach settings, or mobile vans).

Screening for HIV Infection

- In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13–64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.
- All patients initiating treatment for TB should be screened routinely for HIV infection.
- All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a

⁴⁵ The material in this appendix is quoted directly from Centers for Disease Control and Prevention (CDC), "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings," *Morbidity and Mortality Weekly Report*, September 22, 2006. Accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> on June 19, 2012.

new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.

Repeat Screening

- Health-care providers should subsequently test all persons likely to be at high risk for HIV at least annually. Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM [men who have sex with men] or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.
- Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship.
- Repeat screening of persons not likely to be at high risk for HIV should be performed on the basis of clinical judgment.
- Unless recent HIV test results are immediately available, any person whose blood or body fluid is the source of an occupational exposure for a health-care provider should be informed of the incident and tested for HIV infection at the time the exposure occurs.

Consent and Pretest Information

- Screening should be voluntary and undertaken only with the patient's knowledge and understanding that HIV testing is planned.
- Patients should be informed orally or in writing that HIV testing will be performed unless they decline (opt out screening). Oral or written information should include an explanation of HIV infection and the patient should be offered an opportunity to ask questions and to decline testing. With such notification, consent for HIV screening should be incorporated into the patient's general informed consent for medical care on the same basis as are other screening or diagnostic tests; a separate consent form for HIV testing is not recommended.
- Easily understood informational materials should be made available in the languages of the commonly encountered populations within the service area. The competence of interpreters and bilingual staff to provide language assistance to patients with limited English proficiency must be ensured.
- If a patient declines an HIV test, this decision should be documented in the medical record.

Diagnostic Testing for HIV Infection

- All patients with signs or symptoms consistent with HIV infection or an opportunistic illness characteristic of AIDS should be tested for HIV.
- Clinicians should maintain a high level of suspicion for acute HIV infection in all patients who have a compatible clinical syndrome and who report recent high-risk behavior. When acute retroviral syndrome is a possibility, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection.
- Patients or persons responsible for the patient's care should be notified orally that testing is planned, advised of the indication for testing and the implications of positive and negative test results, and offered an opportunity to ask questions and to decline testing. With such notification, the patient's general consent for medical care is considered sufficient for diagnostic HIV testing.

Similarities and Differences Between Current and Previous Recommendations for Adults and Adolescents

Aspects of these recommendations that remain unchanged from previous recommendations are as follows:

- HIV testing must be voluntary and free from coercion. Patients must not be tested without their knowledge.
- HIV testing is recommended and should be routine for persons attending STD clinics and those seeking treatment for STDs in other clinical settings.
- Access to clinical care, prevention counseling, and support services is essential for persons with positive HIV test results.

Aspects of these recommendations that differ from previous recommendations are as follows:

- Screening after notifying the patient that an HIV test will be performed unless the patient declines (opt-out screening) is recommended in all health-care settings. Specific signed consent for HIV testing should not be required. General informed consent for medical care should be considered sufficient to encompass informed consent for HIV testing.
- Persons at high risk for HIV should be screened for HIV at least annually.
- HIV test results should be provided in the same manner as results of other diagnostic or screening tests
- Prevention counseling should not be required as a part of HIV screening programs in health-care settings. Prevention counseling is strongly

encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely (e.g., STD clinics) but should not have to be linked to HIV testing.

- HIV diagnostic testing or screening to detect HIV infection earlier should be considered distinct from HIV counseling and testing conducted primarily as a prevention intervention for uninfected persons at high risk.

APPENDIX B

Table B-1: Point Estimates and Confidence Intervals

Estimate Characteristic	Sample Size	Point Estimate	95-percent Confidence Interval	
			Lower	Upper
Offered HIV tests	324	89.8%	85.9%	92.9%
Rates of Adoption of Routine HIV Testing Practices Among Health Center Sites That Offered Testing				
Determining Whom To Test				
Tested all patients aged 13–64*	289	20.4%	15.9%	25.5%
<i>Had a written HIV testing policy</i>	59	66.1%	54.0%	78.2%
<i>Offered HIV care</i>	59	54.2%	41.6%	66.9%
Tested all adults	289	1.0%	0.2%	3.0%
Tested and targeted high-risk patients *	289	54.7%	49.1%	60.3%
Tested only when patients requested or had symptoms	289	22.8%	18.1%	28.1%
Tested on the basis of some other approach	289	1.0%	0.2%	3.0%
Did not test all patients aged 13–64**	289	79.6%	74.5%	84.1%
<i>Had a written HIV testing policy</i>	230	37.6%	31.4%	43.7%
<i>Offered HIV care</i>	230	23.0%	17.7%	29.1%
Providing Prevention Counseling				
Did not require prevention counseling for all patients *	286	28.7%	23.6%	33.8%
<i>Spent 5 minutes or more counseling</i>	67	25.4%	15.0%	35.7%
Provided prevention counseling for all patients before or after HIV tests	286	71.3%	66.2%	76.4%
<i>Spent 5 minutes or more counseling</i>	202	56.9%	50.3%	63.6%
Gaining Patient Consent				
Gained patient consent with consent for all medical care *	287	26.8%	21.8%	31.8%
Gained patient consent only through a separate HIV-specific written consent form	287	19.2%	14.8%	24.2%
Gained patient consent through a separate HIV-specific written consent along with other methods	287	54.0%	48.4%	59.6%

* Indicates a practice recommended by the Centers for Disease Control and Prevention (CDC).

** Indicates a practice recommended by CDC if patients have previously been tested for HIV or if prevalence of undiagnosed HIV infection is less than 0.1 percent.

Continued on next page

Estimate Characteristic	Sample Size	Point Estimate	95-percent Confidence Interval	
			Lower	Upper
Offering Tests on an Opt-Out Basis				
Provided HIV tests as standard, opt-out tests *	288	14.9%	11.0%	19.6%
<i>Reported increased testing</i>	43	72.1%	58.6%	85.6%
Did not provide HIV tests as standard, opt-out tests	288	85.1%	82.5%	90.2%
<i>Offered tests on an opt-in basis</i>	288	48.9%	43.3%	54.6%
<i>Used a combination of opt-out and opt-in approaches</i>	288	35.8%	30.4%	41.2%
<i>Reported increased testing</i>	245	47.8%	41.7%	53.9%
Health Center Site HIV Testing Policies				
Health center site had a written HIV testing policy	324	75.6%	70.6%	80.2%
<i>HIV testing policy was influenced by CDC recommendation</i>	245	83.7%	78.4%	88.1%
<i>HIV testing policy had been updated since 2006</i>	245	89.8%	85.3%	93.3%
<i>HIV testing policy was influenced by the United States Preventive Services Task Force</i>	245	15.1%	10.9%	20.2%
<i>HIV testing policy was influenced by the American Medical Association</i>	245	6.9%	4.1%	10.9%
<i>HIV testing policy was influenced by the World Health Organization</i>	245	1.6%	0.5%	4.1%
Health center site did not have a written HIV testing policy	324	24.4%	19.8%	29.4%
Health Center Site-Identified Factors That Affected Adoption of CDC-Recommended Practices and HIV Testing				
Received HIV-specific funding	324	43.2%	37.9%	48.5%
<i>Tested all patients 13–64 years of age</i>	140	67.8%	55.9%	79.7%
<i>Did not test all patients 13–64 years of age</i>	140	36.9%	30.8%	43.0%
<i>Offered HIV tests as standard, opt-out</i>	140	62.8%	48.2%	77.4%
<i>Did not offer HIV tests as standard, opt-out</i>	140	40.3%	34.4%	46.3%
Reported that ability to offer only a limited number of free or reduced-cost tests affected HIV testing	331	31.7%	26.8%	36.6%
Reported that patients often could not afford to pay for an HIV test	329	24.0%	19.5%	29.0%
Partnered with others in the community	321	42.6%	37.4%	47.9%
<i>Tested all patients 13–64 years of age</i>	137	61.0%	48.6%	73.4%
<i>Did not test patients 13–64 years of age</i>	137	40.1%	33.9%	46.3%

* Indicates a practice recommended by CDC.

Continued on next page

Estimate Characteristic	Sample Size	Point Estimate	95-percent Confidence Interval	
			Lower	Upper
Identified perception of risk as a factor	324	59.7%	54.6%	64.8%
<i>Patients not comfortable requesting an HIV test</i>	324	37.7%	32.7%	42.8%
<i>Patients not willing to wait or return for test results</i>	324	20.2%	16.0%	25.0%

Source: Office of Inspector General (OIG) analysis of responses from Health Resources and Services Administration (HRSA)-funded health center sites, 2012.

Table B-2: Comparison of Site Characteristics

Comparison of Site Characteristics	Sample Size	Z Value	P Value*
Sixty-six percent of health center sites that tested all patients 13–64 years of age had written HIV testing policies, whereas 38 percent of health center sites that did not test all such patients had written HIV testing policies.	125	16.97	<0.0001
Fifty-four percent of health center sites that tested all patients 13–64 years of age provided HIV care, whereas 23 percent of health center sites that did not test all such patients provided HIV care.	84	8.81	<0.0001
Of health center sites that did not require prevention counseling for all patients, 25 percent reported that providers spent 5 minutes or more counseling patients, whereas 57 percent of health center sites that provided prevention counseling to all patients before or after an HIV test also reported that providers spent 5 minutes or more counseling patients.	132	34.4	<0.0001
Seventy-two percent of health center sites that offered opt-out HIV tests reported that HIV testing had increased over the past 5 years, whereas 48 percent of other health center sites reported increased testing over the past 5 years.	149	28.76	<0.0001
Sixty-eight percent of health center sites that tested all patients aged 13–64 also reported that they received funding specifically for HIV testing, whereas 37 percent of health center sites that did not test all such patients received such funding.	125	16.24	<0.0001
Sixty-three percent of health center sites that offered tests on an opt-out basis received funding specifically for HIV testing, whereas 40 percent of health center sites that required patients to request an HIV test received such funding.	127	16.24	<0.0001
Sixty-one percent of health center sites that tested all patients 13–64 years of age partnered with organizations in their communities to promote HIV awareness, whereas versus 40 percent of health center sites that did not test all such patients had such partnerships.	127	19.7	<0.0001

*A p value of less than 0.01 indicates a statistically significant difference.

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville MD 20857

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TO: Daniel R. Levinson
Inspector General, HHS OIG

FROM: Administrator, HRSA

SUBJECT: OIG Draft Report Comments: HIV Testing in HRSA-Funded Health Center Sites,
OEI-06-10-00290

In response to OIG's request for comments on the draft report, "HIV Testing in HRSA-Funded Health Center Sites," OEI-06-10-00290, attached are the Health Resources and Services Administration's (HRSA) remarks with actions to OIG's recommendations.

If you have any questions, please contact Angela Landeen in HRSA's Office of Planning, Analysis, and Evaluation at 301-443-1550.

/s/

Mary K. Wakefield, Ph.D., R.N.

Attachments
Tab A: HRSA Response to Draft Report
Tab B: OIG Draft Report

**Health Resources and Services Administration's Comments on the Office of the Inspector
General Draft Report "HIV Testing in HRSA-Funded Health Center Sites"
(OEI-06-10-00290)**

The Health Resources and Services Administration (HRSA) remains a committed partner in efforts to help people living with HIV/AIDS (PLWHA) live longer and healthier lives. HRSA also recognizes that health centers are critical partners in meeting the goals of the National HIV/AIDS Strategy (NHAS), which include: reducing HIV incidence, increasing access to high quality care, reducing health disparities, and improving federal coordination and collaboration. For more than 45 years, health centers have delivered comprehensive, high-quality preventive and primary health care to patients regardless of their insurance status or ability to pay. During that time, health centers have become an essential primary care medical home for America's most vulnerable populations. Today, more than 1,200 health centers operate 8,500 service delivery sites that provide care to 20.2 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

In support of the NHAS, HRSA has engaged in a number of activities to highlight the importance of HIV as a national public health concern and to support its grantees in expanding HIV service delivery and improving quality of care. For health centers, a number of training and technical assistance (TA) resources have been developed, including:

- **Reviewing and Updating Health Center Program Policy.** In response to scientific advances in HIV testing and treatment, HRSA issued *Program Assistance Letter (PAL) 2010-13: HIV Testing in Health-Care Settings* (available at <http://bphc.hrsa.gov/policiesregulations/policies/pal201013.html>) in September 2010. The PAL outlines the 2006 CDC guidelines on routine HIV testing.

To further clarify HRSA's expectations around HIV service delivery, HRSA issued *PAL 2011-06: HIV/AIDS Care and Treatment in Health Centers* (available at <http://bphc.hrsa.gov/policiesregulations/policies/pal201106.html>) in June 2011. The PAL supports health center compliance with evidence-based HIV treatment guidelines and provides information on key treatment resources.

- **Providing Grantee Technical Assistance.** HRSA organized and facilitated several grantee TA calls to provide guidance and instruction on expanding and improving HIV service delivery in accordance with established guidelines and best practices. Recordings and materials from these calls are archived on the HRSA website for use by HRSA grantees, staff, and other stakeholders. Topics covered during these all grantee TA calls are outlined below. Links to materials can also be found in the HRSA TA catalogue available at <http://bphc.hrsa.gov/technicalassistance/trainings/granteetacatalog.pdf>.
 - **Improving HIV/AIDS Care in the Health Center Community, National HIV/AIDS Strategy TA Call** (January 2011). Reviewed the NHAS and HRSA's overarching approach in working toward its goals and objectives, and explored how health centers can respond to NHAS' call to expand their involvement in HIV service delivery.

- **Public Health Concerns of the Lesbian, Gay, Bisexual and Transgender Population** (October 2011). Outlined unique needs of the population, including recognizing the importance of cultural competency for providers and organizations, reviewing relevant terminology, and providing an overview of HRSA-supported activities in this area.
- **Promising Practices for Putting the ‘Routine’ into HIV Testing at Health Centers** (October 2012). Provided overview of CDC guidelines for Routine HIV Testing, highlighted promising approaches used by health centers to implement and expand HIV testing, and identified TA resources.
- **Providing Staff Training.** HRSA developed a series of trainings for Project Officers and other staff on HIV disease, programs, and services. In addition to participating in the TA calls described above, staff also completed the following two trainings:
 - Increasing Health Center Understanding of Guidelines & Protocols for HIV/AIDS Prevention, Care and Treatment (May 2011).
 - Using Performance Improvement Activities to Improve Quality and Build Capacity around HIV (November 2011).
- **Supporting Expanded Service Delivery.** Through a joint effort with IIRSA’s HIV/AIDS Bureau, 274 current Ryan White HIV/AIDS Part C Early Intervention Services Program and Health Center Program grantees received approximately \$10.3 million in supplemental funding in fiscal year (FY) 2012 to increase access to care and treatment for people living with HIV. Approximately 14,000 additional HIV-positive patients are expected to be served by the organizations receiving this supplemental funding. In addition, seven community-based organizations funded by the Ryan White HIV/AIDS Program received Health Center Program Planning Grant funding in FY 2011 to build their infrastructure and expand services to provide comprehensive primary health care.
- **Supporting National Awareness Days and Events.** Health centers are encouraged annually to participate in National HIV Testing Day (NHTD) events. Emails to grantees and other partners highlight the importance of HIV testing, providing links to key NHTD resources and encouraging increased responsiveness to the HIV epidemic. A National Twitter Forum on HIV Testing with the CDC in support of National HIV Testing Day was conducted in June 2011. In addition, HRSA produced and released a video titled, “30 Years of AIDS: HRSA’s Commitment” (available at <http://www.hrsa.gov/ourstories/aids/video.html>). This video highlighted HRSA’s extensive involvement in HIV/AIDS service delivery across its various programs. The video featured health centers that have successfully integrated HIV into primary care and provided services to PLWHA across the lifecycle.

- **Collaborating with Agencies across the Department and External Stakeholders.**
HRSA staff remain active contributing members of several workgroups facilitated by various HHS agencies:
 - Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS program (ECHPP) Implementation Workgroup; led by CDC.
 - HHS NHAS Implementation Workgroup; led by the Office of the Assistant Secretary for Health (OASH).
 - HIV/AIDS Indicators Implementation Group (HAIIG); led by OASH.

These groups are working to improve the federal response to HIV through increased communication and collaboration, leveraging of resources, and strategic planning. In addition, HRSA also provides annual updates to the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) and works to implement its recommendations.

With respect to the OIG draft report, HRSA is pleased to have the opportunity to provide the following comments:

OIG Recommendation:

Require health center grantees to establish and report to HRSA two relevant HIV testing metrics: prevalence and positivity.

CDC recommends HIV testing based, in part, on prevalence of undiagnosed HIV in the patient population. HRSA should require health center grantees to determine the prevalence of undiagnosed HIV in their patient populations and report this prevalence to HRSA. Additionally, recognizing that some health center grantees will establish prevalence more quickly than others, HRSA should require health center grantees to report to it regarding their progress toward establishing prevalence. Once a health center grantee tests a sufficient number of patients to establish a prevalence of less than 0.1 percent, CDC indicates that routine testing is no longer warranted. However, few health center sites in our sample reported testing enough patients to establish their prevalence of undiagnosed HIV, suggesting that a HRSA requirement is needed to make progress toward identifying which health center sites should routinely perform HIV tests.

As health center grantees work toward establishing the prevalence of undiagnosed HIV in their patient populations, they should also report to HRSA their HIV positivity—the number of positive HIV tests divided by the number of all HIV tests administered. HRSA already requires each health center grantee to report into the UDS the number of HIV tests provided in the grantee's health center sites each year. However, HRSA does not collect information about how many of those HIV tests resulted in an HIV positive diagnosis. Recently, HHS released seven core indicators for monitoring HHS-funded HIV prevention, treatment, and care, including HIV positivity. Required reporting of HIV positivity would align data collection by HRSA health center grantees with that of other HHS-funded HIV programs and services. Further, required

reporting would raise awareness of HIV testing among health center sites that are critical to reducing the spread of HIV.

HRSA Response:

HRSA concurs with the recommendation. For 2014 reporting, HRSA will begin collecting data on HIV positivity rate as part of health centers' annual Uniform Data System reports. In addition, HRSA will collect data on linkage to HIV medical care. These are two Core HIV Indicators proposed by the HHS Office of the Assistant Secretary for Health/Office of HIV/AIDS and Infectious Disease Policy that align with the NHAS-related goal of "standardizing and streamlining HIV data collection and reducing undue reporting burden while preserving the capacity to monitor the provision of quality HIV services" across HHS programs. In consultation with CDC, HRSA will also explore options for assessing the HIV prevalence rates in health center service areas.

OIG Recommendation:

Provide additional guidance and education regarding the CDC-recommended practices and HIV testing.

HRSA provided guidance regarding the CDC-recommended practices through AIDS Education and Training Centers and a Program Assistance Letter and provided education about HIV testing through a technical assistance call with health center grantees. However, our findings suggest that more guidance and education regarding the CDC-recommended practices and HIV testing is needed. HRSA could provide guidance and education by making additional technical assistance calls, issuing program assistance letters, and offering additional training sessions and educational opportunities to health center grantees and sites. Guidance should include methods for establishing prevalence and for determining HIV positivity. The guidance should include strategies regarding how to incorporate the recommended practices into written HIV testing policies and into primary care services. HRSA guidance should also encourage health center sites to partner with organizations in their community and to raise awareness among patients and staff about patient risk for HIV infection.

HRSA Response:

HRSA concurs with the recommendation. HRSA will continue to support health centers in addressing financial resource barriers, promoting partnerships that improve the ability to adopt recommended practices, facilitating an accurate perception of risk among providers and patients, and employing strategies for enhancing patient comfort with HIV testing. HRSA will provide this support by developing new resources and enhancing existing resources, as described above.

ACKNOWLEDGMENTS

This report was prepared under the direction of Kevin Golladay, Regional Inspector General for Evaluation and Inspections in the Dallas regional office; Blaine Collins, Deputy Regional Inspector General; and Ruth Ann Dorrill, Deputy Regional Inspector General.

Amy Ashcraft served as the team leader for this study, and Lyndsay Patty served as the project leader. Other principal Office of Evaluation and Inspections staff from the Dallas regional office who conducted this study include Leah Bostick, Tom Browning, Ben Gaddis, Jennifer Gist, and Malinda Hicks. Central office staff who provided support include Heather Barton, Kevin Farber, and Christine Moritz.

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.