OPPORTUNITIES FOR IMPROVING

HIV

DIAGNOSIS, PREVENTION & ACCESS TO CARE IN THE U.S.

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Legal Issues: Opt-out Testing and HIV Care

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Objectives

- Briefly identify applicable law
- Summarize those legal principles most likely to be implicated in opt-out HIV testing
- Define the basic elements of informed consent
- Identify most likely legal issues and challenges
- Suggest ways to reduce provider liability risks

Applicable Laws

- Legal issues related to HIV testing, confidentiality and access to care are governed by a range of federal and state laws as well as common law principals and constitutional provisions
- Ethical considerations and professional licensing regulations also come into play
- State and federal guidelines are not legally binding, but can be indicative of the standard of care
- International human rights law also applies and is of special relevance to the treatment of women, children and the incarcerated when addressing HIV testing

State HIV Testing, Reporting and Confidentiality Laws

- State laws provide varying levels of protection for right to choose and confidentiality of HIV testing and notification decisions[1]
- The new CDC testing guidelines could not be implemented in many states without amending state law requiring counseling and written proof of consent prior to testing
- Few jurisdictions mandate the offer of an HIV test in any setting outside of criminal/correctional contexts or for the purpose of securing a marriage license, despite CDC recommendations[2]

The Rehabilitation Act Of 1973, The ADA, and State Disability Laws

- The Rehab Act prevents disability-based discrimination by federal agencies and recipients of states funds
- The Americans with Disabilities Act (ADA) extends this protection to private employment, services offered to the public, and state and local governments[3]
- Treating positive HIV test results differently than other patients diagnostic tests could violate these laws
- Both ADA & Rehab Act apply to HIV, a history of substance abuse, and correctional facilities
  - State laws vary widely; some offer more protection

Constitutional Right to Privacy and Prisoner's Right to Care for Serious Medical Needs

- Federal and state constitutional privacy protections apply to individuals' rights to consent to, and keep confidential, HIV testing
- However, federal courts across the country also confirm that prison inmates have a federal constitutional right to medical care that reflects community standards, and a right to privacy regarding their HIV-positive status[4]

No Discrimination Based on Race or Gender

- Title VII of the Civil Rights Act ensures the right to be offered the highest standard of care without regard to race or gender
- Recent research confirms widespread racial and gender disparities in the use of antiretrovirals to treat HIV disease
  - Even after they present for testing, many women and people of color with HIV/AIDS are not offered antiretroviral therapy and other clinically appropriate care[5]

Ethical Issues

- The ultimate objective of screening is to reduce the morbidity or mortality from a disease among the people screened[6]
- Public health ethics dictate that the primary beneficiary of the screening be those who are screened. In the context of HIV screening, ethics dictate that screening programs include sufficient funding and case management to ensure that everyone with a positive HIV test is offered treatment as part of that screening[7]

Informed Consent

- The provider-patient communications process is a legal and an ethical obligation spelled out in the statutes and case law of all 50 states[8]
- A general consent is not the same legal concept as informed consent[9]
  - General consent covers procedures whose risks and benefits are generally well-known
  - Per AMA: “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”[10]
- Informed consent is central to values of individual autonomy and dignity[11]

How Courts Address the Issue of Informed Consent

- In 1972, the reasonable person standard emerged in a federal appeals court decision on the issue[12]
- Reasonable person standard: required information about risks is determined by what a reasonable person in that patient's position would want to know
- Roughly half the states in the US apply the reasonable person standard

The Information Necessary to Ensure That Consent Is Informed Is Contextual

- Capacity = ability, without regard for age, to understand the nature and consequences of a proposed health service
- Emotional and mental health consequences of a medical procedure are part of related health risks that should be addressed as part of securing legally-adequate consent
- Courts and medical ethicists alike agree that informed consent requires that the health care provider convey that information that a layperson might not otherwise be expected to know
- The Convention on Human Rights and Biomedicine: a patient must be given the correct information about the nature and purpose of a medical intervention, its consequences and risks

Informed Consent and HIV Screening

- "The potential harms of screening may also include 'labeling' effects and the psychological impact of test results or a diagnosis"[13]
- Failure to get consent before HIV testing may violate state and federal constitutional privacy concerns
- State constitutional privacy rights may be more expansive than federal rights, and can protect individuals from privacy invasions by private parties as well as state actors[14]

Stigma and Discrimination: Continuing Consequences of Testing Positive for HIV

- Civil rights violations against people with HIV/AIDS are still widespread throughout rural areas of the United States[15]
- Survey of 43 community-based ASO's in 11 states documented denials of medical treatment, loss of parental rights, workplace discrimination, exclusions from nursing homes and residential facilities, and frequent medical privacy violations[16]

Stigma and Discrimination: Continuing Consequences of Testing Positive (cont'd)

- 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[17]
- 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[18]

Continuing Stigma and Discrimination in Government Policies…More Testing Risks

- Multiple state and federal agencies still have exclusionary policies lacking a sound scientific rationale
  - Current CDC guidelines recommend significant restrictions on health care workers with HIV[19]
  - Multiple federal agencies continue to exclude or restrict the employment or licensing of people with HIV[20]
  - A number of states prohibit the licensing of people with HIV in professions such as barbering, massage therapy, home health care, nursing

Continuing Stigma and Discrimination in Government Policies (cont'd)

- 27 states have laws that criminalize the sexual conduct of those who have tested positive for HIV, most imposing significant terms of imprisonment regardless of mutual consent, whether prophylaxis was used or transmission occurred[21]

HIV Stigma and Discrimination in Health Care

- Studies at urban public hospitals indicate that
  - People of color favor routinely-offered HIV testing but have concerns about privacy
  - Fear and stigma commonly deter testing
  - Distrust and misconceptions, particularly about the importance of testing, are very common[22]
- Many HIV positive adults believe that their clinicians have discriminated against them[23]

The New Guidelines: Potential Legal Hurdles and Pitfalls

- While current state HIV testing laws typically are discussed in terms of patient protections, they also provide important provider protections from liability
- Amending state HIV testing law can be a protracted process, and other provisions of the law generally viewed as essential to patient confidence, such as confidentiality guarantees, become vulnerable
- Institutional patterns of testing without linkage to care, or patterns of racial disparities in linkages to care for those who test positive, could prompt claims of disability or race-based discrimination

Potential Legal Hurdles and Pitfalls (cont'd)

- Absent proof of patient consent, health care providers could face liability on claims of failure to get informed consent in settings, or with populations, for whom general capacity to consent may be questionable
  - Adolescents
  - Emergency room patients dealing with health trauma
  - Other individuals with compromised capacity to consent
  - Language barriers
  - Prisoners, when there is either explicit or tacit pressure to "consent" to testing, or who are subjected to mandatory testing

Other Legal Liability and Ethical Issues

- Truncated pre-test counseling & consent process can reinforce a claim of medical malpractice
- One of the most common factors in patients' decision to file claims is inadequate physician communcation[24]

Other Legal Liability and Ethical Issues (cont'd)

- Legal liability and ethical issues might be raised by individuals disputing they had sufficient knowledge to give "general informed consent" to HIV testing after experiencing negative fallout of a positive test
  - Domestic violence
  - Loss of housing
  - Loss of employment or employment opportunities; loss of insurance
  - Exclusion from training, school and day care programs
  - Psychological trauma exacerbated by failure to assess test readiness or to sufficiently counsel after testing
    - Special issues for adolescents and other vulnerable individuals

Failure to Understand Laws Applicable to HIV Confidentiality Risks Liability Exposure

- Research literature indicates that physicians have relatively limited knowledge regarding state law and institutional policies and procedures on confidentiality issues specific to patients with HIV[25]
- Health care facilities could incur liability from inappropriate disclosures to police, prison personnel
- The constitutional right to privacy also could be asserted in the case of inappropriate disclosures by doctors in state hospitals

Legal Issues in Prisons

- People in correctional settings may have claims about inadequate medical care or privacy violations based on HIV testing without
  - Parallel diagnostic evaluation for Hepatitis C
  - Follow through on other CDC/NIH guidelines for treatment of HIV and treatment of Hepatitis C
  - Procedures to ensure that prisoners can test, and ask questions, in privacy, and without subsequent disclosure of their HIV status to staff and inmates
  - Failure to provide reliable access to medications during incarceration or prior to release

Some Options for Provider and Patient Protection Under the New Testing Guidelines

- Provide training for providers on
  - One size does not fit all regarding pretesting info needs
  - 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

Options for Provider and Patient Protection Under the New Testing Guidelines (cont'd)

- Embrace and expand upon guidelines' recommendation to engage with local ASOs and legal service providers to
  - Assist with test-related counseling
  - Ensure real informed consent
  - Assist with immediate linkage to additional counseling, care and other core services

Provider and Patient Protection (cont'd)

- Written proof of consent may be best protection in situations where capacity to consent may be in question
- Documentation of a well-conducted process protects health care providers from exposure to liability

Provider and Patient Protection (cont'd)

- In correctional settings, ensure that
  - resources are in place to provide standard-of-care treatment to HIV+/Hep C+ inmates before launching routine test offering
  - confidentiality is protected at and subsequent to time of testing
  - testing and treatment protocol guarantees that information about inmates' HIV status can be used only for the purposes for which it is originally obtained, i.e, for diagnosis and treatment
  - Non-medical, security staff play no role in diagnosis, treatment or partner notification activities

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1. See Health Research & Educational Trust, Laws of Individual States, (providing a map, and text, for state statutes related to HIV testing, consent, training, etc.), accessed 11/17/06 at www.hret.org/hret/about/hivmap.html. [Note: Spot checking of most of HRET's charts on aspects of the HIV laws posted at this sight revealed significant inaccuracies; in fairness, the lack of uniformity on basic definitions such as what constitutes HIV related information, or how informed consent or counseling are defined, create challenges in accurately summarizing state law in this regard. In addition, these charts do not include state regulations which may expand upon or clarify statutory provisions on HIV testing and confidentiality. The site is useful, however, for its collection of the actual text of individual state statutes on HIV testing.
2. Id.
3. See M. Crossley, Becoming Visible: The ADA's Impact on Health Care for Persons With Disabilities, 52 Ala. L. Rev. 51 (2000).
4. See Powell v. Schriver, 175 F.3d 107 (2d Cir. 1999); Faison v. Parker, 823 F. Supp. 1198 (E.D. Pa. 1993); Albrecht v. Lehman, 1993 WL 346216 (E.D. Pa. 1993); Hilaire v. Arizona Dept. of Corrections, 934 F.2d 324 (9th Cir. 1991); A.L.A. v. West Valley City, 26 F.3d 989 (10th Cir. 1994).

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6. Coughlin, S., Ethical Issues in Epidemiological Research and Public Health Practice, 3 Emerg. Themes Epidemiol. (Oct. 2006).
7. See id.
8. See American Medical Association, Office of the General Counsel, Division of Health Law, Informed Consent, http://www.ama-assn.org/ama/pub/category/4608.html

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9. See, *e.g.,* Dr. Antonia Novello, Commissioner of the NY State Dept. of Health, *En guardia contra el estigmadel SIDA*, El Diario/La Prensa, 10/24/2006, http://www.hwadvocacy.com/update/El%20Diario.pdf
10. American Medical Association, Office of the General Counsel, Division of Health Law, *Informed* Consent, http://www.ama-assn.org/ama/pub/category/4608.html; B. L. Atwell, *The Modern Age of Informed Consent*, 40 U. Rich. L. Rev. 591 (Jan. 2006).
11. G.P. Smith, *The Vagaries of Informed Consent*, 1 Ind. Health L. Rev. 109 (2004); *See also Salgo v. Leland Stanford Jr. University Board of Trustees* (patient had cause of action for physician's failure to discuss known risks of a medical procedure prior to securing patient's consent), 154 Cal. App. 2d 560 (Oct 1957).
12. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.).
13. Coughlin, S., *Ethical Issues in Epidemiological Research and Public Health* Practice, 3 Emerg. Themes Epidemiol. (Oct. 2006); *see also* Melissa Weddle & Patricia Kokotailo, *Adolescent Substance Abuse Confidentiality and Consent, 49* Pediatric Clinicians N. Am. 301, 310 (2002)(psychological risks of screening warrant close attention to informed consent requirements).
14. E.g., *Leonel v. Amer. Airlines*, 400 F.3d 702 (9th Cir. 2005).(Airlines' testing of flight attendant applicants for HIV without their consent stated claim for privacy violation under CA constitution.); *Doe v. High-Tech Institute, Inc.,* 972 P.2d 1060 (Colo Ct. App. 1998).

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17. *E.g.,* G.M. Herek, J.P Capitanio, K.F Widaman, *Stigma, Social Risk, and Health Policy: Public Attitudes Toward HIV Surveillance Policies and the Social Construction of Illness*, 22 Health Psychology 533-540 (Sept. 2002), http://psychology.ucdavis.edu/rainbow/html/healthpsych2003_pre.PDF, (More than one-third of those surveyed reported that concerns about AIDS stigma would affect their own decision to be tested for HIV); Centers for Disease Control and Prevention, *HIV-Related Knowledge and Stigma – United States, 1999-2000,* 49 MMWR 1062-4 (Dec. 1, 2001); Herek, G.M., *Thinking About AIDS and Stigma: A Psychologist's Perspective*, 30 J. of Law, Medicine and Ethics 594-607 (2002).

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20. The State Department/Foreign Service, Job Corps, Peace Corps, Federal Aviation Administration (FAA) and all branches of the military continue to exclude or significantly restrict the employment or licensing of individuals with HIV.
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