



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUL 18 2007

The Honorable Henry A. Waxman
Chairman, Committee on Oversight and
Government Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter regarding the Centers for Disease Control and Prevention's (CDC) "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings." Please excuse the delay of this response.

The CDC revised recommendations are intended to help the 250,000 to 300,000 HIV infected Americans who are unaware of their infection to learn their HIV status and gain access to life-saving treatment and prevention. The recommendations are based on best practices, and they are intended to comply fully with the ethical principles of informed consent.

As CDC moves forward with the implementation of its revised recommendations, we recognize that we face significant challenges in referring newly identified HIV-infected persons for prevention and care, reducing legislative and regulatory hurdles, and addressing the varied institutional policies of health-care facilities across the nation. These recommendations necessitate changes both in the procedures for conducting HIV testing as well as the institutional processes that facilitate HIV screening.

We appreciate your interest in this important public health issue and your continued support for our HIV/AIDS prevention activities. As requested, enclosed are CDC's responses to the questions addressed in your letter. If you have any comments or questions concerning our responses, please contact Mr. Michael Craig, CDC/Washington Office, at (202) 690-8598.

Sincerely,


Julie Louise Gerberding, M.D., M.P.H.
Director

Enclosure

**The Centers for Disease Control and Prevention's (CDC)
Responses to The May 2, 2007, Letter From
Representative Henry A. Waxman, Chairman, Committee on Oversight and
Government Reform**

1. Provide an update on the implementation of the new guidelines since their introduction in September 2006. Please describe all major steps taken at the federal and state levels, including consultations or collaborations with other agencies and stakeholders. In addition, please describe challenges to implementation that have arisen and steps that are being taken or planned to address them.

The article on “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings” was published in CDC’s *Morbidity and Mortality Weekly Report (Recommendations and Reports)* on September 22, 2006. Since that time, CDC has engaged in an intensive effort to assist stakeholders in deciding how to implement HIV screening in health-care settings, while at the same time assuring that other vital HIV prevention efforts and HIV testing in nonhealth-care settings continue. CDC has engaged community partners, grantees, other federal agencies, and state and local health departments in this process.

Collaborations with agencies, states, and other stakeholders:

- CDC initiated collaboration with a wide range of professional medical associations at a meeting convened by the American Academy of HIV Medicine (AAHIVM) in October 2006. AAHIVM now coordinates six working groups in conjunction with CDC to address various aspects of HIV screening: policy and state-by-state regulatory issues; communications and marketing strategies (including educational materials and implementation tools); reimbursement; correctional facilities; linkage to care; and scientific review/evaluation studies. Representatives from 30 professional organizations are participating across these six workgroups.
- CDC has established an internal HIV Testing Executive Committee with sub-committees mirroring the AAHIVM working groups. The members of these sub-committees concurrently participate on the AAHIVM working groups. The key deliverables for the CDC Executive Committee are to develop implementation guidance for specific settings, educational materials and implementation tools for providers, and a comprehensive evaluation strategy.
- In October 2006, CDC participated in a consultation with the Health Resources and Services Administration (HRSA) to discuss implications of HIV screening for HRSA grantees.
- HRSA is also participating in the President’s Domestic HIV Initiative through an interagency agreement (IAA) with CDC to award additional funds to HRSA’s 11 regional AIDS Education and Training Centers (AETCs) to provide training on HIV screening for clinical practitioners who are not primarily HIV providers. This IAA will also support the National Clinicians’ Consultation Center, a funded HRSA grantee, to field questions and provide technical assistance to providers and the National Minority AIDS Education Training Center, another HRSA

- grantee, to develop clinician tools for discussions about HIV screening with minority patients.
- In March 2007, CDC participated in a Substance Abuse and Mental Health Services Administration (SAMHSA) grantee meeting to discuss the implications of HIV screening in substance abuse treatment centers. CDC is collaborating with SAMHSA on implementation plans for HIV screening in substance abuse treatment programs.
 - Regional workshops to promote HIV screening in emergency departments (EDs) are underway. EDs and health departments are participating in these workshops. These workshops are based on a model that was highly effective in promoting perinatal HIV screening. At the workshops, multidisciplinary teams from local hospitals conduct strategic planning to initiate HIV screening. Follow-up to monitor progress occurs 6 to 9 months afterwards. The following workshops began in February 2007 and have been planned to cover all regions of the country:
 - West (Los Angeles, February 2007)
 - Southeast (Florida, April 2007)
 - Midwest (Chicago, June 2007)
 - Northeast (Boston, August 2007)
 - Mid-Atlantic Region (Washington D.C.; tentatively October 2007)
 - South Central Region (location pending; tentatively January 2008)
 - Ten additional workshops are being planned beginning in February 2008 as part of the President's Domestic HIV Initiative.
 - Additional collaboration and workshops are planned for grantees of the Department of Health and Human Services' (HHS) Office of Population Affairs (OPA) and members of the National Family Planning and Reproductive Health Association.
 - OPA has developed a Program Announcement to fund 70–80 agencies to conduct HIV screening consistent with CDC's recommendations. The program announcement was issued on April 24, 2007, with funds to be awarded by September 1, 2007.
 - In March 2007, CDC co-hosted a consultation with the National Association of State and Territorial AIDS Directors (NASTAD) and the American Hospital Association (AHA) to review issues and challenges to implementing HIV screening in EDs.

Collaboration with state and local jurisdictions:

Many jurisdictions and health-care facilities have requested technical assistance from CDC to initiate HIV screening. CDC has responded with consultations and technical assistance for a variety of professional and governmental groups, including:

- New York State AIDS Advisory Council and HIV Counseling and Testing Workgroup
- Illinois Department of Public Health
- Texas HIV/STD Program
- New York City Department of Health
- The Texas/Oklahoma Regional AETC
- Arizona Department of Health Services

- Stakeholder meetings and provider training in Baltimore and Philadelphia (sponsored by AETCs, Prevention Training Centers, and Reproductive Health Training Centers)

State level activities:

A number of states and jurisdictions have already taken steps to implement HIV screening:

- The New York City Health and Hospital Corporation (the largest health-care provider in New York City) embarked on an “HIV Testing Expansion Initiative.” The stated goals were to increase HIV tests from 50,000 to 100,000 tests per year and to increase the number of patients who knew their HIV status. The initiative succeeded in increasing the number of HIV tests from 58,785 tests in fiscal year 2005 to 92,123 HIV tests in fiscal year 2006. More importantly, the number of persons diagnosed with HIV more than doubled from 720 in fiscal year 2005 to 1,514 in fiscal year 2006.
- New Jersey implemented HIV screening in EDs with rapid HIV tests. The state health department provides counselors and HIV test kits for this screening effort. Twenty-three EDs now conduct HIV screening. Through November 2006, more than 10,000 persons had been screened and 274 (2.6 percent) were found to be HIV- infected.
- In May 2006, the San Francisco Department of Public Health modified the requirements for signed informed consent shortly after the first draft of the revised recommendations was circulated. Subsequently, rates of HIV testing increased and the number of new HIV diagnoses increased from a mean of 20.6 per month to 30.6 per month.¹
- In March 2007, New Mexico amended its statutes to allow for HIV testing during routine medical care in accordance with the revised recommendations.
- The state of Illinois is currently considering House Bill 980 (HB980), which would make Illinois state law consistent with the revised recommendations. HB980 language has been influenced by a wide range of HIV prevention stakeholders including the Illinois Department of Public Health, the AIDS Foundation of Chicago, the American Civil Liberties Union, and others.

Community stakeholders:

CDC has collaborated closely with key stakeholders throughout the development of the revised recommendations and in developing implementation plans. Although the key stakeholders for the revised recommendations are health-care settings, community-based organizations (CBOs) and other community partners play a key role in promoting HIV screening to the at-risk populations they serve.

- The CDC HIV Testing Executive Committee includes a subcommittee on community partners. The goals of this subcommittee are to:
 - address community concerns regarding HIV screening,
 - solicit input for the implementation guidance plan,
 - engage partners in structured monitoring of potential adverse outcomes, and

- encourage partners (particularly CBOs) to establish collaborations with health-care settings.
- In November 2006, CDC co-hosted a 2-day conference, “Opportunities for Improving HIV Diagnosis, Prevention, and Access to Care in the U.S.” This conference, with support from private industry, academia, other federal agencies, and community partners, brought together a diverse group of stakeholders to consider practical issues and address challenges associated with expanded HIV screening in health-care settings.

Challenges to implementation of HIV screening:

CDC and its partners have identified several challenges to implementing the recommendations and opportunities to overcome potential barriers.

- Assuring sufficient funding for HIV screening remains a major consideration. The President’s Domestic HIV Initiative will provide start-up resources for many jurisdictions. In addition, several state and city health departments have provided resources to health-care settings to help support expanded HIV screening.
- Third-party reimbursement for HIV screening in health-care settings must be secured:
 - The AAHIVM Committee on reimbursement includes representation from America’s Health Insurance Plans (AHIP).
 - Aetna, Humana, and Kaiser have announced support for CDC’s recommendations with updated clinical policy bulletins for reimbursement consistent with CDC’s revised recommendations.² Decisions about Medicaid reimbursement for screening are made at the state level. New York Medicaid announced a new specific policy for reimbursement of HIV screening in health-care settings (www.health.state.ny.us/diseases/aids/testing/primarycaremedicaid/index.htm).
- Some jurisdictions have legislative or regulatory restrictions that are not consistent with CDC’s recommendations:
 - CDC continues to encourage expanded HIV screening within existing legal parameters. Major cities, such as Philadelphia and New York City, have begun to expand HIV screening in health-care settings within the provisions of current state law.
 - CDC provides technical assistance (upon request) to state health departments and legislatures as they consider revised legislation. This technical assistance includes examples from jurisdictions, reviews of scientific evidence, and illustrations of emerging field experience with expanded HIV screening.
 - Legislation related to aspects of the revised recommendations is being considered in a number of states including California, Illinois, Maryland, Nevada, and New York.
- Provisions for opt-out HIV screening of pregnant women serve as a model for many jurisdictions. Examples include specific legislation enacted in Florida, and Oregon, and Nevada.

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- ¹ Zetola NM. Association between rates of HIV testing and elimination of written consents in San Francisco. *JAMA*. 2007;297:1061.
- ² Greene J. Expanding screening to save lives. *America's Health Insurance Plans*. Jan-Feb 2007 (newsletter).

2. *Provide an analysis of the cost-effectiveness of the new testing recommendations, based on resources required and infections detected. Please provide a comparison to alternative testing strategies that were or could have been considered.*

In its 2003 launch of the initiative “Advancing HIV Prevention: New Strategies for a changing epidemic,” CDC outlined four priority prevention strategies:

1. Make HIV testing a routine part of medical care
2. Implement new models for diagnosing HIV infections outside medical settings
3. Prevent new infections by working with persons diagnosed with HIV and their partners
4. Further decrease perinatal HIV transmission.

These four complementary strategies aim to effectively reduce barriers to early diagnosis and increase access to quality medical care, treatment and ongoing prevention services. CDC continues to pursue all of the strategies. The revised recommendations address priorities one and four. Other CDC initiatives address HIV testing in nonclinical settings and prevention for HIV-infected persons.

Several cost-effective analyses have evaluated HIV screening in health-care settings in terms of cost per quality-adjusted life-year (QALY) gained and have suggested that one-time screening is cost-effective. Even at an HIV prevalence threshold of 0.1 percent prevalence threshold, cost effectiveness ratios remain less than \$50,000 per QALY, to the generally accepted threshold for cost effective interventions.^{1,2,3} Another cost-effective analysis suggested that one-time screening at an HIV prevalence of 0.1 percent may be cost-effective, especially if the reduction of HIV transmission as a result of screening is considered.⁴ From a broader public health perspective, cost-effective ratios for routine HIV screening in health-care settings are within the range of those for established standard screenings such as type 2 diabetes and hypertension.² The revised recommendations state that screening should be conducted in settings where HIV prevalence is as low as 1 per 1,000 persons (a 0.1 percent HIV prevalence). The prevalence threshold on which the revised recommendations are based is consistent with those noted in published cost-effective analyses. If facilities demonstrate a lower prevalence, screening is not recommended.

Each approach for diagnosing new HIV infections incurs different costs. Preliminary cost data from Advancing HIV Prevention (AHP) demonstration projects, model-based analysis for HIV screening in health-care settings, and the President’s Domestic HIV Initiative are presented in Table 1. Actual costs for detecting a case of acute HIV infection are also included in Table 1. The cost per newly diagnosed HIV infection is lower overall in the model-based analysis for health-care settings, particularly in the ED opt-out scenario. These data suggest that HIV screening is an important addition to the CDC portfolio of HIV prevention and testing strategies.

Table 1: Cost per newly diagnosed HIV infection for different scenarios and settings

Setting or scenario	Cost per newly diagnosed HIV infection*
Model-based analysis for health care settings ^{†‡}	2004
STD opt-in [§]	\$2,767
STD opt-out [¶]	\$2,019
ED opt-out ^{**}	\$1,525
President's Domestic HIV Initiative ⁶	September 2007-September 2008 (projected)
Health-care settings Selected non-clinical settings with \geq 2% HIV prevalence	\$2,248
Screening for acute HIV infection ⁷	November 2002-October 2003
State-funded HIV testing sites	\$17,515
AHP Demonstration project ^{††‡}	2005 (average annual data and range)
Jails ^{§§}	\$9,748 (\$2,451-\$25,288)
CBO outreach ^{¶¶}	\$14,610 (\$3,868-\$25,450)

* For the model-based analysis and AHP demonstration projects, the cost per newly diagnosed HIV infection includes the costs of testing all persons.

† For the model-based analysis, parameters were taken from the literature and internal CDC data. A 1.0% seropositivity rate was assumed. This analysis excludes start-up costs and facility space costs (e.g., it assumes settings are equipped to provide testing).

§ STD opt-in: Patient offered HIV testing and provides written consent for the test. Client-centered pre-test prevention counseling is provided.

¶ STD opt-out: Patient offered testing and receives limited verbal or written information about HIV infection and interpretation of test results. Consent is

required for HIV testing; however, it need not be written consent. Patient is offered, but may decline, client-centered pre-test prevention counseling.

** ED opt-out: Patient presenting to ED is given an HIV test unless he/she declines. Written pretest information (but no prevention counseling) is provided. Consent is required for HIV testing; however, it need not be written consent.

†† The demonstration project analysis includes program start-up costs attributable to staff time, training, travel, facility space, and durable goods and equipment. Demonstration project effectiveness data for entire project period: jail demonstration project: 32,211 persons tested and 269 (0.8% seropositivity) newly diagnosed HIV-positive cases, and CBO demonstration project: 24,149 persons tested and 271 (1.1% seropositivity) newly diagnosed HIV-positive cases.

§§ All four jail project areas are included in cost analysis.

¶¶ Cost effectiveness data were available from two of the eight CBO project areas, which include clinic-based and mobile van testing.

Although costs per newly detected HIV infection in AHP demonstration projects may be higher per case than for screening, these interventions reach populations that have considerably higher rates of HIV transmission and thus warrant additional efforts. Examples include persons with acute HIV infection, who have very high levels of circulating virus, and those who may be core transmitters (identified through social networks). Screening in health-care settings is likely to identify persons who would not otherwise be tested because they do not perceive themselves to be at risk. A study in a Chicago ED found that provider-referral for testing identified many HIV infections but 42 percent of infected patients would have been missed if routine screening had not been conducted.⁸ Because different strategies are necessary for different populations, CDC will continue to support a broad portfolio of HIV testing initiatives justified by relevant scientific evidence.

The cost data in Table 1 are updated and reviewed by CDC on an ongoing basis and will be further refined as HIV screening becomes more widespread. As with any screening

program, cost-effectiveness depends considerably on the prevalence of infection among persons screened. CDC anticipates that routine HIV screening will be introduced incrementally, and that screening criteria will be refined over time. HIV screening in health-care settings tends to be cost-effective because it identifies persons at earlier stages of disease,⁸ with implications for both health-care costs and life expectancy. Persons diagnosed with more advanced disease have substantially higher annual health-care costs than persons diagnosed earlier.⁹ Life expectancy also improves dramatically when HIV infection is detected earlier, with only a slight increase in overall lifetime medical costs (\$230,044 versus \$192,325).¹⁰

¹ 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;352:570-585.

² Walensky RP, Weinstein MC, Kimmel AD, et al. Routine human immunodeficiency virus testing: an economic evaluation of current guidelines. *Am J Med.* 2005;118:292-300.

³ 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;145:797-806.

⁴ 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;352:586-595.

⁵ Centers for Disease Control and Prevention. Unpublished data.

⁶ Centers for Disease Control and Prevention. Expanded and integrated human immunodeficiency virus (HIV) testing for populations disproportionately affected by HIV, primarily African Americans. Unpublished program announcement. Program announcement number: CDC-PS07-768.

⁷ Pilcher CD, Fiscus SA, Nguyen TQ, et al. Detection of acute infections during HIV testing in North Carolina. *N Engl J Med.* 2005;352:1873-1883.

⁸ Lyss SB, Branson BM, Kroc KA, et al. Detecting unsuspected HIV infection with a rapid whole-blood HIV test in an urban emergency department. *J Acquir Immune Defic Syndr.* 2007;44:435-442.

⁹ Chen RY, Accortt NA, Westfall AO, et al. Distribution of health care expenditures for HIV-infected patients. *CID.* 2006;42:1003-1010.

¹⁰ Hutchinson AB, Farnham PG, Dean HD, et al. The economic burden of HIV in the United States in the era of highly active antiretroviral therapy. Evidence of continuing racial and ethnic differences. *J Acquir Immune Defic Syndr.* 2006;43:451-457.

3. Provide an estimate or estimated range of the number of new HIV infections expected to be diagnosed under the new guidelines, with a comparison to the most recent data on newly diagnosed infections.

Several factors influence the number of HIV infections expected to be diagnosed under the revised recommendations. Previous experience with CDC's prenatal HIV screening recommendations suggests that it is too early to develop projections until the revised recommendations are widely endorsed by professional organizations, state legislative and regulatory issues have been addressed, and there is broad adoption of HIV screening in health-care settings.

Several data sources are available to describe HIV testing and diagnosis in the United States today. Data on current HIV diagnosis patterns are available from the 33 states with mature name-based HIV surveillance systems. From 2001 through 2004, the number of annual HIV diagnoses (including those persons diagnosed simultaneously with AIDS) has remained relatively steady (range 38,139–41,207).¹ Although these data cannot be extrapolated to the entire nation, these 33 states account for 63 percent of the AIDS cases reported in the United States.

The National Health Interview Survey (NHIS) and the Behavioral Risk Factor Surveillance System (BRFSS), both nationally representative samples, include questions on HIV testing.² Results from NHIS in 2002 indicate that 10 percent of the United States population 18–64 years of age had been tested for HIV in the preceding 12 months (excluding blood donation) and that between 1987 and 2002, 37.8 percent had been tested at least once in their lives. BRFSS data from 2002 for the same age group indicate that 12.2 percent of the United States population had been tested for HIV in the preceding 12 months. Of note, 48.4 percent (NHIS) and 54 percent (BRFSS) of pregnant women reported they had been tested for HIV in the preceding 12 months.

The large majority of HIV testing in the United States already occurs in health-care settings. For example, NHIS data indicate that 75 percent of persons were tested in physician offices, hospitals, or community clinics. Health-care settings also diagnose the majority of new HIV infections. Data from CDC's Supplement to HIV/AIDS Surveillance (SHAS) project, from 2000–2003, show that 65 percent of HIV infections were diagnosed in physician offices, hospitals, or community clinics.

CDC has developed specific projections for the number of HIV-infected persons expected to be diagnosed through initiatives planned in 2007 and 2008. In fiscal year (FY) 2007, CDC is allocating \$45 million to expand HIV testing and increase the proportion among populations disproportionately affected by HIV (primarily African Americans) who become aware of their infection and can be linked to medical care and prevention services. This effort will support direct services, provider training, social marketing, and evaluation activities. In 2007, CDC expects to test 1.5 million persons for HIV under this initiative and to identify 20,000 HIV-infected persons who are currently unaware of their infection. In the FY 2008 budget, CDC is requesting \$63 million to further expand HIV screening. If funded, CDC expects this will allow testing of an additional 2 million persons and will identify an additional 31,000 HIV-infected persons who are unaware of their infection. These efforts are in addition to CDC's existing HIV counseling and testing programs, through which approximately 3.8 million persons are tested annually.²

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- ¹ Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report, 2004. Vol. 16 Atlanta: US Department of Health and Human Services; 2005.
- ² Centers for Disease Control and Prevention. Number of persons tested for HIV – United States. 2002. Mortality and Morbidity Weekly Report 2004;53:1110-1113.

4. An estimated breakdown of the insurance status of people expected to be diagnosed under the new screening guidelines. Please include estimates of the number of people who would be eligible for Medicaid, Medicare, Veterans' Administration Health Services, and ADAP benefits, as well as those expected to be covered by private insurance.

CDC has identified two data sources that provide plausible estimates for the insurance status of persons who might be diagnosed under the revised recommendations. CDC's Supplement to HIV/AIDS Surveillance (SHAS) from 2003 assessed the insurance status of a sample of patients recently diagnosed with HIV/AIDS, 96 percent of whom were in care. Among these SHAS participants, 31 percent were covered by Medicaid, 4 percent by Medicare, and 17 percent had private insurance. Less than 1 percent had TriCare (military coverage) and approximately 1 percent received care from the Veterans Administration (VA). However, because almost all SHAS participants were receiving medical care, these figures may represent persons with greater access to care, or possibly, those more likely to be insured.

An estimate of insurance status of persons less likely to be in care comes from a 2006 study conducted by HRSA: the Special Projects of National Significance (SPNS). This study of a hard-to-reach population included greater proportions of racial and ethnic minorities, individuals of low socioeconomic status, and persons less likely to be on antiretroviral treatment. This study estimated that in the outreach sample 50.6 percent of persons were covered by Medicaid, 14.7 percent by private insurance, 5.9 percent by Medicare and 28.8 percent had no insurance¹. See the table below for comparison of insurance status from the SHAS and SPNS programs.

Insurance Status	SHAS Recently Diagnosed Sample	HRSA/SPNS Outreach Sample
<i>Medicaid</i>	31.2%	50.6%
<i>Medicare</i>	3.8%	5.9%
<i>VA</i>	1.2%	*
<i>TriCare</i>	.68%	*
<i>Private</i>	17.0%	14.7%
<i>Uninsured</i>	*	28.8%
<i>Other</i>	24.0%	*

* Note that the data sources used varying measures of insurance status. Insurance through the VA and TriCare systems were not assessed in the HRSA/SPNS project, and uninsured status was not measured in the SHAS program. "Other" was an option in the SHAS study only.

¹ Cunningham, W.E. et al. Health services utilization for people with HIV infection: Comparison of a population targeted for outreach with the U.S. population in care. *Medical Care* 2006;44:1038-1047.

5. Current HIV testing reimbursement policies for Medicaid, Medicare, Veterans' Administration Health Services, and private insurers.

All Medicaid programs and private insurers reimburse for HIV testing if it is considered medically necessary (diagnostic testing). However, Medicaid screening reimbursement policies differ on a state-by-state basis. For example, New York State's Medicaid program recently announced it would reimburse HIV screening in emergency departments; most other states have not yet made explicit determinations. The Veterans Administration Health Services covers screening under any conditions. Medicare does not pay for any disease screening unless it is specifically authorized by Congress. However, the majority of persons eligible for Medicare are 65 and older, outside the age range (13–64) specified in CDC's revised recommendations.

Many private insurers are currently developing reimbursement policies for HIV screening, taking into account the U.S. Preventive Services Task Force (USPSTF) and CDC's revised recommendations. Although comprehensive information from private insurers is not yet available, the February 2007 newsletter of America's Health Insurance Plans, a national trade organization representing over 1,300 companies, featured executives from the Humana, Aetna, and Kaiser Permanente health plans, who voiced their support for CDC's revised recommendations and their intention to reimburse for HIV screening.

6. Current and planned funding for federal or state purchase of HIV rapid tests and other testing supplies, including any central bulk purchases.

HIV testing is a fundamental strategy for HIV prevention programs and remains a critical priority for CDC. Rapid HIV tests play an increasingly integral role in HIV testing programs. A recent survey conducted by NASTAD found that 81 percent of health departments currently support rapid testing programs, and 91 percent indicated plans to support rapid HIV testing during the following year.¹ Health departments use various mechanisms to purchase rapid tests, including direct procurements, negotiations with companies, and use of third-party vendors. A variety of rapid tests are being used depending on the costs and setting, underscoring the importance of flexibility in health department choice. States are allowed to purchase rapid HIV tests, as well as other HIV tests, with CDC prevention funds; CDC strives to ensure that states have the flexibility to purchase whichever HIV test is most appropriate for their specific settings.

In FY 2007, state and local testing programs will be supplemented with \$35 million to expand and integrate HIV testing for populations disproportionately affected by HIV, primarily African Americans. Eligibility for these funds is limited to those CDC funded jurisdictions with at least 140 AIDS cases among blacks diagnosed in 2005; these jurisdictions accounted for 95 percent of the AIDS cases among blacks in 2005. The use of these funds to purchase rapid test kits is authorized in the program announcement language. CDC is not planning a direct bulk purchase of HIV test kits in 2007. With this funding, CDC's goal is to test 1.5 million persons for HIV and to identify 20,000 HIV infected persons who are unaware of their infection. Funds may be used to support HIV screening, testing, and linkage to care; and CDC is strongly encouraging jurisdictions to focus at least 80 percent of their program activities on expanded and innovative HIV testing activities in clinical settings.

¹ NASTAD. Rapid HIV Testing Assessment. October 2006.

7. Any patient or healthcare provider educational materials on HIV testing issued by federal agencies based on the new guidelines.

CDC and other federally-funded organizations are actively producing educational materials on HIV screening in health-care settings. For example:

- Several HRSA-funded AETCs have developed clinician support tools, curricula, and presentations. These materials cover a range of topics including HIV screening in health-care settings, rapid testing, and the opt-out approach to HIV screening for pregnant women. Examples include *Making HIV Testing Routine*, *HIV Testing in Emergency Departments*, and the *Pocket Guide to Integrating HIV Testing into Substance Abuse Treatment Centers*. A complete inventory of these materials and other information associated with AETC training sessions and workshops are available at www.aids-ed.org/aidsetc?page=et-aetc-testing.
- CDC is developing setting-specific guidance documents to assist health-care providers as they undertake routine HIV screening. These are modeled after CDC's widely distributed *Rapid HIV-1 Antibody Testing for Women in Labor with Unknown HIV Status: A Practical Guide and Model Protocol*. Modules are being developed with the participation of active practitioners for specific health-care settings: primary care (e.g., community health centers [CHCs], general medicine, adolescent medicine/pediatrics, family planning/gynecology); hospitals (e.g., EDs/urgent care, inpatient services, labor and delivery); prenatal care, substance abuse treatment and STD clinics; and correctional health facilities.
- In May 2007, CDC launched a campaign—*One Test. Two Lives.*—to promote HIV screening of pregnant women. CDC produced a resource kit for this campaign that includes a poster and brochures for patients and an HIV resource guide and information for obstetric providers. The resource kit also includes materials developed by professional provider organizations, for example, the American College of Nurse-Midwives' position statement supporting the revised recommendations.
- CDC provided technical assistance and funding to the American College of Obstetricians and Gynecologists for the development of educational materials for patients and health-care providers to promote routine prenatal HIV screening. Examples include an informational brochure about HIV testing (*HIV and Other Important Pregnancy Tests*) and a patient information pamphlet about HIV disease (*HIV and Pregnancy*). These materials are available at www.acog.org/goto/pHIV.

8. *Compilation of behavioral data relied on by CDC in making new recommendations on prevention counseling for people who test negative.*

- The revised recommendations state that prevention counseling should not be required as part of HIV screening programs in health-care settings. Prevention counseling is strongly encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely (e.g., STD clinics) but need not be linked to HIV testing.
- The central goal of the revised recommendations is to maximize the number of persons who are aware of their HIV infection. The benefits for HIV-infected persons to learn their HIV status and receive prevention counseling have been well demonstrated, particularly in terms of reduction in future HIV risk behaviors.¹ Examples of these behaviors include deliberate abstinence,^{2,3} reduced number of sexual partners,³ decreases in unprotected anal or vaginal intercourse,⁴ especially with partners who were uninfected or of unknown status,⁵ and increased condom use.³
- The benefits of providing typical prevention counseling in conjunction with HIV testing for HIV negative persons are less clear.⁶⁻¹⁰ For example, a meta-analysis of 27 studies published in 1985–1997 (before widespread implementation of CDC’s 1993 technical guidance on counseling) examined the effects of counseling and testing on sexual risk behavior. The analysis showed that prevention counseling in conjunction with HIV testing had little effect on reducing these behaviors among uninfected persons.⁶
- Randomized controlled trials (e.g., EXPLORE and project RESPECT) have demonstrated that carefully implemented prevention counseling in high-risk settings (e.g., STD clinics) can lead to changes in behavior and decreased STD incidence.⁷⁻⁹
- Carefully controlled, theory-based prevention counseling in STD clinics has helped uninfected participants reduce their risk behaviors compared with participants who received only a didactic prevention message from health-care providers.^{6,11}
- CDC found no published evidence of increases in risk behavior among persons testing negative for HIV who did not receive prevention counseling.
- The expected behavior of clinicians and facilities that might implement HIV screening is a key factor in successfully implementing HIV screening. CDC considered whether a requirement for HIV counseling might diminish institutional adherence to HIV screening protocols, reducing the feasibility of HIV screening in clinical settings. Physicians in busy clinical health-care settings seem more likely to conduct screening than counseling. In a recent observational study in a primary care practice, patients were up-to-date on 55 percent of recommended screening services, but only on 9 percent of health habit counseling services.¹² As the revised recommendations were being developed, CDC also relied on the experience of demonstration projects of HIV screening in EDs. Data from three of the EDs were published recently.¹³ One of the EDs offered HIV screening in accordance with the *Revised Recommendations*, while two of the EDs offered rapid HIV testing through HIV counselors and with pre-test counseling. In the

screening-based ED. more patients were offered testing (47.7 percent versus 3.6 percent and 2.1 percent), more persons were tested for HIV (6,368 versus 1,700 and 1,288), and most importantly, more persons were diagnosed with HIV (65 versus 10 and 13).

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- ¹ Marks G, et al. 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;39:446-453.
 - ² Bogart LM, et al. Patterns and correlated of deliberate abstinence among men and women with HIV/AIDS. *American Journal of Public Health.* 2006;96:1078-1084.
 - ³ Centers for Disease Control and Prevention. Adoption of protective behaviors among person with recent HIV infection and diagnosis—Alabama, New Jersey, and Tennessee, 1997-1998. *Morbidity and Mortality Weekly Report.* 2000;49(23): 512-515.
 - ⁴ Richardson JL, et al. Effect of brief safer-sex counseling by medical providers to HIV-1 seropositive patients: a multi-clinic assessment. *AIDS.* 2004;18:1179-1186.
 - ⁵ Centers for Disease Control and Prevention. High-risk sexual behavior by HIV-positive men who have sex with men—16 sites, United States, 2000-2002. *Morbidity and Mortality Weekly Report.* 2004;53(38):891-894.
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9. A description of how CDC plans to assess the programmatic and behavioral impact of the new recommendations on prevention counseling.

CDC will assess the programmatic and behavioral impact of the revised recommendations through a monitoring and evaluation plan that includes demographic information, HIV incidence and prevalence, and HIV testing and risk behaviors. Existing data sources for this monitoring and evaluation plan include CDC's HIV/AIDS case surveillance, HIV incidence surveillance, National HIV Behavioral Surveillance and BRFSS, the National Survey of Family Growth, the AHA Health Research and Education Trust Survey, and a multi-site evaluation of HIV screening in EDs. By collecting and reviewing data from a variety of populations (e.g., adults, adolescents, groups at high risk for HIV) and health-care settings (e.g., hospitals, EDs), CDC will be able to assess adoption of the revised recommendations as well as the impact on HIV risk behaviors, and HIV transmission.

Furthermore, CDC is working to develop a system to monitor adverse or unintended consequences of routine HIV testing and mechanisms to capture qualitative data on patient and provider experiences. As currently planned, the system will allow CDC to collect information on testing strategies, venues and outlets for testing, lessons learned, and adverse effects.

In addition, CDC has established an IAA with HRSA to work with the National Association of Community Health Centers to develop HIV screening implementation models for primary health-care clinics. Through this IAA, implementation and evaluation guidance for CHCs will be developed based on a pilot project in six CHCs that support 21 treatment clinics. A key component of the pilot project is the evaluation of the implementation of HIV screening in CHCs. The evaluation plan will monitor the extent to which HIV screening is conducted in these clinical settings, the effect on the flow of patients and delivery of medical services, the demographic characteristics of persons screened for HIV, and linkage of newly identified HIV-positive individuals to care. The evaluation will also include interviews with staff and patients to document their experience with the HIV screening program.

The information collected through these evaluation activities will help to formulate future revisions to the recommendations as well as guidance for implementation, technical assistance, and training in support of HIV screening.