

cludes with high certainty that early detection and treatment of HIV . . . would result in substantial public health benefit [and that] earlier initiation of ART in HIV positive persons . . . could substantially reduce disease burden” — there could have been no public surprise. The same month, the Pacific Northwest Evidence-based Practice Center’s unambiguous review of the evidence favoring routine HIV screening had been published.<sup>5</sup>

The debate over HIV screening has extended over 25 years, driven initially by concerns about discrimination and the appropriate rigor of consent procedures. More recently, controversy has centered on the scope of screening efforts — whether they should

be targeted at the groups at highest risk or should be a routine element of clinical practice. With the USPSTF recommendations, the curtain will at last come down on that debate. What remains to be seen is whether routine screening provided at no cost to patients will substantially alter the persistent inability to identify 20 to 25% of Americans with HIV infection. Failure will have measurable clinical consequences for those who enter care too late and public health consequences for the imperative to reduce HIV transmission in populations.

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## Updating the HIV-Testing Guidelines — A Modest Change with Major Consequences

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The U.S. Preventive Services Task Force (USPSTF) recently released a draft statement assigning a grade A recommendation to screening for human immunodeficiency virus (HIV) in the general population 15 to 65 years of age. The proposed guidelines cite an updated systematic evidence review of the benefits and potential harms of HIV screening. Since the previous evidence review was published in 2005, new studies have shown that antiretroviral therapy can reduce transmission by HIV-infected persons and that earlier initiation of such therapy can reduce morbidity and mortality and improve quality of life.<sup>1,2</sup>

When the USPSTF considered clinical guidelines for HIV screen-

ing in 2005, it issued a grade A recommendation for testing only in high-risk populations (such as injection-drug users or men who have sex with men) or in high-prevalence areas (such as the District of Columbia or the Bronx, New York). No recommendation (also called a grade C recommendation at the time) was offered for or against routine screening in the general population or in low-prevalence areas.<sup>1,2</sup> In contrast, the new USPSTF draft recommendations are similar to guidelines issued by the U.S. Centers for Disease Control and Prevention (CDC) in 2006. The CDC transformed the paradigm of HIV testing by recommending that such testing be moved into routine care, that all

adults up to 65 years of age be tested, and that special consent and pretest counseling processes for HIV testing be eliminated.<sup>3</sup> However, the CDC guidelines did not have the force of a mandate, and ultimately states and private health plans had latitude to define local testing policies and reimbursement mechanisms.

On the surface, the proposed guidelines of the USPSTF appear to represent a modest change, since they resemble the 2006 CDC recommendations regarding general-population screening. In practice, they have large implications for the way HIV testing is financed in the era of national health care reform. In addition, moving testing into routine care affects both the resources

required for HIV treatment in future years and the costs that will be borne by various public and private payers.

Under the Affordable Care Act (ACA), USPSTF recommendations play a critical role in determining not only which preventive services will be reimbursed by public and private health plans, but also how they will be reimbursed. New federal rules have already required that private insurance and Medicare plans offer their enrollees all preventive services that receive a grade A or B recommendation without requiring a copayment or other out-of-pocket payments from enrollees. In 2013, state Medicaid programs will also have new financial incentives (a 1% increase in the federal matching rate) to offer preventive care services without out-of-pocket costs.<sup>4</sup> These changes mean that if the draft recommendations of the USPSTF are adopted, most persons younger than 65 years of age who have public or private insurance coverage will be able to receive an HIV test without an out-of-pocket expenditure.

Improved coverage for HIV testing and reductions in the number of uninsured people should assist state and local health departments in expanding HIV testing. Although the CDC provides funding to states and local jurisdictions for such testing, it does not have the funds to cover testing for the entire general population for which screening would now be recommended. Health departments will need to be able to bill testing costs to other payers if they wish to add resources to implement widespread HIV testing.

Finally, the proposed grade A recommendation can have im-

portant effects on clinical practice. Clinicians will no longer need to consider patients' risk status or the prevalence of HIV in a given population before offering testing; it will be clear that HIV testing for all patients 15 to 65 years of age will be reimbursed by public and private payers. These changes are critical to transforming HIV testing into a routine medical screening procedure.

Yet the cost of HIV testing itself is only the tip of the iceberg. We previously estimated that doubling the frequency of

whom are currently uninsured and rely on safety-net programs.<sup>5</sup>

The most visible ACA provisions for expanded insurance coverage of HIV care are the subsidized state-based health insurance exchanges and Medicaid expansion. These provisions are combined with various measures for encouraging greater use of primary care, including redirecting federal funds from safety-net hospitals to community health centers, funding for training of primary care providers, and increased Medicare and Medicaid payments to primary care pro-

***The cost of routine HIV testing itself is only the tip of the iceberg. Most of the additional cost is for treating people with newly diagnosed HIV infection, and even with health care reform, key financial and capacity challenges remain for HIV treatment.***

testing from the current population average of once every 10 years would cost an additional \$2.7 billion over 5 years. Testing costs represent less than 20% of this total. Most of the additional cost is for treating people with newly diagnosed HIV infection. Since our analysis was conducted before the ACA was passed, we predicted that the majority of increased treatment costs would be borne by discretionary programs such as the Ryan White HIV/AIDS Program, which supports care for uninsured and underinsured Americans with HIV infection. Because these budgets are fixed annually by Congress, they have limited capacity for expansion. In addition, in recent years, most HIV infections have occurred in members of low-income minority groups, many of

viders.<sup>4</sup> In theory, the coverage expansions in the ACA should alleviate our concern about the financing of treatment. Many HIV-infected patients will gain comprehensive health insurance coverage through public or private payers, which will improve access to treatment and alleviate the strain on discretionary programs. Yet health care reform will not fix all gaps in health care delivery, and key financial and capacity challenges remain for HIV treatment.

There is likely to be substantial interstate variation in the implementation of health care reform.<sup>4</sup> Most implementation tasks fall to state governments, and the Supreme Court has ruled that states cannot be penalized for not expanding their Medicaid programs. States will continue to

have substantial latitude in defining minimum benefits for Medicaid and private insurance plans, including the breadth of prescription-drug coverage, which could substantially affect the quality of HIV care.

Although most HIV-infected patients should be better off, some will continue to fall through insurance-coverage cracks. Many immigrants are excluded from coverage provisions; paperwork and eligibility requirements may make it difficult for low-income patients to navigate the enrollment and reenrollment processes; and out-of-pocket costs for health insurance premiums and copayments may affect uptake and utilization of private insurance. Consequently, there will continue to be an important role for safety-net funding sources. However, the future of the Ryan White program and other discretionary safety-net programs that support the workforce of HIV care providers is uncertain; the current authorization for the Ryan White program expires in

2013. Major reductions in safety-net funding would make it difficult to support HIV-infected patients who cannot successfully navigate the new environment or afford subsidized insurance with sufficiently generous benefits to cover their care. Finally, the shift of funding from safety-net hospitals to community health centers may reduce capacity at HIV clinics affiliated with hospitals serving low-income patients.

The rationale for a grade A recommendation from the USPSTF is that there is “high certainty that the net benefit is substantial.”<sup>2</sup> In the case of HIV screening, that benefit can be achieved only if people identified as HIV-infected are effectively linked to and retained in HIV care and are supported in adhering to an effective antiretroviral regimen. The proposed USPSTF recommendations may remove financial barriers to routine HIV screening, but that is only the first step in ensuring that all HIV-infected Americans have access to the full continuum of care.

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## When to Start ART in Africa — An Urgent Research Priority

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The history of the HIV–AIDS epidemic was profoundly altered by the introduction of antiretroviral therapy (ART). More than 8 million people in low-income and middle-income countries have received lifesaving ART over the past decade, yet in 2011 an estimated 34 million people were living with HIV infection, 6.8 million were eligible for treatment but lacked access to ART, 2.5 million became newly infect-

ed, and 1.7 million died of HIV-related disease.<sup>1</sup>

Long-standing debate regarding the appropriate timing of ART initiation in the course of HIV infection was recently accentuated by the recognition of the prevention benefit that ART provides by reducing viral load and infectiousness. Mathematical models, ecologic analyses, and results from the HIV Prevention Trials Network (HPTN) study HPTN

052, a randomized, controlled trial that showed reduced HIV transmission from early, as compared with deferred, ART in the infected member of an HIV-discordant couple,<sup>2</sup> all stimulated discussion of a “test and treat” approach, whereby all HIV-infected persons would initiate ART immediately after their HIV diagnosis, with anticipated reductions in transmission. A fundamental question remaining is what is best