Preaching to the Choir: Advocating Routine HIV Testing

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SB 350

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For the first 25 years of the AIDS epidemic, HIV testing was treated differently from all other types of medical diagnostic testing. Formal pretest and posttest counseling was required, and patients had to give written informed consent before being tested. The need for testing was focused primarily on assessment of risk, which required the taking of a detailed sexual and drug use history for which few clinicians had the time, training, or inclination. The rationale for this particular form of "HIV exceptionalism" was mostly historical, dating back to times when concerns about stigma; discrimination; and loss of insurance, jobs, or housing outweighed any modest benefit that might have been derived from early medical care.

The risk to benefit ratio changed almost overnight with the advent of the HAART era in 1996. The benefits of early diagnosis increased dramatically, while the risks associated with an HIV diagnosis, although not completely eliminated, decreased significantly. Now, data from numerous observational cohort studies suggest that there is a benefit to diagnosis at even earlier stages of HIV disease. For example, the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) study found that mortality was 70% lower in patients who started therapy when their $CD4^+$ cell counts were between 350/µL and 500/µL than in those who waited until their $CD4^+$ cell count had fallen to below 350/µL, the current standard of care.[1]

In September 2006, the CDC dramatically changed its recommendations for HIV screening.[2] The new approach involved routine testing of everyone between the ages of 13 and 64 in all health care settings in the United States. It was recommended that written informed consent no longer be required. Instead, testing should be performed on an "opt-out" basis, meaning that patients should be informed verbally or in writing that they will be tested, which they can then refuse without compromise of their health care. Pretest counseling, while desirable, should no longer be required for HIV screening. Those who test positive should understand the results and have access to HIV care.

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For the most part, the response to the new CDC recommendations has been favorable. Dozens of professional societies have endorsed routine testing, including most recently the American College of Physicians. However, 2 years later, implementation of the guidelines remains poor.[3] A recent article by Bartlett and colleagues[4] documented the multiple barriers to widespread implementation of the new HIV screening policy. Several states continue to require written informed consent and formal pretest counseling, although the number is gradually decreasing with changes in state legislation. Other obstacles to widespread implementation have included persistent concerns about the lack of mandatory counseling and the potential for stigma or discrimination.

It is clear that our previous approaches to HIV diagnosis and prevention have not worked. Almost one-quarter of the 1.1 million Americans infected with HIV are believed to be unaware of their serostatus,[2] and this group may account for 50% to 70% of new sexually transmitted infections. Persons infected with HIV are frequently in advanced stages of disease before the diagnosis is made; surveillance data have found that in nearly 40% of patients, HIV infection was diagnosed within a year of a subsequent AIDS diagnosis.[5] Furthermore, the average $CD4^+$ cell count at the time of initiation of antiretroviral therapy for US patients between 2003 and 2005 was only 187/µL.[6] Bartlett and colleagues[4] extrapolated Maryland data nationally and estimated that late presentation resulted in 100,000 life-years lost.

Another barrier to routine testing is the cost of the test and concerns about the cost-effectiveness of a routine screening strategy. However, cost-effectiveness analyses have estimated that routine HIV screening costs $50,000 to $64,000 per quality-adjusted life-year in areas where the prevalence is 0.05% to 0.1%.[7-9] This cost estimate puts routine HIV screening in the range of other routinely recommended interventions, such as Pap smears and screening colonoscopy, and screening for HIV involves a much simpler test in terms of clinician time, effort, and training. Of course, the cost-effectiveness increases in areas of higher seroprevalence.

Although the risk of discrimination and stigma cannot be eliminated entirely, bad outcomes from HIV testing itself remain anecdotal and few in number, while the consequences of delayed diagnosis are plentiful and often

tragic. Not long ago, a patient was referred to me after having been hospitalized for several weeks with respiratory failure and acute respiratory distress syndrome as a result of *Pneumocystis* pneumonia (PCP). He had required mechanical ventilation and was now receiving home oxygen therapy.

In reviewing this patient's medical history, I learned that a few years earlier he had been hospitalized for several days with an unexplained febrile illness. He had been seen by numerous consultants, and his workup was exhaustive but nondiagnostic. He was ultimately sent home on an empiric treatment regimen for a combination of Rocky Mountain spotted fever and Lyme disease, despite the lack of serological evidence for either. During his extensive evaluation, no HIV test was ever performed, presumably because of the absence of any identifiable risk factors, although there was no indication in the medical record that anyone had asked him about HIV risk. Several months after this initial hospitalization, his wife was told she had "viral meningitis"—an unlikely diagnosis in the middle of winter. Again, no HIV test was performed, and the possibility of acute retroviral syndrome was not entertained; she was only later found to be HIV-positive, after her husband was hospitalized with PCP.

One could argue that these 2 cases represent not a failure of HIV screening but a failure of multiple physicians to recognize clinical manifestations of HIV disease. Nevertheless, had the HIV serology been a routine test rather than one that required informed consent after the asking of potentially embarrassing questions, the husband would have avoided a long, painful, and expensive second hospitalization, and his wife might have avoided infection altogether.

Advocating routine HIV testing to readers of this journal may be "preaching to the choir," since the burden of responsibility falls not on HIV practitioners but on clinicians working in primary care practices, emergency departments, and walk-in clinics. Nevertheless, clinicians who treat persons with HIV/AIDS must now become vocal advocates for routine HIV screening. HIV infection is unique in that we have the ability to test for a highly treatable but otherwise fatal disease with an inexpensive and accurate test, yet so often fail to do so. □

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CORRECTION: In Dr Gallant's Editorial in the February issue, the CASCADE cohort study was misidentified. The study is the Concerted Action on SeroConversion to AIDS and Death in Europe study and not the cardiovascular drug study that is referred to by the same acronym. We regret the error.

—John Hawes, Editor

EXHIBIT 2
DATE 3/31/09
SB 350

SB 350 – Routine HIV Screening

Sponsored by Senator Kim Gillan

Overview:

SB 350 is a bill that would provide for routine HIV screening and incorporate the screening into a patient's general informed consent for medical care. The bill also incorporates prenatal and labor and delivery HIV screening into general informed consent for medical care in an effort to prevent the spread of HIV. Privacy issues related to general informed consent for medical care are covered under the Health Insurance Portability and Accountability Act (HIPAA).

Current Situation:

HIV testing and screening in the state of Montana is currently provided for in statute and requires that a person must specifically seek out HIV diagnostic testing, have pre and post counseling and sign a written consent form.

Change Requested:

In concert with the recommendations from the Centers for Disease Control and Prevention, SB 350 would provide for routine HIV screening and incorporate the screening into a patients' general informed consent for medical care. This bill would allow a patient to "opt-out" of HIV screening and that decision would be documented in the patient's medical chart.

SB 350 Would:

- Remove barriers to HIV testing in a healthcare setting as pre and post-test counseling are sometimes viewed as onerous.
- De-stigmatize HIV testing as eventually, every patient seeking care in a healthcare setting would know his/her HIV status provided that she/he did not opt out of testing.
- Decrease HIV transmission in Montana as it has been proven that people who are not aware of their HIV positive status are more likely to transmit the disease than those who know their HIV status.
- Significantly reduce the chances of HIV transmission to newborns by ensuring that HIV positive mothers received proper treatment and monitoring throughout their pregnancies.
- Save money as the average lifetime cost of care for someone with HIV is $200,000.
- The total lifetime cost for Americans newly diagnosed with HIV/AIDS during 2002 was approximately $36.4 billion which includes almost $7 billion in direct medical costs and almost $30 billion in productivity losses.

Added Benefits of Routine HIV Screening:

- 25% of people in the United States with HIV do not know that they are infected.
- HIV can be reliably diagnosed prior to symptom development and patients are more likely to be tested if testing is suggested by a medical provider.
- Routine testing helps de-stigmatize the disease.
- Early entry into HIV care increases the likelihood of a longer, healthier life. 39% of people with HIV in the US are not diagnosed until they are in the late stages of the disease.
- Transmission rates are higher in people who do not know they have HIV. People who know their positive HIV status are more likely to engage in risk reduction measures.

Source of information compiled from the Centers for Disease Control and Prevention by RiverStone Health, Billings, MT 59101.