



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

AUG 27 2008

The Honorable Henry A. Waxman
Chairman, Committee on Oversight and
Government Reform
U.S. House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Waxman:

Thank you for your follow up 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.

As you know, CDC's revised recommendations are intended to help the estimated 250,000 to 300,000 HIV-infected Americans who are unaware of their infection to learn their HIV status and access life-saving treatment and prevention. The objectives of these recommendations are to increase HIV screening of patients, including pregnant women, in healthcare settings; foster earlier detection of HIV infection; identify and counsel persons with previously unrecognized HIV infection and link them to clinical and preventive services; and further reduce perinatal transmission in the United States. In addition, the recommendations are based on best practices, and are intended to comply fully with the ethical principles of informed consent and the changing landscape of prevention and treatment options for persons living with HIV. Enclosed are detailed responses to the questions you asked concerning the recommendations.

I appreciate your continued interest in this very important health issue and I hope this information is helpful. If you have any questions, please contact Mr. Michael Craig of the CDC/Washington Office at (202) 245-0600.

Sincerely,


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

Enclosure

The Centers for Disease Control and Prevention (CDC)
Responses to the December 20, 2007, Letter From
Representative Henry A. Waxman, Chairman, Committee on Oversight and Government
Reform

1. Please provide “a more detailed explanation of CDC's interpretation of the data on the effectiveness of counseling with testing for HIV negative persons, and on the potential risk of delinking the two in high-risk environments.”

The primary goal of the *2006 Revised Recommendations* is to increase the number of HIV-infected persons who are aware of their infection. Most evaluations of counseling with HIV testing (such as Project Respect, which conducted recruitment from 1993–1996¹) occurred before the widespread availability of effective, highly active antiretroviral therapy. At that time, and in the absence of effective therapy, there was less benefit from learning an HIV-positive diagnosis, and reducing the risk of HIV acquisition through effective counseling was perceived to be the more important goal. With the advent of effective therapy, the relative benefit of early diagnosis of HIV infection has increased substantially. Given the availability of effective therapies, there is an even greater benefit from testing; thus while we want counseling to occur, it should not be at the expense of people getting tested. Notwithstanding, CDC continues to encourage prevention counseling, and the *2006 Revised Recommendations* specify “prevention counseling should be offered or made available through referral in all healthcare facilities serving patients at high risk for HIV and at facilities (e.g., sexually transmitted disease [STD] clinics) in which information on HIV risk behaviors is elicited routinely.”

Project Respect was an efficacy trial of structured, theory-based counseling with HIV testing for high-risk STD clinic patients. Compared with the control (standardized, short, personalized educational messages), prevention counseling resulted in a 30% reduction in sexually transmitted infections (STI) at 6 months, and a 20% reduction at 12 months. However, STI re-infection rates were not trivial (a range of 7.2% to 14.6% of participants were diagnosed with STDs), depending on type of intervention and follow-up session. Furthermore, the beneficial effect of the counseling intervention found during the initial six month follow up period declined during the subsequent six month follow up period. Project Respect 2 was conducted to evaluate whether a booster session at six months could potentiate the prevention benefit.² Although self-reported risk behaviors were reduced in the group that received booster counseling six months after HIV testing and counseling, rates of STDs were not significantly different between the control and counseled groups.

¹ Kamb ML, Fishbein M, Douglas JM, Jr., et al. *Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial*. Project RESPECT Study Group. *JAMA* 1998; 280(13):1161-1167.

² Metcalf CA, Malotte CK, Douglas JM Jr, et al. *Efficacy of a booster counseling session 6 months after HIV testing and counseling: a randomized, controlled trial (RESPECT-2)*. *Sex Transm Dis*. 2005; 32(2):123-9.

Project Respect demonstrated the benefit from counseling with HIV testing for high-risk persons in an efficacy trial—that is, when it was delivered under optimum (research) conditions with many resources and high-quality staff.³ Although no data exists on the adoption of and adherence to these counseling standards in the United States, challenges in turning this research into practice have impeded widespread implementation, particularly in STD clinics.⁴ Furthermore, it is important to note that men who have sex with men (MSM) were not included in Project Respect and that MSM continue to account for approximately half of all new HIV diagnoses.

Costs are a major consideration for program effectiveness: many interventions are too costly to be maintained in real-world settings. Clinic logistics are cited as the single most important impediment to implementation of structured prevention counseling. Although brief counseling requires only two 20-minute sessions, such an additional time commitment (over and above a typical 30–45 minute visit) may be prohibitive given the patient workload and staff constraints.⁵ The logistical and cost constraints that affect the ability to provide prevention counseling in specialized settings serving predominately high-risk persons pose an even greater barrier in overburdened care settings such as emergency departments. This drawback is compounded by the fact that these providers serve a much more diverse population and deal with a larger array of healthcare problems than those encountered by STD providers. Experience has shown that when counseling is required with HIV testing in busy healthcare settings, most patients receive neither.^{6,7} CDC has recommended counseling and testing for HIV in acute-care hospitals since 1993. Data from the National Hospital Ambulatory Care survey show that, in 2004, fewer than 0.5% of patients aged 15–64 were tested for HIV in emergency departments.⁸

There has been speculation that receipt of an HIV-negative test result without adequate counseling might lead to an increase in risk behavior among persons who test negative. A single study by CDC authors published 20 years ago suggested that such an increase of risk behaviors might occur.⁹ However, the same authors were unable to reproduce this finding using subsequent years' data from the same clinic population, nor have other investigators documented this phenomenon.

³ Kamb ML, Dillon BA, Fishbein M, et al. *Quality assurance of HIV prevention counseling in a multi-center randomized controlled trial*. Public Health Reports 1996; 3 (suppl 1)99-107.

⁴ Rietmeijer CA. *Risk reduction counseling for prevention of sexually transmitted infections: how it works and how to make it work*. Sex Transm Infect. 2007 Feb; 83(1):2-9.

⁵ Rietmeijer CA. *Risk reduction counseling for prevention of sexually transmitted infections: how it works and how to make it work*. Sex Transm Infect. 2007 Feb; 83(1):2-9.

⁶ Fincher-Mergi M, Cartone KJ, Mischler J, et al. *Assessment of emergency department healthcare professionals' behaviors regarding HIV testing and referral for patients with STDs*. AIDS Patient Care and STDs. 2002; 16(11):549-53.

⁷ Burke RC, Sepkowitz KA, Bernstein KT, et al. *Why don't physicians test for HIV? A review of the US literature*. AIDS 2007; 21:1617-24.

⁸ McCaig LF, Nawar EW. *National Hospital Ambulatory Medical Care Survey: 2004 emergency department summary*. Advance data from vital and health statistics; no 372. Hyattsville, MD: National Center for Health Statistics. 2006

⁹ Otten M W Jr, Zaidi AA, Wroten JE, et al. *Changes in sexually transmitted disease rates after HIV testing and posttest counseling, Miami, 1988 to 1989*. Am J Public Health. 1993 Apr; 83(4):529-33.

Based on the totality of this evidence, CDC has recommended that counseling not be required in healthcare settings; however, CDC recognizes the value of prevention counseling and recommends that it be offered or made available through referral in all healthcare facilities serving patients at high risk for HIV and at facilities (e.g., STD clinics) in which information on HIV risk behaviors is elicited routinely.

2. *Please provide “an update on this evaluation system (to collect information on testing strategies, venues and outlets for testing, lessons learned and adverse effects) with regard to monitoring of preventing counseling and risk behaviors.”*

To help monitor provision of HIV testing, CDC has funded a new project—the Assessment of HIV Testing in Clinical Settings (AHITS). AHITS is an 18-month project (September 2007–March 2009) to (1) determine the extent to which HIV testing is conducted in clinical settings and HIV-infected individuals are identified; and (2) assess programmatic activities supported by CDC’s supplemental funding to promote HIV testing in clinical settings, identify barriers to these activities, and the strategies used to address them. In-depth qualitative analysis will be conducted in six health department jurisdictions.

CDC has also established a cooperative agreement with the HRSA-funded AIDS Education and Training Centers’ (AETC) National Evaluation and Resource Center at the University of California at San Francisco and the University of Medicine and Dentistry of New Jersey. Under this agreement, the Centers will develop and pilot test an evaluation toolkit for healthcare providers to assess patient preferences, satisfaction, attitudes, and acceptance of HIV testing. Domains included in the patient instrument include patient perspectives on reasons for accepting or declining an HIV test; pressure/coercion to take the test; confidentiality and privacy; satisfaction with the testing process; attitudes toward testing and risk behavior; and stigma. The toolkit is designed to be used independently in a variety of healthcare settings, including hospitals, private primary care settings, and STD clinics. The toolkit will be disseminated through the AETC's National Evaluation Center and National Resource Center.

3. *Please provide a “description of extramural research the U.S. government is funding to assess behavioral interventions for HIV prevention, including the impact of prevention counseling and testing on subsequent risk behavior for HIV-negative persons.”*

The National Institute on Drug Abuse of the National Institutes of Health is conducting a study, "HIV Rapid Testing and Counseling in Drug Abuse Treatment Programs in the U.S.," Clinical Trials Network Protocol CTN0032. This randomized controlled trial, led by investigators at the University of California at San Francisco and the University of Miami School of Medicine, is being carried out in collaboration with CDC. Persons receiving drug abuse treatment will be recruited to participate in a multi-center HIV testing and counseling study to assess the relative effectiveness of three HIV testing strategies on increasing receipt of test results: (1) on-site HIV rapid testing with brief, participant-tailored prevention counseling, (2) on-site HIV rapid testing with information only, and (3) referral for off-site HIV testing and counseling. The study will also assess the effectiveness of the three testing strategies in reducing HIV risk behaviors. Participants complete a baseline assessment to obtain demographic information and information on HIV testing behaviors and sexual and drug-using risk behaviors. Participants will be randomly assigned to one of these three testing groups. After one month, participants will

complete a follow-up assessment to determine whether or not they received their HIV testing results; at six months, participants will complete a follow-up assessment to assess any changes in their HIV risk behaviors.

While not a CDC-funded project, the Agency for Healthcare Research and Quality has commissioned a systematic review of Behavioral Counseling to Prevent Sexually Transmitted Infections (including HIV) for consideration by the U.S. Preventive Services Task Force. This review includes an assessment of counseling interventions provided with HIV testing. Further information on the status of this project is available from Mary B. Barton, M.D., M.P.P., Scientific Director of the U.S. Preventive Services Task Force with the Agency for Healthcare Research and Quality.

CDC continues to conduct behavioral and operational research to develop, test, synthesize, and package sustainable interventions to prevent HIV transmission. This research is targeted toward population sub-groups disproportionately affected by the HIV epidemic.

CDC has forwarded your request for additional information regarding National Institute of Health's (NIH) behavioral research addressing HIV to NIH for response under separate cover.