



Routine HIV Testing, Public Health, and the USPSTF — An End to the Debate

Ronald Bayer, Ph.D., and Gerald M. Oppenheimer, Ph.D., M.P.H.

The U.S. Preventive Services Task Force (USPSTF) is poised to release recommendations on screening for human immunodeficiency virus (HIV) infection that will endorse the routine testing of adults

and adolescents, a position first adopted by the Centers for Disease Control and Prevention (CDC) in 2006. Based on an exacting systematic examination of the new evidence on clinical and public health benefits of early identification of HIV infection that has emerged since 2005, when the initial USPSTF review led to rejection of routine screening, the new recommendations will be a critical guide to clinical practice. They will also carry important policy implications, since the Affordable Care Act (ACA) mandates that all public and private health plans provide coverage for USPSTF-recommended preventive services without patient copayments.

In recent years, USPSTF decisions have sometimes attracted widespread attention, stirring sharp controversy when the task force has challenged well-established clinical practices after determining that there was insufficient evidence of benefit. Most notably, such a controversy occurred in 2009, when the USPSTF recommended against annual mammographic screening for women 40 to 50 years of age. More recently, a recommendation against routine prostate-cancer screening provoked acrimony and denunciations from urologic societies and the National Medical Association.

In the case of HIV screening, the anticipated recommendations, rather than challenging prevailing

consensus, will offer what many believe is a long-overdue acknowledgment of the evidence as interpreted by the CDC, the American College of Physicians, the Infectious Diseases Society of America, and the American Congress of Obstetricians and Gynecologists.

Approximately 56,000 people in the United States become infected with HIV each year. Many will not be identified for years. It is widely accepted that 20 to 25% of the estimated 1.1 million Americans living with HIV are unaware of their status. They consequently lose a critical opportunity to initiate antiretroviral therapy (ART) early, and they pose a public health hazard as sources of ongoing transmission. That gap and its consequences have haunted public health discussions of HIV testing for years, raising fundamental questions. Were the exacting consent procedures for HIV testing too burdensome? Were de-

mands for pretest counseling incompatible with the routinization of screening?

Nevertheless, when it first considered the issue in 2005, the USPSTF found that the evidence was insufficient to justify routine HIV screening of U.S. adults and adolescents.¹ A year later, the CDC concluded that routine opt-out HIV screening was imperative,² underscoring a profound disagreement over the appropriate direction for clinical and public health practice.

When the CDC announced its recommendations, 21 states already had laws or regulations that made routine opt-out screening

possible. Five years later, much had changed. A 2011 review of laws and policies concluded that “nearly all states’ laws and administrative codes were compatible with current CDC HIV testing recommendations on consent and counseling.”³

2010, the process of reviewing its previous positions. The Pacific Northwest Evidence-based Practice Center (formerly known as the Oregon Evidence-based Practice Center), which had conducted the earlier analysis, was charged with the responsibility of review. The scope of its work and the issues it would address were determined by a careful consultative process involving the task force itself. The center’s report, which represented a dramatic shift from 2005, was presented to the USPSTF in March 2012.

The report indicated that data from new studies, including sev-

risk populations to identify asymptomatic but infected persons was justified because of the profound effect of antiretroviral agents. Put more succinctly, to reduce the incidence of new disease, treatment is a form of prevention. It is noteworthy that new biologic evidence about treatment and prevention has resolved questions from 2005 that centered on the inadequacy of epidemiologic findings. Strikingly, the report fails to mention “fears of rejection, abandonment, verbal abuse, and physical assault” — matters that had featured prominently in the 2005 discussion of the potential burdens of routine screening.

On the basis of this systematic review, which was discussed at the USPSTF meeting in March 2012, chairperson Virginia Moyer proposed that the C grade of 2005 — “the balance of benefits and harms is too close to justify a general recommendation” — be replaced by an A grade — “a strong recommendation that clinicians provide screening since the benefits substantially outweigh potential harms.” With committee approval, Moyer and her colleague Douglas Owens assumed the challenge of preparing an evidence-based recommendation.

As they began their work, they were acutely aware not only of the strength of the new evidence regarding the benefits of routine HIV screening but of the intense clinical, public health, and political interests in their conclusions. The Panel on Antiretroviral Guidelines for Adults and Adolescents of the Department of Health and Human Services had just recommended that all persons with HIV infection begin ART. The secretary of health and human services, relying on a study by the Institute of Medicine, had already included

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eral randomized, controlled trials, showed that there was a lower risk of death or AIDS-defining illnesses in HIV-infected persons when ART was initiated when CD4+ counts were between 350 and 500 cells per cubic millimeter, as compared with delaying or not initiating ART. It also examined a recent randomized, controlled trial involving HIV-discordant couples in nine countries⁴ that, buttressed by a number of observational studies, provided “strong evidence” that treatment with ART significantly reduces sexual transmission of HIV. Other evidence indicated that counseling of seropositive persons does not reduce risky behavior.

Consequently, screening of low-

the USPSTF began, at the end of

| Estimated Number and Percentage of Adults and Adolescents Who Received a Diagnosis of Human Immunodeficiency Virus (HIV) Infection, with Information on HIV-Testing History, 2006–2009.* | | | | |
|--|----------------------------|---------------------------------------|---|------------------|
| Characteristic | Diagnosis of HIV Infection | | | |
| | | Testing-History Information Available | Previous Negative HIV Test | No Previous Test |
| | no. | no. (% of total) | no. (% of those with testing-history information) | no. |
| Total | 125,104 | 57,476 (45.9) | 34,049 (59.2) | 23,427 (40.8) |
| Age at diagnosis | | | | |
| 13–29 yr | 38,521 | 21,734 (56.4) | 14,220 (65.4) | 7,513 (34.6) |
| 30–39 yr | 32,339 | 14,816 (45.8) | 9,386 (63.4) | 5,430 (36.7) |
| 40–49 yr | 33,179 | 13,244 (39.9) | 7,252 (54.8) | 5,992 (45.2) |
| ≥50 yr | 21,065 | 7,683 (36.5) | 3,191 (41.5) | 4,492 (58.5) |
| Race or ethnic group | | | | |
| Black | 62,824 | 29,945 (47.7) | 16,756 (56.0) | 13,188 (44.0) |
| Hispanic | 25,234 | 11,135 (44.1) | 6,490 (58.3) | 4,644 (41.7) |
| White | 33,377 | 14,781 (44.3) | 9,846 (66.6) | 4,935 (33.4) |
| Other | 3,669 | 1,616 (44.0) | 957 (59.2) | 659 (40.8) |
| Transmission category† | | | | |
| Male | 92,849 | 42,613 (45.9) | 25,627 (60.1) | 16,986 (39.9) |
| Male-to-male sexual contact | 65,908 | 31,493 (47.8) | 20,317 (64.5) | 11,176 (35.5) |
| Intravenous drug use | 8,889 | 3,104 (34.9) | 1,431 (46.1) | 1,674 (53.9) |
| Male-to-male sexual contact and intravenous drug use | 3,696 | 1,781 (48.2) | 1,151 (64.6) | 630 (35.4) |
| Heterosexual contact | 14,167 | 6,186 (43.7) | 2,710 (43.8) | 3,476 (56.2) |
| Other | 188 | 48 (25.7) | 17 (35.8) | 31 (64.2) |
| Female | 32,255 | 14,863 (46.1) | 8,422 (56.7) | 6,441 (43.3) |
| Intravenous drug use | 5,330 | 2,306 (43.3) | 1,356 (58.8) | 950 (41.2) |
| Heterosexual contact | 26,776 | 12,499 (46.7) | 7,048 (56.4) | 5,451 (43.6) |
| Other | 149 | 58 (39.1) | 18 (31.2) | 40 (68.9) |

* Data are from the National HIV Surveillance System for 18 jurisdictions (the states of Alabama, Arizona, Colorado, Connecticut, Florida, Indiana, Louisiana, Michigan, Mississippi, New Jersey, New York, North Carolina, South Carolina, Texas, Virginia, and Washington and the cities of Chicago and Philadelphia). The estimated numbers resulted from statistical adjustment that accounted for reporting delays and missing risk-factor information but not for incomplete reporting. Because the column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total. Adapted from the *Morbidity and Mortality Weekly Report* 2012;61:443.

† Heterosexual contact was defined as heterosexual contact with a person known to have, or to be at high risk for, HIV infection. Other transmission categories included hemophilia, blood transfusion, perinatal exposure, and any risk factor not reported or not identified.

HIV screening and counseling for sexually active women as a preventive service under the ACA, thereby creating a hard-to-justify distinction between men and women. A letter to Dr. Moyer on March 8, 2012, signed by 47 community-based and public health organizations, including the National Alliance of State

and Territorial AIDS Directors, the National Association of County and City Health Officials, the National Coalition of STD Directors, and the National Association of People with AIDS, urged the task force to align its position with that adopted by the CDC 7 years earlier. Finally, U.S. Representative Maxine Waters

(D-CA) and 40 Democratic colleagues in the House of Representatives had again introduced legislation that would have mandated health insurance coverage of routine HIV screening.

When, in November 2012, the task force posted its draft recommendation for public comment — explaining that “USPSTF con-

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.⁵

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.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Center for the History and Ethics of Public Health, Department of Sociomed-

ical Sciences, Mailman School of Public Health, Columbia University, New York.

This article was published on February 20, 2013, at NEJM.org.

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DOI: 10.1056/NEJMp1214535

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

Erika G. Martin, Ph.D., M.P.H., and Bruce R. Schackman, Ph.D.

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.^{1,2}

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.^{1,2} 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.³ 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