December 20, 2007

The Honorable Julie Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Gerberding:

Thank you for CDC's response to my letter regarding the agency's revised HIV testing guidelines. In light of CDC's recent announcement that the agency will soon be releasing new estimates of annual new HIV infections in the United States, figures that are expected to be higher than past estimates, I am writing with further questions about a change to prevention counseling recommendations.

At issue is whether prevention counseling should be provided in conjunction with testing. Earlier guidelines recommended combined counseling and testing for people at high risk for HIV infection and for all people in settings with prevalence of 1% or more.[1] The new guidelines note that prevention counseling has been documented to change the behavior of people who test positive for HIV, and continues to recommend that it be provided along with testing for these patients. However, if a patient tests negative, the guidelines state that "prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in Healthcare settings."[2] 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 "should not have to be linked to HIV testing."[3]

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[1] Centers for Disease Control and Prevention, *Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings* and Technical guidance on HIV counseling Morbidity and Mortality Weekly Report 1993;42 (No. RR- 2).

[2] Centers for Disease Control and Prevention, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*. Morbidity and Mortality Weekly Report 55(RR14); 1-17, CDC (Sep. 22, 2006). *Id.*

[3] *Id.*

In my letter, I asked for a compilation of the behavioral data CDC relied on in determining that prevention counseling at the time of testing should not be required for HIV-negative people. CDC's response included two assertions. First, it noted that evidence does not indicate that combined counseling and testing has a positive behavioral impact on high-risk, HIV-negative people. Second, it stated that no negative effects have been documented when counseling is de-linked from testing. Because these characterizations appear to represent a shift from certain past CDC findings, I am writing to request clarification and a more detailed account of how CDC is monitoring and analyzing the role of counseling with testing in prevention.

Benefits of Counseling and Testing

As CDC's letter noted, evidence indicates that people who test positive for HIV change their behavior after counseling and testing. However, the letter also stated that "the benefits of providing typical prevention counseling in conjunction with HIV testing for HIV negative persons are less clear."[4] It described a 1999 meta-analysis which concluded that "HIV counseling and testing appears to provide an effective means of secondary prevention for HIV-positive individuals but, as conducted in the reviewed studies, is not an effective primary prevention strategy for uninfected participants."[5]

CDC acknowledged the demonstrated effectiveness of "carefully implemented prevention counseling in high-risk settings" for people who are HIV negative.[6] It did not, however, make clear whether these successful programs linked such counseling to testing. In fact, one of the "carefully implemented" programs that CDC mentioned did involve counseling in conjunction with testing. As reported by CDC in 1998, a client-centered counseling and testing program called Project RESPECT led to significant increases in condom use and decreases in STD rates among patients at STD clinics who tested negative for HIV.[7]

When the 1999 meta-analysis that CDC referred to was published, it was criticized by several CDC authors of the Project RESPECT study, who stated that the authors of the meta-

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[4] Dr. Julie Gerberding, *supra* note 1.

[5] Letter from Dr. Julie Gerberding to Rep. Henry A. Waxman (Jul. 18, 2007) (Attached). The meta-analysis cited was Weinhardt, Lance S., Michael P. Carey, Johnson T. Blair, Bickham Nicole L. "Effects of HIV Counseling and Testing on Sexual Risk Behavior: A Meta-Analytic Review of Published Research, 1985-1997." *American Public Health Association*, 89 (9); 1397-1405 (1999).

[6] Letter from Dr. Julie Gerberding to Rep. Henry A. Waxman (Jul. 18, 2007) (Attached).

[7] 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) 280:1161–7.

analysis "inappropriately used their findings to evaluate CDC's client-centered HIV prevention counseling model":

> In client-centered counseling, the counselor helps the client identify and commit to a single step he or she can take to reduce HIV risk and develop strategies for overcoming personal barriers to behavior change. This counseling approach is categorically different from the information-driven approaches that were used in earlier studies.[8]

These authors noted that of the 27 studies included in the meta-analysis, 23 were published before it was found that client-centered counseling in conjunction with testing could in fact lead to behavior change.

As recently as July 2006, a CDC Morbidity and Mortality Weekly Report article on the evolution of HIV/AIDS prevention programs referred to Project RESPECT's client-centered counseling and testing as an effective intervention for HIV-negative persons at risk of infection, stating: "This approach substantially increased condom use and decreased new sexually transmitted diseases (STDs) among HIV-seronegative patients at STD clinics."[9]

Furthermore, a recent review of evidence on counseling and testing for those who test negative for HIV and are at high risk of infection concluded that "[a]mong persons who test negative for HIV, counseling before and after the test clearly has a beneficial effect on risk behaviors and STD incidences in real-world settings."[10]

Potential Risks of Providing Testing Without Counseling

CDC also stated in its July response that the agency found "no published evidence of increases in risk behavior among persons testing negative for HIV who did not receive prevention counseling."[11] However, in a 2005 study of HIV infection among young men who have sex with men, Janssen et al. noted that testing without counseling might reinforce risk behaviors in at-risk HIV-negative persons:

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[8] Kamb ML, Peterman, Thomas, Wolitski, Richard, et al. Prevention Counseling for HIV-Negative Persons. Letter to the Editor. American Journal of Public Health. Vol. 90, No. 7; 1152 (July 2000).

[9] Centers for Disease Control. *Evolution of HIV/AIDS Prevention Programs — United States 1981-2006*, MMWR, 55(21); 597-603 (Jun. 2, 2006).

[10] Holtgrave, David and Jean McGuire. *Impact of Counseling in Voluntary Counseling and Testing Programs for Persons at Risk for or Living with HIV Infection,* Clinical Infectious Diseases 45:S420-3 (2007).

[11] Dr. Julie Gerberding, *supra* note 1.

> Among infected-unaware [men who have sex with men], we found that (1) nearly half who had been tested within the past year ... did not receive any counseling, (2) that perceived low risk for infection was associated with having tested HIV negative, and (3) of those who engaged in [unprotected anal intercourse], approximately half did so because they perceived themselves or their partners to be HIV negative or at low risk for infection. Our findings, thus, support several reports suggesting that many persons who voluntarily test for HIV are not counseled and that the combination of testing negative with inadequate or no counseling can reinforce behaviors that lead to HIV acquisition and transmission.[12]

CDC has not explained whether and how this potential negative effect was assessed when it created its new recommendations.

Conclusion

I appreciate the context in which CDC's recommendations are made. As you noted, the agency had to take into account how the guidelines would function in the real world. A primary challenge was how to promote expanded screening without placing untenable demands on the time of busy healthcare practitioners.

My concern is that CDC's characterization of the data on the impact of counseling for at-risk people who test negative does not seem to address the data described above. If linked counseling is effective — or if its absence is harmful — it is important to assess ways to make that counseling available with testing, even if the healthcare provider who performs the test is not the person who provides the counseling. I therefore request 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.

In my original request letter, I requested information on the plan in place to assess the programmatic and behavioral impact of the new recommendations, particularly pertaining to prevention counseling. Your response indicated that a system is being developed that will allow CDC to "collect information on testing strategies, venues and outlets for testing, lessons learned and adverse effects."[13] I request an update on this evaluation system with regard to monitoring of preventing counseling and risk behaviors.

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[12] Janssen RS, et al. *Unrecognized HIV infection, risk behaviors, and perceptions of risk among young men who have sex with men: opportunities for advancing HIV prevention in the third decade of HIV/AIDS*, J Acquir Immune Defic Syndr; 15;38(5):603-14 (Apr. 2005).

[13] Dr. Julie Gerberding, *supra* note 1.

Finally, I request a description of any extramural research the U.S. government is funding to assess behavioral interventions for HIV prevention, including the impact of prevention counseling with testing on subsequent risk behavior for people who test negative. Please work with the National Institutes of Health (NIH) to compile this list for both CDC- and NIH-funded programs.

I request a response by January 16, 2008. If you have any questions, please contact Jesseca Boyer or Naomi Seiler at (202) 225-5060.

Sincerely,

Henry A. Waxman
Chairman

Enclosure

cc: Dr. William Zerhouni
NIH Director

Tom Davis
Ranking Minority Member