OBAMA-BIDEN TRANSITION PROJECT

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Revise Flawed HIV-Testing Recommendations

Issue

The Centers for Disease Control and Prevention's ("CDC") current HIV testing recommendations do not require consent and pre-test counseling. As a result, patients do not fully understand their test results, HIV, or their rights with respect to the privacy of the results.

Short Answer

The CDC should revise its HIV testing recommendations to include specific written informed consent and pre-test counseling requirements.

Background

In 2006, the CDC released its "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings" ("CDC Recommendations").[1] In these recommendations, the CDC recommends eliminating requirements for specific consent to HIV testing and pre-test prevention counseling, which focuses on individual risk assessment and risk reduction. Currently, state law governs HIV testing policies and many states have statutes and regulations that do not follow the CDC Recommendations. New York, for example, requires specific written informed consent.[2] Although state law is determinative for HIV testing policies, some states have changed their policies to conform more closely to CDC Recommendations.[3] Thus, the CDC Recommendations, while not determinative law for each state, effectively serve as a nationwide model and influence individual states' HIV testing policies.[4]

The CDC Recommendations are intended to make HIV testing more routine in order to prevent and to treat HIV and AIDS on a widespread basis; however, the CDC Recommendations fail to fully protect patients' decision-making autonomy. By not requiring specific written consent, the CDC Recommendations may lead health care providers to test patients who have not been

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[1] *See* CTRS. FOR DISEASE CONTROL AND PREVENTION, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, 55 (RR14) MORBIDITY AND MORTALITY WEEKLY REP. 1 (Sept. 22, 2006), http://www.cdc.gov/mmwr/PDF/rr/rr5514.pdf.

[2] *See* NAT'L HIV/AIDS CLINICIANS' CONSULTATION CTR., COMPENDIUM OF STATE HIV TESTING LAWS: QUICK REFERENCE GUIDE 34 (Mar. 6, 2006), http://www.nccc.ucsf.edu/StateLaws /Index.html. The Compendium, last updated in March 2008, locates and details HIV testing laws on a state-by-state basis.

[3] Illinois, for example, required specific written consent until June 2008. Effective June 1, 2008, Illinois requires only general consent and names the CDC Recommendations as a model for Illinois HIV testing policies. *See* 410 ILCS 305/2(4) (2008); 410 ILCS 305/4 (2008), http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1550&ChapAct=410%C2%A0ILCS%C2%A0305/&ChapterID=35&ChapterName=PUBLIC+HEALTH&ActName=AIDS+Confidentiality+Act.

[4] *See* NAT'L ALLIANCE OF STATE AND TERRITORIAL AIDS DIRS. (NASTAD), REPORT ON FINDINGS FROM AN ASSESSMENT OF HEALTH DEPARTMENT EFFORTS TO IMPLEMENT HIV SCREENING IN HEALTH CARE SETTINGS 22-23 (hereinafter, "NASTAD REPORT") (June 26, 2007), http://www.nastad.org/Docs/Public/Publication/2007626_NASTAD_Screening_Assessment_Report_062607.pdf. The NASTAD Report, a study of the health departments of all 65 states, territories, and cities funded by the CDC's HIV prevention efforts, found that over one third of the health departments were planning to change their requirements for HIV testing to conform to the CDC Recommendations.

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adequately informed of the medical, social, and emotional ramifications of testing and test results. Under the CDC Recommendations, some patients may not even realize that, in addition to other medical procedures being performed, HIV testing is being performed as well. Furthermore, without pretest counseling, some patients might not understand HIV testing and test results and, as a result, unknowingly put others at risk.

Informed consent, an ethical and legal cornerstone of medical practice, requires that a patient be informed of the risks and benefits of HIV testing before consent is obtained.[5] By not requiring specific written informed consent, health care entities that follow the CDC Recommendations encounter instances in which the patient has little or no knowledge of the risks and benefits of HIV testing or, in some cases, instances in which the patient may not know that he or she is being tested. The CDC's view that requiring specific written informed consent would be a barrier to increased HIV testing is flawed because written informed consent is an element of many other routine health care services, such as vaccinations, yet reduced utilization of these health care services has not occurred.[6] Many states have voluntarily adopted specific written informed consent and pre-test counseling requirements, further showing that these essential safeguards can be implemented in a streamlined manner.[7] Specific written informed consent not only protects patients, who have a right to make informed decisions regarding health care testing and treatment, but it also documents patients' decisions, thus avoiding potential liability in malpractice and discrimination lawsuits.[8] Additionally, counseling-centered testing may be more cost-effective than the CDC's current opt-out testing policy: one study found that for the same monetary cost, targeted counseling and testing services would prevent and newly diagnose far more HIV infections than the CDC's policy does.[9]

Recommendation

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[5] *See* ABA Comment Letter to the CDC Recommendations (Aug. 22, 2006), http://www.champnetwork.org/media/aba.pdf.

[6] *See* AIDS Alliance for Children, Youth, and Families Comment Letter to the CDC Recommendations (Mar. 24, 2006), http://www.champnetwork.org/media/AIDS-Alliance.pdf; *see also* NASTAD REPORT, *supra* note 4 (suggesting that written consent and pretest counseling may not be actual barriers to routine HIV testing because many health departments maintain them as part of streamlined testing procedures).

[7] For example, by streamlining pretest counseling, using educational videos and pamphlets and expanding the pool of staff who were trained to give counseling, the New York City Health and Hospitals Corporation (HHC) was able to increase the number of patients tested in HHC hospitals by 63% in 2006. This was accomplished according to New York law, which requires written informed consent. *See* NYC HEALTH AND HOSPS. CORP., "Rapid Testing and More Routine Testing Reaches Patients Not Commonly Known to Be at Risk, Including More Women and Teens" (Oct. 3, 2006), http://www.nyc.gov/html /hhc/html/pressroom/press-release-20061003.shtml.

[8] *See* LAMBDA LEGAL & ACLU AIDS PROJECT, *The Importance of Informed Consent and Counseling in HIV Testing* (Mar. 8, 2007), http://www.lambdalegal.org/ourwork/publications/general/ informed-consent.html.

[9] *See* David R. Holtgrave, *Costs and Consequences of the US Centers for Disease Control and Prevention's Recommendations for Opt-Out HIV Testing*, 4 PUB. LIBRARY OF SCI. (PLOS) MED. e1194 (June 12, 2007), http://medicine.plosjournals.org/perlserv/? request=get-document&doi=10.1371%2Fjournal.pmed.0040194. Holtgrave found that for the same one-year programmatic cost of $864,207,288, targeted counseling and testing services would newly diagnose 188,170 HIV infections (versus 56,940 under the opt-out program) and would prevent 14,553 HIV infections (versus 3,644 under the opt-out program). The cost per infection averted would be $59,383 with targeted services, a much lower cost than the $237,149 cost per infection averted under the opt-out program.

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The CDC should revise its HIV testing recommendations to replace its opt-out consent policy with a requirement of specific written informed consent and preventive pre-test counseling with risk assessment and risk reduction components.

Authority

The CDC has the authority to issue HIV testing guidelines because Congress has granted the CDC broad authority to assist disease prevention efforts of entities and individuals engaged in disease prevention.[10]

[10] 42 U.S.C. § 280b(b) (2008).