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## INCREASING ACCESS TO VOLUNTARY HIV TESTING: A SUMMARY OF EVIDENCE OF THE IMPORTANCE OF SPECIFIC WRITTEN CONSENT AND PRE-TEST COUNSELING IN HIV TESTING

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Increasing the numbers of people living with undiagnosed HIV who get tested, so that they will learn their status and get into care earlier, has our support. But expanded testing should be done with specific, written consent and after some counseling, for the reasons summarized below.

### WHAT THE CDC RECOMMENDS REGARDING CONSENT AND COUNSELING FOR HIV TESTING<sup>1</sup>

- The CDC continues to state that:
  - Testing must be voluntary and free from coercion.
  - Patients must not be tested without their knowledge.
  - Obtaining informed consent is an ethical obligation.<sup>2</sup>
  
- The CDC now recommends:
  - Testing should be “opt-out,” with specific signed consent for HIV testing not required.
  - Consent for HIV testing should be incorporated into the patient’s general informed consent for medical care.
  - “Prevention counseling” -- which CDC defines as a process focused on risk assessment and developing a plan for risk reduction -- should not be required prior to testing.
  - But prior to testing, patients should receive information, orally or in writing, that includes “an explanation of HIV infection and the meanings of positive and negative test results” and “should be offered an opportunity to ask questions and to decline testing.”

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<sup>1</sup> Centers for Disease Control and Prevention (CDC) (2006) Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings, *MMWR*, 55(No. RR-14), 1-17 at 2, 7-8, 13 (hereinafter “CDC, Revised Recommendations”).

<sup>2</sup> The CDC defines “informed consent” as “[a] process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions.” CDC, Revised Recommendations at 2.

## WHY SPECIFIC WRITTEN CONSENT AND PRE-TEST COUNSELING ARE BENEFICIAL

- The risk of testing patients without their knowledge is avoided by requiring specific, written consent for an HIV test.
  - This is a real concern. Up to 16% of the pregnant women tested under an opt-out testing system without a written consent requirement in Arkansas did not even know that they had been tested for HIV.<sup>3</sup>
- Health care providers benefit from requiring specific written informed consent, by documenting that they have satisfied their ethical and legal obligations to obtain informed consent.<sup>4</sup>
- Communication between the patient and health care provider, which CDC acknowledges is an important part of informed consent, is more likely when specific written consent and counseling are required. Trust between patients and health care providers is greater if they have a dialogue about health care; with greater trust comes an increased likelihood that the patient will seek and continue needed treatment.
  - Studies show that patients' rates of adherence to prescribed treatment are higher where their trust in their physician is high.<sup>5</sup> This is especially important given the low rates at which newly diagnosed HIV-positive patients are linked to follow-up care in some settings.<sup>6</sup>
  - Trust in a personal physician was the strongest predictor of willingness to initiate antiretroviral treatment in a population of primarily African-American and Hispanic inmates and was a strong predictor of preventive services use among African Americans.<sup>7</sup>
  - A person who is tested without realizing it or without understanding the possible significance of the test is more likely to be alienated from care. This is especially of concern because some of the populations facing increased infection rates are already mistrustful of public health efforts.<sup>8</sup>

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<sup>3</sup> CDC (2002) HIV Testing of Pregnant Women -- United States and Canada, 1998-2001, *MMWR*, 51, 1013-1016.

<sup>4</sup> American Medical Association (Sept. 1998) Informed Consent, available at <http://www.ama-assn.org/ama/pub/category/4608.html>.

<sup>5</sup> Thom, D.H. *et al.* (1999) Further Validation and Reliability Testing of the Trust in Physician Scale, *Med Care*, 37(5), 510-517; Safran, D.G. *et al.* (1998) Linking Primary Care Performances to Outcomes of Care, *Journal of Family Practice*, 47(3), 213-218; Etchells, E. *et al.* (1996) Bioethics for Clinicians: 1. Consent, *Can Med Assoc J*, 155(2), 177-180.

<sup>6</sup> Lyons, M. *et al.* (2004) Emergency Department HIV Testing and Counseling: An Ongoing Experience in a Low-Prevalence Area, *Annals of Emergency Medicine*, 46(1), 22-28 (finding that only 35% to 64% of newly diagnosed HIV-positive emergency department patients are successfully linked to follow-up care post-diagnosis).

<sup>7</sup> Altice, F.L. *et al.* (2001) Trust and Acceptance of and Adherence to Antiretroviral Therapy, *Journal of AIDS*, 28(1), 47-58; *see also* O'Malley, A.S. *et al.* (2004) The Role of Trust in Use of Preventive Services Among Low-Income African-American Women, *Prevention Medicine*, 38(6), 777-785 (survey found that trust in a personal physician was strongly associated with use of preventive health services among low-income African-American women).

<sup>8</sup> Bogart, L.M. & Thorburn, S. (2005) Are HIV/AIDS Conspiracy Beliefs a Barrier to HIV Prevention Among African Americans?, *Journal of AIDS*, 38(2), 213-218; Malebranche, D. (2005) Adverse Health Outcomes Among African Americans. Living with HIV: Nature or Nurture, *Positively Aware*, 16(6), 26-29; Klonoff, E.A.

- The significant emotional and legal dimensions to an HIV diagnosis – which make HIV infection different from many other diseases – can be addressed.
  - There is no cure for HIV and anyone who tests positive will need to follow a care regimen -- often very complicated, expensive, and with significant side effects -- for the rest of his or her life.
  - The significant legal consequences include mandatory confidential reporting of the names of anyone diagnosed with HIV; in order to give truly informed consent, people should be informed of those and be informed that in many states they have the option of anonymous testing.
  
- Stigma still attaches to an HIV diagnosis and people living with HIV still experience discrimination.
  - 26% of adults with HIV believed they had experienced discrimination from a health care provider since being diagnosed with HIV, according to a 2005 study.<sup>9</sup>
  - 41% of the respondents in a 2006 study agreed “people often behaved negatively around them once they learned of their HIV status.”<sup>10</sup>
  - 56% of the skilled nursing facilities, 26% of the plastic and cosmetic surgeons, and 47% of the obstetricians surveyed in Los Angeles County from 2003 to 2005 refused to treat any people living with HIV.<sup>11</sup>
  - From 2002 to 2006, HIV-related employment discrimination claims were filed at an average rate of about one per day, according to data obtained from the U.S. Equal Employment Opportunity Commission. This is only a small decline from the number of claims filed during the period 1994 to 2001.<sup>12</sup>
  - A 2006 survey found that only 1 in 4 respondents reported that they would be very comfortable having an HIV+ roommate and only 29% reported that they would be very comfortable with their child having an HIV+ teacher.<sup>13</sup>
  
- People are more likely to agree to be tested if they understand more about HIV and its treatment.
  - One study of prenatal testing found that 92% of the women surveyed reported they would be more likely to get tested if they knew about treatment to reduce mother to child infection. Another study found

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& Landrine, H. (1999) Do Blacks Believe that HIV/AIDS is a Government Conspiracy Against Them?, *Preventative Medicine*, 28, 451-457.

<sup>9</sup> Schuster, M.A. *et al.* (2005) Perceived Discrimination in Clinical Care in a Nationally Representative Sample of HIV-Infected Adults Receiving Health Care, *Journal of General Internal Medicine*, 20, 807-813.

<sup>10</sup> Vanable, P.A. *et al.* (2006) Impact of HIV-Related Stigma on Health Behaviors and Psychological Adjustment Among HIV-Positive Men and Women, *AIDS and Behavior*, 10(5), 473-482.

<sup>11</sup> Sears, B. & Ho, D. (2006) HIV Discrimination in Health Care Services in Los Angeles County: The Results of Three Testing Studies, *The Williams Institute*, UCLA School of Law available at <http://www.law.ucla.edu/williamsinstitute/publications/Discrimination%20in%20Health%20Care%20LA%20County.pdf>.

<sup>12</sup> Based on “ADA Charges Filed with EEOC and State and Local FEP Agencies Where the Alleged Basis Was HIV,” obtained from U.S. EEOC by Lambda Legal on Dec. 15, 2006 (on file with Lambda Legal).

<sup>13</sup> Kaiser Public Opinion Spotlight (2006) Attitudes about Stigma and Discrimination Related to HIV/AIDS, available at <http://www.kff.org/spotlight/hivUS/index.cfm>.

acceptance of prenatal HIV testing greater among women with a strong belief about the benefits of testing and knowledge about how transmission from the mother occurs and can be prevented.<sup>14</sup>

- Information about HIV disease and the nature of HIV testing is important for all tested patients, not just those who test positive.
  - Many patients have serious misconceptions about the nature of HIV testing and pre-test counseling can clear those up. One study of patients in an urban intensive care setting found that patients doubted the accuracy of rapid HIV tests and did not understand the importance of being tested for HIV when no physical symptoms of the disease were present.<sup>15</sup>
- People who test negative need counseling so they fully understand that they might still be infected and highly infectious and understand how to avoid transmitting the virus.
  - The HIV tests typically used look for antibodies to the virus, which usually develop six weeks to six months after infection. Before the antibodies develop, a person infected with HIV will not test positive, but may be highly infectious.<sup>16</sup>
  - Studies have estimated that almost half of all HIV transmissions occur when a person with acute HIV infection unknowingly transmits HIV to others.<sup>17</sup>
  - This risk needs to be explained to all persons tested, so that those who test negative understand that they may still have HIV, how transmission can be avoided, and that testing negative is not a form of prevention.
- Increased offers of testing provide an excellent opportunity to educate patients about HIV and thus change risk behaviors and reduce the HIV/AIDS stigma that is fueled by misinformation about the routes of HIV transmission.
  - Many people still lack basic knowledge about what does and does not put them at risk for HIV. The 2006 Kaiser survey found that 37% of the public believed that HIV could be transmitted through kissing; 22% believed that transmission could occur through sharing a drinking glass; and 16% believed that transmission could occur through touching a toilet seat. More than 4 in 10 adults held at least one of these misconceptions.<sup>18</sup>

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<sup>14</sup> Kropp, R. *et al.* (2005) Unique Challenges to Preventing Perinatal HIV Transmission Among Hispanic Women in California: Results of a Needs Assessment, *AIDS Education & Prevention*, 17, 22; Fernandez, M.I. *et al.* (2000) Acceptance of HIV Testing During Prenatal Care, *Public Health Reports*, 115, 460-468.

<sup>15</sup> Hutchinson, A.B. *et al.* (2004) Understanding the Patient's Perspective on Rapid and Routine HIV Testing in an Inner-City Urgent Care Center, *AIDS Education and Prevention*, 16, 101.

<sup>16</sup> Pope, M. & Haase, A.T. (2003) Transmission, Acute HIV-1 Infection and the Quest for Strategies to Prevent Infection, *Nature and Medicine*, 9, 847-852; Pilcher C.D. *et al.* (2004) Acute HIV Revisited: New Opportunities for Treatment and Prevention, *Journal of Clinical Investigation*, 113, 937-945.

<sup>17</sup> Cates, W. *et al.* (1997) Primary HIV Infection: A Public Health Opportunity, *American Journal of Public Health*, 87(12), 1928-1930; Wawer, M.J. *et al.* (2005) Rates of HIV-1 Transmission per Coital Act, By Stage of HIV-1 Infection, in Rakai, Uganda, *Journal of Infectious Diseases*, 191, 403-409.

<sup>18</sup> Kaiser Public Opinion Spotlight (2006).

- A 2005 study revealed that 33% of male respondents and 46% of female respondents incorrectly believed HIV transmission could occur through unprotected sex between two uninfected men.<sup>19</sup>
- The Kaiser survey found that those with misconceptions about HIV transmission were much more likely to express discomfort with working with someone with HIV.<sup>20</sup>

## **MANY MORE PEOPLE CAN BE TESTED AND LEARN THEIR STATUS WITHOUT ELIMINATING SPECIFIC CONSENT AND PRE-TEST COUNSELING**

- Patient concerns about specific consent and pre-test counseling are not significant barriers to testing.
  - A 2006 Kaiser Family Foundation survey found that the biggest reason people reported for not getting tested is that they did not think they were at risk.<sup>21</sup> This shows the need for more information, not less.
  - The same study showed that most people did not think that they would experience stigma because they were tested for HIV. However, the study found that stigma against those who test positive still exists and roughly half of those surveyed said that there is a lot of discrimination against people with AIDS.
  - Offering testing to everyone, rather than offering it only to those considered at risk, will reduce or eliminate any stigma associated with testing.
  
- There are successful models that result in more people being tested without abandoning safeguards ensuring that testing is informed and voluntary.
  - New York City Health and Hospitals Corporation (HHC) increased the number of patients tested in HHC hospitals by 63% in 2006, by using rapid testing and streamlining pre-test counseling, while continuing to use HIV-specific written consent, which is required by New York law.<sup>22</sup>
  - Authors of one study found that routinely recommending HIV counseling and testing can be feasible and effective in an emergency department setting, despite the time constraints present in that setting, and concluded that emergency room testing can be increased by streamlining counseling and providing some information in writing, as well as by involving non-physician staff in counseling.<sup>23</sup>

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<sup>19</sup> Herek, G. *et al.* (2005) When Sex Equals AIDS: Symbolic Stigma and Heterosexual Adults' Inaccurate Beliefs about Sexual Transmission of AIDS, *Social Problems*, 52(1), 15-37.

<sup>20</sup> Kaiser Public Opinion Spotlight (2006); *see also* Herek, G. *et al.* (2002) HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991-1999, *American Journal of Public Health*, 92(3), 371-377 (discussing link between misinformation about HIV and stigma against people living with HIV).

<sup>21</sup> Kaiser Public Opinion Spotlight (2006).

<sup>22</sup> NYC Health and Hospitals Corporation, *Rapid Testing and More Routine Testing Reaches Patients Not Commonly Known to Be at Risk, Including More Women and Teens*, Oct. 3, 2006 available at <http://www.nyc.gov/html/hhc/html/pressroom/press-release-20061003.html>

<sup>23</sup> Rothman, R. (2004) Current Centers for Disease Control and Prevention Guidelines for HIV Counseling, Testing, and Referral: Critical Role of and a Call to Action for Emergency Physicians, *Annals of Emergency Medicine*, 44(1), 31.

- Perinatal transmission of HIV has been virtually eliminated in the United States, including in states that require specific written informed consent, such as Massachusetts, Pennsylvania and Michigan.<sup>24</sup>

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<sup>24</sup> Massachusetts STD and HIV/AIDS Surveillance Report: 2005, available at [http://www.mass.gov/dph/cdc/aids/2005\\_surveillance.pdf](http://www.mass.gov/dph/cdc/aids/2005_surveillance.pdf); HIV/AIDS Surveillance Biannual Summary: Commonwealth of Pennsylvania, June 2005, available at [http://www.dsf.health.state.pa.us/health/lib/health/epidemiology/biannual\\_summary\\_june2005.pdf](http://www.dsf.health.state.pa.us/health/lib/health/epidemiology/biannual_summary_june2005.pdf); Status of the HIV/AIDS Epidemic in Michigan, 2005, available at [http://www.michigan.gov/documents/Review\\_MI\\_05\\_final\\_161086\\_7.pdf](http://www.michigan.gov/documents/Review_MI_05_final_161086_7.pdf)