Routine HIV Testing Hits the Primary Care Clinic

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In September 2006, the Centers for Disease Control and Prevention (CDC) recommended screening all persons 13–64 years of age for human immunodeficiency virus (HIV) infection.¹ Prior to this, screening recommendations were targeted to specific high-risk individuals and settings, and to all pregnant women. The rationale for expanded screening is that early diagnosis can reduce morbidity and mortality,² and that persons who know their HIV status will modify their risk behaviors and reduce transmission.³ Furthermore, an estimated 25% of persons with HIV infection remained undetected with the existing screening strategy. Recently, the American College of Physicians and the HIV Medicine Association have come out in support of the CDC's screening recommendation.⁴ Other organizations, such as the US Preventive Services Task Force, have not come out for or against the CDC recommendations, in part due to limited direct evidence on the benefits of screening.⁵ As new evidence emerges, key issues to consider for any screening program are the validity of the screening test, the feasibility of implementing the screening program, and the overall effectiveness in improving health outcomes.

In this issue of JGIM, Myers and colleagues describe their experience of systematically implementing the CDC recommendations within six community care centers in the South-eastern US⁶. With programmatic support and some funding, the practices developed a systematic procedure to implement screening within the practice that did not directly involve the health care provider. In this study, over 16,000 persons were offered HIV testing, and of the 10,769 persons who accepted testing, 19 received a false-positive result, whereas 17 were confirmed positive, of whom 12 were successfully referred to care. Three patients did not have confirmatory testing. The findings from this study demonstrate key issues involving screening test validity and feasibility.

VALIDITY

The study used a commercially available rapid test assay, with a published specificity of 99.7%–99.8%.⁷ Rapid tests yield results in 20–30 min and can be performed on either saliva or whole blood from a fingerstick, as was used in the Myers study. Use of rapid tests can increase the number of patients

receiving their results and the number who access HIV care.^{8,9} However, the frequency of false-positive results from rapid HIV testing has been a subject of recent controversy. The Myers study results are consistent with the published sensitivity of 99.8. Thus, in a population where the actual prevalence is 0.2% (2 in 1,000), the test is expected to produce 4 positive results per thousand, of which 2 are true positive and 2 are false positive. However, recent results from emergency department use in Boston reported the specificity of rapid testing was only 96.9%,¹⁰ and five of every six positive tests in their sample was a false positive. The impact of a false-positive HIV test can be difficult to measure, but is likely associated with significant psychosocial distress among both the individual patient and those around him or her.¹¹ Traditional (non-rapid) HIV testing does not provide an immediate result, but because confirmatory testing can be performed before the patient receives a result, the specificity is substantially higher (99.99%).¹² Thus, while rapid testing has advantages in some settings, the high false-positive rate raises the question of whether rapid tests are the best option for mass screening in primary care clinic settings.

FEASIBILITY

The Myers study also presents findings on the feasibility of implementing a recommended service into clinical practice. The study shows that implementing the CDC recommendations is complicated and will not be easy. Rapid tests require up-front costs, a special CLIA waiver, trained clinic staff, and time and effort related to running the test assay and communicating results to patients. If “highly motivated” clinics that serve higher risk populations receive funding and receive free test kits can only provide the testing to 28% of the recommended sample, then what should be expected from practices that are not highly motivated, have lower risk populations, and do not incorporate systematic efforts or offer free testing? If screening is to be successfully implemented, we need more information on barriers to implementation and how to remove them.

At present, there is relatively little implementation guidance for primary care settings. In 2006, the Society of General Internal Medicine (SGIM) received a grant from the CDC to study the uptake of HIV screening among general internists. The SGIM group has conducted focus groups of clinician advisors, developed an online membership survey, and also created a web site (www.sgim.org/index.cfm?pageId=391) to help providers and trainees overcome barriers to implementation of routine HIV screening.

Feasibility is also impacted by patient acceptability, provider acceptance, and policy and financing issues. In the Myers

study, 67% of patients offered testing received it, suggesting that HIV testing is reasonably acceptable to patients. The clinics included in the paper by Myers et al. served a low-income, mostly minority population in the Southeastern US. Thus, the overall prevalence of only 2 in 1,000 is likely to be higher than that in neighboring, private practice clinics that serve fewer poor and uninsured patients. Clinician burnout could occur if providers feel the test is not useful or if patients express annoyance or embarrassment, as shown by evidence that physicians consider the local disease prevalence in their decisions regarding screening for sexually transmitted diseases.¹³

Other barriers to HIV screening exist at the policy level. While 34 states have changed their laws to conform to CDC recommendations for opt-out testing without written consent requirements, several states with high HIV prevalence have not adopted changes.¹⁴ Additional reimbursement strategies may also be needed. Although more private insurers are covering routine HIV testing, very few Medicaid programs have adopted coverage,¹⁵ and uninsured patients would have to pay for the test themselves. The resulting uncertainty about reimbursement for testing is a major barrier that should be addressed.

EFFECTIVENESS

The effectiveness of a screening program is ideally measured as a reduction in morbidity and mortality compared to alternate testing strategies. Prior to the new CDC recommendations, providers focused on persons with known risk factors for HIV infection such as injection drug use, men who have sex with men, or persons residing in high-prevalence communities or settings. The Myers study does not provide information regarding individual risk behaviors or the number of HIV infections detected prior to the new guidelines, so it is unclear whether most of the persons found to have HIV might have been detected anyway through targeted screening. Also, with a mass screening program, it is crucial that there is screening coverage within the most relevant populations. Although the clinics in the Myers study offered HIV testing as routine, younger patients and Latinos were less likely to be offered testing (although more likely to accept testing if offered). It was also notable that testing was completed at similar rates in insured and uninsured persons, but this may differ in settings where testing is not available for free.

Beyond screening rates, effectiveness will hinge on access to care, as detection alone will not improve morbidity and mortality. One argument for rapid testing is that 30% of persons who have a positive test from a routine (non-rapid) blood test are lost to follow-up.¹⁶ However, it is not clear whether that proportion is much different from the 5 of 17 (29%) persons with a positive rapid test result in the Myers study who were not successfully linked to HIV care. Another study that reported use of rapid testing in the Emergency Department found that 13 of 26 persons with a preliminary positive result were lost to follow-up.¹⁷ Plans to enhance access to care must be incorporated into testing strategies.

Effectiveness evaluations of screening for infectious diseases may also consider the public health benefits of reduced transmission. Mathematical models that consider the impact of testing and treatment in a high-risk population suggest a decline in secondary cases of anywhere from 3% to 26%, depending on the frequency of testing and the threshold

of initiation of antiretroviral treatment.¹⁸ However, the model assumed testing offer rates of 80% of the general populace, and no routine testing program has yet come close to those rates. Moreover, little is known about the changes of risk behaviors among persons with HIV infection detected through mass screening in primary care settings.

In summary, screening for HIV infection makes sense for many reasons, yet several issues need to be considered. Are the benefits of rapid tests really worth the potential costs, clinic staff time, and additional false-positive tests? Are there measures that clinical practices can use to increase the rate of screening over the 28% described in this study? Will health care providers still support the screening recommendations if the prevalence rate is very low in their population? And is a universal screening program in primary care clinics truly more effective compared to previous, targeted screening programs? Additional data on these issues are needed to ensure that screening recommendations for HIV infection are founded on the best evidence possible.

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REFERENCES

- Centers for Disease Control and Prevention. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR* 2006;55(No. RR-14):1-17.
- Bhaskaran K, Hamouda O, Sannes M, et al. Changes in the risk of death after HIV seroconversion compared with mortality in the general population. *JAMA*. 2008;300(1):51-9.
- Marks G, Crepaz N, Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. *AIDS*. 2006;20:1447-50.
- Qaseem A, Snow V, Shekelle P, et al. Screening for HIV in health care settings: a guidance statement from the American College of Physicians and HIV Medicine Association. *Ann Intern Med*. 2009;150:125-31.
- Chou R, Huffman L. Screening for human immunodeficiency virus: focused update of a 2005 systematic evidence review for the US Preventive Services Task Force. Rockville, MD: Agency for Healthcare Research and Quality; 2007. AHRQ publication no. 07-0597-EF-1.
- Myers JJ, Modica C, Dufour MS, Bernstein C, McNamara K. Routine rapid HIV screening in six community health centers serving populations at risk. *J Gen Intern Med*. 2009.
- Uni-Gold Recombigen Package Insert. Available at www.unigoldhiv.com, accessed September 2009.
- Anaya HD, Hoang T, Golden JF, Goetz MB, Gifford A, Bowman C, et al. Improving HIV screening and receipt of results by nurse-initiated streamlined counseling and rapid testing. *J Gen Intern Med*. 2008;23(6):800-7.
- Centers for Disease Control and Prevention. Rapid HIV testing in emergency departments—three US sites, January 2005-March 2006. *MMWR Morb Mortal Wkly Rep*. 2007;56:597-601.
- Walensky RP, Arbelaez C, Reichmann WM, et al. Revising expectations from rapid HIV tests in the emergency department. *Ann Intern Med*. 2008;149:153-60.
- Bhattacharya R, Barton S, Catalan J. When good news is bad news: psychological impact of false positive diagnosis of HIV. *AIDS Care*. 2008;20(5):560-4.
- MacDonald KL, Jackson JB, Bowman RJ, et al. Performance characteristics of serologic tests of human immunodeficiency virus type 1 (HIV-1) antibody among Minnesota blood donors. Public health and clinical implications. *Ann Intern Med*. 1989;110:617-21.
- Cook RL, Wiesenfeld HC, Ashton MA, Krohn MA, Zamborsky T, Scholle SH. Chlamydia screening practices of primary care physicians. *J Adolesc Health*. 2001;28:204-10.

14. **Mahajan A, Stemple L, Shapiro M, King J, Cunningham W.** Consistency of state statutes with the Centers for Disease Control and Prevention HIV testing recommendations for health care settings. *Ann Intern Med.* 2009;150:263–9.
15. **Cheever L, Lubinski C, Horberg M, Steinberg J.** Ensuring access to treatment for HIV infection. *Clin Infect Dis.* 2007;45:S266–74.
16. Centers for Disease Control and Prevention. Advancing HIV prevention: new strategies for a changing epidemic—United States 2003. *MMWR Morb Mortal Wkly Rep.* 2003;52:329–32.
17. **Brown J, Shesser R, Simon G, et al.** Routine HIV screening in the emergency department using the new US Centers for Disease Control and Prevention Guidelines: results from a high-prevalence area. *J Acquir Immune Defic Syndr.* 2007;46:395–401.
18. **Walensky RP, Paltiel AD, Losina E, et al.** Test and treat DC: forecasting the impact of a comprehensive HIV strategy in Washington DC. 5th IAS Conference on Pathogenesis, Treatment and Prevention, Cape Town. Poster no. LBPEC04. 2009. Available at <http://www.ias2009.org/pag/Abstracts.aspx?AID=3748>, accessed September 2009.