

Making HIV Tests ‘Routine’: Concerns and Implications

By Heather D. Boonstra

Well over two decades after the AIDS epidemic burst onto the American scene, an estimated 40,000–55,000 people in the United States are still newly infected each year—a statistic that has remained relatively unchanged since 1998. A staggering one in four individuals with HIV—about 250,000 Americans—are believed to be unaware they are infected with the virus. Moreover, close to 40% of people who test positive for HIV are diagnosed within just one year of developing full-blown AIDS, and the majority of those who get an HIV test late in the course of their infection do so because they are already ill.

Against this backdrop, the Centers for Disease Control and Prevention (CDC) recently recommended that HIV testing be a standard part of medical care for every American aged 13–64. Expanded HIV testing has widespread support among physicians, public health officials, patient advocates and AIDS organizations, who agree that intensified efforts are critical, both to ensure that HIV-positive people live longer, healthier lives and to enhance prevention efforts. At the same time, many AIDS organizations and human rights groups have raised concerns about making HIV tests “routine” (i.e., patients not wishing to be tested must affirmatively opt out) and what effect this might have on stigma and discrimination, informed consent, the availability of HIV testing in other settings and medical care costs. In addition, there is real concern that the CDC’s HIV testing initiative—itsself part of a larger federal initiative largely focused on identifying and providing services, including behavior-change counseling, to HIV-positive individuals—represents a retreat from more comprehensive

HIV prevention efforts. Although the paradigm shift toward “prevention for positives” has considerable merits on its own terms, advocates charge that it calls into question the nation’s commitment to broader primary prevention efforts aimed at people at risk of contracting HIV.

CDC Recommendations

The CDC’s guidelines for HIV testing in health care settings, issued on September 22, 2006, recommend that all teenagers and adults up to age 64 be routinely tested for HIV as a normal part of medical practice, irrespective of an individual’s risk factors or HIV prevalence in the community. Under the guidelines, health care providers would inform their patients that HIV testing is planned, give them basic information about HIV and the meaning of the test results, and offer an opportunity to ask questions and to decline testing. If the test results are positive, providers would personally contact patients and ensure that they are linked to clinical care, counseling and support. HIV-negative test results, on the other hand, could be conveyed in the same way as results of other diagnostic or screening tests.

To promote expanded testing and streamline the process for providers, the CDC recommends that patients no longer be asked to sign a separate consent form for HIV testing. Instead, consent for HIV testing would be incorporated into general consent for medical care, unless the patient explicitly opts out. In addition, the CDC recommends eliminating requirements for extensive pretest prevention counseling in general health care settings. This recommendation is based, in large part, on research indicating that counseling in conjunction with testing is not effective for

behavior change, except among those who actually test positive. It also arises from a concern that some health care providers perceive requirements for prevention counseling as a barrier to offering testing, because of time constraints or discomfort discussing their patients' risk behaviors. According to the CDC, prevention counseling is still an essential part of "comprehensive" HIV prevention efforts and is strongly encouraged in settings in which risk behaviors are routinely assessed, such as in an STD or family planning clinic.

The CDC recommendations for routine HIV testing do not have the force of law, but signal a new standard of care and reflect a worldwide trend toward expanded HIV testing (see box). The guidelines supplement the CDC's 2003 launch of

an initiative entitled "Advancing HIV Prevention: New Strategies for a Changing Epidemic," which itself represented a significant break from the past. Until recently, the CDC mainly targeted its prevention efforts at persons at risk of becoming infected, by providing funding to state and local health departments and community-based organizations for a range of programs aimed at promoting healthy behaviors, including school-based programs, peer-to-peer interventions, client-centered counseling and personalized risk-reduction strategies. With its new initiative, the CDC shifted its focus from these primary prevention activities for HIV-negative individuals to secondary prevention activities for people living with HIV. The "prevention for positives" initiative consists of four key components: making HIV testing a routine part of medical care, imple-

Routine HIV Testing Is a Global Issue

As resources and programs devoted to HIV treatment and care have increased globally, so has pressure to expand the availability of HIV testing in developing countries. According to surveys in Sub-Saharan Africa, only about 12% of people who want to be tested are currently able to do so, and the majority of people living with HIV are tested after they already have developed AIDS. In light of this, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) released in May 2007 operational guidance on provider-initiated HIV testing in health facilities. The guidance recommends that HIV testing be a standard part of medical care for all patients attending health facilities in generalized HIV epidemics. With routine testing, all patients would be offered a test, regardless of the reason they came in for care, and tested unless they specifically decline.

The guidance from WHO and UNAIDS seeks to ensure that human rights are protected even as governments more aggressively pursue expanded testing. The testing policy acknowledges that implementation of routine HIV testing will depend on the situation in each country, including local epidemiology; the available infrastructure, financial and human resources; the standard of HIV prevention, treatment, care and support; and the existing social, policy and legal frameworks for protection against adverse consequences of HIV testing, such as HIV-related discrimination and violence. Along these lines, the guidance implores governments to "ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harms to patients."

Nevertheless, the implementation of routine HIV testing in resource-poor

countries remains difficult and controversial—especially in comparison to the United States. Whereas in industrialized countries, the gradual process of making HIV testing more routine has taken place against a backdrop of access to treatment and care, strong civil institutions and legal protections, these linkages and protections are almost nonexistent in many developing countries. Making HIV testing routine may not be feasible in areas where treatment is lacking, the health system is inadequate, patients are typically disempowered, and stigma and discrimination are widespread. At the same time, the argument for expanded HIV testing may be most compelling in those areas of the world where HIV is spreading throughout the general population. These countries are facing a public health emergency that threatens to damage the very fabric of societies.

menting rapid HIV tests outside medical settings, preventing new infections by working with HIV-positive people and their partners, and decreasing perinatal HIV transmission through routine HIV testing of pregnant women.

Times Change

Clearly, the AIDS epidemic in the United States is very different today than when the disease was first identified 25 years ago. At a minimum, three major developments have combined to justify, at least to some extent, the new recommendations for routine HIV testing: advances in the treatment of HIV infection; the development of simpler, faster testing technology; and new evidence about the impact of behavior-change counseling among people who are tested and learn their HIV status.

Availability of antiretroviral treatment. In the early days of the epidemic, the value of HIV testing was questionable, at best. Because there was no effective treatment for HIV infection, people diagnosed with the

virus would invariably die of AIDS.

Moreover, infection carried such stigma that people justifi-

ably shied away from being tested lest they lose their job, insurance and medical care, and be socially ostracized. With the advent of effective treatment in the 1990s, the usefulness of HIV testing became evident, and testing was encouraged for people whose behavior or demographic characteristics placed them at high risk of infection. At the time, patient advocacy groups pushed hard for policies to ensure that tests were undertaken only with specific consent, preferably in writing, and only after counseling, as an extra measure of protection from discrimination.

This approach to HIV testing—based on assessment of an individual’s risk—began to shift, however, after it was discovered in 1994 that administering treatment to HIV-positive women during pregnancy greatly reduces the likelihood of perinatal transmission. In 1999, the Institute of Medicine (IOM) first advocated for a national policy of routine testing for pregnant women. In its report, *Reducing the Odds: Preventing*

Perinatal Transmission of HIV in the United States, the IOM advised that patients be tested unless they refused and recommended eliminating the requirements for pretest counseling and written consent. That same year, the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics backed the IOM recommendations, and in 2001, the CDC modified its guidelines for pregnant women to emphasize HIV testing as a routine part of prenatal care. Indeed, routine testing of pregnant women and treatment for those who are HIV-positive is widely credited with reducing the incidence of HIV in newborns, from approximately 1,650 per year in 1991 to about 200 in more recent years.

Advent of rapid HIV tests. The development of new “rapid tests” for HIV shows great promise for expanding HIV testing in both clinical and nonclinical settings. Conventional HIV tests are invasive and slow, taking days or even weeks to

run. Many individuals fail to return for their results: According to the CDC, about one in three individuals

with positive results using a conventional test do not return to learn their results. Since 2002, six rapid HIV tests have been approved by the Food and Drug Administration. These tests provide results in as little as 10 minutes, and four of them are approved for use outside a traditional laboratory, so they can be offered in nonclinical settings. Not surprisingly, both patients and providers say they prefer rapid HIV tests to conventional tests, and a significant proportion of patients say they would not have been tested that day if the rapid test had not been available.

New evidence on behavior change. It has long been assumed that HIV testing itself was an effective prevention strategy. The expectation was that individuals who learned they were HIV-positive would take steps to avoid transmitting the virus to others and that HIV-negative individuals would change their behavior after testing to avoid infection in the future. Research has confirmed that HIV testing is effective for people

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living with HIV. According to a 2005 meta-analysis published in the *Journal of Acquired Immune Deficiency Syndromes* comparing HIV-positive individuals aware of their status with HIV-positive individuals unaware of their status, the prevalence of unprotected sex with uninfected partners is substantially reduced (by 68%) after people become aware of their infection. The effectiveness of HIV testing on the behavior of people living with HIV was also considered by an earlier analysis published in the *American Journal of Public Health*. This meta-analysis of 27 studies published between 1985 and 1997 found that after testing, HIV-positive individuals reduce their frequency of unprotected sex and increase their condom use, relative to HIV-negative and untested individuals.

That earlier analysis, however, also looked at the effectiveness of HIV testing on the behavior of HIV-negative individuals, and it showed a different impact. HIV testing, at least as it was implemented in the studies reviewed, did not appear to be an effective intervention for the primary prevention of HIV infection, in that HIV-negative individuals did not reduce their risk behavior after testing relative to untested participants.

Concerns with Routine Testing

Medical, public health, human rights and AIDS organizations have almost universally welcomed the federal government's commitment to expanded testing and early diagnosis. Some prominent AIDS organizations, including the San Francisco AIDS Foundation and amfAR, The Foundation for AIDS Research, also strongly support the concept of routine testing and have endorsed the CDC guidelines. Many groups, however, have serious concerns about the guidelines and, in response, have crafted their own set of 15 principles for expanded HIV testing. The principles were authored by the AIDS Foundation of Chicago, the Center for HIV Law and Policy and Lambda Legal, and they have been endorsed by more than 70 groups, including the AIDS Alliance for Children, Youth and Families, the American Civil Liberties Union, Gay Men's Health Crisis, Human Rights Watch, the National Association of People with AIDS and the National Minority AIDS Council.

Among the most important concerns of many AIDS activists is that routine testing may inadvertently exacerbate stigma and discrimination against people living with HIV. Many Americans still have a high level of discomfort in interacting with people living with HIV. According to a 2008 survey of nearly 5,000 Americans aged 18–44 that was conducted on behalf of amfAR, one in five respondents indicated they would be less than fully comfortable having a close friend who is HIV-positive. Some 60–70% said they would be less than fully comfortable with an HIV-positive person as their doctor, child-care provider or dentist.

Because HIV-related stigma and discrimination are still major problems in the United States, AIDS activists say that HIV testing cannot be treated in the same way as other diagnostic or screening tests. According to David Munar, AIDS Foundation of Chicago's associate director for policy and communication, the emotional and psychological issues ignited by the social stigmatization of HIV infection are "extraordinary." "Although many officials would like to compare HIV screening with screening for cholesterol, heart disease or diabetes, they are not analogous. To make such comparisons is to betray a significant lack of understanding of what living with HIV is like today in America....It is certainly wished by the HIV-positive community that people living with HIV be treated in the same way that any other patient with a chronic medical condition is treated, but the reality is they are not—we are not. HIV infection is different."

Another major concern arises from the fact that many men and women with HIV are among society's most vulnerable individuals. AIDS activists are especially concerned that in the absence of pretest counseling and written consent, routine testing may inadvertently pave the way for lower-quality or unethical testing programs. The CDC recommendations explicitly state that testing must be voluntary and undertaken only after patients have been provided adequate, appropriate information, and that patients should be offered the opportunity to ask questions and to decline testing. Nevertheless, it is easy to imagine that in a busy clinic, harried doctors could take shortcuts. Activists fear that testing could

become so routine, with the information provided prior to the testing so cursory, that patients may not receive adequate information about the meaning of their test results or even be aware that they have the right to opt out. AIDS activists also criticize the CDC's routine testing model as insufficient for reaching people who are infected but have little or no contact with the health care system. The fact remains that many people tested late in the course of their infection (within a year of developing AIDS) also lack regular access to health care. Compared with those who had their first positive test at least five years before developing AIDS, those who tested late are more likely to be young and black or Hispanic and to have been exposed to HIV through heterosexual contact, and less likely to have a high school diploma.

According to activists, routine testing is simply not suitable for all settings, popula-

tions and clinical contexts, and should be accompanied by testing opportunities through community-based and other outreach programs that are tailored to patients' needs.

Finally, AIDS activists question who will bear the cost of routine HIV testing. Whereas a conventional HIV blood test can cost as little as \$5, new rapid tests by finger prick or oral swab could cost \$15 or more. This is a concern for the large and ever-rising numbers of uninsured Americans. But even many people who have coverage would be burdened with the cost of the test. Theoretically, Medicaid reimburses for HIV testing if it is considered medically necessary, but few states have a specific policy for reimbursement of HIV testing in health care settings, regardless of an individual's risk factors. Moreover, as of February 2007, only three insurers had announced plans to support the CDC's recommendations with updated clinical bulletins for reimbursement.

Reinvigorating HIV Prevention

Since the release of the CDC guidelines, a number of cities and states have taken a second look at their HIV testing policies and practices. In May 2006, for example, San Francisco's

Department of Public Health eliminated requirements for written consent and pretest prevention counseling in its public medical clinics and hospitals. The shift in policy had an almost immediate impact on the number of people tested. Between June and December 2006, the monthly rate of HIV tests increased by one-third and the number of people who tested positive per month increased by 50% after the change in policy.

Because the CDC's recommendations do not have the force of law, however, testing practices in many parts of the country may be slow to change. Policies in some states requiring written consent or extensive pretest counseling will need to be changed, which may be easier in some states than others. Another question is

how quickly rapid testing technology—a key component of routine testing—will be widely available

and utilized across the country. According to a survey conducted by the National Alliance of State and Territorial AIDS Directors of 31 CDC-funded health departments across the nation, only 42% used rapid tests in 2006; that proportion has grown slowly since and is expected to reach only 60% this year. One key component, of course, is cost. Some hospitals and medical centers have been offering rapid tests for free, thanks to government funding and support from companies that sell them. CDC officials acknowledge, however, that additional resources to support implementation of HIV testing are unlikely.

Over and above these implementation challenges, however, AIDS advocates question what impact the CDC's initiative may have on broader primary prevention efforts aimed at people at risk of contracting HIV but not yet infected. "Increasing HIV testing is necessary, but not sufficient, for stemming the AIDS epidemic," says Judy Auerbach, deputy executive director for science and public policy at the San Francisco AIDS Foundation. "Testing should not be regarded as the sole strategy for HIV prevention. Rather, it has to be viewed as one part of a comprehensive

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set of strategies, drawing on programs that have shown to be effective for populations at greatest risk for infection. But there have been no assurances by the U.S. government that prevention services will be available for all people who need them. In the absence of this, it's reasonable to wonder what the true impact of expanded HIV testing will be on stemming new infections."

Indeed, support for comprehensive HIV prevention efforts has waned over the course of the Bush administration. Experts estimate that between FY 2002 and FY 2007, the CDC's inflation-adjusted prevention budget decreased by about 20%. Today, prevention makes up only 3% of domestic federal AIDS spending. Securing political support to increase funding for effective and evidence-based interventions to prevent the spread of HIV is a challenge, not the least because prevention necessarily requires confronting sexuality—something policymakers are often loath to do.

Moreover, if STD and family planning clinics are being asked to bear the primary burden of providing extensive HIV prevention counseling to those at risk but not infected—on top of incorporating HIV testing into routine care—the question remains the extent to which these services will be supported. Publicly funded family planning providers currently serve about one in three women of reproductive age who obtains an HIV test. Yet, many of these agencies face enormous financial challenges that threaten their ability to provide even core family planning services. "We could not be more positive about the CDC recommendations," says Leslie Tarr Laurie, president and CEO of Tapestry Health, an organization with a long history of integrating HIV services with reproductive health care and the first in western Massachusetts to offer rapid HIV testing. But, she says, "It is an enormous challenge to cobble together the funds to fully implement the recommendations both for routine testing and for comprehensive prevention," citing prevention counseling, rapid tests in and outside the clinic setting, and partner notification and follow-up efforts—the package of services she says is necessary "to ensure that those who test positive are connected as early as possible to medical

care and that those at risk but not infected get the prevention counseling they need and deserve."

Laurie laments that the Title X family planning program provides dedicated HIV prevention support to only a small number of selected clinics around the country—those with specific HIV–family planning integration grants. Indeed, the Office of Population Affairs, with funds from the Minority AIDS Initiative, currently supports HIV integration projects in 77 Title X–supported clinics, for a total of \$10.3 million. Funded projects are required to implement the CDC's HIV testing recommendations, to provide training and technical assistance in HIV prevention counseling and testing and to establish linkages with community-based agencies providing HIV-related health and social services. Not surprisingly, grant recipients report that the supplemental funds have allowed them to greatly expand their HIV prevention activities. But the extent to which routine HIV testing occurs in family planning programs without these grants is unknown.

In short, given the number of people who are still being infected with HIV in the United States each year, there will continue to be a need for comprehensive, primary prevention efforts—and to ensure that these efforts are supported and adequately funded. Congress appears to have recognized this as far as the global AIDS pandemic is concerned. Bills currently moving through the House and Senate to reauthorize the President's Emergency Plan for AIDS Relief acknowledge that prevention is the only long-term, sustainable way to turn the tide against AIDS globally. With no cure and no vaccine or microbicide on the near horizon, it is time to likewise bring this strategy home and to comprehensively reinvigorate the domestic HIV prevention agenda. The CDC guidelines for routine testing may be a down payment, and even an important one, but much more needs to be done.

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