
INCREASING ACCESS TO VOLUNTARY HIV TESTING: THE IMPORTANCE OF INFORMED CONSENT AND COUNSELING IN HIV TESTING

INTRODUCTION

In September 2006, the Centers for Disease Control and Prevention (CDC) published updated guidelines on voluntary HIV testing in health care settings.¹ The CDC now recommends that medical providers offer all persons ages 13 to 64 voluntary HIV testing without risk assessments as a routine part of medical care. We agree that increasing access to testing and care is a critically important goal. Far too many people do not know their HIV status, and we support efforts to help people living with undiagnosed HIV learn their status and gain access to necessary care and support services.

The CDC's recommendations include the following:

- Recommending opt-out screening in medical settings, which means "performing HIV screening after notifying the patient that 1) the test will be performed and 2) the patient may elect to decline or defer testing. Assent is inferred unless the patient declines testing."²
- Recommending that all HIV testing be informed and voluntary, but that specific written consent to HIV testing is not necessary.³
- Recommending that pretest prevention counseling (which is focused on individual risk assessment and risk reduction) should not be required as part

¹ See Centers for Disease Control and Prevention, Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings, *MMWR* (No. RR-14), 1-17 (2006), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> (hereinafter "CDC, Revised recommendations").

² In opt-in screening, by contrast, a patient is also offered the chance to be tested, but must affirmatively state that he/she wants HIV testing before testing may be performed.

³ The recommendations elsewhere state that a general consent to medical care should be deemed sufficient consent to HIV testing. See CDC, Revised recommendations, at 8. However, in light of the pervasive statements indicating that all HIV testing must be voluntary and informed (see, e.g., CDC, Revised recommendations, at 4, 7, 8), we do not believe this suggests that a doctor may test a patient for HIV with nothing more than a general consent to treatment. Rather, read together, the CDC is simply indicating its belief that specific written consent to HIV testing should not be required, but patients must still give their consent to HIV testing.

of a testing regimen, although it is encouraged in settings such as STD clinics.⁴

The CDC is right that HIV testing must remain informed and voluntary. And expanding voluntary HIV testing is an important humanitarian and public health goal. But some of the CDC's new recommendations conflict with long-established laws on consent and testing currently in place in many states, which were designed to ensure that patients were not tested for HIV without their informed consent and that people seeking HIV testing are given information about HIV and the consequences of HIV testing.

After reviewing medical and public health policy literature and talking with medical providers and advocates, it is clear that several of the specific recommendations may in fact be counter-productive. Before we rush to abandon the protections existing in state law, it is important to examine the real barriers to HIV testing, and the real benefits of specific informed consent and pre-test counseling.

Providing culturally appropriate HIV counseling and requiring specific consent for HIV testing may take more time and effort than testing people without these protections. But there does not need to be a trade-off. Innovative programs have been successfully implemented to increase access to voluntary testing by streamlining counseling and consent, without sacrificing patient education and autonomy. Because people who are tested with their knowledge are more likely to get the care they need, we believe that providing such information is a critical component of increasing access to HIV testing and treatment for those people living with HIV.

THE REAL BARRIERS TO TESTING

In the current debate about HIV testing, advocates for eliminating statutory or regulatory safeguards have often implied that we need to change state laws that require written consent to HIV testing or pre-test counseling because these laws deter individuals from agreeing to get tested.⁵ But this is a fictional problem. A 2006 Kaiser Family Foundation survey about attitudes about HIV testing found that:

The biggest reason people report for not being tested is that they don't feel they're at risk (61% of those who have never been tested). Smaller shares of those who haven't been tested say it is because their doctor never recommended it (21%), they worry about confidentiality (13%), they don't know where to get tested (10%), they don't like needles or giving blood (8%), or they're afraid they'll test positive (3%) (Chart 3).

⁴ The CDC explains that the HIV prevention counseling that is the subject of its recommendations is "[a]n interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing a plan to take specific steps to reduce risks." CDC, Revised recommendations, at 2.

⁵ See, e.g., *New York Times*, op. ed. (contending that HIV testing consent requirements "beyond the general consent forms signed by patients all too often scares patients away from a test that would help them") (Sept. 25, 2006).

⁶ The Henry J. Kaiser Family Foundation, "2006 Kaiser Family Foundation Survey of Americans on HIV/AIDS" (May 2006) (available at <http://www.kff.org/kaiserpolls/upload/7521.pdf>) (summary).

This survey makes clear that the number one reason patients don't get tested is because they don't think they're at risk, not because of informed consent requirements. Indeed, based on this finding, we know that **people need more information about why they may be at risk for HIV, not less.**

This survey also shows that stigma related to testing, which the CDC also argues deters testing, isn't an important factor in why people do or don't get tested:

Stigma around HIV testing is not a concern for most people (62% say that finding out they had an HIV test would make no difference in how people they know would think of them); still, about one-fifth (21%) say they believe people would think less of them if they found out they had been tested (Chart 6).

This research calls into question the CDC's argument that eliminating specific consent will help increase testing by reducing stigma about HIV testing.⁷

If patients aren't the problem, then what is? Logic and common sense tell us that many medical providers may believe the time it takes to obtain consent for HIV testing or to do pre-test prevention counseling is not worth it, especially if they're not reimbursed by insurance companies for that time.⁸ However, in several of the studies that the CDC claims show that specific written consent and counseling are barriers to testing, a majority of providers actually stated that neither were significant barriers to testing.⁹

Another possible barrier might be that providers and patients may not be comfortable discussing risk behaviors. But if testing is routinely offered to all patients, regardless of risk behavior, this problem would be eliminated.

Importantly, the CDC has already acknowledged that **there are successful models that encourage providers to offer HIV testing to a broader range of people without abandoning safeguards that ensure that testing is informed and voluntary.**¹⁰ For example, 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, by streamlining pre-test counseling, using educational videos and pamphlets and expanding the pool of staff who were trained to give counseling. Through the use of rapid tests and making HIV testing a routine offer of care for patients in emergency departments, outpatient clinics, and other

⁷ CDC, Revised recommendations, at 5.

⁸ See, e.g., Rebecca V. Liddicoat, et al., *Assessing Missed Opportunities for HIV Testing in Medical Settings*, 19 J. GEN. INTERNAL MED. 349 (2004); Richard E. Rothman, *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*, 44 ANNALS EMERGENCY MED. 31, 33 (2004).

⁹ See Karen Troccoli, et al., *Human immunodeficiency virus counseling and testing practices among North Carolina providers*, 100 OBST. GYNECOL. 420, 424 (2002) (cited in CDC, Revised recommendations, at 3); Melissa Fincher-Mergi, et al., *Assessment of emergency department healthcare professionals' behaviors regarding HIV testing and referral for patients with STDs*, 16 AIDS Patient Care STDS, 549, 551 (2002) (cited in CDC, Revised recommendations, at 5).

¹⁰ CDC, Revised recommendations, at 6 [citing Rothman, *supra* note 8, at 33 (finding that emergency room testing can be increased by streamlining the counseling and providing some information in writing, as well as by involving non-physician staff in counseling)].

health care settings, HHC was able to more than double the number of HIV-positive patients identified. All this was done consistent with New York law, which requires written informed consent, and patients overwhelmingly agreed to be tested.¹¹ Routine HIV testing with streamlined counseling and consent procedures substantially has increased the number of people tested in the related context of prenatal testing for HIV.¹²

If there are ways to significantly increase the number of people who choose to get tested for HIV without abandoning important protections that have real benefits to patients, why wouldn't we try those first?

THE BENEFITS OF SPECIFIC CONSENT

The majority of experts, including the CDC, agree that HIV testing should be voluntary and informed. The CDC recommendations define "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 about HIV, the risks and benefits of testing, the implications of HIV test results, how the test results will be communicated and the opportunity to ask questions.¹³

Eliminating the protections gained through specific written consent would put people at risk of uninformed or even involuntary testing.

Despite the CDC's emphasis that testing must be voluntary, free from coercion and not undertaken without patient knowledge, the recommendation to eliminate specific written consent requirements could undermine that goal by eliminating the safeguards necessary to ensure that meaningful consent has been given. For example, a study of Michigan's efforts to implement a routine, opt-out HIV testing regime for pregnant women found that fewer than half of the women felt very comfortable refusing testing, and one in five did not feel at all comfortable refusing HIV testing.¹⁴ Women in the study who were younger, unemployed, and without a regular healthcare provider were less likely to feel comfortable not consenting to the test. And a study of prenatal screening in

¹¹ 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.shtml>.

¹² CDC, Revised recommendations, at 4. Notably, perinatal transmission of HIV in the United States has been virtually eliminated, including in states that require specific written informed consent, such as Massachusetts, Pennsylvania and Michigan. See, e.g., Massachusetts STD and HIV/AIDS Surveillance Report: 2005, available at 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 Status of the HIV/AIDS Epidemic in Michigan, 2005, available at http://www.michigan.gov/documents/Review_MI_05_final_161086_7.pdf

¹³ CDC, Revised recommendations, at 2.

¹⁴ Paula Schuman, et al., *Voluntary HIV Counseling and Testing of Pregnant Women—An Assessment of Compliance With Michigan Public Health Statutes*, 6 MEDSCAPE GEN. MED. 52 (2004).

Arkansas, which uses an opt-out testing system with no written consent, found that up to 16% of the women tested did not even know that they had been tested for HIV.¹⁵ These studies show that **opt out testing may not be truly voluntary and may lead to people being tested without even knowing it.** This is especially troubling because voluntary prenatal testing is widely accepted when women are able to choose testing under an opt-in model and the benefits of testing are explained.

Written consent ensures that people know that they are agreeing to an HIV test, and is an efficient way to be sure that people are given information about HIV, what HIV test results mean, and the consequences of testing positive or negative. It is also a good way to encourage communication between a provider and patient about HIV. Medical providers have legal and ethical obligations to give patients information about testing, and to ensure that HIV testing is voluntary. As the AIDS Coordinating Committee of the American Bar Association has explained: “The risks and benefits of an HIV test ... involve complex physical, emotional, social and legal consequences, and thus cannot be encompassed by a general medical consent.”¹⁶ The American Academy of HIV Medicine agrees: “[A] general consent to care does not meet the legal standard of informed consent for agreeing to have an HIV test in most instances.”¹⁷ **Obtaining documented informed consent is the best way to avoid potential liability in malpractice and discrimination lawsuits.**

Without written consent, there is a serious risk that people could be tested for HIV without having even basic information about the disease or the test, or even without their knowledge, particularly in busy urgent care settings. If doctors find themselves too busy to get written consent, what assurance do we have that they will take the time to get verbal assent and provide necessary information? A better solution would be to streamline the consent form and process, not to abandon these safeguards.

Eliminating the safeguards associated with specific consent also ignores the fundamental reality that HIV is different from many other diseases. A positive HIV diagnosis is a life-altering event, not something that can be treated quickly and then moved on from. HIV remains an incurable disease that requires adherence to a specific and often challenging treatment regimen. And, more than twenty-five years after its initial discovery, HIV is still associated with significant social stigma and discrimination. Like genetic testing, which carries a different cost-benefit analysis for every individual, consent to HIV testing should remain truly informed and voluntary.

A physician’s duty to obtain a patient’s informed consent before providing medical treatment is not only a legal formality—**tangible benefits result from the doctor-patient dialogue that the informed consent requirement envisions, including increased trust**

¹⁵ Centers for Disease Control and Prevention, *HIV Testing of Pregnant Women—United States and Canada, 1998-2001*, MMWR, 51, 1013-16 (2002).

¹⁶ Letter from Shelley D. Hayes, Chair, and Richard T. Andrias, Immediate Past Chair, AIDS Coordinating Committee, to Bernard M. Branson, M.D. dated Aug. 22, 2006, *available at* <http://www.abanet.org/AIDS/Letter%20to%20Dr.%20Branson.pdf>.

¹⁷ AAHIVM Comments on the Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings dated Mar. 27, 2006, *available at* http://64.177.16.246/web//images/stories/pdfs/cdc_testing_aahivm_comments.pdf.

and a greater likelihood that a patient will be linked to follow up care.¹⁸ Given the already low rates at which newly diagnosed HIV-positive patients are linked to follow-up care,¹⁹ eliminating informed consent for HIV testing is particularly ill advised because it may do little to increase the number of people receiving early medical care.

Finally, specific informed consent is necessary to make sure that individuals considering an HIV test have important information about the legal consequences of testing positive. Unlike high cholesterol or high blood pressure, the government requires mandatory confidential reporting of the names of anyone diagnosed with HIV. Because a positive HIV diagnosis triggers mandatory reporting of your name, HIV status and deeply personal medical and behavioral information to the state, legal principles of informed consent require that information about HIV and about what will be done with a positive test result must be provided to anyone before they are tested for HIV. Individuals should also be told that they have the option of getting tested anonymously if they prefer (if this is available in their state).

THE BENEFITS OF PRE-TEST COUNSELING

When looking at the issue of pre-test counseling, we should first consider what the CDC is really saying. Some well-meaning advocates and policy advisers appear to be interpreting the CDC's recommendations as suggesting that any state laws requiring pre-test counseling of any kind must be eliminated in order to implement "routine" testing. In fact, the CDC recommendations focus on a very specific form of individualized, pre-test HIV prevention counseling, and the CDC concluded that there is not enough evidence to agree that this type of pre-test counseling for everyone is a good prevention tool.²⁰ In contrast, in many states, the rules requiring "counseling" simply require that doctors tell patients what an HIV test means, what will be done with the test results, and some basic information about HIV and how it is transmitted. This is exactly the kind of information that the CDC maintains is a component of informed consent. Thus, before providers rush to abandon all counseling, it is very important to examine what kind of information or counseling is required under state law. Further, **states should not remove counseling requirements that are consistent with the CDC's recommendations.**

Studies suggest that **pretest counseling that explains the nature of HIV testing and gives patients information about HIV disease provides many patients with important information they don't already know.** For example, one study of patients in an urban intensive care setting revealed that patients have serious misconceptions about the

¹⁸ Studies show that patients' adherence to prescribed treatment correlates with increased physician disclosure. Edward Etchells, et al., *Bioethics for Clinicians: 1. Consent*, 155 CAN. MED. ASS'N J. 177, 179 (1996) [citing J.A. Hall, et al., *Meta-Analysis of Correlates of Provider Behavior in Medical Encounters*, 26 MED. CARE 657 (1988)].

¹⁹ For example, one study found that only 35% to 64% of newly diagnosed HIV-positive emergency department patients were successfully linked to follow-up care post-diagnosis. Michael S. Lyons, et al., *Emergency Department HIV Testing and Counseling: An Ongoing Experience in a Low-Prevalence Area*, 46 ANNALS EMERGENCY MED. 22, 27 (2005).

²⁰ See CDC, Revised recommendations, at 6, 8.

nature of HIV testing.²¹ Patients doubted the accuracy of rapid HIV tests, and were under the false impression that if they left the hospital and subsequently tested positive, the health department would contact them to inform them of their results. Patients were also confused about the confidentiality of HIV testing and issues of informed consent. In addition, the study revealed that many patients don't understand the importance of being tested for HIV when they do not have physical symptoms of the disease. Focusing all counseling resources on post-test counseling is therefore ill advised.

An additional benefit of pretest counseling is that such **counseling increases testing consent rates among patients**.²² Studies have shown that this link between pretest counseling and consent occurs even in testing regimes where patients are routinely offered HIV tests and then given the opportunity to either accept or decline testing.²³ This fact is not surprising – when people have the benefits of HIV testing explained to them, they are far more likely to choose to protect their health.

While pre- and post-test counseling are critically necessary for those who will learn that they have HIV, there is another important reason why counseling is also needed for those who test negative: **Without accurate information about what a negative test result means, some individuals unknowingly may be putting others at even greater risk.** Typical HIV screening tests for antibodies to the virus, which typically develop from within a month and a half to up to six months after infection. During this time after initial infection but before developing antibodies, in a stage known as “acute HIV infection,” a person infected with HIV will not test positive. However, during that same time he or she actually has a significantly higher viral load than is typical later on—and a higher viral load generally is associated with a greater risk of transmission.²⁴ In fact, studies have estimated that almost half of all HIV transmissions occur when a person with acute HIV infection unknowingly transmits HIV to others.²⁵ Thus, a person who tests negative during

²¹ Angela B. Hutchinson et al., *Understanding the Patient's Perspective on Rapid and Routine HIV Testing in an Inner-City Urgent Care Center*, 16 AIDS EDUC. & PREVENTION 101, 111 (2004).

²² See, e.g., Lindy Samson & Susan King, *Evidence-Based Guidelines for Universal Counseling and Offering of HIV Testing in Pregnancy in Canada*, 158 CAN. MED. ASS'N J. 1449, 1451 (1998).

²³ See Rhonda Y. Kropp, et al., *Unique Challenges to Preventing Perinatal HIV Transmission Among Hispanic Women in California: Results of a Needs Assessment*, 17 AIDS EDUC. & PREVENTION 22, 35 (2005). Nearly 40% of the participants in Kropp's study were unaware that ZDV treatment could reduce the risk of mother-child transmission, but 92% indicated that such knowledge would increase their willingness to be tested. *Id.* These findings led the authors of the study to conclude that “[t]o improve HIV test acceptance by Hispanic women, culturally appropriate pretest counseling with information on treatment to reduce perinatal HIV transmission is needed.” *Id.* at 36.

²⁴ See, e.g., Melissa Pope, et al., *Transmission, acute HIV-1 infection and the quest for strategies to prevent infection*, 9 NATURE & MEDICINE, 847-852 (2003); Christopher Pilcher, et al., *Acute HIV revisited: new opportunities for treatment and prevention*, 113 J. OF CLINICAL INVESTIGATION, 937-45 (2004).

²⁵ See, e.g., Willard Cates, Jr., et al., *Primary HIV infection—a public health opportunity*, 87 Am. J. Public Health, 1928-30 (1997) (“Mathematical models suggest that the primary HIV infection interval makes a disproportionate contribution to the HIV epidemic, perhaps accounting for as many as half of the existing infections at any point in time.”); Maria J. Wawer, et al., *Rates of HIV-1*

this period needs to know that they may still have HIV, and that merely testing negative is not a form of prevention. Without counseling to explain this critical information, people may unknowingly put themselves and their loved ones at high risk.

In rushing to abandon any educational component to HIV testing, medical providers also may lose an excellent opportunity to educate patients about HIV and how to begin to change risk behaviors. The 2006 Kaiser Family Foundation survey showed that, unfortunately, many people still lack basic information about what does, and what does not, put them at risk of getting HIV.²⁶ This **lack of knowledge is intrinsically connected to the fear and stigma that fuel the discrimination that too often follows a positive diagnosis.**

CONCLUSION

While efforts to encourage doctors to offer HIV tests to more patients are to be commended, eliminating safeguards created in recognition of the fact that learning you have HIV is not like any other diagnosis—because of the nature of HIV disease, its treatment, and the stigma and discrimination still associated with having HIV—is not the answer.

Abandoning protections that require doctors testing patients for HIV to obtain specific consent and to provide pretest counseling goes against long-standing principles of patient autonomy in medical decision-making and ignores the important benefits that informed consent and counseling provide to patients being tested for HIV.

OTHER RESOURCES

For other resources on why written informed consent and counseling are important components of HIV testing, see:

- American Bar Association comments on the CDC recommendations, available at <http://www.champnetwork.org/media/aba.pdf>
- American Academy of HIV Medicine comments to the CDC, available at <http://www.champnetwork.org/media/AAHIVM.pdf>
- AIDS Alliance for Children, Youth and Families comments to the CDC, available at <http://www.champnetwork.org/media/AIDS-Alliance.pdf>
- National Association of People with AIDS (NAPWA) comments on CDC recommendations, available at http://www.napwa.org/documents/routine_testing_counseling.pdf

transmission per coital act, by stage of HIV-1 infection, in Rakai, Uganda, 191 J. OF INFECTIOUS DISEASES, 403-09 [2005].

²⁶ Kaiser Public Opinion Spotlight, "Attitudes about Stigma and Discrimination Related to HIV/AIDS" (2006), available at <http://www.kff.org/spotlight/hivUS/index.cfm>.

- Comments on the CDC recommendations by community-based organizations serving people living with HIV, available at http://www.aidschicago.org/pdf/2006/adv_testing_statement.pdf
- Ann Fisher, Catherine Hanssens & David Schulman, *The CDC's Routine HIV Testing Recommendation: Legally, Not so Routine*, 11 HIV/AIDS Policy & Law Review 17 (Dec. 2006), available at <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=955>