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## The CDC Tests the Waters

June 27 was National HIV Testing Day. It's a good time to look back at the CDC's revised HIV [testing recommendations](#), announced in September 2006. The issue is becoming more critical, with a new CDC estimate of annual HIV incidence expected this fall. That estimate, partly based on actual survey data, could boost the predicted number of new HIV infections each year from 40,000 to as high as 60,000.

The CDC recommendations called for routinely incorporating HIV testing into regular medical care. In an effort to find the estimated 250,000 Americans with undiagnosed HIV, the CDC wants everybody to be tested, at emergency rooms, public clinics, doctors' offices – wherever they interact with the medical system. One highly controversial break with the past involved expediting testing by dispensing with individual HIV prevention counseling as well as specific written informed consent.

HIV testing, though dubbed "routine" by the CDC, was not supposed to be routinely repeated except in people who have high-risk behaviors. But how do you determine which HIV-negative persons are at "high risk" of contracting the virus if you omit individual counseling? That question remains unresolved.

Robert Janssen, director of the CDC's Division of HIV/AIDS Prevention (DHAP), told HHSWatch, "We're still developing implementation guidelines. We're looking at how to determine high risk and conduct repeat testing. Patients at STD clinics are by definition high risk. It's more challenging in the Emergency Room."

## Money for Some, Not for Long

To help work through the issues, at the end of May the CDC announced a \$35 million [grant program](#) for health departments in areas with substantial AIDS caseloads among African Americans. The 26 states and cities will use the grants primarily for pilot projects that expand HIV testing availability in the black community. In so doing, the CDC is combining its revised testing guidelines announced last September and last March's [Heightened National Response](#) initiative for focusing on HIV prevention among African Americans as the US racial group hardest hit by the epidemic. It should be recalled, though, that the response to the epidemic in African Americans extends far beyond testing to a broad range of social and economic issues (see HHSWatch [January 2007](#) and [April 2007](#).)

The grant program, nonetheless, is the first visible step toward promoting either initiative. Janssen said, "We will get very different proposals, and they will help us see how to move testing forward. We are looking for facilities where there is a high level of HIV, because that's the kind of place with undiagnosed infections."

However, many of the people most susceptible to HIV, such as young black gay men and other MSM, do not use medical facilities very much. The grant announcement does require that applicants work with community-based organizations with a record of high HIV detection and encourages innovative outreach methods. Still, the grants place control of the program in the hands of the health departments who will receive the money. These agencies will need to complete a very complicated application in six weeks. Then 80% of grants they receive

have to go to HIV testing in clinical settings, i.e., traditional outpatient and inpatient facilities.

Finally, although the CDC is asking organizations to embark on major testing efforts, it only guarantees funding for one year. This year's money is coming from a pool of funds diverted from other CDC activities. Next year's budget is quite uncertain (see below). Taken together, these restrictions don't encourage the outside-the-box thinking that the CDC says it wants.

### **Routine Screening Becomes Targeted Testing**

Of course, the CDC's grant announcement indicates that grantees must conform to the CDC's strategies, the revised testing guidelines in particular. But in the end, the effort is transformed. As the grant announcement says, "Applicants are required to initiate new testing programs targeted to populations, primarily African American, in which the disproportionate burden of HIV is greatest." In this scheme, African Americans are an explicitly targeted population due to their HIV risk. And although they are demonstrably in great need of extensive assistance in avoiding HIV, they won't receive the personal prevention counseling required by past testing guidelines.

Economic realities compel a more targeted approach: The CDC's goal with this \$35 million is to test 1.5 million people and find 20,000 undiagnosed HIV infections – an expected cost of \$1,750 per new HIV diagnosis. At this rate, the CDC would need nearly \$5 billion to test the entire US population aged 13 to 64. The cost per new HIV diagnosis would be almost \$20,000, assuming that there are 250,000 undiagnosed Americans and that all are found. Generalized testing is rather wasteful according to this rough projection of the CDC's own program goals.

More sophisticated mathematical modeling bears out this conclusion. They also find a benefit to including HIV prevention counseling sessions for targeted populations.

David Holtgrave, formerly director of Intervention Research and Support at the CDC's DHAP and now a department chair at Johns Hopkins, ran his own calculations based on various testing and counseling strategies. In an [article](#) published this June, Holtgrave found that if \$900 million were devoted to targeted counseling and testing services (in communities with at least a 1% HIV rate), three times more undiagnosed HIV infections would be detected than if the same amount is spent on the CDC's mass screening approach: 188,170 versus 56,940. The targeted counseling and testing would also prevent more new infections than mass screening (14,553 infections averted versus 3,644), resulting in a cost per infection averted of only 25% that of the CDC's favored approach.

### **He Who Pays the Piper...**

A major objection to such calculations is that they assume that the CDC will carry the burden for testing everybody. Janssen argued, "Our budget for prevention is \$650 million whereas the federal HIV health care budget is \$7 billion. In contrast to the outreach testing performed in community settings, HIV screening in clinics is a medical indication, and the healthcare system should pay. One purpose for the pilot programs underwritten by the grants is to jump start testing until reimbursement becomes a reality."

At present, insurers and Medicaid usually pay for testing only when there is a specific reason for it. According to a [survey](#) by the National Association of State and Territorial AIDS Directors, 35 of 55 locales directly funded by DHAP prevention programs are moving to implement the CDC testing recommendations, mostly in clinics serving high-risk populations. The states as well as the CDC cite financial constraints as a

reason why the testing recommendations are encountering resistance from healthcare providers. The CDC is now putting considerable effort into persuading third-party payers to reimburse generalized HIV screening. A major tactic is to gain the endorsement of physicians' organizations.

That would prove the medical basis of the testing recommendations. Still, the NASTAD survey found a very low rate of reimbursement. A major part of the funding struggle lies ahead, and its outcome will determine the extent of "routine" HIV screening.

## New Dissent on HIV Testing Policy

- The United States Prevention Services Task Force (USPSTF) is a panel that advises HHS's Agency for Healthcare Research and Quality on the evidence supporting changes in disease prevention strategies. In March 2005, the USPSTF issued its own HIV testing recommendations. These generally followed the CDC's testing policy at the time, which stressed targeting testing interventions in high-prevalence communities. The USPSTF explicitly did not recommend for or against routine testing of persons without identifiable HIV risks. The CDC's new call for general HIV screening of all Americans aged 13 to 64 prompted this other HHS branch to revisit its 2005 statement on HIV testing policy. But an exhaustive USPSTF [review](#) of the evidence, published in April, pointed out methodological flaws in the studies the CDC cited to support its new recommendations.

The USTPF concluded, "After reviewing new studies on HIV screening, we found insufficient evidence to change the main conclusions of our 2005 evidence synthesis... [We] found no new studies evaluating the effects of routine screening in low-risk populations on the proportion of HIV-infected persons diagnosed at later stages of disease, on test notification rates, entry into care, or uptake of recommended interventions. Nor did we find new studies evaluating the effects of opt-out testing without prevention counseling in non-pregnant, low-risk persons, as advised in the 2006 CDC recommendations."

- On June 26, Lambda Legal, along with the AIDS Foundation of Chicago, the Center for HIV Law and Policy, CHAMP and other organizations, issued a striking alternative to the CDC's testing recommendations. "[Expanding the Availability and Acceptance of Voluntary HIV Testing](#)" lays out 15 principles for efforts that seek to inform more people of their undiagnosed HIV infections while preventing new infections. In its introduction, the document states:

"To ensure that the important stated goals of more widely-offered testing are accomplished, a coalition of people living with HIV and the legal, medical and service organizations representing them... has framed these core principles, grounded in sound medical and public health science, ethics and human rights, to be followed by public and private decision-makers as they implement expanded HIV testing services. The fundamental elements – that HIV testing must always be informed, voluntary, confidential, and supported by health care and other services, and that it is always most effective when offered by someone trusted and trustworthy – apply to all persons, including pregnant women and the incarcerated, and to testing issues beyond the current discussions about implementing the new CDC recommendations."

## Congress Abandons HIV Prevention

The new Democratic Congress promised to charge ahead with the federal budget. But the faster Congress charges, the more mystery surrounds the final endpoint for this year's budget process. One thing is certain: HIV prevention is getting short shrift. The CDC will have trouble advancing its HIV priorities, including testing.

The House appropriations subcommittee considering the combined Department of Labor-HHS-Education budget boosted CDC HIV prevention activities by \$63 million in the budget's initial "markup." This nearly 10% increase is \$30 million less than the Bush administration requested. The amount approved in the House would be enough to continue this year's HIV testing initiatives plus a little bit leftover to reverse years of slowly declining funding.

Programs funded through the \$2.1 billion Ryan White AIDS CARE Act, which largely focuses on treatment, would receive an extra \$99 million in this initial version of the budget. The Ryan White total is \$79 million more than the administration requested, but it falls far short of what advocates were seeking. The AIDS Drug Assistance Program (ADAP), for example, would receive an increase of \$41 million. The state-administered ADAPs provide HIV medications for low-income persons. Four state ADAPs already have a total of over 500 persons on ADAP waiting lists, and five other states have introduced cost-containment measures by limiting enrollment or covered drugs. Increasing Ryan White is vital to expanding HIV testing because these funds would support care referrals for persons with newly detected HIV.

Under the Senate version of the budget, ADAP would receive only a \$25 million increase. There would be next to no increase for other Ryan White care programs, and none at all for CDC HIV prevention efforts. HIV prevention instead

faces an effective cut in the Senate Appropriations Committee version of the budget. The committee assigned \$30 million of the CDC prevention funds to the Early Diagnosis Grant program, included in last year's Ryan White reauthorization at the insistence of Sen. Tom Coburn (R-OK).

The grants are a reward to states that change their laws to allow HIV testing without specific informed consent (see HHSWatch, [October 2006](#)). The CDC did not request this program. It is generally disliked, and the FY 2007 budget blocked funding for the programs. The House is following suit this year, but not the Senate, which apparently fears that Sen. Coburn will block Labor-HHS budget approval unless his program receives budgetary authorization.

### **Abstinence Doesn't Work for Veto Protection, Either**

In all, the House version of the Labor-HHS-Education budget is \$10.5 billion over the President's proposal, and the Senate version is \$9 billion over. Since Bush has threatened to veto budgets that exceed his requests, all these numbers may turn out to be imaginary. The budget process would have to start up again this fall, under more restrictive conditions.

House appropriators did search for a way to build a veto-proof two-thirds majority for their budget. They decided that they would sacrifice teen sex education. As a result, the President got his request for the Community-Based Abstinence Education (CBAE) grants, a \$28 million (25%) increase to \$138 million. However... enough Republican representatives have declared their support for Bush's eventual veto to sustain that veto in the House. Also, the Senate appropriators cut community-based abstinence by 25%, leaving only enough to support grants issued in previous years. The Senators also added a measure permitting more federally funded stem cell research, thus further ensuring a veto.

*This HHSWatch was written by David Gilden*

**HHSWatch**, a watchdog newsletter from CHAMP, monitors and reports on activities related to HIV prevention at Health and Human Services agencies, including CDC, NIH, HRSA and SAMHSA.

HHSWatch is a resource for community members, policy advocates, researchers and anyone interested in more fully understanding and tracking the committees, panels and administrators whose recommendations and decisions affect our work.

*HHSWatch is committed to providing an outlet for those concerned about infringements upon science-based HIV prevention and treatment, and will respect your wishes for confidentiality. If you are interested in contributing information or suggesting a story, please contact [champ@champnetwork.org](mailto:champ@champnetwork.org).*



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