Nonconsented Human Immunodeficiency Virus Testing Among Critically Ill Patients

Intensivists’ Practices and the Influence of State Laws

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Background: Human immunodeficiency virus (HIV) testing can improve care for many critically ill patients, but state laws and institutional policies may impede such testing when patients cannot provide consent.

Methods: We electronically surveyed all US academic intensivists in 2006 to determine how state laws influence intensivists’ decisions to perform nonconsented HIV testing and to assess intensivists’ reliance on surrogate markers of HIV infection when unable to obtain HIV tests. We used multivariate logistic regression, clustered by state, to identify factors associated with intensivists’ decisions to pursue nonconsented HIV testing.

Results: Of 1026 responding intensivists, 765 (74.6%) had encountered decisionally incapacitated patients for whom HIV testing was wanted. Of these intensivists, 168 pursued testing without consent and 476 first obtained surrogate consent to testing. Intensivists who believed nonconsented HIV testing was ethical (odds ratio, 3.8; 95% confidence interval, 2.2-6.5) and those who believed their states allowed nonconsented testing when medically necessary (odds ratio, 2.3; 95% confidence interval, 1.6-3.4) were more likely to pursue nonconsented HIV tests; actual state laws were unrelated to testing practices. Of the intensivists, 72.7% had ordered tests for perceived surrogate markers of HIV infection in lieu of HIV tests; more than 90% believed these tests were sufficiently valid to base clinical decisions on.

Conclusions: Most US intensivists have encountered decisionally incapacitated patients for whom HIV testing may improve care. Intensivists’ decisions to pursue nonconsented testing are associated with their personal ethics and often erroneous perceptions of state laws, but not with the laws themselves. Uniform standards enabling nonconsented HIV testing may minimize inappropriate influences on intensivists’ decisions and reduce intensivists’ reliance on perceived surrogate markers of immunodeficiency.

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Human immunodeficiency virus (HIV) testing can often improve diagnostic and therapeutic efficiency for critically ill patients. However, requirements that patients consent to testing present substantial barriers to testing because up to 40% of patients lack the capacity to make decisions within 24 hours of admission to an intensive care unit (ICU) and more than 80% of patients receiving mechanical ventilation experience delirium during their ICU stay. These impediments are clinically relevant because intensivists are likely to encounter patients for whom HIV testing is warranted—at least one-quarter of HIV-infected Americans are unaware of their diagnosis and, despite advances in the diagnosis and treatment of HIV disease, 40% of HIV-infected patients admitted to ICUs have not previously been diagnosed.

To improve the efficient diagnosis and treatment of HIV infection in the United States, the Centers for Disease Control and Prevention has recently suggested removing requirements for specific consent before HIV testing. However, these guidelines conflict with most states’ laws, which generally require written consent for HIV testing and make only modest and variable exceptions for emergency testing among critically ill patients who lack decisional capacity. Thus, if these state laws, physicians’ perceptions of state laws, or other potential barriers to nonconsented testing continue to have influence, the Centers for Disease Control and Prevention guidelines might have limited influence.
US critical care training programs in departments of internal medicine, anesthesiology, or surgery. We pilot tested our questionnaire by administering it to 15 faculty members at our institutions with expertise in critical care medicine, HIV medicine, or questionnaire design, and modified the instrument based on their feedback.

We administered the final questionnaire from March 15 through May 31, 2006, and tracked respondents using commercially available software (http://www.surveymonkey.com). We calculated the response rate as the number of intensivists completing more than 80% of questionnaire items within 2 weeks of the third and final invitation to participate, divided by the number of eligible physicians contacted.12 We compared demographic characteristics of responders and nonresponders to ascertain the potential for nonresponse bias.

QUESTIONNAIRE

On the questionnaire’s cover page, we specifically instructed intensivists not to consider cases of occupational exposure when responding because HIV testing in such cases is subject to unique laws and standards of practice.13,14 For all other ICU circumstances, we asked intensivists whether they believed they should be allowed to order HIV tests among decisionally incapacitated patients any time the physician deems the information important, only in a medical emergency, only after first obtaining surrogate consent, or never. We next asked if intensivists had ever ordered or recommended ordering an HIV test for a decisionally incapacitated patient without consent, and to describe the result of their most recent effort to obtain such a test.

Intensivists who had both encountered patients for whom they believed HIV testing would be useful and pursued such testing without first obtaining consent from a surrogate decision maker were considered to have pursued nonconsented testing. This group was compared with those who tested after first seeking surrogate consent; those who chose not to pursue HIV testing were excluded from this analysis.

We used a previously published categorization of US state laws governing consent requirements for HIV testing to group physicians into those practicing in states that (1) allow nonconsented testing whenever the physician believes the result would improve the patient’s immediate medical care, (2) allow nonconsented testing only in a “medical emergency” or “life-threatening situation,” (3) prohibit nonconsented testing but allow testing with surrogate consent provided by an appropriate surrogate decision maker, or (4) make no exceptions to a general requirement for the patient’s specific consent1 (Table 1). We solicited intensivists’ perceptions of their state laws by asking them which of these descriptions they believed matched their own state laws. We categorized intensivists as believing their state laws allowed nonconsented testing in some circumstances if they believed their state was in category 1 or 2. Finally, we asked intensivists whether they had ever ordered a surrogate test for HIV-induced immunodeficiency when faced with a patient of unknown HIV status in whom they could not test for HIV itself. We solicited which tests they had or-dered a surrogate test for HIV-induced immunodeficiency when faced with a patient of unknown HIV status in whom they could not test for HIV itself. We solicited which tests they had ordered (white blood cell count, absolute lymphocyte count, CD4 lymphocyte count, CD4/CD8⁺ lymphocyte ratio, or other) and whether they believed the immediate clinical utility of these tests was superior to HIV testing, equal to HIV testing, inferior to HIV testing but adequate to base some clinical decisions on, or of no clinical value.

ANALYSES

To evaluate whether actual state laws, physicians’ perceptions of state laws, physicians’ views of the propriety of nonconsented HIV testing, and physicians’ specialty influenced inten-

Table 1. US State Laws Regarding Nonconsented HIV Testing of Incompetent Patients

<table>
<thead>
<tr>
<th>Cases in Which HIV Testing of Incompetent Persons Is Permitted Without Specific Consent</th>
<th>States or Territories (No. [%])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whenever a physician expects the test result would improve the patient’s immediate medical care</td>
<td>Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, Hawaii, Illinois, Indiana, Kentucky, Mississippi, New Hampshire, and Utah (13 [25])</td>
</tr>
<tr>
<td>Only in an “emergency” and/or “life-threatening” situation</td>
<td>Georgia, New Mexico, Ohio, Pennsylvania, West Virginia, and Wisconsin (6 [12])</td>
</tr>
<tr>
<td>If next of kin or legal guardian provides surrogate consent</td>
<td>California, Florida, Maryland, Montana, New York, North Carolina, North Dakota, and Rhode Island (8 [16])</td>
</tr>
<tr>
<td>No cases specified</td>
<td>Alaska, District of Columbia, Idaho, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Jersey, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, and Wyoming (24 [47])</td>
</tr>
</tbody>
</table>

Abbreviation: HIV, human immunodeficiency virus.

Data adapted from Halpern.1
Nonconsented HIV testing is only allowed if authorized surrogates are unavailable.
Health facility may perform nonconsented HIV testing if it “informs the patient in writing upon admission that an HIV test may be performed without written consent.”
General consent to medical procedures and tests covers HIV testing, but general consent is also required of incompetent patients.

METHODS

Following approval by the University of Pennsylvania institutional review board, we conducted an Internet-based survey of US intensivists using methods described previously.13,14 Briefly, we identified e-mail addresses for intensivists affiliated with all US critical care training programs in departments of internal medicine, anesthesiology, or surgery. We pilot tested our questionnaire by administering it to 15 faculty members at our institutions with expertise in critical care medicine, HIV medicine, or questionnaire design, and modified the instrument based on their feedback.

We administered the final questionnaire from March 15 through May 31, 2006, and tracked respondents using commercially available software (http://www.surveymonkey.com). We calculated the response rate as the number of intensivists completing more than 80% of questionnaire items within 2 weeks of the third and final invitation to participate, divided by the number of eligible physicians contacted.12 We compared demographic characteristics of responders and nonresponders to ascertain the potential for nonresponse bias.
Among 2333 potentially eligible intensivists, 1026 completed questionnaires, yielding a response rate of 44.0%. This represents the minimal response rate because it assumes that all nonresponders saw the e-mail invitations and were eligible to respond by virtue of being intensivists. The true response rate for this study lies somewhere between 44% and 96%.

Slightly fewer responders than nonresponders were internists (68.6% vs 72.8%; P = .03). Similar proportions of responders and nonresponders (28.7% vs 29.8%; P = .56) were from states whose laws allow nonconsented testing in some circumstances. There were no differences in the proportion of male respondents among responders and nonresponders (80.7% vs 83.2%; P = .13) or in these groups’ distribution of geographic regions (P = .51).

INTENSIVISTS’ BELIEFS REGARDING NONCONSENTED TESTING

Overall, 77.0% of intensivists believed that HIV testing among decisionally incapacitated ICU patients should be allowed whenever the physician believes the test would influence immediate care. 21.8% believed such testing should only be allowed in medical emergencies, and 1.3% believed such testing should never be allowed. Of the intensivists, 62.6% believed they should be able to test for HIV without first obtaining surrogate consent. This proportion was identical (62.7%) among intensivists practicing in the 8 states whose laws allow surrogate consent for HIV testing in lieu of a decisionally incapacitated patient’s consent.

KNOWLEDGE OF STATE LAWS

Only 25.6% of intensivists correctly identified the specific circumstances, if any, under which their state laws permitted HIV testing without the patient’s specific consent. Because we assessed knowledge of state laws using a 4-choice multiple choice questionnaire, 25.0% would be expected to correctly identify their state laws by chance alone.

Among 397 physicians practicing in states that made no exceptions for nonconsented testing, 338 (85.1%) believed some exception existed. Among 124 intensivists practicing in states that allow nonconsented testing whenever medically necessary, only 32 (25.8%) were aware of this fact.

PURSUIT OF NONCONSENTED HIV TESTS

Overall, 765 intensivists (77.0%) had encountered decisionally incapacitated ICU patients for whom HIV tests were deemed important. Among these intensivists, 476 (62.2%) obtained HIV test results after first obtaining surrogate consent, 168 (22.0%) pursued nonconsented testing, 15 (2.0%) pursued testing but could not recall whether they had first obtained surrogate consent, and 106 (13.9%) chose not to pursue testing (percentages do not total 100 because of rounding). The characteristics of these groups are described in Table 2. The reasons given by the latter group for not pursuing testing are as follows: (1) thought laboratory would not allow test without patient’s consent (60 intensivists [62.5%]), (2) thought it was unethical to test incompetent patients (27 intensivists [28.1%]), (3) thought “local guidelines” would not permit testing (6 intensivists [6.2%]), (4) thought it was illegal to test incompetent patients (1 intensivist [1.0%]), (5) thought CD4 lymphocyte count “provided some information” (1 intensivist [1.0%]), and (6) thought it was adequate to assume patient was HIV infected without testing, based on clinical suspicion (1 intensivist [1.0%]) (percentages do not total 100 because of rounding). (The numbers total 96 because 10 of the 106 intensivists who chose not to pursue testing provided no reason for this decision.)

Among the 168 intensivists who pursued nonconsented testing, 110 (65.5%) obtained the test results, 35 (20.8%) had their requests blocked by their laboratory, 22 (13.1%) were advised by colleagues or institutional officials to rescind their requests for testing, and 1 (0.6%) asked a court to grant permission for testing but permission was denied.

We compared the 476 intensivists who first obtained surrogate consent for testing with the 168 who pursued nonconsented testing in a clustered multivariate regression model. Intensivists who had pursued nonconsented HIV tests were more likely to believe that nonconsented HIV testing of decisionally incapacitated patients was ethical (odds ratio, 3.8; 95% confidence interval, 2.1-6.5), to believe their state laws contained exceptions allowing nonconsented testing when medically necessary (odds ratio, 2.3; 95% confidence interval, 1.6-3.4), and to have been in practice for more than the median of 19 years (odds ratio, 1.5; 95% confidence interval, 1.0-2.1). Actual state laws (odds ratio, 0.8; 95%
confidences similar to other studies. Cognizance of the dissuasion of colleagues and institutional administrators, and laboratory policies precluding HIV testing without surrogate consent, were important that they pursued testing (with or without surrogate consent) despite barriers presented by state laws, indicating the absence of confounding by unmeasured surrogate markers in lieu of HIV testing.

A total of 869 intensivists (86.6%) had encountered at least 1 patient in their careers for whom they considered HIV testing important, but for whom they were unable to obtain an HIV test (some of these physicians successfully obtained HIV tests for other patients). Among these 869 intensivists, 632 (72.7%) ordered tests for presumed surrogate markers of HIV infection in at least 1 case. Among the 869 physicians who encountered patients for whom they considered HIV testing important, the most commonly ordered tests were a CD4 lymphocyte count (58.7%), a CD4/CD8+ lymphocyte ratio (25.3%), and an absolute lymphocyte count (25.1%). Among intensivists who had ordered surrogate tests, 90.5% thought these tests were at least sufficient to base clinical decisions on. Among the 237 intensivists (27.3%) who had chosen not to order surrogate tests for HIV, 52.3% abstained because they considered these markers unreliable and 43.9% considered it unethical to use surrogate markers in lieu of HIV testing.

Table 2. Characteristics of Intensivists

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Intensivists (n=1026)</th>
<th>Group That Pursued Nonconsoned HIV Testing (n=168)</th>
<th>Group That Pursued HIV Testing With Surrogate Consent (n=476)</th>
<th>Group That Did Not Pursue HIV Testing (n=106)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>822/1004 (81.8)</td>
<td>130/165 (78.8)</td>
<td>377/473 (79.7)</td>
<td>88/101 (87.1)</td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>312 (30.6)</td>
<td>38 (22.8)</td>
<td>143 (30.1)</td>
<td>41 (38.7)</td>
</tr>
<tr>
<td>South</td>
<td>295 (28.9)</td>
<td>66 (39.5)</td>
<td>139 (29.3)</td>
<td>31 (29.2)</td>
</tr>
<tr>
<td>Midwest</td>
<td>231 (22.7)</td>
<td>39 (23.4)</td>
<td>115 (24.2)</td>
<td>16 (15.1)</td>
</tr>
<tr>
<td>West</td>
<td>181 (17.8)</td>
<td>24 (14.4)</td>
<td>78 (16.4)</td>
<td>18 (17.0)</td>
</tr>
<tr>
<td>Specialty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicine</td>
<td>683 (69.8)</td>
<td>121 (73.8)</td>
<td>323 (69.5)</td>
<td>76 (81.7)</td>
</tr>
<tr>
<td>Surgery</td>
<td>101 (10.3)</td>
<td>10 (6.1)</td>
<td>54 (11.6)</td>
<td>7 (7.5)</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>168 (17.2)</td>
<td>27 (16.5)</td>
<td>77 (16.6)</td>
<td>8 (8.6)</td>
</tr>
<tr>
<td>Other</td>
<td>26 (2.7)</td>
<td>6 (3.7)</td>
<td>11 (2.4)</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Professional time in the ICU, %</td>
<td>30 (20-50)</td>
<td>30 (20-50)</td>
<td>35 (20-50)</td>
<td>30 (20-50)</td>
</tr>
</tbody>
</table>

Abbreviations: HIV, human immunodeficiency virus; ICU, intensive care unit.

Table 3. Regression Models of Variables Associated With Pursuit of Nonconsonented HIV Tests (vs Obtaining Surrogate Consent)

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Odds Ratio (95% Confidence Interval)</th>
<th>Unconditional Model</th>
<th>Conditional Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief that nonconsonented testing was ethical</td>
<td>3.8 (2.1-6.5)</td>
<td>3.4 (2.0-5.6)</td>
<td></td>
</tr>
<tr>
<td>State law makes exception for nonconsonented testing</td>
<td>0.8 (0.6-1.2)</td>
<td>b</td>
<td></td>
</tr>
<tr>
<td>Belief that state law makes exception for nonconsonented testing</td>
<td>2.3 (1.6-3.4)</td>
<td>2.3 (1.5-3.6)</td>
<td></td>
</tr>
<tr>
<td>Medical specialist (vs surgery or anesthesiology)</td>
<td>1.4 (0.9-2.1)</td>
<td>1.5 (0.9-2.4)</td>
<td></td>
</tr>
<tr>
<td>Practice duration &gt;19 y</td>
<td>1.5 (1.0-2.1)</td>
<td>1.5 (1.1-2.3)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: HIV, human immunodeficiency virus.

a Hosmer-Lemeshow χ²=6.09 (P=.64), indicating adequate fit of the model.
b This variable drops out of the conditional model because there is no variance in state laws among intensivists within the same state.
c We combined surgeons and anesthesiologists for this analysis because they often practice in the same intensive care units and, therefore, their practices were hypothesized to be more similar to each other than to medical specialists’ practices. Indeed, surgeons and anesthesiologists did not differ in their probability of pursuing nonconsonented testing (P=.40).
d Physicians were dichotomized at the median practice duration of 19 years.

In this national survey, we found that more than three-quarters of US intensivists have encountered decisionally incapacitated patients for whom HIV testing was deemed clinically important. Among these intensivists, 84.2% believed that determination of HIV status was so important that they pursued testing (with or without surrogate consent) despite barriers presented by state laws, the dissuasion of colleagues and institutional administrators, and laboratory policies precluding HIV testing with-
out consent. Of the 16.0% of intensivists who chose not to pursue HIV testing despite believing it was indicated, most made such decisions based on prior recognition of these same barriers.

The results indicate that intensivists’ perceptions of their state laws and personal beliefs regarding the propriety of nonconsented HIV testing are associated with their testing decisions, but that actual state laws are not. The absence of association between actual state laws and physicians’ practices seems to be attributable to misunderstanding of state laws, rather than disregard for state laws. This conclusion is suggested by the observations that academic intensivists were no more likely than chance to identify the circumstances in which their state laws allowed HIV testing without a patient’s specific consent and that physicians’ perceptions of state laws were strongly associated with their practices.

This study also reveals that nearly two-thirds of intensivists believe they should be able to test decisionally incapacitated patients for HIV when clinically indicated without first obtaining surrogate consent. Obtaining surrogate consent for HIV testing represents a suboptimal approach for several reasons. First, appropriate surrogates may be difficult to find quickly, and many critically ill patients lack surrogates altogether. Second, because surrogates may be unable to extract their own reasons for wanting the patient to be tested from what the patient would want, they may be unable to act purely on the patient’s behalf. Finally, if we accept the many reasons for eliminating requirements for the patient’s consent to HIV testing, then there would be no need for surrogate consent.

The study’s last main finding is that when forced to manage critically ill patients without knowledge of HIV status, many intensivists attempt to circumvent barriers to HIV testing by ordering other laboratory tests thought to indicate HIV-induced immunocompromise. In addition to the ethical contentiousness of such an approach, there are important clinical problems with relying on surrogate tests. Two of the most commonly ordered surrogate markers have significant scientific limitations: absolute lymphocyte counts provide little knowledge of immune function or HIV status, and CD4 lymphocyte counts are extremely unreliable in critically ill patients. Although the ratio of CD4/CD8 T lymphocytes may be preserved in critical illness, only one-third of intensivists ordering surrogate tests ascertained this ratio. It is, therefore, troubling that most intensivists have ordered presumed surrogate tests for HIV infection when unable to obtain HIV tests and that almost all of these physicians believe such tests provide sufficient assessment of immune function to guide clinical decisions.

Reliance on surrogate testing also may lead to delays in the initiation of antiretroviral therapy. Because current recommendations for the management of critically ill patients with HIV include consideration of starting antiretroviral therapy and because initiation of such therapy requires actual HIV testing (and possibly viral load determination), testing merely for presumed surrogate markers of infection may produce substandard care.

Although our reported response rate of 44.0% is a conservative underestimate and we found no meaningful differences between responders and nonresponders to suggest nonresponse bias, we cannot exclude the possibility that unmeasured differences between these groups exist. For example, intensivists who had encountered the difficult choices of pursuing or not pursuing nonconsented HIV testing may have been more likely to respond. If so, our results may overestimate the proportion of intensivists who have encountered decisionally incapacitated patients for whom HIV testing is important. However, even if none of the nonresponding intensivists had encountered such patients, our results would suggest that more than one-third of intensivists have encountered this dilemma.

A second limitation is that we surveyed only academic intensivists. Our results, therefore, may not adequately capture the views and practices of intensivists in nonacademic settings. However, because academic intensivists are responsible for training the next generation of intensivists, their perspectives may have importance beyond their own practices.

Third, we assessed physicians’ self-reports of their behaviors, rather than their actual testing patterns. Given the confidential nature of HIV testing, it would have been difficult, if not impossible, to track physicians’ ordering of these tests and to link orders with the presence or absence of consent forms. If systematic differences between physicians’ stated and actual practices exist, the self-reports may underestimate the true proportion of intensivists who have pursued nonconsented HIV testing if some physicians were hesitant about acknowledging this potentially illegal behavior.

Finally, we assessed physicians’ testing practices, rather than patient outcomes. This design served the goals of our study—to describe national views on a contentious practice and to identify influences on physicians’ decision making. However, assessing physicians’ decisions does not enable an assessment of whether current state laws result in actual harm to patients.

In conclusion, there are at least 2 different sets of conclusions one may draw from this study’s main findings: that intensivists’ perceptions of state laws, but not the laws themselves, are associated with their decisions to pursue nonconsented HIV testing. If one believes the state laws governing consent for HIV testing are appropriate, then the findings should prompt interventions to educate physicians so that their practices better correspond to the law. Alternatively, if one does not believe these laws serve patients’ best interests, then the laws’ observed ineffectiveness reflects yet another reason to change or abolish them.

We agree with previous commentators’ that current state laws no longer serve the goals intended when these laws were enacted during an era of widespread discrimination and ineffective treatment. These laws not only limit the early identification and treatment of disease but, as our results suggest, they may also stimulate unforeseen and unfortunate outcomes, such as prompting reliance on surrogate consent to testing and surrogate markers of immunodeficiency. Because professional knowledge of varying state laws is poor, and agreement with them is low, we suggest that the optimal solution is to replace these laws with national standards based on the new Centers for Disease Control and Prevention recommendations.
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Author Contributions: Dr Halpern had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Halpern, Ward, Luce, and Curtis. Acquisition of data: Halpern, Metkus, and Luce. Analysis and interpretation of data: Halpern, Metkus, Fuchs, Ward, Siegel, Luce, and Curtis. Drafting of the manuscript: Halpern, Ward, and Luce. Critical revision of the manuscript for important intellectual content: Halpern, Metkus, Fuchs, Siegel, Luce, and Curtis. Administrative, technical, and material support: Metkus. Study supervision: Fuchs, Ward, Luce, and Curtis.

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REFERENCES


