CONSIDER THE FOLLOWING 3 NEWLY ADMITTED PATIENTS. The first patient has marked hypoxemia requiring mechanical ventilation and is found to have nonspecific, bilateral, alveolar infiltrates on chest radiography. The second patient has had a severe change in mental status and on brain imaging has an enhancing lesion exerting a mass effect. The third patient has high fevers, ventilator-dependent respiratory failure, and diffuse nodular infiltrates on chest radiography, with negative blood, urine, and sputum cultures after 48 hours.

In each of these cases, the next steps in physicians’ diagnostic and therapeutic algorithms could be usefully informed by knowledge of the patients’ immunocompetency. Knowing that these patients had recently used immunosuppressive therapies, or were infected with the human immunodeficiency virus (HIV), would substantially increase the probabilities of Pneumocystis jiroveci pneumonia in the first patient, toxoplasmosis in the second patient, and disseminated fungal or mycobacterial infections in the third patient. Indeed, knowledge of immunocompromise would result in disease probabilities that surpass many clinicians’ treatment thresholds,1 leading them to treat these conditions empirically, rather than await the results of bronchoscopy in the first patient, brain biopsy in the second, or lung biopsy in the third. Because of the complication risks and financial costs of these procedures, some clinicians may even forgo them entirely unless or until evidence arose that the patients were not responding to empirical therapy. Thus, knowledge of immunosuppression would lead to earlier application of potentially life-saving therapies, and might reduce the costs and complications associated with potentially unnecessary procedures.

Speaking with family members or other health care professionals should reveal the use of immunosuppressive drugs; but for many patients, a history of HIV testing may be absent or unavailable. Because laws and standards of practice currently prevent HIV testing without specific consent, emergency HIV testing, which can be completed in 10 to 30 minutes, cannot proceed among patients who are mentally incompetent (ie, those lacking the capacity to make informed decisions).

Forced to treat these patients without knowledge of HIV status, many physicians might order tests for presumed surrogate markers of HIV-induced immunocompromise. However, among the potential surrogate markers, absolute lymphocyte counts provide little knowledge of immune function or HIV status,2 and CD4 lymphocyte counts are unreliable in critically ill patients.3 Although the ratio of CD4:CD8 lymphocytes may be preserved in critical illness,3 testing for this ratio in lieu of formal HIV testing represents a deceitful attempt to get around current restrictions.

Current Policies
When Bayer first described “HIV exceptionalism” in 1991, he noted that “the effort to sustain a set of policies treating HIV infection as fundamentally different from all other public health threats will be increasingly difficult. Inevitably, HIV exceptionalism will be viewed as a relic of the epidemic’s first years.”4 Nearly 25 years since the epidemic began, this prediction remains unrealized with regard to HIV testing.

Except for tests for heritable genetic disorders, HIV is the only laboratory, radiographic, or pathologic test for which specific consent is broadly required. For all other tests, there is widespread belief that either implicit consent, or a general consent to medical care, is adequate to protect autonomous choice.5

Specific consent for HIV testing is required in all 53 US states and territories.6 In 34 (64%) of these, no exceptions to this general rule have been enacted to allow nonconsented HIV testing among patients who are incompetent (TABLE).6 Among the remaining 19 states, 6 permit testing only in an “emergency” or “life-threatening” situation (neither of which is defined in these states’ laws), and 13 simply require that physicians believe the test result will influence the patient’s acute management. The American Medical Association7 and British General Medical Council8 also support nonconsented HIV testing when physicians believe this information is diagnostically important and patients have already provided general consent to care.

Author Affiliations: Department of Medicine, Center for Clinical Epidemiology and Biostatistics, Center for Education and Research on Therapeutics, and Center for Bioethics, University of Pennsylvania School of Medicine, Philadelphia. Corresponding Author: Scott D. Halpern, MD, PhD, MBioethics, Center for Clinical Epidemiology and Biostatistics, 115 Blockley Hall, 423 Guardian Dr, Philadelphia, PA 19104-6021 (shalpern@ceeb.med.upenn.edu).

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Despite this support, nonconsented HIV testing among patients who are incompetent is rarely conducted, even in states where statutes support the practice. Case law provides little guidance. In both the United States and England, physicians have been disciplined for performing nonconsented HIV tests on competent patients. However, a search of the Lexis/Nexis, Westlaw, and MEDLINE databases (June 5, 2005) identified no decisions regarding whether physicians could perform nonconsented HIV testing among patients who are incompetent. Lack of legal precedent and varying state laws may generate fear of legal retribution for clinicians considering nonconsented HIV testing. Laboratories’ absolute requirements for consent create an additional barrier.

Arguments Against Nonconsented HIV Testing

In an era characterized by increasing respect for patient autonomy and the democratization of clinical medicine, it may seem incongruous to suggest rescinding the requirement for specific consent for HIV testing among critically ill patients. There are at least 3 arguments against such a change.

First, being diagnosed with HIV, or even suspected of being infected, has long been associated with stigmatization and discrimination. Despite substantial progress in providing legal protections for patients with HIV, such as inclusion under the Americans with Disabilities Act, the potential remains for discrimination in social or occupational settings. Although specific consent is not required for testing for other stigmatizing infections, such as syphilis, tuberculosis, and hepatitis C, this inconsistency might be viewed as supporting more restrictive consent requirements for these other diseases rather than fewer restrictions for HIV.

A second argument is that some patients, even those who do not fear future discrimination per se, may simply not wish to be tested for HIV. Even if such wishes stem from erroneous views (eg, that options for therapy are limited, or that insurers or employers can legally discriminate against patients who are infected), testing a patient against his or her wishes may be to commit a wrong (in an ethical sense) or battery or negligence (in a legal sense). Because HIV still invokes unique stigmas and fears, such testing should not be considered as “routine” and thereby governed by a general consent to treatment.

However, when confronting an unarousable patient with red blood cells in the cerebrospinal fluid and enhancement of the temporal lobe on brain imaging, clinicians do not deliberate about whether the patient wishes or would agree to be tested for herpes simplex virus. When a patient without previously diagnosed liver disease presents with jaundice and encephalopathy, clinicians do not refrain from testing for viral hepatitis out of concern that the patient who is infected.

Inconsistency alone does not incriminate the standard for HIV, but clinicians should assume that most patients who are incompetent would desire any serologic testing that could improve their care if they were competent and aware of their clinical circumstances. It is therefore difficult to justify the exceptional treatment of HIV in the case of patients who are incompetent.

The third argument for retaining the requirement for specific consent prior to HIV testing is that if patients at risk for HIV were aware that they could be tested without their consent, they may avoid contact with health care professionals. This limited contact could confer a net public health loss: index patients would lose the opportunity to be treated with effective therapies and their sexual or needle-sharing contacts would remain unaware of their risk. Because at-risk groups continue to mistrust the government and medical professionals with regard to HIV, policy changes that appear to rescind their rights could lead to further alienation and limited acceptance of future public health interventions.

Such consequences are less likely if nonconsented HIV testing is limited to critically ill patients. Unlike the response to mandatory premarital HIV testing in Illinois, where couples responded by getting married elsewhere, criti-
cally ill patients lack the luxury of mobility. Still, public awareness of a “step backwards” in HIV privacy rights may produce a more generalized decline in health care visits.

Arguments for Nonconsented HIV Testing

The first reason to support nonconsented HIV testing among critically ill patients is that such testing may improve the quality and efficiency of their care. Second, because most patients would likely choose to be tested if they were competent and aware of their clinical circumstances, allowing such testing may respect patients’ autonomy even when they cannot voice it.

Third, although HIV infection retains unique features, the need to consider it an exceptional illness requiring exceptional policies has been weakened. HIV exceptionalism facilitated the understanding of a new, terrifying illness during its first decade, but in retrospect, HIV has much more in common with earlier epidemics, such as tuberculosis and syphilis, than was initially appreciated. Indeed, maintain- ing exceptional policies for HIV may perpetuate stigmatization by reinforcing the belief that patients with HIV are “different.” Requiring consent for HIV testing risks perpetuating stigmatization while simultaneously limiting the quality of care that at-risk persons may receive. The disenfranchised group is thus doubly harmed.

Finally, social epidemiology does not justify the maintenance of exceptional HIV policies because heart disease, chronic obstructive pulmonary disease, and many cancers share the propensity of HIV to affect underserved populations.

Surrogate Consent

Rather than pursuing nonconsented HIV testing among patients who are incompetent, surrogate consent from a health care proxy, court-appointed guardian, or relative or friend might be required instead. Laws in 8 states support this approach (Table). Requiring surrogate consent is also consistent with standards for obtaining consent for research in critically ill patients.

However, assuming that most patients who are incompetent would wish to be tested for HIV if they were competent and aware of its clinical importance, surrogate consent is unnecessary because proceeding with testing is itself an enactment of these patients’ autonomous choice. Although some patients may choose not to be tested in these circumstances, broadly requiring surrogate consent is unlikely to help identify these patients. First, many critically ill patients with HIV will lack surrogates with sufficient insight into their wishes to provide meaningful consent. Second, it is difficult, and potentially antagonizing, to raise the specter of HIV among friends or relatives who may believe the patient has no risks for infection.

Third, because HIV remains socially and politically sensitive, it would be difficult for surrogates to extract their own biases from the decision. Another alternative to nonconsented HIV testing is to require physicians who believe HIV testing is in the patient’s best interest to obtain a court order to proceed. However, because the benefits of HIV testing for critically ill patients may be directly related to how quickly the test result is obtained, any requirement for legal intervention will substantially limit its utility. Courts are also unlikely to have immediate access to information about a particular patient that would change the default assumption that patients would wish to be tested if competent.

Maintaining Confidentiality After Testing

Having obtained information regarding the patient’s HIV status, the physician adopts responsibility for ensuring its confidentiality. State laws for handling HIV-related information in cases of occupational exposures can guide physicians in responding to patients who were tested for HIV while incompetent. Accordingly, physicians should inform patients who regain competency that the test was obtained, explain why it was obtained, counsel patients regarding interpretation of the test, explain what can be done for those testing positive, and allow patients to obtain their test results if they wish. Patients should still be given the option to know whether they are infected because they would have had that option if they had been competent at the time of testing. For patients who test positive and are informed of this result, the physician who ordered the test should ensure proper follow-up with an HIV specialist.

Conclusions

The concerns with nonconsented HIV testing among patients who are incompetent—that it will reduce health care contacts among at-risk populations, it risks future stigmatization for those found to be positive, and it fails the rare patient who values the avoidance of such testing over optimal care—are insufficient to justify substantial limitations to the efficient diagnosis and treatment of our sickest patients. The arguments supporting nonconsented HIV testing among patients who are incompetent are not limited to the critically ill; testing is similarly warranted among other incompetent patients who may benefit from testing. For example, in patients with insidious changes in mental status of unclear etiology, identifying HIV infection would raise the possibilities of HIV dementia or progressive multifocal leukoencephalopathy, and prompt antiretroviral therapy may effectively treat these diseases.

State laws and laboratory policies should be modified or reinterpreted so that nonconsented HIV testing is allowed whenever the physician determines that tests for HIV infection and immune dysfunction are likely to alter the patient’s diagnostic or therapeutic management in a clinically meaningful way; the patient is unable, according to widely accepted criteria, to consent to or refuse HIV testing; and effective therapies are available to treat patients found to be immunocompromised. This final restriction implies
that resources must be available both to treat the acute illness and to treat HIV in the long term. Because there is limited utility in stabilizing a critically ill patient with HIV for whom long-term antiretroviral therapy is unavailable, non-consented HIV testing may not be justifiable in resource-limited settings.

Financial Disclosures: None reported.

Acknowledgment: I thank David Casarett, MD, MA, Jason Karlawish, MD, University of Pennsylvania School of Medicine, Philadelphia, and John Luce, MD, University of California, San Francisco, for their comments on an earlier version of this article, and for the extraordinary efforts of the students of Tulane Law School for compiling state-by-state laws regarding HIV and AIDS, and publishing their findings in their Law & Sexuality Journal. None of these parties received compensation for their efforts.

REFERENCES

Disclosing Individual Results of Clinical Research
Implications of Respect for Participants

David I. Shalowitz, AB
Franklin G. Miller, PhD

CONTROVERSY EXISTS ABOUT THE RESPONSIBILITY OF investigators to communicate the results of research to study participants. These research results may be categorized as either general study results, which represent aggregate data usually published by the research team, or individual results, which are research findings relevant to particular participants. Disclosure of individual research results has become particularly contentious in the context of genetics research, for which genotypes of individual participants often become known to investigators. However, disclosure of individual results should be addressed in all research involving human participants.

When aggregate results of research correlate with aspects of the health and well-being of participants, disclosing individual results has the potential to significantly affect the lives of participants. Accordingly, investigators and institutional review boards (IRBs) should consider when and how participants should be informed of individual research results. This article reviews previously articulated policies on sharing research data with participants and proposes an alternative ethical approach for communicating individual study results based on respect for research participants. Translating this approach into workable guidelines for investigators and IRBs will require careful thought and discussion, ideally guided by further empirical research assessing the preferences of research participants to receive individual study results and their reactions to such disclosure.

Author Affiliations: Department of Clinical Bioethics, National Institutes of Health, Bethesda, Md.

Corresponding Author: Franklin G. Miller, PhD, Department of Clinical Bioethics, National Institutes of Health, Bldg 10, Room 1C118, Bethesda, MD 20892 (fmiller@cc.nih.gov).