

# Screening for HIV Infection

## A Healthy, "Low-Risk" 42-Year-Old Man

Howard Libman, MD, Discussant

**DR REYNOLDS:** Mr Y is a 42-year-old executive who presented to establish care with a new physician. His only request was cholesterol testing. He is in excellent health and has no significant medical history. He was born in Europe but has lived in the United States for many years. Mr Y is divorced and currently sexually active with 1 female partner. He was tested for human immunodeficiency virus (HIV) more than 10 years ago and the result was reportedly negative. He has had about 10 lifetime female sexual partners and 2 during the past decade. He has no history of sexually transmitted diseases, has not received blood product transfusions, and has never used injection drugs. His physical examination results are normal. He declined the offer by his physician to have an HIV test performed.

### MR Y: HIS VIEW

In general, I'm not a big fan of medical tests or needles, to be honest with you. And as long as I don't have to get tests for things, I prefer not to. Part of it is just my general sense of well-being. But also, it's sort of an acceptance that if there's a test being done, something's wrong. I generally believe that if I don't feel that there's anything wrong with me, then there probably isn't. I was going to get the cholesterol test anyway. And so my doctor just offered the HIV test at the same time. I was a little surprised, to be frank, about the suggestion. And I think my first instinct or reaction was to just say, "I don't believe I need an extra test, and I'd rather not be tested." Now, having thought about it a little bit more, I still don't really think I need to be tested. I just don't see myself as being HIV-positive.

If I had a new sexual partner, I don't know if I would ask about her history. I can't imagine that would be an easy discussion to have. I would probably use some protection, at least at first, until a discussion about sexual history was possible and then figure out what to do next. This is what happened with my current partner. And, whether I'm right or wrong, I really don't see myself as a high risk. And so, HIV to me seems like such a low probability, almost null, that I think it was really a question of

Human immunodeficiency virus (HIV) infection meets many, if not all, of the established criteria that justify routine screening, and screening for HIV infection can be cost-effective depending on the population studied. In 2006, the Centers for Disease Control and Prevention recommended that HIV screening be included as part of routine care for most of the adult US population, but implementation of this policy has been slow. Mr Y is a 42-year-old man at relatively low risk of HIV infection who was offered testing by his primary care physician but declined it. He does not consider HIV infection to be a realistic possibility given his behavioral history and does not understand the purpose of being tested. The discussion that follows addresses the rationale for HIV screening, its potential benefits and risks, current testing options, and barriers to incorporating it into routine care.

JAMA. 2011;306(6):637-644

www.jama.com

having an extra test for the sake of an extra test. So I didn't really feel that I needed it.

It's hard for me to imagine receiving a positive test result for HIV. But, I imagine any way you receive it can't be easy. In a way, I think that receiving it in the mail would be difficult simply because I imagine you'd have a lot of questions about "what now?"

How does the CDC [Centers for Disease Control and Prevention] decide which illnesses to test everybody for? What are the criteria? I'm obviously not a doctor, but I can think of other illnesses that I'm not screened for. What makes HIV different? HIV says something about your sexual behavior.

The conference on which this article is based took place at the Medical Grand Rounds at Beth Israel Deaconess Medical Center, Boston, Massachusetts, on March 25, 2010.

**Author Affiliation:** Dr Libman is Professor of Medicine, Harvard Medical School, and Director of the HIV Program of Healthcare Associates, Beth Israel Deaconess Medical Center, Boston.

**Corresponding Author:** Howard Libman, MD, Beth Israel Deaconess Medical Center, 330 Brookline Ave, Shapiro Clinical Center, Room 621A, Boston, MA 02215 (hlibman@bidmc.harvard.edu).

**Clinical Crossroads at Beth Israel Deaconess Medical Center** is produced and edited by Risa B. Burns, MD, series editor; Tom Delbanco, MD, Howard Libman, MD, Eileen E. Reynolds, MD, Marc Schermerhorn, MD, Amy N. Ship, MD, and Anjala V. Tess, MD. **Clinical Crossroads Section Editor:** Margaret A. Winker, MD, Deputy and Online Editor.



CME available online at [www.jamaarchivescme.com](http://www.jamaarchivescme.com) and questions on p 661.

It's not associated with any particular group, but, you know, there is still some stigma attached to it. And I think testing everybody for HIV sort of has a negative connotation. So, in short, my question is, "What makes HIV different from all other diseases, and why do I need to be tested for it?"

### AT THE CROSSROADS: QUESTIONS FOR DR LIBMAN

Who is at risk of HIV infection in the United States? For whom is HIV screening indicated? What is the rationale for routine HIV screening? What are its benefits and risks? What are the testing options for HIV infection? What are the barriers to incorporating HIV screening into routine care? Is informed consent necessary? How should test results be communicated? What would you recommend for Mr Y?

**DR LIBMAN:** Mr Y presents the common scenario of a patient at some but not very high risk of acquiring HIV infection who is reluctant to be tested. Should his request be honored without comment, or should he be encouraged to be screened? If the latter, how strong should that recommendation be?

### Epidemiology

Despite considerable medical progress during the past 2 decades, HIV infection remains a leading cause of illness and death in the United States. In 2006 (the most recent data available), approximately 1 106 400 US residents were living with HIV infection, and 56 300 newly diagnosed cases were identified.<sup>1</sup> Twenty-one percent of HIV-infected persons in the United States are unaware of their serostatus.<sup>2</sup> Such individuals may present late for care, are unable to benefit from medical advances, and appear more likely to transmit HIV infection to others. Studies suggest that being aware of one's HIV serostatus may decrease the risk of infecting others.<sup>3-5</sup>

In 2009, 57% of newly diagnosed cases of HIV infection in the United States were transmitted by male-to-male sexual contact, 31% of cases by heterosexual contact, 9% of cases by injecting drug use, and 3% of cases by male-to-male sexual contact and injecting drug use.<sup>6</sup> Thirty-four percent of cases were among persons aged 13 to 29 years, 24% among those aged 30 to 39 years, 25% among those aged 40 to 49 years, and 17% among those aged 50 years or older.<sup>6</sup> In 2008, among male cases, 46% were among African Americans, 32% were among non-Hispanic whites, and 19% were among Hispanics; among female cases, 67% were among African Americans, 18% were among non-Hispanic whites, and 13% were among Hispanics.<sup>6</sup> As a 42-year-old white man, Mr Y falls into an epidemiologic category that accounts for a substantial number of newly diagnosed HIV cases annually in the United States, although he is not at high risk of the infection based on his behavioral history.

Campsmith et al<sup>2</sup> used a back-calculation method and surveillance data to estimate the US prevalence of diagnosed and undiagnosed HIV infection in 2006. Among those liv-

ing with HIV, these rates varied by race/ethnicity, age, and risk behavior. Undiagnosed infections were higher in African Americans and Hispanics compared with non-Hispanic whites (22% vs 19% of those living with HIV), in persons younger than 25 years compared with those aged 25 to 34 years and 35 years or older (48% vs 28% and 20%), and in heterosexual persons and men who have sex with men compared with injecting drug users (27% and 24% vs 14%). Overall, the rate of undiagnosed HIV infection, while substantial in all groups, was 9 times higher in African Americans than non-Hispanic whites and 3 times higher in Hispanics than non-Hispanic whites. In a report based on 2008 data from the National HIV Behavioral Surveillance System, the percentage of men who have sex with men who were unaware of their HIV diagnosis varied widely based on age, race/ethnicity, and care site.<sup>7</sup>

Specific behaviors convey different risks of acquiring HIV infection. It is estimated that among sexual behaviors, unprotected receptive anal intercourse with a person who is HIV-infected is associated with the highest risk (1% per act), unprotected receptive and insertive vaginal intercourse with an intermediate risk (0.03%-0.2%), and unprotected receptive oral sex with the lowest risk (0.06%).<sup>8-10</sup> However, these data are approximate and may vary depending on the viral load of the source, the presence of other sexually transmitted diseases in both persons, male circumcision (for insertive vaginal intercourse), and other factors.

### Indications for HIV Screening

Human immunodeficiency virus infection meets many, if not all, of the following established criteria to justify routine screening for a medical condition: (1) it is a significant disorder that can be detected before symptoms develop; (2) treatment is more beneficial when begun before symptoms develop; (3) the screening test is reliable, inexpensive, and acceptable to patients and clinicians; and (4) the cost of screening is reasonable in relation to anticipated benefits.<sup>11</sup>

Studies have demonstrated that HIV screening is generally cost-effective.<sup>12-16</sup> Estimated costs per quality-adjusted life-year (QALY) have ranged from \$38 600 to \$113 000 depending on the population studied.<sup>12-14</sup> Sanders et al<sup>13</sup> calculated that routine HIV screening would cost \$15 078 per QALY in a population with a prevalence of 1% and less than \$50 000 per QALY in a population with a prevalence of greater than 0.05%. These data are similar to those for other generally accepted screening tests, such as mammography and colonoscopy. Comparable results for HIV screening have been noted whether or not a transmission benefit is assumed.<sup>15,16</sup>

Before 2006, clinicians were advised to use historical and clinical criteria to determine if patients were at risk of HIV infection and whether to recommend screening.<sup>17</sup> However, there are considerable obstacles in performing an HIV risk assessment, and physicians have traditionally not done it well.<sup>18,19</sup> In addition, some patients may choose not to dis-

close their sexual orientation to their primary care clinician.<sup>20</sup> Overall HIV testing rates in the United States between 2000 and 2005 were relatively low (only 37% ever tested; 10% tested during the previous year), and the rates did not change significantly during the 6-year survey period.<sup>21</sup> Even more striking was the finding that only 22% of self-reported high-risk patients had been tested during the previous year.

When it became evident that perinatal transmission could be significantly reduced by initiation of antiretroviral therapy in pregnant HIV-infected women, an “opt-out” approach to HIV screening, which involves incorporating the test as part of routine prenatal care, was successfully implemented.<sup>22</sup> In 2006, the CDC expanded its recommendations for voluntary HIV screening to include all persons aged 13 to 64 years in health care settings unless the prevalence was determined to be less than 0.1%.<sup>23</sup> However, epidemiologic data are not available for most care sites, making it difficult to carve out exclusions. The CDC advised testing all patients as part of routine health care and those at “high risk” at least annually using an opt-out approach with no separate consent or requirement for pretest or preventive counseling. The CDC defines persons at high risk as being injecting drug users and their sex partners, those who exchange sex for money or drugs, sex partners of known HIV-infected persons, and men who have sex with men or heterosexual persons who themselves or whose sex partners have had more than 1 sex partner since their most recent HIV test.<sup>23</sup>

The goal of these revised recommendations was to destigmatize HIV testing and incorporate it into general medical care. While some success has been reported in the past 5 years, routine HIV screening has not been broadly implemented because of a variety of impediments. In an attempt to address these barriers, in 2010 the CDC’s Division of HIV/AIDS Prevention launched a new phase of its Act Against AIDS campaign entitled “HIV Screening. Standard Care.” to assist physicians in making HIV testing a routine part of health care.<sup>24</sup>

In addition to the CDC, 2 other professional organizations in the United States have published HIV screening recommendations. The American College of Physicians (ACP) concurs with the CDC that routine screening should be recommended to all patients at least once with the need for repeat testing determined on an individual basis.<sup>25</sup> The US Preventive Services Task Force (USPSTF) advises screening in patients at increased risk of HIV infection, defined as “1 or more risk factors or receiv(ing) health care in high-prevalence or high-risk clinical setting,” as well as in all pregnant women.<sup>26,27</sup> The USPSTF defines individuals at risk of HIV infection as men who have had sex with men after 1975; men and women having unprotected sex with multiple partners; past or present injecting drug users; men and women who exchange sex for money or drugs or have sex partners who do; persons whose past or present sex partners were

HIV-infected, bisexual, or injecting drug users; persons being treated for sexually transmitted diseases; and persons with a history of blood transfusion between 1978 and 1985.<sup>26</sup> The USPSTF describes high-risk clinical settings as sexually transmitted disease clinics, correctional facilities, homeless shelters, tuberculosis clinics, clinics serving men who have sex with men, and adolescent health clinics with a high prevalence of sexually transmitted diseases. It makes no recommendations for or against screening persons not considered at increased risk of HIV infection or not being seen in a high-risk clinical setting.

Reasons for discordance between the CDC/ACP and USPSTF guidelines may include differences in interpretation of the strength of indirect evidence, perceived benefits and risks in low-risk settings, and cost-effectiveness data. Therefore, the reluctance that Mr Y feels about HIV screening mirrors the lack of consensus on screening someone in his low-risk category.

Internationally, the World Health Organization has advocated that HIV screening, which should be voluntary, confidential, and undertaken with consent, be performed in all patients presenting for care in countries with a generalized HIV epidemic.<sup>28</sup> In countries with concentrated or low-level epidemics, HIV screening is recommended in patients presenting for care in antenatal, tuberculosis, and sexual health clinics.<sup>28</sup> Specific HIV screening policies vary by country.

Based on clinical experience, contraindications to HIV screening would be the inability of patient to understand the implications of the result because of cognitive impairment, acute psychosis, or major depression or suicidality.

### Rationale, Benefits, and Risks

The rationale for routine HIV screening can be summarized as follows: (1) many HIV-infected persons are unaware of their serostatus; (2) patients access health care regularly without being tested and late diagnosis is common; (3) awareness of HIV infection leads to reduced high-risk sexual behaviors; and (4) effective treatment of HIV infection, which benefits most patients as well as the general public health, is available.

In a 2000-2003 study, 45% of patients were diagnosed as having HIV infection within 12 months of an AIDS diagnosis.<sup>29</sup> These “late testers” were more likely to be young, heterosexual, less educated, and African American or Hispanic in comparison with “early testers” (HIV diagnosis >5 years prior to AIDS diagnosis). Not surprisingly, late testers more often had HIV testing performed because of symptoms, while early testers usually requested it because they viewed themselves or their partners as at risk or because it was recommended by their primary care clinicians as part of routine care. In 2007, the percentage of persons with newly diagnosed HIV infection who had a late diagnosis had decreased to 32.3%, with individual state data varying between 25.0% and 47.2%.<sup>30</sup>

Several studies suggest that awareness of HIV serostatus is associated with a decreased risk of transmission to others. Marks et al<sup>3</sup> estimated that the 25% of HIV-positive patients who were unaware of their serostatus are responsible for 54% to 70% of new cases of HIV infection. A meta-analysis of 11 HIV risk behavior studies showed that unprotected anal/vaginal sex with HIV-negative partners was 68% lower in persons aware vs unaware that they were HIV-positive.<sup>31</sup> Transmission rates have been estimated to be 8.8% to 10.8% among HIV-positive persons who are unaware of their serostatus and 1.7% to 2.4% among those who are aware.<sup>3,32,33</sup>

The morbidity and mortality of HIV infection has been reduced significantly with the introduction of effective combination antiretroviral therapy in the mid-1990s.<sup>34</sup> Department of Health and Human Services guidelines for when to start antiretroviral therapy continue to evolve over time, with recent studies indicating a benefit for earlier treatment.<sup>35</sup> Current indications for initiation of antiretroviral therapy in HIV-infected patients include any of the following criteria: (1) CD4 cell count less than 500/ $\mu$ L; (2) AIDS-defining diagnosis regardless of CD4 cell count; (3) HIV-associated nephropathy; (4) coinfection with hepatitis B virus (HBV) when HBV treatment is indicated; and (5) pregnancy.

Randomized controlled trial data support the benefit of antiretroviral therapy in patients with a CD4 cell count of 350/ $\mu$ L or less, and observational cohort data support it in those with a CD4 cell count greater than 350/ $\mu$ L.<sup>34,36,37</sup> There may even be clinical benefit in treating patients with a CD4 cell count greater than 500/ $\mu$ L, although no consensus exists among experts on whether to recommend antiretroviral therapy in this group.<sup>35,37</sup>

In addition to antiretroviral therapy, potential individual health benefits of HIV screening include initiation of opportunistic infection prophylaxis, which may also result in fewer complications and hospitalizations and decreased mortality. Patients receiving effective antiretroviral therapy appear less likely to transmit HIV infection to seronegative sexual partners. This association has been shown in observational studies of both men who have sex with men and heterosexual persons and in a recent randomized controlled trial of heterosexual serodiscordant couples.<sup>38-40</sup> Other potential public health benefits include reduction of perinatal, sexual, and parenteral transmission and improved epidemiologic monitoring.

Risks of HIV screening include false-positive and false-negative test results (see below) and adverse psychological reactions, breach of patient confidentiality, and social stigma associated with a positive test result. The Americans With Disabilities Act provides protection to HIV-infected persons against discrimination in the workplace and public accommodation.<sup>41</sup> However, they still may face obstacles in obtaining individual health, life, or disability insurance, which are determined by company underwriting practices.

### Testing Options and Characteristics

Human immunodeficiency virus testing is generally accomplished using a 2-step process.<sup>42</sup> Initially, most often an immunoassay is performed for screening, although a chemiluminescent assay may be used alternatively. If the result is negative, the test is reported as negative. If the result is positive, most often a Western blot assay is performed for confirmation, although an immunofluorescent assay or qualitative HIV plasma RNA may be used alternatively. Immunoassays, which have been developed for HIV-1, HIV-2, or a combination of the viruses, can be used on serum, plasma, dried blood, oral mucosal transudate, or urine.<sup>43</sup> The immunoassay is low in cost, has a standardized method, and is highly sensitive (sensitivity, 99.7%; specificity, 98.5%).<sup>44</sup> Western blot, which is more specific (sensitivity, 99.3%; specificity, 99.7%) than the immunoassay but more subjective in interpretation, is an immunochromatographic assay.<sup>44</sup> The results are read as positive (at least 2 HIV bands present [p24 + gp120/160 or gp41 + gp120/160]), negative (none present), or indeterminate (any band[s] present that do not meet criteria for a positive test result).

False-positive and false-negative immunoassay and Western blot results are uncommon.<sup>43</sup> False-positive results occur very rarely, with causes including autoimmune disorders, the patient being an HIV vaccine recipient, and clerical or technical laboratory error.<sup>43</sup> False-negative results in high-prevalence populations have been estimated to be 0.3% and in low-prevalence populations to be 0.001%.<sup>45,46</sup> However, the rate of false-negative results in a population will vary depending on the incidence of HIV, testing frequency, and what generation immunoassay is used. Causes of false-negative results include the window period (time between contracting HIV infection and development of antibody), group O or N (both seen mainly in Africa) HIV-1 infection, clerical or technical laboratory error, and, rarely, late-stage HIV disease.<sup>43</sup>

Rapid HIV antibody testing has become available over the past several years.<sup>47</sup> It is an immunoassay, the results of which are available to communicate to the patient in 15 to 20 minutes. A 60-second rapid test was approved by the US Food and Drug Administration (FDA) in 2010.<sup>48</sup> Positive test results should be confirmed with a Western blot assay. Rapid HIV testing may be especially useful in emergency departments or urgent care clinics for high-prevalence populations, recent occupational or nonoccupational exposures, and women in labor with unknown HIV serostatus. Its operating characteristics appear to be similar to those of other immunoassays.<sup>49</sup>

An FDA-approved home kit is available for anonymous HIV testing.<sup>50</sup> Patients provide a blood sample on filter paper using a lancet, and it is mailed to a reference laboratory, where an immunoassay is performed. Positive results are confirmed with an immunofluorescent assay. Test results are available in 7 to 10 days. Its operating character-

istics appear to be similar to those of the conventional 2-step testing protocol.<sup>51</sup>

Human immunodeficiency virus plasma RNA testing is usually reserved for patients in whom acute infection is suspected.<sup>42</sup> In this setting, an HIV antibody test (which will likely have negative or indeterminate results) together with an HIV viral load test (which usually has positive results at a high level [millions of copies per milliliter]) are often used.<sup>35</sup> A combined antibody/antigen (p24) test was recently approved by the FDA for diagnosis of acute HIV infection.<sup>52</sup>

### Experience With and Barriers to Implementation

Despite the 2006 CDC recommendations to incorporate routine HIV screening into medical care and some notable successes,<sup>53-55</sup> many challenges remain,<sup>56</sup> and its general adoption appears to be slow.<sup>57</sup> The CDC published results from the National Health Interview Survey to estimate the percentage of persons aged 18 to 64 years who reported ever being tested for HIV in the United States.<sup>30</sup> This percentage was stable at approximately 40% between 2001 and 2006 and increased modestly to 45% in 2009.

A literature review published in 2007 identified 41 barriers to HIV testing from 17 studies.<sup>58</sup> Insufficient time, burdensome consent process, lack of knowledge/training, perceived lack of patient acceptance, pretest counseling requirements, competing priorities, and inadequate reimbursement were most commonly reported.

The use of rapid testing in conjunction with nurse-initiated streamlined counseling was shown to be an effective means of HIV screening in a primary care practice at a Veterans Administration medical center.<sup>53</sup> Testing rates were 40.2% with standard physician counseling and standard testing, 84.5% with nurse-streamlined counseling and standard testing, and 89.3% with nurse-streamlined counseling and rapid testing. The implementation of an opt-out inpatient program at another Veterans Administration medical center was not as successful.<sup>59</sup> Only 24% of 3457 patients accepted testing, with 10 positive results (1.2%). Written informed consent, which was still required by federal regulations at the time of this study, may have reduced the acceptance rate.

Between 2003 and 2005, an effort was made to mainstream HIV screening at a Denver sexually transmitted diseases clinic by using an opt-out approach, having clerical staff rather than clinicians obtain informed consent, and making rapid testing available.<sup>54</sup> The percentage of patients receiving a syphilis test who also had an HIV test performed increased from 79% before these changes were implemented to 96% afterward.

In the District of Columbia, where the HIV case rate is nearly 10 times that of the United States overall, an initiative was launched in 2006 to promote the implementation of routine HIV screening at publicly supported sites.<sup>55</sup> From 2004 to 2008, the number of HIV tests increased by 335% (from 16 748 to 72 864), including a

415% increase among African American patients. There was a small but statistically significant increase in CD4 cell counts obtained within 3 months of new HIV diagnoses, suggesting earlier detection.

In a high-volume Denver hospital emergency department, the staff alternated between opt-out and physician-initiated HIV testing during 4-month blocks from 2007 to 2009 to determine which approach was superior.<sup>60</sup> During the opt-out periods, 6702 (24%) of 28 043 eligible patients were screened, yielding 10 new cases of HIV infection. During the physician-initiated periods, 243 (0.8%) of 29 925 eligible patients completed HIV testing, yielding 4 new cases of HIV infection. The authors concluded that opt-out testing identified only a modestly increased number of patients in this low-prevalence setting.

In the 2006 Kaiser Family Foundation Survey of Americans on HIV/AIDS, patient barriers to testing included lack of perceived risk (61%), test not recommended by physician (21%), concern about confidentiality (13%), did not know where to get tested (10%), did not like needles or giving blood (8%), and fear of testing positive (3%).<sup>61</sup> Mr Y exemplifies these challenges, as he specifically notes that he does not believe he is at risk and does not like needles.

In a 2009 national, cross-sectional, Internet-based survey of Society of General Internal Medicine members (1592 contacted; 515 [32%] responded), 88% were aware of the 2006 CDC recommendations, but only 52% had increased HIV testing, 61% offered HIV screening regardless of risk, and a median of 2% of patients seen in the past 30 days were screened for HIV infection.<sup>62</sup> Barriers cited by respondents included (1) other priorities at the time of visit (79%); (2) lack of time (64%); (3) patient reluctance/refusal (64%); and (4) informed consent requirements (49%). Results of a physician focus group revealed 5 areas that require attention to implement routine HIV screening in primary care practice.<sup>63</sup> These included (1) guideline justification (accepted by most clinicians but needs to be explained better); (2) clinical settings (implementation challenges are often setting-specific); (3) state and local regulations (may be restrictive, require informed consent, and not be well understood); (4) financial barriers (cost and variable reimbursement policies); and (5) education needs (development of setting-specific materials).

In September 2006, statutory regulations of 16 states were inconsistent with the CDC recommendations on HIV testing and precluded implementation of 1 or more of its provisions.<sup>64,65</sup> The general trend over time has been for more states to modify their regulations to make them consistent with the guidelines.<sup>65,66</sup> However, state regulations on HIV testing remain complex and are not well understood by clinicians.<sup>67</sup> As of early 2011, written informed consent was still mandated in 5 states, including Massachusetts, where Mr Y declined to be tested.<sup>67</sup> In Massachusetts, the Department of Public Health esti-

mates that 21% of the 25 000 to 27 000 persons infected with HIV do not know their serostatus and that 31% of persons with recent HIV diagnoses progress to AIDS within 2 months of entering care.<sup>68</sup>

The elimination of written informed consent for HIV testing appears to result in a substantially increased rate of screening.<sup>69</sup> In September 2006, the San Francisco Department of Public Health removed the requirement for written informed consent as long as oral consent was documented in the medical record. In the 7 months after the policy was implemented, testing rates increased significantly from 13.5 to 17.9 per 1000 visits.

The stigmatizing effect of HIV infection,<sup>70</sup> while hard to quantify and more subtle than in the early years of the epidemic, has also likely contributed to the difficulty of incorporating HIV screening into routine care. Patients, including Mr Y, may be reluctant to be tested because of perceived connotations about their sexual and/or drug use behaviors.

### Patient Counseling

Patient counseling, while often useful, should not be construed by health care practitioners as a barrier to testing. Whether counseling is mandated, the clinician should emphasize the individual health benefits from early diagnosis of HIV infection and may wish to consider discussion of at least some of the following issues: (1) risk behaviors and risk reduction measures; (2) meaning of positive and negative results; and (3) assessment of personal and social supports. The clinician should explain that standard test results may not be available for several days and discuss in advance with the patient how he/she would like them communicated. Telephone notification of results appears to be an acceptable and at least as effective means of communication as a return visit.<sup>71</sup> Of 3334 patients offered telephone notification from 1998 to 2002 at public clinics in King County, Washington, 2780 (83%) elected to receive it. The general approach in my medical practice is to inform patients of negative results by mail and positive results by telephone with same-day availability for an appointment to discuss the implications in person.

If test results are positive, it is important to assess the patient's emotional reaction and ability to cope, to anticipate the need for immediate support and follow-up, and to plan for appropriate medical evaluation. If test results are negative, it is essential to restate the possibility of seroconversion if the patient is involved in high-risk behaviors and to dispel any beliefs regarding "invulnerability" or "immunity" to HIV infection.

### RECOMMENDATIONS FOR MR Y

Human immunodeficiency virus infection meets established criteria for routine screening, and screening is cost-effective. Targeted testing of "high-risk" patients has not proved to be an effective strategy because of the difficulties in performing an accurate risk assessment. A substantial mi-

nority of HIV-infected persons do not know their serostatus despite previous encounters with the health care system. There are important individual and public health benefits in identifying these patients early in the course of their disease. However, significant patient, clinician, and regulatory barriers to implementing routine HIV screening on a broad scale remain.

Mr Y appears to be averse to screening in general, and stigma associated with HIV infection seems to add to his reservations about testing for it. Based on Mr Y's history, his risk of HIV infection is relatively low but it is certainly not zero. In the absence of clinical symptoms and signs, patients and health care practitioners have traditionally not been skilled at predicting whether HIV infection is present, and the consequences of a delayed diagnosis may be significant. I recommend that Mr Y reconsider his decision not to be tested and that his physician encourage him to have it done. There is very little to be lost by doing so and potentially much to be gained.

### QUESTIONS AND DISCUSSION

**QUESTION:** In primary care, there are a lot of preventive interventions that we can potentially do, including screening for cancers, domestic violence, guns in the home, texting while driving . . . the list just goes on and on. How would you rank the importance of HIV testing compared with some of these other issues?

**DR LIBMAN:** HIV testing is hard to rank in this list, and its relative importance will vary from patient to patient. It is difficult for clinicians to do individual risk assessments in the office, and there are clear benefits from knowing if someone is HIV-positive. I think the problem with the CDC recommendations is that HIV testing is not the same as other routine screening interventions in the minds of most patients and health care practitioners. There are psychological implications of being tested for some patients and a variety of practical impediments to routine screening for clinicians. The key point is that HIV testing is too low on the preventive health care list right now. It should be higher.

**QUESTION:** Should primary care practitioners be responsible for all HIV testing? I would argue that part of the unspoken problem here is that there is not enough commitment to testing outside of clinical settings in high-prevalence populations. Why is there not more emphasis on testing in nonclinical settings?

**DR LIBMAN:** I think there has been an ongoing effort by public health organizations to target individuals who are at high risk of HIV infection, educate them about risk reduction, and find innovative ways of getting more of them tested. The CDC is currently in the process of reviewing and updated its recommendations for HIV counseling, testing, and referral in non-health care settings.<sup>72</sup> The CDC and ACP would probably agree that the health care setting is an important venue but not the only

one. Clinicians need to be better at incorporating HIV testing into their practice. I think nurses have traditionally been more effective at it than physicians and that streamlining or eliminating the need for written consent and making rapid testing more available will go a long way toward achieving the goal of increased screening of the US population.

**Conflict of Interest Disclosures:** The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

**Additional Contributions:** We thank the patient for sharing his story and for providing permission to publish it.

## REFERENCES

- Hall HI, Song R, Rhodes P, et al; HIV Incidence Surveillance Group. Estimation of HIV incidence in the United States. *JAMA*. 2008;300(5):520-529.
- Campsmith ML, Rhodes PH, Hall HI, Green TA. Undiagnosed HIV prevalence among adults and adolescents in the United States at the end of 2006. *J Acquir Immune Defic Syndr*. 2010;53(5):619-624.
- 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(10):1447-1450.
- Cassels S, Menza TW, Goodreau SM, Golden MR. HIV serosorting as a harm reduction strategy: evidence from Seattle, Washington. *AIDS*. 2009;23(18):2497-2506.
- Wilson DP, Regan DG, Heymer KJ, Jin F, Prestage GP, Grulich AE. Serosorting may increase the risk of HIV acquisition among men who have sex with men. *Sex Transm Dis*. 2010;37(1):13-17.
- Centers for Disease Control and Prevention. Diagnoses of HIV infection and AIDS in the United States and dependent areas, 2009. <http://www.cdc.gov/hiv/surveillance/resources/reports/2009report>. Accessed March 2, 2011.
- Centers for Disease Control and Prevention. Prevalence and awareness of HIV infection among men who have sex with men—21 cities, United States, 2008. *MMWR Morb Mortal Wkly Rep*. 2010;59(37):1201-1207.
- European Study Group on Heterosexual Transmission of HIV. Comparison of female to male and male to female transmission of HIV in 563 stable couples. *BMJ*. 1992;304(6830):809-813.
- Leynaert B, Downs AM, De Vincenzi I; European Study Group on Heterosexual Transmission of HIV. Heterosexual transmission of human immunodeficiency virus: variability of infectivity throughout the course of infection. *Am J Epidemiol*. 1998;148(1):88-96.
- Varghese B, Maher JE, Peterman TA, Branson BM, Steketee RW. Reducing the risk of sexual HIV transmission: quantifying the per-act risk for HIV on the basis of choice of partner, sex act, and condom use. *Sex Transm Dis*. 2002;29(1):38-43.
- World Health Organization. *Principles and Practice of Screening for Disease*. Geneva, Switzerland: World Health Organization; 1968.
- Walensky RP, Weinstein MC, Kimmel AD, et al. Routine human immunodeficiency virus testing: an economic evaluation of current guidelines. *Am J Med*. 2005;118(3):292-300.
- Sanders GD, Bayoumi AM, Sundaram V, et al. Cost-effectiveness of screening for HIV in the era of highly active antiretroviral therapy. *N Engl J Med*. 2005;352(6):570-585.
- Paltiel AD, Weinstein MC, Kimmel AD, et al. Expanded screening for HIV in the United States—an analysis of cost-effectiveness. *N Engl J Med*. 2005;352(6):586-595.
- Paltiel AD, Walensky RP, Schackman BR, et al. Expanded HIV screening in the United States: effect on clinical outcomes, HIV transmission, and costs. *Ann Intern Med*. 2006;145(11):797-806.
- Sanders GD, Bayoumi AM, Holodny M, Owens DK. Cost-effectiveness of HIV screening in patients older than 55 years of age. *Ann Intern Med*. 2008;148(12):889-903.
- Centers for Disease Control and Prevention. Revised guidelines for HIV counseling, testing, and referral. *MMWR Recomm Rep*. 2001;50(RR-19):1-57.
- Wenrich MD, Curtis JR, Carline JD, Paauw DS, Ramsey PG. HIV risk screening in the primary care setting: assessment of physicians' skills. *J Gen Intern Med*. 1997;12(2):107-113.
- Epstein RM, Morse DS, Frankel RM, Frearey L, Anderson K, Beckman HB. Awkward moments in patient-physician communication about HIV risk. *Ann Intern Med*. 1998;128(6):435-442.
- Bernstein KT, Liu KL, Begier EM, Koblin B, Karpati A, Murrill C. Same-sex attraction disclosure to health care providers among New York City men who have sex with men: implications for HIV testing approaches. *Arch Intern Med*. 2008;168(13):1458-1464.
- Ostermann J, Kumar V, Pence BW, Whetten K. Trends in HIV testing and differences between planned and actual testing in the United States, 2000-2005. *Arch Intern Med*. 2007;167(19):2128-2135.
- Centers for Disease Control and Prevention. Revised recommendations for HIV screening of pregnant women. *MMWR Recomm Rep*. 2001;50(RR-19):63-85.
- Branson BM, Handsfield HH, Lampe MA, et al; Centers for Disease Control and Prevention. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep*. 2006;55(RR-14):1-17.
- Centers for Disease Control and Prevention. Act Against AIDS campaign. <http://www.actagainstaids.org/provider/hssc/index.html>. Accessed July 2, 2011.
- Qaseem A, Snow V, Shekelle P, Hopkins R Jr, Owens DK; Clinical Efficacy Assessment Subcommittee, American College of Physicians. 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(2):125-131.
- US Preventive Services Task Force. Screening for HIV. July 2005. <http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm>. Accessed September 20, 2010.
- Chou R, Huffman LH, Fu R, Smits AK, Korthuis PT; US Preventive Services Task Force. Screening for HIV: a review of the evidence for the US Preventive Services Task Force. *Ann Intern Med*. 2005;143(1):55-73.
- World Health Organization. *Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities*. 2007. [http://www.who.int/hiv/pub/guidelines/9789241595568\\_en.pdf](http://www.who.int/hiv/pub/guidelines/9789241595568_en.pdf). Accessed July 14, 2011.
- Centers for Disease Control and Prevention. Late vs early testing of HIV—16 sites, United States, 2000-2003. *MMWR Morb Mortal Wkly Rep*. 2003;52(25):581-586.
- Centers for Disease Control and Prevention. Vital signs: HIV testing and diagnosis among adults—United States, 2001-2009. *MMWR Morb Mortal Wkly Rep*. 2010;59(47):1550-1555.
- Marks G, Crepaz N, Senterfitt JW, Janssen RS. Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs. *J Acquir Immune Defic Syndr*. 2005;39(4):446-453.
- Holtgrave DR, Anderson T. Utilizing HIV transmission rates to assist in prioritizing HIV prevention services. *Int J STD AIDS*. 2004;15(12):789-792.
- Holtgrave DR, Pinkerton SD. Can increasing awareness of HIV seropositivity reduce infections by 50% in the United States? *J Acquir Immune Defic Syndr*. 2007;44(3):360-363.
- Palella FJ Jr, Deloria-Knoll M, Chmiel JS, et al; HIV Outpatient Study Investigators. Survival benefit of initiating antiretroviral therapy in HIV-infected persons in different CD4<sup>+</sup> cell strata. *Ann Intern Med*. 2003;138(8):620-626.
- US Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. January 10, 2011. <http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf>. Accessed July 17, 2011.
- Emery S, Neuhaus JA, Phillips AN, et al; Strategies for Management of Antiretroviral Therapy (SMART) Study Group. Major clinical outcomes in antiretroviral therapy (ART)-naïve participants and in those not receiving ART at baseline in the SMART study. *J Infect Dis*. 2008;197(8):1133-1144.
- Kitahata MM, Gange SJ, Abraham AG, et al; NA-ACCORD Investigators. Effect of early vs deferred antiretroviral therapy for HIV on survival. *N Engl J Med*. 2009;360(18):1815-1826.
- Porco TC, Martin JN, Page-Shafer KA, et al. Decline in HIV infectivity following the introduction of highly active antiretroviral therapy. *AIDS*. 2004;18(1):81-88.
- Castilla J, Del Romero J, Hernando V, Marincovich B, García S, Rodríguez C. Effectiveness of highly active antiretroviral therapy in reducing heterosexual transmission of HIV. *J Acquir Immune Defic Syndr*. 2005;40(1):96-101.
- HIV Prevention Trials Network. Initiation of antiretroviral treatment protects uninfected sexual partners from HIV infection (HPTN Study 052) [press release]. May 12, 2011. [http://www.hptn.org/web%20documents/PressReleases/HPTN052PressReleaseFINAL5\\_12\\_118am.pdf](http://www.hptn.org/web%20documents/PressReleases/HPTN052PressReleaseFINAL5_12_118am.pdf). Accessed July 16, 2011.
- US Department of Justice. Questions and answers: the ADA and persons with HIV/AIDS. <http://www.ada.gov/pubs/hivqanda.txt>. Accessed March 2, 2011.
- Aberg JA, Kaplan JE, Libman H, et al; HIV Medicine Association of the Infectious Diseases Society of America. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV Medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis*. 2009;49(5):651-681.
- Bartlett JG. Diagnostic assays for HIV infection. Waltham, MA: UpToDate Inc; February 2010. [http://www.uptodate.com/contents/diagnostic-assays-for-hiv-infection?source=search\\_result&selectedTitle=1%7E150](http://www.uptodate.com/contents/diagnostic-assays-for-hiv-infection?source=search_result&selectedTitle=1%7E150). Accessed July 14, 2011.
- Centers for Disease Control. Update: serologic testing for HIV-1 antibody—United States, 1988 and 1989. *MMWR Morb Mortal Wkly Rep*. 1990;39(22):380-383.
- Farzadegan H, Vlahov D, Solomon L, et al. Detection of human immunode-

- iciency virus type 1 infection by polymerase chain reaction in a cohort of seronegative intravenous drug users. *J Infect Dis*. 1993;168(2):327-331.
46. Busch MP, Eble BE, Khayam-Bashi H, et al. Evaluation of screened blood donations for human immunodeficiency virus type 1 infection by culture and DNA amplification of pooled cells. *N Engl J Med*. 1991;325(1):1-5.
  47. Centers for Disease Control and Prevention. Rapid HIV testing. July 24, 2009. <http://www.cdc.gov/hiv/topics/testing/rapid/>. Accessed September 20, 2010.
  48. US Food and Drug Administration. INSTI HIV-1 antibody test. November 30, 2010. <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm235024.htm>. Accessed March 2, 2011.
  49. Martin CA, Keren DF. Comparison of murex single-use diagnostic system with traditional enzyme immunoassay for detection of exposure to human immunodeficiency virus. *Clin Diagn Lab Immunol*. 2002;9(1):187-189.
  50. Home Access Health Corporation. The Home Access HIV-1 test system. [http://www.homeaccess.com/hiv\\_test.asp](http://www.homeaccess.com/hiv_test.asp). Accessed September 20, 2010.
  51. Frank AP, Wandell MG, Headings MD, Conant MA, Woody GE, Michel C. Anonymous HIV testing using home collection and telemedicine counseling: a multicenter evaluation. *Arch Intern Med*. 1997;157(3):309-314.
  52. US Food and Drug Administration. Abbott Architect HIV Ag/Ab combo. June 18, 2010. <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/ucm216291.htm>. Accessed March 2, 2011.
  53. Anaya HD, Hoang T, Golden JF, et al. Improving HIV screening and receipt of results by nurse-initiated streamlined counseling and rapid testing. *J Gen Intern Med*. 2008;23(6):800-807.
  54. Brooks L, Rietmeijer CA, McEwen D, Subiadur JA, Mettenbrink CJ. Normalizing HIV testing in a busy urban sexually transmitted infections clinic. *Sex Transm Dis*. 2009;36:127-128.
  55. West-Ojo T, Samala R, Griffin A, et al; Centers for Disease Control and Prevention. Expanded HIV testing and trends in diagnoses of HIV infection—District of Columbia, 2004-2008. *MMWR Morb Mortal Wkly Rep*. 2010;59(24):737-741.
  56. Centers for Disease Control and Prevention. HIV testing challenges. October 30, 2006. <http://www.cdc.gov/hiv/topics/testing/challenges.htm>. Accessed September 20, 2010.
  57. Paddock C. CDC recommendations for routine HIV testing largely ignored. November 21, 2008. <http://www.medicalnewstoday.com/articles/130267.php>. Accessed September 20, 2010.
  58. Burke RC, Sepkowitz KA, Bernstein KT, et al. Why don't physicians test for HIV? a review of the US literature. *AIDS*. 2007;21(12):1617-1624.
  59. Siegel M, Kennedy L, Rexroth K, et al. Better but not ideal acceptance of routine inpatient HIV point-of-care testing among veterans in a high prevalence area. *J Acquir Immune Defic Syndr*. 2010;55(2):205-210.
  60. Haukoos JS, Hopkins E, Conroy AA, et al; Denver Emergency Department HIV Opt-Out Study Group. Routine opt-out rapid HIV screening and detection of HIV infection in emergency department patients. *JAMA*. 2010;304(3):284-292.
  61. Kaiser Family Foundation. Survey of Americans on HIV/AIDS. May 8, 2006. <http://www.kff.org/kaiserpolls/pomr050806pkg.cfm>. Accessed September 20, 2010.
  62. Korhuis PT, Berkenblit GV, Sullivan LE, et al. General internists' beliefs, behaviors, and perceived barriers to routine HIV screening in primary care. *AIDS Educ Prev*. 2011;23(3)(suppl):70-83.
  63. Bashook PG, Edison MI, Sullivan LE, et al. Physician barriers to implementing routine HIV testing in primary care settings: a qualitative analysis. *J Gen Intern Med*. 2008;23(suppl 2):367.
  64. Commonwealth of Massachusetts. General laws: section 70F: HLTV-III test; confidentiality; informed consent. <http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section70F>. Accessed July 16, 2010.
  65. Mahajan AP, Stemple L, Shapiro MF, King JB, Cunningham WE. Consistency of state statutes with the Centers for Disease Control and Prevention HIV testing recommendations for health care settings. *Ann Intern Med*. 2009;150(4):263-269.
  66. Bartlett JG, Branson BM, Fenton K, Hauschild BC, Miller V, Mayer KH. Opt-out testing for human immunodeficiency virus in the United States: progress and challenges. *JAMA*. 2008;300(8):945-951.
  67. National HIV/AIDS Clinicians' Consultation Center. Compendium of HIV state testing laws. 2011. [http://www.nccc.ucsf.edu/consultation\\_library/state\\_hiv\\_testing\\_laws](http://www.nccc.ucsf.edu/consultation_library/state_hiv_testing_laws). Accessed March 14, 2011.
  68. Gatty B. Positives are clear but impediments exist. *HIV Specialist*. 2010; 10-13 Spring.
  69. Zetola NM, Klausner JD, Haller B, Nassos P, Katz MH. Association between rates of HIV testing and elimination of written consents in San Francisco. *JAMA*. 2007;297(10):1061-1062.
  70. Sontag S. *AIDS and its Metaphors*. New York, NY: Farrar Straus & Giroux; 1989.
  71. McKinstry LA, Goldbaum GM, Meischke HW. Telephone notification of HIV test results: impact in King County, Washington. *Sex Transm Dis*. 2007;34(10):796-800.
  72. Centers for Disease Control and Prevention. *Consultation on Revised Guidelines for HIV Counseling, Testing, and Referral in Non-Health-Care Settings*. September 2009. <http://www.cdc.gov/hiv/topics/testing/resources/other/consultation.htm>. Accessed September 20, 2010.