The CDC's routine HIV testing recommendation: legally, not so routine

Editor's Note: This issue of the Review *marks the beginning of a new collaboration between the Canadian HIV/AIDS Legal Network and the American Bar Association (ABA), led by the ABA AIDS Coordinating Committee,[i] and including the ABA Sections of Individual Rights and Responsibilities[ii] and International Law.[iii] ABA members and other U.S.-based lawyers will contribute occasional articles reporting on and analyzing developments in the United States related to HIV/AIDS and the law. The ABA and the Legal Network will work together in interacting with the new editorial board and increasing the Review's visibility and readership in the U.S.*

In this feature article, Ann Hilton Fisher, Catherine Hanssens and David I. Schulman (from the ABA) analyze the new guidelines on HIV testing from the U.S. Centers for Disease Control and Prevention (CDC) and find them wanting. The authors argue that the CDC's recommendation to do away with specific written informed consent for HIV tests is primarily based on a false assumption that the process of securing informed consent constitutes a barrier to HIV testing; and that, on the contrary, streamlined HIV testing, with rapid testing and counselling tailored to each individual's needs, has proven effective while retaining informed consent.

Introduction

Now that the U.S. Centers for Disease Control and Prevention (CDC) has recommended HIV testing for all Americans aged 13–64 presenting for health care who do not explicitly object,[1] the states must determine whether and how to revise state law provisions on pre-test counselling and proof of consent. When doing so, states should carefully consider an element overlooked by the CDC — the fundamental legal doctrine, and underlying purpose, of informed consent. That doctrine holds that except in emergency situations, all patients at all times must consent to the medical care that is offered them.

Without consent, any touching is potentially unlawful. Though only several decades old, this doctrine is imbedded in the public's understanding of patient autonomy. A state's failure to preserve informed consent as central to diagnosis for HIV — a serious illness with serious medical and social consequences — could undermine this important doctrine for a wide range of medical care beyond testing for HIV.

It is not clear why the CDC concluded that the absence of informed consent is sufficient predicate for HIV testing, particularly when there is no evidence that requiring informed consent is a barrier to testing. A general consent by definition covers only those procedures whose risks and benefits are generally well-known; the risks and benefits of HIV testing, like those of genetic testing, are complex.[2]

[i] The ABA AIDS Coordinating Committee (http://www.abanet.org/AIDS/home.html), under the auspices of the ABA Section of Individual Rights and Responsibilities, is comprised of liaisons appointed by various ABA entities and affiliated bar associations. Its mission is to develop and promote the Association's ongoing AIDS-related activities and to educate lawyers and the public about HIV/AIDS legal issues through public hearings, publications, national practitioner conferences and policy development, and to advocate for effective implementation of ABA policy on those issues.

[ii] Created in 1966, the ABA Section of Individual Rights and Responsibilities (http://www.abanet.org/irr/home.html) provides leadership within the ABA and the legal profession in protecting and advancing human rights, civil liberties and social justice. It fulfills this role by raising and addressing often complex and difficult civil rights and civil liberties issues in a changing and diverse society, and ensuring that protection of individual rights remains a focus of legal and policy decisions.

[iii] The ABA Section of International Law (http://www.abanet.org/intlaw/home.html) serves as the gateway to international practice for more than 400 000 members of the legal profession. It long has been the home of leading experts in international law and a network for those who practice in international settings. It provides reliable and expert knowledge and perspectives on cutting-edge international legal issues to satisfy the information needs of its members, and is a leader in advocacy for international legal policy and the rule of law.

There are risks as well as benefits to the individuals tested, often depending on the timing and circumstances of the test itself. Informed consent may be abandoned under the narrow circumstances when public health exercises its emergency powers to take such draconian measures as quarantining those exposed to anthrax. But the CDC is not claiming its recommendation is based on those emergency powers.

As the American Medical Association (AMA) points out, "Informed consent is … a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention."[3] What constitutes sufficient information to ensure that consent is informed is contextual, determined by the nature and complexity of the condition at issue and the consequences of the diagnosis and subsequent care. The patient should have an opportunity to ask questions for a better understanding of the treatment or procedure to allow an informed decision to proceed or to refuse a particular course of medical intervention.[4] This communication process is both an ethical and legal obligation spelled out in statutes and case law in all 50 states.

The CDC has long-recognized that the risks of HIV testing are not routine. Researchers have documented that the fear of stigma is a major barrier to testing.[5] In response, the CDC has recommended that newly-tested HIV-positive persons be referred promptly to legal counselling on how to prevent discrimination by maintaining the confidentiality of these test results.[6] Fortunately, established practice in HIV testing and care provides excellent models for obtaining informed consent without undue burden, as we discuss below.

Faulty assumption

The CDC's recommendation to forgo specific written informed consent for HIV tests in order to make testing routine rests primarily on a critical faulty assumption: that the process of securing informed consent presents a substantial barrier to busy health care professionals who would otherwise offer HIV testing to their patients. However, the experience in Illinois is illustrative of how health care providers committed to increasing HIV testing can do so efficiently and effectively while respecting their patients' fundamental right to informed consent.

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In August 2005, the Illinois Department of Public Health initiated a pilot program to increase HIV testing of pregnant women. The Statewide Perinatal Rapid Testing Implementation in Illinois program (PRTII) sent workers into every Illinois birthing hospital to help labour and delivery room staff create systems for offering counselling and rapid HIV tests to women in active labour who did not have HIV tests already in their records.

These women were in medical crisis. Most had no previous prenatal care and thus no established relationship with the medical providers charged with counselling them about HIV testing. It would be difficult to imagine a population presenting more "barriers" to informed consent. Yet one year after PRTII began, the percentage of women accepting HIV testing rose from 86.7 to 97.1. By the middle of 2006, that percentage rose to 98.3. Similar results have been obtained in similar programs in other states, such as California.

In fact, contrary to the CDC's and others' interpretation that the U.S. perinatal testing experience demonstrates that informed consent prior to HIV testing is dispensable, perinatal transmission of HIV has been all but eliminated in this country[7] *with* informed consent in most states. Data from the Perinatal Guidelines Project further supports the experience of Illinois — i.e., that the vast majority of women accept HIV testing if it is recommended by their health-care provider[8] — and also strongly suggest that "opt-out" approaches that eliminate proof of consent can result in substantial numbers of women not even knowing whether they had been tested.[9]

The lesson is obvious. Nearly all people offered HIV testing in a thoughtful, careful way — even people in the midst of a medical trauma — accept the offer. The few who do not accept it typically have good reason not to at that particular time; skilled counselling could ensure they return to test when the time is right for them. State legislatures can be assured that there is no basis to abandon the fundamental legal right of patients to informed consent in order to make HIV testing more "routine."

Other concerns

The CDC's conclusion that it has the authority to recommend the abandon-

ment of a fundamental legal doctrine rests on other faulty assumptions. It mischaracterizes state HIV testing laws as dated responses to a past time when stigma and the lack of effective treatment warranted special pre-test counselling, proof of consent, and assurances of confidentiality.[10] Such laws, the reasoning continues, are interfering with HIV diagnosis and prevention.[11] Some public health officials, particularly in New York City, have even insisted that such laws are a primary cause of racial disparities in HIV testing.[12]

This reasoning relies to a surprising extent on serious mischaracterizations of AIDS' short history of research on why some people delay HIV testing and doctors do not offer it, and of informed consent in general, a doctrine that emerged *prior* to the enactment of state HIV testing statutes.[13] Authors who assert that informed consent consumes an excess of doctors' time and discourages patient testing do not offer supporting evidence for these arguments because there is none.[14]

The CDC's recommendation also ignores the fact that streamlined HIV testing, with rapid testing and counselling tailored to each individual's needs, has proven effective while retaining informed consent. New York City (a jurisdiction with a detailed state HIV counselling and testing law) recently reported a 63 percent increase in HIV testing in the year since streamlined counselling and rapid testing was implemented.

Citing this report, the continuing reality of stigma in hard-hit communities, and the unique nature of HIV, New York State Health Commissioner Dr. Antonia Novello, a former U.S. Surgeon General, recently rejected the CDC's recommendation as unwise. In an op-ed, Dr. Novello argued that increased HIV testing must not occur at the expense of adding one more problem to those who, unaware of their status, or in denial about their behaviour, or in a situation where language barriers impede their comprehension, or in a situation where they fear violence or deportation, might not be able to cope with the newly acquired diagnosis.[15] The protection of confidentiality and dignity of New Yorkers, as well as the assurance of care and freedom of choice, must be respected.[16]

Legal and ethical principles dictate that informed consent remain an integral element of HIV testing.

Some who support the CDC's position argue that it eliminates the "AIDS exceptionalism" that has been inconsistent with "traditional" public health laws.[17] The tragedy of this position is that it privileges an antiquated notion of patient autonomy and consent predating modern civil rights understandings. State HIV testing and confidentiality laws, adopted more recently than infectious disease control statutes governing most other health conditions, do more than merely reflect the past and continuing reality of HIV stigma and its practical consequences. They incorporate the evolving understanding of a patient's right to information and autonomy in making treatment decisions, a right undermined by proposals for a reversion to the outdated "doctor knows best — you don't need to know" approach.[18]

Conclusion

The late Dr. Jonathan Mann, a seasoned public health practitioner and the first director of the World Health Organization's Special Program on AIDS, pioneered the principle that human rights are integral to advancing public health.[19] The legacy of Dr. Mann, considered one of the most important figures in the 20th century fight against global disease and social injustice, still serves as a powerful refutation of the current fashion of pitting human rights *in opposition* to public health principles.[20]

Legal and ethical principles dictate that informed consent remain an integral element of HIV testing.[21] While the CDC's new guidelines may appear to serve physician convenience in the short term, they may also expand physician liability exposure[22] while accommodating the eroded quality of care associated with the shift to managed care.[23] With most patients confronting multiple forms at every health care encounter, it is ironic that the one form relevant to protecting their autonomy is the one that health care providers purportedly find burdensome, particularly when there are multiple creative, effective ways to secure informed consent for HIV testing that involve little provider time.

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Editor's Note: See also "Routine HIV testing: three perspectives" in the AIDS 2006 Supplement in this issue.

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[1] B.M. Branson et al, "Revised recommendations for HIV testing of adults adolescents, and pregnant women in health-care settings, *MMWR Rec. Rep.* 55, RR-14 (2006): 1–17.

[2] New York State Health Commissioner Dr. Antonia Novello recently emphasized, in response to the CDC's release of its new testing guidelines, that general consent for a medical exam is not the same as the consent required prior to HIV testing, and that written consent provides important protections for high-risk groups such as women and youth. See www.hwadvocacy.com/update/El%20Diario.pdf.

[3] AMA, Office of the General Counsel, Division of Health Law, "Informed Consent," http://www.ama-assn.org/ama/pub/category/4608.html.

[4] Ibid.

[5] See, e.g., G.M. Herek, J.P. Capitanio and K.F. Widaman, "Stigma, social risk, and health policy: public attitudes toward HIV surveillance policies and the social construction of illness," *Health Psychology* 22, 3 (2004); 533–540. At http://psychology.ucdavis.edu/rainbow/html/health-psych2003_pre.PDF.

[6] *Morbidity and Mortality Weekly Report* (MMWR) 50, RR-19 (2001). At www.cdc.gov/mmwr/PDF/RR/RR5019.pdf.

[7] See, e.g, T.R. Frieden et al, "Applying public health principles to the HIV epidemic," *New England Journal of Medicine* 353 (2005): 2397–2402, p. 2399.

[8] M.I. Fernandez et al, "Acceptance of HIV testing during prenatal care," *Public Health Reporter* 115 (2000): 460–468.

[9] Centers for Disease Control and Prevention, "HIV testing of pregnant women — United States and Canada, 1998–2001," *MMWR* 51 (2002): 1013–1016.

[10] See L.O. Gostin, "HIV screening in health care settings – public health and civil liberties in conflict?," *Journal of the American Medical Association*, 296 (2006): 2023–2025; New York Department of Health and Mental Hygiene, *Memorandum in Support of Proposed Legislation, "An Act to Amend the Public Health Law, in Relation to Improving the Care of Persons Living with HIV/AIDS."* At www.nyc.gov/html/doh/downloads/pdf/ah/ah-memo-support.pdf.

[11] L.O. Gostin.

[12] New York Department of Health.

[13] See B.L. Atwell, "The modern age of informed consent," University of Richmond Law Review 40, 591 (2006).

[14] See, e.g., L.O. Gostin.

[15] See New York State Health Commissioner.

[16] Ibid.

[17] See R. Bayer and A.L. Fairchild, " Changing the paradigm for HIV testing — the end of exceptionalism," *New England Journal of Medicine*, 355, 7 (2006): 647–649.

[18] See, e.g., B.L. Atwell.

[19] See, e.g., www.globalhealth.org/view_top.php3?id=238.

[20] But see L.O. Gostin, Gostin characterizes the "civil rights paradigm that informed AIDS policy" as something distinct from "public health strategy," and argues that a continued focus on human rights seems unjustified in view of scientific and social developments over the last decade.

[21] E. B. Cooper, "HIV disease in pregnancy: ethics, law and policy," *Obstetrics and Gynecology Clinics of North America* 24 (1997): 899–910 .

[22] See, e.g., AMA.

[23] P. Salgo, "The doctor will see you for exactly seven minutes," *New York Times*, op ed, 22 March 2006.