

Legal and Ethical Implications of Opt-Out HIV Testing

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New guidelines from the Centers for Disease Control and Prevention recommend that opt-out screening for human immunodeficiency virus (HIV) without written patient consent be part of routine clinical care and imply that state HIV-associated laws in conflict with this approach should be amended. However, HIV testing and treatment issues are governed by a range of federal and state laws, common law principles, constitutional provisions, and various codes of ethics. Patient testing protocols should satisfy the legal definition of informed consent, to reduce risk of liability for providers (i.e., health care professionals and facilities). Rigid application of the new guidelines may trigger legal claims, especially if there is no link to care for persons with a positive test result, no proof of informed consent, or inadequate counseling. Ensuring confidentiality, better test training for providers, and provider collaboration with HIV service organizations can reduce the risk of patient claims, but state and federal laws, codes of ethics, and concerns about provider liability should temper reflexive wholesale adoption of guidelines that recommend opt-out screening.

In September 2006, the Centers for Disease Control and Prevention (CDC) issued revised recommendations for HIV testing of adults, adolescents, and pregnant women in health care settings [1]. The guidelines recommend that opt-out HIV screening, with no separate written consent, be a routine part of care in all health care settings. The guidelines also somewhat cryptically suggest that, where state or local laws impose more-stringent requirements in the areas of counseling, written consent, confirmatory testing, and how to communicate test results to patients, “jurisdictions should consider strategies to best implement these recommendations within current parameters and consider steps to resolve conflicts with these recommendations” [1, p. 13].

Despite the focus on state laws that explicitly address the minimum requirements of HIV testing and confidentiality, legal requirements and liability issues af-

fecting health care professionals and facilities (hereafter referred to as “providers”) can arise from a number of other federal and state legal principles implicated by “opt-out” testing. Guidelines that no longer recommend counseling and informed consent for HIV testing for all patients and eliminate the need for written proof that these processes occurred produce legal pitfalls for providers. This article summarizes the legal implications of adopting the CDC’s routine opt-out testing recommendations and discusses the legal and ethical concerns raised. It also suggests strategies for implementing policies that reduce the risk of provider liability, are respectful of patients, and help achieve the goals of increasing the proportion of HIV-infected people who know their serostatus, while being sensitive to the implications of more-widespread testing, particularly for vulnerable populations (e.g., women, adolescents, and incarcerated persons).

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PATIENT-PROTECTION LAWS ASSOCIATED WITH TESTING FOR AND TREATMENT OF HIV INFECTION

The legal issues related to HIV testing, confidentiality of test results, and access to care for HIV infection are

governed by a wide range of federal and state laws, as well as common law principles and constitutional provisions (table 1). International human rights law applies, particularly with regard to the treatment of vulnerable populations, as do ethical considerations and professional-licensing regulations. Although CDC–US Public Health Service guidelines reflect standards of care when they apply to medical regimens for the treatment and control of disease—matters within the agencies’ area of expertise—they are not legally binding, and courts are unlikely to afford the guidelines deference to the extent that they attempt to redefine applicable law.

State laws on HIV testing, reporting of test results, and confidentiality. State laws provide various levels of protection for an individual’s right to autonomy and informed decision making in choosing or refusing to be tested for HIV [2] (comments on select references appear in the Appendix, table A1). Generally, however, the CDC testing guidelines could not be implemented in many states without amending state laws governing counseling and written proof of consent for testing.

Laws preventing discrimination against disabled persons. The Rehabilitation Act of 1973 prevents disability-based discrimination by federal agencies and recipients of federal funds. The Americans with Disabilities Act (ADA) extended this protection to private employers and service establishments (including health care providers and hospitals) and to state and local governments [21]. Relying on the ADA, an AIDS service organization challenged its city’s failure to provide HIV-infected individuals with adequate linkage to services and care, and a court found that the city violated the ADA’s requirement of

reasonable accommodations. Treating a positive HIV test result differently from the way in which results of other diagnostic tests are handled (i.e., as a medical end in itself rather than as the basis for entry into care) could violate these laws. Because the Rehabilitation Act and the ADA also apply to individuals with a history of substance abuse and to persons in correctional facilities, HIV-infected individuals who have a presumed or actual history of drug use and/or who are incarcerated are protected from treatment that does not parallel the level of care afforded to similarly situated individuals who may not have a drug history or those in whom other diseases have been diagnosed. Providers also should be aware that some state disability antidiscrimination laws offer more-expansive coverage and protections than federal law.

Constitutional right to privacy. Federal and state constitutional protections of the right to privacy apply to individuals’ rights to consent to HIV testing and to keep all aspects of the test confidential. This includes the right to choose whether and when to accept health care interventions, particularly when sensitive personal matters or consequences are involved.

Consequently, a failure to get informed consent before HIV testing may violate state and federal constitutional-privacy concerns. Some states’ constitutional privacy protections are broader than those of the federal constitution and protect individuals from privacy invasions by private parties as well as by state government employees [3, 22].

Constitutional right of prisoners to receive appropriate medical care. HIV-infected inmates of prisons and jails have a constitutional right to treatment that reflects community stan-

Table 1. Applicable laws and guidance associated with HIV testing and care.

Laws and guidance	Comment(s)
State HIV laws	State laws vary widely in the degree of protection provided
Common law principles	Extend to areas such as negligence/malpractice and informed consent
International human rights law	Especially relevant to the treatment of women, children, and incarcerated persons
State and federal agency guidelines	Help define standards of care when related to matters within the promulgating agency’s area of expertise but are not legally binding
The Rehabilitation Act of 1973	Prohibits discrimination based on disability by federal agencies, contractors, and those receiving federal funds
The Americans with Disabilities Act	Extends Rehabilitation Act protections to private businesses and to state and local governments, including those involved in the provision of health care services
Federal and state constitutional rights to privacy and to adequate health care while incarcerated	Privacy rights apply to consent for HIV testing and confidentiality of test results and extend to persons in prisons or jails; constitutional prohibitions against inappropriate punishment effectively create an affirmative right to health care for persons in prisons or jails
Title VI of the Civil Rights Act of 1964, as well as federal and state antidiscrimination laws	Together, guarantee equality of treatment, including the provision of medical care, irrespective of race or gender

dards, as well as a right to privacy regarding their infection status [23–27]. Indeed, a prisoner’s right to health care is clearer than that of unincarcerated citizens because prisoners must rely on corrections officials to provide for their medical needs.

Prohibitions against racial and gender discrimination. Title VI of the Civil Rights Act of 1964, state antidiscrimination laws, and equal protection guarantees ensure the right to be offered appropriate care without regard to race or gender. Despite this, the Institute of Medicine and other agencies confirm widespread racial and gender disparities in the offer and use of antiretroviral agents to treat HIV disease [4, 28–30]. Many women and people of color with diagnosed HIV infection or AIDS are not offered antiretroviral therapy and other clinically appropriate care. Scaled-up HIV screening of minority populations that is not matched with proportionately scaled-up linkages to care and access to treatment could be the basis for a legal challenge based on antidiscrimination laws such as Title VI.

ETHICS AND PATIENT CONSENT IN THE CONTEXT OF HIV SCREENING

The elimination of the need for informed consent and for written proof of consent has multiple legal and ethical implications beyond state HIV testing and confidentiality laws. The ultimate objective of screening for a disease is to reduce the morbidity and mortality rates among the people who are screened [31]. As a matter of public health ethics, the primary beneficiaries of the screening must be the individuals who are screened. As the new CDC guidelines emphasize, “[l]inking patients who have received a diagnosis of HIV infection to prevention and care is essential. HIV screening without such linkage confers little or no benefit to the patient” [1, p. 6]. Ethics dictates that HIV testing programs include sufficient funding and case management to ensure that everyone who tests positive for HIV is offered linkage to care as an integral part of the screening process [31]. Although an individual’s knowledge of their HIV serostatus may reduce their tendency to engage in conduct that risks transmission, a testing program that identifies this altruistic by-product of testing as its end point is not medically or ethically acceptable.

In addition to general medical and public health ethical considerations, specific professional codes of ethics come into play. For example, replacing informed consent and counseling before and after the test with a passive opt-out system effectively conflicts with the Code of Ethics of the American Nurses Association, which states that “[t]he nurse strives to provide patients with opportunities to participate in planning care, assures that patients find the plans acceptable, and supports the implementation of the plan” [5, 32].

Informed consent versus general consent. The concept of informed consent, achieved through the process of physician-patient communication, is a legal and ethical obligation spelled

out by statute and case law in all 50 states [33, 34]. Informed consent is a legal concept, not a medical concept, and it is central to values of individual autonomy and dignity [6, 35]. Informed consent and general consent are 2 distinct legal concepts. General consent covers procedures, conditions, and outcomes for which the risks and benefits are generally well known [7, 8]. Informed consent, however, is characterized by a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention [33, 34]. A protocol that allows a patient’s silence to be construed as consent cannot be characterized as informed consent. Unlike testing for most other infectious diseases, testing for HIV involves risks and benefits that may not be apparent to the patient. Unlike other sexually transmitted diseases and tuberculosis, HIV infection is a lifelong condition, typically requires decades of management with potentially toxic drugs, causes death, and results in social and economic exclusion unparalleled by other current health conditions.

Contextual information and informed consent. The legal definitions and primary elements of informed consent may be fairly consistent, but whether the provider-patient communications process satisfies these definitions hinges on the medical, social, and personal context in which it occurs. Relevant context includes such factors as the invasiveness of a proposed procedure, as well as the extent to which the average reasonable patient is likely to need or want additional information in order to fully understand what is at stake. The individual’s age and ability to communicate effectively with the provider are also relevant considerations, as is the routine or emergent nature of the medical intervention (in an emergency, a physician can, without a patient’s consent, initiate a medical intervention necessary to preserve life).

Capacity is defined as the ability, irrespective of age, to understand the nature and consequences of a proposed health

Table 2. Checklist to help ensure that an informed consent procedure for HIV testing is appropriate and legally adequate.

Responsibilities required of the provider

Confirm the subject has the capacity (i.e., ability), irrespective of age, to understand the nature and possible consequences of the proposed health care intervention (e.g., the HIV test).

Ensure that the possible emotional and mental health consequences of a medical procedure are part of the related health risks that are addressed with the patient. The most important and potentially harmful consequences of screening frequently are negative-labeling effects and the psychological impact of the test result or diagnosis.

Be aware that courts and medical ethicists agree that informed consent requires that the health care provider convey all the information a lay person might not be expected to know.

The Convention on Human Rights and Biomedicine requires that a patient receive the correct information about the nature, purpose, consequences, and risk of a medical intervention.

Table 3. Potential legal hurdles and pitfalls of a literal application of the new CDC guidelines.

Hurdle or pitfall	Comment
State laws require patient counseling and proof of informed consent	Current state HIV testing laws are normally discussed in terms of patient protection. Amending state HIV testing law can be a protracted process. Some provisions of the law generally regarded as essential to patient confidence (e.g., confidentiality guarantees) may be eroded.
No linkage to care	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.
No proof of informed consent	Health care providers could face liability on claims of failure to get informed consent in settings where or from populations for whom the general capacity to consent may be questionable. Persons associated with higher risk of not providing informed consent include adolescents, patients presenting to the emergency room with trauma, patients for whom language is a barrier, and prisoners who consent to testing under explicit or tacit pressure or who are subjected to mandatory testing.
Inadequate counseling before or after testing	An inadequate pretest counseling and consent process could reinforce and support a claim of medical malpractice. One of the most common factors in patients' decisions to file claims is inadequate communication by physicians. Apart from cases of HIV infection, there is a correlation between the extent of communication and the extent to which an unsatisfactory outcome produces a malpractice claim. Liability and ethical issues can be raised by individuals who, after experiencing negative outcomes following a positive test result, dispute that they had sufficient knowledge to give informed consent to HIV testing. Negative outcomes could include domestic violence, loss of housing, loss of employment or employment opportunities, loss of insurance, exclusion from educational and day care programs, psychological trauma exacerbated by a failure to assess their readiness for testing, and suicide.
Poor understanding of HIV law	Physicians have a relatively limited knowledge of state law and of institutional policies and procedures on confidentiality issues specific to patients infected with HIV. Health care facilities providing testing could face potential liability claims because of inappropriate disclosures. Inappropriate disclosures by doctors in state facilities could trigger claims involving violation of the constitutional right to privacy.

service. This requires the provider to ensure that the patient currently has the ability to understand the nature and consequences of an intervention, such as an HIV test, and a diagnosis. Capacity and the ability to give legally adequate consent can be compromised as a consequence of substance abuse, mental impairment, language limitations, or even the medical condition serving as the primary reason for presenting for care.

It is a common misunderstanding that the very minor physical risks of an HIV test are the only factors relevant to informed consent. On the contrary, adverse effects on emotional health and mental health are risks that should be addressed as part of securing legally adequate consent. Accordingly, informed consent to HIV testing would include an understanding of the risks of negative “labeling” and of the adverse psychological effects of a positive test result or an AIDS diagnosis [9, 31].

Courts' approaches to informed consent. Courts take 2 distinct approaches to the issue of informed consent. In 1972, a federal appeals court first articulated the modern “reasonable patient” standard under which the necessary information on risks is determined by what a reasonable person in that patient's position would want to know [36]. Approximately half of US states have adopted this approach. Under the older, traditional approach, the duty to disclose information relevant to a pro-

cedure is determined by what a “reasonable physician” would disclose under similar circumstances.

The modern approach reflects the view that the standard of disclosure exercised by many in the medical profession bears little relationship to the information a patient actually needs to make an informed choice. Because the patient bears the consequences of a medical diagnosis or treatment, it is the patient's right to know all the material facts. Supporters of the reasonable patient standard argue that physicians' inclination to offer more-cursory disclosures renders them unsuited to determine the parameters of a patient's right to know. The right to know is, after all, a nonmedical issue and, as such, is outside the physician's professional expertise. A standard that determines a doctor's duty to inform a patient on the basis of that patient's need or desire to know serves to encourage less authoritarian and, ultimately, more-productive relationships between physicians and their patients [37].

The trend towards a patient-based standard of consent is consistent with consensus reflected in international law. The Convention on Human Rights and Biomedicine states that a patient must be given the correct information about the nature and purpose, consequences, and risks of a medical intervention (table 2).

Table 4. Some options for both patient and provider protections under the new Centers for Disease Control (CDC) HIV testing guidelines

Ensure that health care providers are well trained and that they understand that
The information needed for both the provider's and the patient's protection will hinge on the particular setting and people involved (i.e., one size does not fit all).
Informed consent can be secured in many ways and with modest time investment.
It is impossible for a provider to determine the patient's capacity to consent without first communicating with the patient.
Written proof of consent may be the best protection against liability for providers, particularly when a patient's capacity to consent is not clear.
Documentation of a well-conducted consent and counseling process protects providers from exposure to liability, and maintaining such protections are not prohibited under the CDC guidelines.
Patients often fear rejection or violence and being ostracized by their communities, and the provider's view of what is best for the patient may differ from the patient's.
Embrace the CDC recommendation to engage with AIDS service organizations that can
Assist with test-related counseling and help ensure real informed consent.
Assist with links to provision of additional counseling, care, and other core services.
For incarcerated persons, ensure that
Adequate care provision is in place before implementing routine testing.
Confidentiality is protected in the pretest and posttest periods and that protocols guarantee that HIV status information will only be used for diagnosis and treatment.
Neither security or untrained staff are involved in diagnosis, treatment, or partner notification.

STIGMATIZATION AND DISCRIMINATION: CONTINUING CONSEQUENCES FOR PEOPLE WITH HIV INFECTION

The ongoing consequences of a positive HIV test result are an important element in assessing the legal and ethical relevance of informed consent. The legitimacy of patient concerns about negative labeling—a potential harmful consequence of screening—is borne out by the stigmatization and discrimination still strongly associated with a positive test result. Violation of the civil rights of people with HIV infection and AIDS remains widespread throughout the United States. Surveys continue to document frequent denials of medical treatment, loss of parental rights, workplace discrimination, exclusion from nursing homes and residential facilities, and violations of privacy [10]. In fact, a December 2006 study documented that 25%–50% of skilled nursing facilities, obstetricians, and cosmetic surgeons in Los Angeles County deny treatment to HIV-positive patients.

A recent lawsuit for discrimination, in which emergency medical technicians in Philadelphia allegedly refused to touch an acutely ill HIV-infected person or help him onto a stretcher, illustrates the problem [11]. Research has demonstrated continued social ostracism of people infected with HIV; some studies showed that concerns about the impact of stigmatization and discrimination on individuals, their families, and their communities affect the decision to get tested [13, 38, 39]. A 2004 study of violence against young homosexual men found they were more likely to experience verbal harassment, discrimination, and physical violence if they were HIV positive [40].

HIV-associated stigmatization and discrimination are reinforced by government agencies with exclusionary policies that lack sound scientific basis. CDC guidelines still recommend unfounded restrictions on practices of health care workers infected with HIV [14]. Other federal agencies, such as the State Department, the Federal Aviation Administration, the Peace Corps, and all branches of the military, continue to restrict the employment or licensing of healthy qualified people with HIV infection. A number of states prohibit the licensing of HIV-infected persons for professions such as barbering, massage therapy, and home health care. Twenty-four states criminalize the sexual activity of people with HIV, with most states imposing terms of imprisonment regardless of whether there was mutual consent, prophylaxis was used, or HIV transmission occurred [15–20, 41].

Recent studies also document that many people of color who support the notion of routinely offered HIV testing are deterred from being tested, because of concerns about privacy and stigmatization and distrust or misconceptions about the importance of testing [42]. Some persons even avoid testing, because they believe that they could become infected with HIV during the test [42]. A recent national study of 2466 HIV-infected adults receiving care in the United States showed that 25% believed their clinicians discriminated against them after they first tested positive [43].

NEW CDC GUIDELINES: POTENTIAL LEGAL HURDLES AND PITFALLS

Reactive, unrefined application of the new CDC guidelines could trigger a range of legal claims (table 3). Institutional patterns of HIV testing without linkage to care, as well as evidence of racial disparities in linkages to care for those who test positive, could provide the basis for a disability or race-based discrimination claim. Moreover, amending state law is a protracted process and could result in dilution of important confidentiality protections.

Without proof of patient consent, health care providers could face liability regarding claims of failure to get informed consent

for patients whose general capacity to provide consent may be in question, such as adolescents, emergency department patients, immigrants, and people with language barriers (table 3).

An abridged pretest counseling and consent process can reinforce a claim of medical malpractice. For individuals who have experienced negative consequences as a result of a positive or false-positive HIV test, an inadequate explanation of the test—its purpose, benefits, limitations, and emotional and legal consequences and the meaning and medical significance of a positive and negative test result—can result in successful malpractice claims. Inadequate physician communication is one of the most common factors in patients' decisions to file claims against their doctors [44, 45].

The risk of legal liability or ethical conflicts following the negative consequences of a positive HIV test is heightened in vulnerable patients for whom a positive HIV test poses an increased social risk. Typical fallout of a positive test result can include domestic violence, loss of housing, loss of employment or job opportunities, and psychological trauma (table 3).

Limited knowledge of state and HIV confidentiality laws is another potential source of liability for physicians [46]. Inappropriate disclosures by staff of state facilities may also trigger constitutional-privacy claims. In correctional settings, inmates may have claims relating to inadequate medical care or privacy violations, if HIV testing is conducted without privacy or with coercion, without protections against disclosure to staff and inmates, or without access to medications and related care during incarceration and prior to release.

PATIENT AND PROVIDER PROTECTION UNDER THE NEW CDC TESTING GUIDELINES: SOME OPTIONS

Training: one size does not fit all. Although current state HIV testing laws typically are viewed as patient protection, requiring documented, adequate counseling and patient engagement can also protect providers from liability while improving the consistency, quality, and outcome of care.

Perhaps the best general advice is to ensure adequate training for providers. People and their circumstances differ, so the information needed for both the provider's and the patient's protection will hinge on the particular setting and people involved (table 4). Well-informed providers who understand that it is impossible to confirm a person's capacity to consent without 2-way communication are going to be better at securing real consent while reducing liability risks.

Recommendations: a partial embrace, an adjusted focus, and selected expansion of the new guidelines. The CDC's inconsistent guidance on the process that should precede testing—recommending opt-out screening while repeatedly emphasizing the importance of informed consent—does nothing

to resolve potential liability issues. Providers are best protected by embracing those provisions that offer the least chance of conflict with other patient legal protections. This is underscored by the CDC's own insistence that the new guidelines "are intended to comply fully with the ethical principles of informed consent" [1]. Those jurisdictions where an opt-out approach would be at odds with local HIV statutes and informed consent law may be best advised, as the CDC states, to simply "consider strategies to best implement these recommendations within current parameters" [1].

Providers also should embrace the guidelines' recommendation to communicate with local AIDS service organizations, including legal-service agencies. These agencies can greatly assist with the training and care connection plans that should precede implementation of any routine testing initiative, and with the discrimination and other fallout that can follow a diagnosis of HIV infection (table 4).

Although the guidelines do not recommend written proof of consent, they offer little argument against it. Written documentation of consent may still be the best protection against liability. Although it is unquestionably true that the central element of informed consent is the meaningful receipt of information rather than the signing of a form, in the hospital setting some states presume valid consent when there is written documentation to that effect [47, 48]. With a written consent on file, a patient would have a nearly insurmountable burden to legal claims against their provider for negligence or for inadequate consent, in the event of negative consequences following an HIV test and diagnosis. Ultimately, with the available evidence that well-run HIV testing programs with tailored counseling and proof of consent are health protective and cost-effective, is the additional liability risk created by reversion to less modern approaches to patient autonomy worth it?

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APPENDIX

Table A1. Supporting comments for select references.

Reference(s)	Comment(s)
[2]	This source provides a map and text for state statutes related to, inter alia, HIV testing, consent, and training. Because of the lack of uniformity among the states regarding such basic definitions as “informed consent” or “counseling,” the actual texts of the individual state statutes on HIV testing are more useful than the provided summaries. State regulations, which may expand upon or clarify statutory provisions, are not included.
[3]	The plaintiff stated a cognizable right of privacy under the state constitution for the defendant’s nonconsensual HIV testing of flight attendant applicants.
[4]	Assessment of a multistate sample of HIV patients already in care in major sites of primary care for HIV infection, including New York City, revealed that many eligible women and African American patients still did not receive anti-retroviral therapy.
[5]	Dr. Webb spoke before the New York State Assembly Health Care Committee in her capacity as Executive Director of the Association of Nurses in AIDS Care (ANAC). The ANAC represents nearly 2500 HIV nurses working as clinicians, educators, researchers, and administrators in clinics, hospitals, prisons, universities, public health departments, and various levels of government.
[6]	In this case, a patient had cause of action in which the physician failed to discuss the known risks of a medical procedure prior to securing the patient’s consent.
[7]	At the time of writing, Dr. Novello was the Commissioner of the New York State Department of Health.
[8]	This source provides a discussion in English about the op-ed article by Dr. Antonia Novello [7].
[9]	The article highlights how the psychological risks of screening warrant close attention to informed consent requirements.
[10]	In this example, a national survey of 43 community-based AIDS service organizations reported an alarming number of nursing homes and psychiatric facilities in large metropolitan areas, such as Los Angeles, that refuse to accept clients infected with HIV. Often, a lack of experience in caring for such patients was cited as the basis for refusing admission.
[11]	The court ruled that an HIV-positive plaintiff stated a cognizable civil rights claim. The plaintiff alleged that a city emergency medical team that responded to his 911 call denied him medical assistance or treatment, refused to help him to the ambulance, and told him that “if you cough on me, I can press charges against you.” Ultimately, the case settled for \$50,000 [12].
[13]	More than one-third of those surveyed reported that concerns about AIDS-associated stigmatization would affect their own decision to be tested for HIV.
[14]	It is important to note that, in this article, the phrase “exposure-prone invasive procedures” refers in part to the transmission of hepatitis C virus, which is ~100 times as infectious as HIV.
[15–20]	These are examples of state statutes that forbid sex for people infected with HIV, regardless of mutual consent or the use of measures to protect against HIV transmission.

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