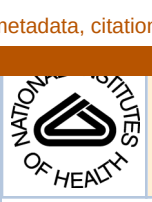

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Routine HIV Screening in North Carolina in the Era of the Affordable Care Act: Update on Laws, Reimbursement, and Tests

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Abstract

Eighteen percent of the 1.2 million human immunodeficiency virus (HIV)–infected individuals in the United States are undiagnosed, with North Carolina accounting for the eighth largest number of new HIV diagnoses in 2011. In an effort to identify more HIV-infected individuals by reducing physician barriers to HIV testing, the Centers for Disease Control and Prevention have expanded their HIV screening recommendations to adolescents and adults without HIV risk factors or behaviors, eliminated federal requirements for pretest counseling, and modified the informed consent process. In 2010, the Office of National AIDS (acquired immunodeficiency syndrome) Policy released the first-ever national HIV/AIDS strategy, with the goal of reducing new infections, increasing access to care, improving HIV outcomes, and reducing HIV racial/ethnic disparities. In 2013, the US Preventive Services Task Force released A-level recommendations recommending nonrisk-based HIV screening for adults and adolescents that are consistent with the recommendations of the Centers for Disease Control and Prevention. In concert with these federal recommendations, the majority of states have modified their consent and counseling requirements. The implementation of the Patient Protection and Affordable Care Act will add requirements and incentives for federal (Medicare), state (Medicaid), and private (insurance) payers to reimburse physicians and patients for nonrisk-based HIV screening.

Keywords

routine human immunodeficiency virus screening; cost-effectiveness; recommendations; written consent; pretest counseling; posttest counseling

According to the latest World Health Organization data (2011), 34 million individuals are infected with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) worldwide.[1] Globally, 2.7 million new cases are diagnosed and approximately 2 million patients die each year.[1] This worldwide pandemic hits close to home, with 1.2 million individuals in the United States infected with HIV and 18% undiagnosed.[2] In an effort to identify more HIV-infected individuals, the Centers for Disease Control and Prevention (CDC) released recommendations expanding their HIV screening recommendations to adolescents and adults without HIV risk factors or behaviors,

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eliminated pretest counseling requirements, and modified the HIV testing consent process.[3] In 2010, the Office of National AIDS Policy released the first-ever national HIV/AIDS strategy, with the goals of reducing new infections, increasing access to care, improving HIV outcomes, and reducing HIV racial/ethnic disparities.[4] In 2013, the US Preventive Task Force (USPSTF) recommended nonrisk-based HIV screening for adults and adolescents with an A-level endorsement.[5] In concert with these federal recommendations, the majority of states have modified legal requirements eliminating pretest counseling and written consent to decrease physician barriers to testing[6]; however, despite these federal and state policy changes, many physicians remain unaware of new HIV screening recommendations and policies.[7,8] The purpose of this study was to increase physicians' knowledge of HIV/AIDS epidemiology, rationale for early HIV/AIDS diagnosis, HIV/AIDS testing state policies, HIV screening recommendations in healthcare settings, reimbursement for routine HIV screening, and new HIV testing technologies.

HIV Epidemiology

Eighteen percent of the 1.2 million people infected with HIV in the United States remain undiagnosed,[6] and more than 50% of these individuals transmit the virus to others unknowingly.[9] Furthermore, the number of new HIV infections in the US has remained unchanged at approximately 50,000 new infections per year.[10] Racial/ethnic disparities in HIV epidemiology have increased during the past 2 decades, with approximately half of all new HIV/AIDS cases occurring in African Americans nationally.[11] North Carolina and other southern states have the highest percentage of HIV-infected individuals (27%) living in rural areas as compared with other geographic regions in the United States.[12]

Men who have sex with men (MSM) continue to be the group that is at highest risk for contracting HIV, accounting for 57% of all incident HIV cases in North Carolina in 2010.[13] The proportion of MSM transmission of HIV has increased in every racial group, with a 14% increase in this transmission category between 2006 and 2010. The proportion of men who report MSM as a risk factor for HIV transmission is 72% among African American men. Heterosexual transmission was estimated to account for 39% of new infections in North Carolina in 2010, with heterosexual sex being the primary mode of transmission for women, who represented 24% of new diagnoses. African American women bear the greatest racial disparity in HIV diagnoses in North Carolina, having an HIV infection rate that is 17 times higher than that of white women. African American women with few individual risk factors are at risk because of the high rate of concurrent or overlapping partnerships, higher HIV prevalence in their partners, and high-risk sexual networks.[14]

Rationale for Early HIV/AIDS Diagnosis

Chart reviews of newly diagnosed HIV-infected individuals show that despite interfacing with the healthcare system years before they are diagnosed, multiple opportunities to test for HIV were missed.[15] This means that patients often are diagnosed as having advanced HIV (eg, low $CD4^+$ T-lymphocyte cell counts). Late testing increases the risk of HIV transmission to others and increases individual morbidity and mortality. In North Carolina, >25% of HIV-infected individuals were diagnosed late as having advanced HIV disease.[13] Increasingly, the focus on early diagnosis is vital because new data are emerging, suggesting individual- and population-level benefits of both the early treatment of infected individuals and the preemptive prophylaxis of those who are uninfected but at high risk. In July 2012, the Food and Drug Administration (FDA) approved the use of a fixed-dose antiretroviral medication, tenofovir/emtricitabine, for the prevention of HIV among individuals at high risk of infection and those who may engage in sexual activity with HIV-infected partners.[16]

The CDC quickly provided guidance for the use of preexposure antiretroviral prophylaxis in heterosexuals at high risk for contracting HIV.[17]

National HIV/AIDS treatment guidelines recommend highly active antiretroviral therapy for all HIV-infected individuals, regardless of the stage of HIV infection.[18] Initiation of antiretroviral therapy at earlier stages of HIV has been shown to reduce HIV transmission to uninfected partners by 96%.[19] Statistical models demonstrate that routine HIV screening with subsequent antiretroviral therapy for those who test positive for HIV is cost-effective, even in areas of low prevalence.[20] Routine testing is a key component to assist in the early treatment of people infected with HIV and the use of counseling and preexposure prophylaxis of those who are at risk for infection.

National and State HIV Screening Policies and Health Laws

On July 13, 2010, the White House released the first national HIV/AIDS strategy. This strategy has three major goals: to reduce new HIV infections, to increase access to care and improve health outcomes for people living with HIV, and to reduce HIV-related health disparities. In an effort to decrease the number of new HIV infections, the CDC revised their HIV testing recommendations for adults and adolescents in 2006. The CDC expanded their recommendations from the targeted testing approach ("performing an HIV test for subpopulations of persons at higher risk, typically defined on the basis of behavior, clinical, or demographic characteristics") to a routine screening approach ("performing an HIV test for all persons in a defined population").[3] The CDC recommends HIV testing for all patients between the ages of 13 to 64 years in all healthcare settings as long as the prevalence of HIV disease is at least 1 in 1000.[3] Routine HIV screening meets the criteria of a good screening test and has been found to be cost-effective in multiple studies.[21] The CDC no longer recommends pretest HIV counseling and recommends posttest counseling only to individuals testing positive for HIV.[3] In addition, the CDC recommends an "opt-out" consent approach. In an opt-out consent approach to screening, patients are notified that HIV testing will be conducted. Patients who do not want to be tested have the option to opt out.

The majority of states, including North Carolina, have modified their HIV testing laws to be consistent with the CDC's 2006 HIV testing recommendations for adolescents, adults, and pregnant women.[6] An important and universal part of these modifications has been a move away from requiring separate written informed consent to perform an HIV test, which makes a patient more likely to refuse the test and increases physician time. Most states also have eliminated the requirement for pretest counseling.

Changes to the law do not alleviate physicians of the duty to inform the patient of the purpose, nature, risks, benefits, and potential consequences (the usual elements of informed consent)of an HIV test.[3] This information can be provided verbally or in writing (eg, in a brochure) as long as the patient has the opportunity to ask questions before consenting. States have varying protections in place to ensure that informed consent is obtained despite the lack of a distinct form. For example, some states require documentation of consent in the medical record (eg, Pennsylvania, Wisconsin), some require patients to initial a clause in a general medical consent form that explicitly provides for an HIV/AIDS test or allows the patient to opt out (eg, Massachusetts, New York), some require pretest counseling (eg, Montana), and others maintain the requirement for specific informed written consent when testing is performed outside a healthcare facility (eg, Maryland).[22]

Professional Organizations and HIV Screening Recommendations

Many professional societies and government agencies recommend routine HIV screening. In July 2013, the USPSTF released HIV screening guidelines recommending routine HIV

screening in patients 15 to 65 years old regardless of risk factors or behaviors in all healthcare settings.[5] USPSTF upgraded this recommendation from a C level to an A level in light of recent findings.[23] Some of the medical professional organizations' and government agencies' HIV screening recommendations are listed in the Table.

Public and Private Reimbursement for Routine HIV Screening

Another barrier to physician HIV testing has been concern for adequate reimbursement for time spent counseling patients, administering the test, and following up results.[30] In addition, reimbursement for laboratory costs is another concern for providers. Routine HIV screening can be reimbursed by either the public or private sector. Public sector funding includes the Center for Medicare and Medicaid Services. Medicare does not cover nonrisk-based or routine HIV screening for nonpregnant adults unless upon a beneficiary's request.[31] In contrast, Medicaid may pay for routine HIV screening as a preventive benefit, with almost half of all states covering routine HIV screening as of 2010, and there are some private insurance companies that cover routine HIV screening as well.[32] In North Carolina, the largest private insurer, Blue Cross Blue Shield, reimburses providers and patients for routine HIV screening (P. Leone, personal communication, 2011)

Public and private reimbursement for HIV testing has expanded to routine screening.[5] Medicare is required to reimburse USPSTF A- and B-level recommendations. The Patient Protection and Affordable Care Act states (Medicaid) will receive a 1% increase in federal funding if its Medicaid program covers preventive services rated A or B by the USPSTF (beginning January 2013).[33] Beginning in 2013, the Affordable Care Act requires most private insurers to cover preventive services rated A or B by the USPSTF without imposing cost sharing on the patient.[34] The American Medical Association and the American Academy of HIV Medicine have released guidelines for the appropriate billing codes for routine HIV screening.[35]

New HIV Testing Technology

New HIV testing technologies address challenges to the expansion of HIV screening, including patients not returning for HIV test results, failure of the third-generation HIV antibody test to detect HIV early on, and the need to expand HIV testing beyond clinical settings. These new testing modalities are the rapid HIV tests and the fourth-generation HIV tests. There are six FDA-approved rapid HIV tests.[36] The rapid test detects HIV antibodies using the enzyme-linked immunosorbent assay from oral or blood specimens. The tests are called rapid tests because of the quick turnaround time for the results, ranging from 3 to 20 minutes. The sensitivity and specificity of the tests are >99%.[36,37] Positive tests are preliminary and require a confirmatory test, either a Western blot or an immunofluorescent test. The rapid HIV test (approved July 3, 2012) is the OraQuick In-Home HIV Test (OraSure Technologies, Bethlehem, PA) that can be done by patients in their own home.[37] Like other oral HIV tests, patients should collect oral fluid specimens by swabbing their upper and lower gums. The turnaround time for the results ranges from 20 to 40 minutes. Although the specificity of the test is equivalent to the previously discussed oral tests (99.8%), the sensitivity is lower (92%) among untrained self-testers in clinical studies; therefore, "one false negative result would be expected out of every 12 test results in HIV-infected individuals."[37] In June 2010, the FDA approved the first fourth-generation combination antigen/antibody test. The fourth-generation combination assay allows for early HIV diagnosis because it detects both the p24 antigen (early HIV protein) and the HIV antibody.[36] HIV can be detected as early as 15 days after HIV infection by the fourth-generation combination assay compared to 35 days by the first-generation HIV tests.[38] Although the widespread adoption of these new HIV testing technologies may lead to

increased testing among difficult-to-reach populations, their effect on the epidemic has yet to be estimated, particularly if the technologies are not coupled with linkage to HIV treatment and care.

Conclusions

At 50,000 new HIV cases per year, the United States has one of the highest numbers of new infections in the developed world. Although the epidemic has continued to disproportionately affect MSM, it increasingly has become concentrated among African American men and women. Earlier identification of HIV by routine screening coupled with antiretroviral therapy is a cost-effective strategy with the potential to improve both individual and population outcomes. The removal of the requirements for written consent and pretest counseling in the majority of states may decrease barriers for healthcare providers to screen for HIV. The A-level recommendation by the USPSTF expands reimbursement for routine HIV screening from both public and private payers. New HIV tests such as the fourth-generation HIV test can further facilitate earlier HIV diagnoses by reducing the window for seroconversion; therefore, it is important that all healthcare providers become knowledgeable about the latest HIV screening recommendations, policies, health laws, and novel HIV tests.

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Key Points

- Nonrisk-based or routine human immunodeficiency virus (HIV) screening is cost-effective in healthcare settings, even in areas of low prevalence.
- The Centers for Disease Control and Prevention and the US Preventive Services Task Force (A-level recommendations) both recommend nonrisk-based or routine HIV screening in healthcare settings.
- The majority of states no longer require written consent or pretest counseling before performing an HIV test.

Table

HIV screening recommendations of professional medical societies and government agencies

Organization	Recommendations
AAP[24]	All adolescents 16–18 y, in whom HIV prevalence >0.1%
AAFP[25]	All adolescents and adults 18–65 y for HIV infection
ACP and HMA[26]	All adolescents and adults >13 y, no upper age limit defined
ACEP[27]	Offer based on local community prevalence (emergency departments)
ACOG[28]	All women 19–64 y
CDC[3]	All adolescents and adults 13–64 y in healthcare settings, unless undiagnosed HIV prevalence <0.1%
	Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings.
IOM[29]	All sexually active women annually
USPSTF[5]	All adolescents and adults ages 15–65 y
	Grade A level recommendation

American College of Emergency Physicians; ACOG, American College of Obstetrics and Gynecology; ACP, American College of Physicians; CDC, Centers for Disease Control and Prevention; HIV, human immunodeficiency virus; HMA, HIV Medicine Association; IOM, Institute of Medicine; USPSTF, US Preventive Services Task Force.