



The Public Health Case for Patient-Centered HIV Testing & Care

Catherine Hanssens, JD, Ex. Dir.
The Center for HIV Law & Policy
New York, NY

chanssens@hivlawandpolicy.org

www.hivlawandpolicy.org

Objectives

- Define terms, outline key provisions of current CDC guidelines for CBOs
- Identify key public research supporting opt-in testing and, more generally, patient-centered care
- Identify key legal and ethical principles implicated in HIV testing
- Propose fundamental principles to guide HIV testing programs

IOM Definition of Patient-Centered Care

Patient-Centered – Care is delivered with “compassion, empathy, and responsiveness to the need, values, and expressed preferences of the individual patient” and ensures that patients “have the education and support they need to make decisions and participate in their own care.”

THE AMA ON INFORMED CONSENT

Informed consent consists of the physician discussing with the patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure;
- The risks and benefits of not receiving or undergoing a treatment or procedure.

THE CDC ON INFORMED CONSENT

Obtaining informed consent is a legal and ethical pre-requisite to the provision of medical services and procedures, including an HIV test.

In the Revised Recommendations*, CDC 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 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.

* 2006 Revised Recommendations for HIV testing, p. 2.1

CDC Interim Guidelines for CBOs

Principles of HIV CTR

Core principles include:

- Protect confidentiality of clients seeking or receiving testing
- Obtain informed consent before HIV testing, taking into consideration ability to consent (sobriety, etc.) and document it
- Test counselors must be trained, cultural competence
- Seek input from community-based planning groups and service providers, staff from programs within CBO such as needle exchange, and representatives of target population

Interim CDC Guidelines for CBOs (continued)

Training of testers must include, in part, how to:

- Perform the test, including pre-and post-test procedures
- Integrate rapid testing into an overall counseling and testing program and have a quality assurance program
- How to document and deliver confirmatory test results for preliminary positives
- Ensure confidentiality
- Establish guidelines and standards to ensure that consent is informed

Interim CDC Guidelines for CBOs (continued)

Training of testers also must include, in part, how to:

- Client-centered HIV prevention counseling
- Provide and help interpret test results, including the meaning of negative/nonreactive test results
- Linking clients to medical and social services
- Conducting test in a private area or room where confidentiality of clients can be assured
- Be sensitive to the demographic, cultural and epidemiologic profile of their communities
- Know relevant state laws, including ability to inform clients about them

Interim CDC Guidelines for CBOs (continued)

Quality Assurance program should be in place to ensure test counselors receive adequate training, annual updates, continuing education and supervision to, in part:

- Provide client-centered HIV prevention counseling
- Provide information to persons before testing
- Understand the history of HIV, its transmission and prevention
- Understand comprehensive risk counseling and services

The HIV Community on Informed Consent

- In April 2009, the Ford Foundation held a Women and HIV Strategic Advocacy Convening for 14 organizations working on issues related to women and HIV/AIDS.
- Attendees determined a series of policy recommendations to guide the new Office of National AIDS Policy (ONAP) to achieve better outcomes for women living with and affected by HIV.
- The group concluded that “the health of individuals and the public demand that HIV testing programs be fully informed, consensual, voluntary, confidential or anonymous, and supported, directly or by referrals, with appropriate education, counseling, health care, mental health care, and social services.
- Mandatory counseling and offering of voluntary testing should be included in primary care services, including routine gynecological and sexual and reproductive health services, and other key points of entry for ongoing primary care.

The HIV Community on Informed Consent (continued)

- In 2007-2008, a coalition of more than 70 medical, HIV service, legal, human rights and related organizations from across the country endorsed a set of fundamental principles to guide stakeholders working on expanded testing.
 - The principles serve as a roadmap for expanding the availability and acceptance of HIV screening while maintaining informed written consent, counseling on the meaning and implications of test results, linkage to care, and respect for individuals' rights.
 - The principles are based on the ethical and public health concept that everyone has a stake in achieving an expanded testing paradigm in a way that produces long-term benefits for those living with or at risk of HIV.

Expanding the Availability and Acceptance of Voluntary HIV Testing: Fundamental Principles to Guide Implementation

- 1. People living with undiagnosed HIV infection must be reached and offered testing.**
- 2. Any HIV testing program must provide the highest standard of care.**
- 3. Everyone offered testing must be educated about HIV and the significance of positive and negative test results.**
- 4. People who test positive for HIV antibodies must be linked to care.**
- 5. Expanded HIV testing must be carefully planned, implemented and monitored.**
- 6. People with HIV/AIDS and other stakeholders must be included in formulating plans for expanded testing.**
- 7. Patients' human rights and informed consent are consistent with, and not opposed to, the goal of expanded HIV testing.**
- 8. Expanded HIV testing must be tailored to different clinical settings, populations, and patient needs.**

The 15 Fundamental Principles (continued)

- 9. Clinicians, medical directors and other providers must receive training and education in delivering high-quality testing programs.**
- 10. Clinicians, medical directors and other providers must receive training and education in making appropriate service referrals and linkages to care.**
- 11. Community-based HIV prevention interventions must be expanded in tandem with efforts to expand voluntary HIV testing in healthcare settings.**
- 12. Special attention must be paid to the prevention and care needs of at-risk populations.**
- 13. Expanded testing and the provision of care to all existing and new HIV cases require new and adequate funding.**
- 14. Testing protocols must address insurance issues.**
- 15. Efforts to assist those with undiagnosed and untreated or unmonitored HIV infection must be evaluated.**

Dr. David Holtgrave, PACHA, on VCT

In 2006, Holtgrave reviewed evidence demonstrating that a multi-component, multi-level, evidence-based comprehensive national HIV prevention plan for the United States is most effective.

His review of the evidence demonstrates that targeted HIV counseling and testing has substantially more public health benefits than opt-out testing, at the same cost.

(see www.hivlawandpolicy.org for recent Holtgrave articles, slides)

Sexually Transmitted HIV Incidence by Awareness of Serostatus

- Persons aware of HIV infection account for 30% to 46% of new sexual transmissions
- Persons unaware of HIV infection account for 54% to 70% of new sexual transmissions
 - That is, the majority of the 32,000 sexually transmitted HIV infections in the US in a given year are from persons unaware they are living with HIV
- Hence, counseling and testing can have major impact for PLWH/A

Impact of “C” in VCT for Persons Testing HIV Seronegative (Holtgrave)

- CDC’s Project RESPECT*
- 4 arms in RCT (all arms included HIV testing)
 - 4 session counseling
 - 2 session (pre- and post-test) counseling
 - Didactic information
 - Didactic information and no follow up until final time point (to control for impact of repeated surveys)
- STD clinics in Baltimore, Denver, Long Beach, Newark, San Francisco (5,758 HIV- clients)

*Kamb ML et al. *JAMA*. 1998;280:1161-1167.; 1. Holtgrave DR et al. *Int J STD AIDS*. 2004;15:789-792.
2. Marks G et al. *AIDS*. 2006;20:1447-1450.
3. Holtgrave, Pinkerton. *JAIDS*. (2007)

Project RESPECT Press Release from CDC (Holtgrave)

- “This study showed that it’s not how much you talk to people about HIV prevention that matters most – but how you talk to them....,” Dr. Helene Gayle
- “According to CDC, the brief sessions used in this study...are feasible to implement in busy health care settings.”
- “In this study, the approach was implemented with existing clinic staff, in not much more time than that required for didactic messages, and cost only \$8 additional dollars per client to implement.”
- “With this program the ideal can be real, with few additional resources.”

Holtgrave Summary

- What is the impact of the “C” (counseling) in VCT?
 - Does anyone include C&T in an evidence-based bundle of prevention services?
 - Yes (and in outstanding journals)
 - What is the impact for persons testing HIV+?
 - VCT bundle impacts risk behavior and transmission rates
 - What is the impact for persons testing HIV-?
 - Pre- and post-test counseling impacts risk behaviors and STD incidence rates in “real world” settings
- What if “typical” counseling is not up to standard of care?
 - Fix it or get another service partner to provide it, but don’t toss it

Prenatal HIV testing: more support for counseling and informed consent

- Perinatal transmission of HIV has been virtually eliminated in the United States, including in states that require specific written informed consent, such as Massachusetts, New York, Pennsylvania and Michigan
- Only two states mandate newborn testing and most, including New York, have required counseling of pregnant women prior to testing.
- Data from the Perinatal Guidelines Project: vast majority of women accept HIV testing *if it is recommended by their health-care provider*; strongly suggests that “opt-out” approaches that eliminate counseling and documented consent results in substantial numbers of women not even knowing whether they had been tested.

What Improved Prenatal Testing Rates?

- Overwhelming evidence: delays in HIV testing of pregnant women due to:
 - a lack of prenatal care
 - *physician disinclination to offer testing* due to inadequate training or understanding of when to offer testing, time pressures, and discomfort with discussing sexual issues or in otherwise complying with current standards of HIV counseling.
- Solution: mandated offer of voluntary [opt-in] HIV testing in Illinois and New York, e.g. resulting in virtually universal, voluntary acceptance of HIV testing. (Illinois law also requires state prisons to offer *voluntary* HIV testing for all new inmates, and increased HIV testing in those correctional facilities by 475% between 2005 and 2007 after law mandated test offer.)

...more evidence supporting opt-in testing with counseling and documented consent

- Surveys about pre-natal HIV testing: providing more information about HIV testing is more likely to encourage people to accept testing. See, e.g., R. Kropp *et al.*, *Unique Challenges to Preventing Perinatal HIV Transmission Among Hispanic Women in California: Results of a Needs Assessment*, AIDS EDUCATION & PREVENTION 17, 22 (2005); M.I. Fernandez *et al.*, *Acceptance of HIV Testing During Prenatal Care*, 115 PUBLIC HEALTH REPORTS 460-468 (2000).
- At the 2008 National Summit on HIV Diagnosis, Prevention and Access to Care, a number of health care providers from busy hospital and clinic settings reported high rates of HIV testing uptake in expanded rapid test programs that included not only streamlined pre-test counseling but written documentation of consent. A. Hilley, J. Bell-Merriam, S. Criniti, E. Aaron & S. Garg, *Implementing Routine HIV Testing in the Emergency Department of an Urban University Hospital*, Nov. 2008 , http://www.hivforum.org/storage/hivforum/documents/HIV%20Summit/2008%20National%20Summit%20Posters/101_aaron.pdf.

...and more evidence supporting opt-in testing with counseling and documented consent

- Additional public research has found that specific consent and pre-test counseling are not meaningful barriers to testing
 - Kaiser Family Foundation, Kaiser Public Opinion Spotlight, *Attitudes about Stigma and Discrimination Related to HIV/AIDS* (2006), at <http://www.kff.org/spotlight/hivUS/index.cfm> (concluding that the primary reason people reported not getting tested was because they didn't think they were at risk, not because of a signed consent form)
 - J. Omi, New York City Health and Hospitals Corporation, *Integration of HIV Testing Within Medical Care in a Large Public Hospital System*, Nov. 2008 Slide presentation, 2008 National Summit on HIV Diagnosis, Prevention and Access to Care (Nov. 19, 2008), at http://www.hivforum.org/storage/hivforum/documents/HIV%20Summit/Presentations/1120_tr_a_3_01_berg_track.pdf (concluding that “[w]ritten informed consent has not been a significant barrier to achieving exceptional increases in the number of unique patients testing for HIV.”).

...and still more evidence supporting opt-in testing with counseling and documented consent

- 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.¹² R. 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 OF EMERGENCY MEDICINE 31 (2004).

...and more evidence supporting opt-in testing with counseling and documented consent

“Expanded HIV Testing Initiative” undertaken by the New York Health and Hospitals Corporation (“HHC -- nearly 5 million annual visits and 19,000 patients with HIV infection in care. The target was 150,000 per year. In FY 2008, the HHC documented 160,900 tested. In addition, the number of positive HIV tests more than doubled since FY 2004, to 1,863 in FY 2008.

...and still more evidence supporting opt-in testing with counseling and documented consent

- In a November, 2008 summary of expanded testing activities across the country, the CDC reported the most impressive statistics from New York while noting negligible testing increases generally across the country and in many states with no such patient protections.
- See B. Branson, Centers for Disease Control and Prevention, *Overview of Routine/Expanded HIV Testing in the US*, Slide presentation, 2008 National Summit on HIV Diagnosis, Prevention and Access to Care (Nov. 19, 2008); see also 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, at <http://www.nyc.gov/html/hhc/html/pressroom/press-release-20061003.shtml>

Racial Disparities in HIV Care: if counseling and documented consent were the issue, then why...?

- National data indicate that minority Americans, including New Yorkers, have far poorer health outcomes than whites from preventable, treatable conditions such as cardiovascular disease, diabetes, asthma, cancer and HIV/AIDS.
- Last 20 years of research: racial disparities continue in the actual quality of health care, even when controlling for social determinants and insurance. Proof of disparities appear in, e.g., prescription of pain relievers, cardiac diagnostic and therapeutic procedures, treatment of pneumonia, treatment of congestive heart failure referral for renal transplantation and even immunizations.
- April, 2006 report on racial and ethnic disparities in breast cancer: African American women, who have more advanced disease upon diagnosis and higher mortality rates than white women, were less likely to receive adequate mammography screening. Lower rates of disease, but more likely to die from it.

Racial Disparities in HIV Care: if counseling and documented consent is the issue, then why...?

- The CDC's Nov 2009 report on STIs found:
 - * 1.2 million cases of chlamydia were reported in 2008, up from 1.1 million in 2007.
 - * Blacks, who represent 12 percent of the U.S. population, accounted for about 71 percent of reported gonorrhea cases and almost half of all chlamydia and syphilis cases in 2008.
 - * Black women 15 to 19 had the highest rates of chlamydia and gonorrhea.
 - * 63 percent of syphilis cases were among men who have sex with men.
 - * Syphilis rates among women increased 36 percent from 2007 to 2008.

Racial Disparities in HIV Care: if counseling and documented consent is the issue, then why...?

- Recent data produced by a multistate sample of HIV patients *already in care in major HIV primary care sites, including New York City*, revealed that *many eligible women and African American patients* still did not receive antiretroviral therapy.
- Evidence of this type of racial disparity for care provided to those *who already have tested positive and presented for care* has been duplicated in a number of studies.
- The fact that in some states the disparity may be somewhat greater for HIV than other diseases is explained at least in part by the congruence of both the much higher association of intravenous drug use and homelessness with HIV/AIDS than diabetes and other diseases, and the measurable disinclination of physicians to initiate or continue HAART for HIV positive patients who are current or former IDUs.

The Public Health Consequences of Accommodating Provider Sexphobia

- American squeamishness about talking about sex has helped keep common sexually transmitted infections far too common, especially among vulnerable teens. Accommodating this squeamishness in our health care professionals has had severe public health consequences.
- Overall, CDC estimates that 19 million new sexually transmitted infections occur each year, almost half among 15- to 24-year-olds
- John Douglas, Director of the division of sexually transmitted diseases at the U.S. Centers for Disease Control and Prevention:
"We have among the highest rates of STDs of any developed country in the world. We are not honestly and openly dealing with this issue and it's the larger issue of sexual health."

Stigma and Discrimination: Continuing Consequences of Testing Positive

- Studies continue to document both the continued social ostracism of those with HIV, and reports from many respondents that concerns about stigma, and fears that a breach in confidentiality could lead to discrimination or rejection in their families and communities, would affect their personal decisions to get tested
- A 2004 study of violence against young gay men found they were more likely to experience verbal harassment, discrimination, and physical violence if they were HIV positive
- The majority of states have made it a crime for people who test positive to engage in sex, in many cases even when the sex is protected and even when transmission has not occurred; prosecutions appear to be on the rise, particularly of gay men.

HIV Stigma and Discrimination in Health Care

- Recent studies at urban public hospitals indicate that
 - People of color have concerns about privacy
 - Fear and stigma commonly deter testing
 - Distrust and misconceptions, particularly about the importance of testing, are very common
- Many HIV positive adults believe that their clinicians have discriminated against them
- VA-supported study of upstate NY, released February 2008, showed that HIV positive people continue to experience stigma and discrimination in health care

It's not just State Laws

- International human rights law also applies and is of special relevance to the treatment of women, children and the incarcerated when addressing HIV testing
- Ethical considerations and professional licensing regulations also come into play
- State and CDC guidelines are not legally binding – they are *recommendations*, and do not have the force of law
- Laws and guideline identify the floor, not the ceiling – *Do the Right Thing*, based on the client's best interests.

Ethical Issues

- The ultimate objective of screening is to reduce the sickness and death from a disease among the people screened.
- Public health ethics dictate that the primary beneficiary of the screening be those who are screened. In the context of HIV screening, screening programs must include sufficient funding and case management to ensure that everyone with a positive HIV test is offered treatment as part of that screening.
- “Linking patients who have received a diagnosis of HIV infection to prevention and care is essential. HIV screening without such linkage confers little or not benefit to the patient.” (2006 CDC Revised Recommendations for HIV Testing in Health-Care Settings)

Some Final Considerations on Patient-Centering a Testing Protocol

- All primary care providers should be competent and incentivized to offer sexual health care counseling, testing and referrals.**
- One size does not fit all for pretest counseling – e.g., first-time tester versus regular tester have different needs for information**
- Informed consent can be secured through multiple means and, in most situations, with modest time investment**
- It is legally impossible to determine capacity to consent without pre-test patient/provider communication**
- Reality that many patients still fear being ostracized by their communities; many fear rejection or violence by their partners**

Where Should the Obligation to Increase Testing Focus?

- Dr. Philomina Gwanfoghe, Missouri Dept of Health and Senior Services:

“It has been repeatedly demonstrated that certain racial/ethnic minority patients receive diagnosis and treatment recommendations differing from those of similar white patients...[E]ven when their insurance and income are the same as ... whites, minorities often receive fewer tests and less sophisticated treatment for a panoply of ailments, including heart disease, cancer, diabetes and HIV/AIDS...[Researchers] suggest that patients could receive training in effective doctor-patient interaction. Oddly, the most important issue related to such training is not addressed: **Why do black and economically disadvantaged patients need to do something extra...in order to receive the diagnosis and treatment they deserve by virtue of being patients?...**Let us start at the right place. Considering that health care providers, rather than patients, are the more powerful actors in clinical encounters, providers’ behaviors are a more important target for intervention efforts.”

MA Model Informed Consent for HIV Testing

My signature below indicates that:

- 1. I agree to be tested for HIV.
- 2. I have been given information about the test.
- 3. All of my questions about the test have been answered.
- 4. I understand that this consent will expire one year from the date it is signed. I understand that I may withdraw my consent at any time.
- 5. My decision to be tested is completely voluntary.

Name (please print)

Signature

Date