UNIVERSAL HIV TESTING IN HEALTH CARE SETTINGS AS AN OPTION TO INCREASE IDENTIFICATION OF UNDIAGNOSED HUMAN IMMUNODEFICIENCY VIRUS (HIV)

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In 2006, Centers for Disease Control and Prevention (CDC) estimated that approximately 1.2 million people in the United States were living with HIV. Of those, 25 percent, or 300,000 persons, were estimated to be unaware of their infection.[1] In an effort to significantly decrease the number of undiagnosed infections, CDC published guidelines that same year for what is known as "universal testing." These guidelines included three principle differences from those previously disseminated, which generally recommended testing only for those deemed by providers as at risk. These three differences included: 1) the recommendation to offer HIV testing to all people between the ages of 13 and 64 who were accessing medical services for any reason, 2) the recommendation to provide HIV testing on an opt-out basis with no written consent required, and 3) the elimination of the requirement to offer pre-test counseling. Repeat annual testing is recommended for high-risk individuals. Such universal screening is not necessary in settings shown to yield less than one case per 1,000 persons tested (CDC 2006).

One major reason for the change in CDC's recommendations surrounding HIV testing stemmed from concern over the large number of people with HIV who were not tested until they were already sick and/or their immune systems were already substantially compromised. An assessment of people who were newly diagnosed with HIV and interviewed in 2002 and 2003 showed that 44 percent reported opting to test for HIV due to illness (CDC 2003). Thirty-eight percent of those newly diagnosed with HIV have AIDS within a year, and 17,000 people die each year despite treatment advances because of late diagnoses (Morris 2009). Earlier diagnosis and linkage to health care is critical to slow the progression of disease, improve health outcomes and quality of life, and reduce mortality (Petroll, et al 2008).

An assessment of 2008 cases in Colorado showed similar results, with 45 percent reporting testing due to illness. Some people were extremely sick when they received testing, with at least 10 percent of those for whom this information was available having opportunistic infections such as Pneumocystis pneumonia (PCP) and/or lose, single-digit CD4 counts. Thirty-five percent of the people diagnosed that year were determined to have AIDS at the time of their first HIV diagnosis. Given that all of those diagnosed with HIV had not yet received any diagnostic CD4 testing at the time of the review, the actual percentage of those with AIDS at first diagnosis is likely to have been higher. The highest percentage of AIDS cases relative to HIV cases was seen in people from Latin American countries, among which 65 percent had immediate AIDS diagnoses. Review of the cases from 2008 also showed that 23 percent of those for whom this information was available had never previously tested for HIV, and another 15 percent had not been tested in over five years. Forty-three percent of the Latin American immigrants diagnosed with HIV in 2008 had never previously been tested. Surprisingly, 20 percent of men who have

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[1] Based on more recent methods for estimating HIV prevalence, CDC announced in 2008 that an estimated 1.1 million persons were living with HIV disease in 2006, of which 21 percent, or approximately 232,700 persons, were unaware of their infection.

sex with men (MSM) diagnosed with HIV in 2008 had never previously been tested. Half of the other men in the sample had also never previously received testing.

Another rationale for CDC's changes in testing guidance concerned the potential for HIV transmission by those who were unaware of their infections. Research has shown that people who are unaware that they have HIV account for more than half of new sexually transmitted HIV infections each year, and the majority of those that know they are living with HIV significantly reduce their risk behavior and take precautions to not transmit HIV (Marks 2006). Also, reduction of viral load resulting from the initiation of highly active anti-retroviral treatment (HAART) diminishes the likelihood of transmission so that even those who do not change their behavior become less of a public health threat when receiving medical care (CDC 2006). A third rationale for the change in CDC's recommendations is based on the assumption that offering HIV testing to everyone who accesses medical care and removing the requirement for pre-test risk assessments will help reduce the stigma surrounding HIV testing, making it likely that more people will accept testing (CDC 2006). Eliminating the counseling requirement also reduces the time needed for testing, which could improve the willingness of providers to offer testing and for patients to accept it (Petroll, et al 2008). A fourth reason for the change is that some people are unaware of their risk for HIV, and under traditional risk-based testing many are not diagnosed. Research has shown that up to 25 percent of people do not fall into high-risk categories at the time of their HIV diagnosis (Morris 2009). In certain health care settings that have adopted universal screening, the percentage of patients who have tested positive often exceeded that observed at publicly funded counseling and testing sites (CDC 2006).

Universal testing as described above is appropriate for all health care settings including: hospitals (including emergency departments), acute-care clinics, public health clinics, community clinics, sexually transmitted infection clinics, tuberculosis clinics, substance abuse treatment clinics, correctional health care facilities, and other primary care settings. Such universal, opt-out screening conforms to Colorado state statute, and allows for consent for HIV testing to be incorporated into patients' general consent for medical care (Colorado Department of Public Health and Environment (CDPHE) 2007). Universal HIV testing projects based in health care settings and funded by CDPHE should be developed utilizing the guidance developed by CDC in 2006 as well as the *2007 Prevention Guidelines* developed by CDPHE. Based on these guidances and further review of the literature, HIV testing in health care settings projects should include the following features:

- All patients between the ages of 13 and 64 should be tested for HIV as part of routine care unless they decline such testing.
- Sites must have a one percent positivity rate.
- Testing should be offered on an opt-out basis. This means that testing should be voluntary and undertaken only with the patient's knowledge and understanding. Testing must be free of coercion. General consent for medical care is sufficient to allow for HIV testing. Neither signed consent nor is pre-test counseling is required.
- Patients should be informed verbally or in writing that HIV testing will be performed unless they decline. Easily understood materials in appropriate languages should be available, as should appropriate interpreters for those who are not English speaking. Patients should be given verbal or written information, including information explaining the meaning of positive and negative test results, and they should be offered an opportunity to ask questions and to

decline testing. If a patient declines an HIV test, this decision should be documented in the patient record.

- As specified in Colorado statute (CRS 25-4-1405.5), HIV testing in health care settings cannot be provided anonymously.
- Providers offering HIV rapid testing must utilize devices approved by the U.S. Food and Drug Administration and must adhere to applicable manufacturer, legal, and regulatory guidelines. In addition, an appropriate CLIA certification must be in effect for the clinic providing rapid testing.
- Patients at high risk for HIV infection should be advised of the need for annual retesting and should be referred to prevention counseling.
- Patients who test HIV-positive should receive results through direct personal contact, and all of the following should be addressed: active linkage to HIV partner counseling and referral services; brief risk assessment and counseling; collection of accurate locating information; screening for mental health, substance abuse, and comprehensive risk counseling and services (CRCS); and active linkage to medical care, as well as mental health, substance abuse and CRCS services, as appropriate.
- All patients seeking treatment for sexually transmitted infections (STIs) should be offered testing during each visit for a new complaint. This includes patients seeking care in STI clinics.
- Human Immunodeficiency Virus testing should be offered annually to: MSM, injection drug users (IDUs), persons who exchange sex for money or drugs, sex partners of people living with HIV, and heterosexual persons who themselves or whose sex partners have had a new or more than one sex partner in the previous three months.
- Providers should encourage testing for patients and their prospective partners before they initiate a new sexual relationship.
- Providers must collect and report the following: test/client identification number, date of testing, site identification number, age, sex, race, ethnicity, self-reported HIV testing history, specimen type, test type (conventional vs. rapid), test results, and receipt of test results. When feasible, HIV risk behavior should also be collected and reported. Although client name does not need to be reported to CDPHE on people testing negative, it must be collected and maintained as part of the patient record.
- For all clients testing positive, providers must collect the following additional information: name, address, date of birth, county of residence, housing situation, pregnancy and prenatal care, incarceration history, recent diagnosis with another STI, injection drug use behavior, sexual behaviors, non-behavioral risks, and any referrals made.
- As defined in Colorado regulation (6 CCR-1009-9, Regulation 1), diagnosed cases of Acquired Immune Deficiency Syndrome (AIDS), HIV-related illness, and HIV infection, regardless of whether confirmed by laboratory tests, shall be reported to CDPHE within seven days of diagnosis.

References

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