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Title:

Consistency of State Statutes with the Centers for Disease Control & Prevention HIV Testing Recommendations for Health Care Settings

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Abstract

In September 2006, the Centers for Disease Control and Prevention released 'Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Healthcare Settings' to improve screening and diagnosis. The CDC now recommends that all patients in all healthcare settings be offered opt-out HIV screening without separate written consent and prevention counseling. State law on HIV testing is widely assumed to be a barrier to implementing the recommendations. To help policymakers and providers better understand their own legal context and to correct possible misunderstandings about statutory compatibility, we performed a state-by-state review (including District of Columbia) of all statutes pertaining to HIV testing and systematically assessed the consistency of these laws with the new recommendations. We developed criteria for classifying state statutory frameworks as consistent, neutral, or inconsistent with the new recommendations, and we examined the implications for implementation of the CDC Recommendations in these various legal contexts. We found that statutory frameworks of 35 states were either consistent with or neutral to the new CDC Recommendations, enabling full implementation. Statutory frameworks of 16 states were inconsistent with the new CDC Recommendations, precluding implementation of one or more of the novel provisions without legislative change. In the 2 years since release of the recommendations, 9 states have passed new legislation to move from inconsistent to consistent with the guidelines. Indeed, state statutory laws were evolving in only one direction: toward greater compliance with the CDC Recommendations. Policymakers, provider groups, consumer advocates, and other stakeholders should ensure that HIV screening practices comply with existing state law and work to amend inconsistent laws if interested in implementing the CDC Recommendations.

KEYWORDS: HIV; screening; statutes; recommendations; CDC.

Introduction

Timely HIV testing persists as a major public health challenge in the U.S. 300,000 of the more than 1 million persons in the U.S. who are HIV infected are unaware of their HIV seropositivity (1). This group of undiagnosed individuals tends to receive HIV testing late in the course of the disease (2) and unknowingly infects others, accounting for the majority of new HIV infections (3).

Over the last decade, CDC recommendations evolved from risk-assessment based testing to “routine voluntary counseling and testing” for all adults in all health care settings. Despite the revised guidelines, low HIV screening rates persist (4). According to providers, barriers to screening include the written informed consent process, time constraints of the patient encounter, and discomfort with discussing HIV risk behavior (5,6). Patient-level barriers include low self-perceived risk and fear of stigmatization (7). Due to such barriers, missed opportunities for earlier diagnosis of HIV infection are common (8,9).

In response to this, the CDC recommended a new paradigm for HIV testing in September 2006 – ‘opt-out’ HIV screening of all patients in all health care settings (1). In the CDC’s version of opt-out testing, the provider notifies the patient that HIV testing will be performed and offers the patient the opportunity to ask questions and to decline testing. In this paradigm, separate written consent and prevention counseling are not required for HIV testing. The target population for screening is all patients (ages 13 – 64) who present to ERs, primary care, and other healthcare settings. Expanding on 2001 recommendations for HIV testing of pregnant women (10), the 2006 recommendations specifically advocate opt-out screening, stipulating that HIV testing be included in the panel of routine prenatal screening tests. Though not without

controversy (11-14), the shift to opt-out screening is intended to expand HIV testing by destigmatizing the testing process and ameliorating provider- and patient-level barriers.

Although these recommendations represent an opportunity to increase HIV screening, the potential for state laws to enable or obstruct implementation of the recommendations is not well understood. Existing literature on laws relating to HIV testing provides a limited summary of the types of state laws that may conflict with routine HIV testing (15,16) or focuses on federal law that may have ramifications for opt-out HIV testing (17). There has been no published state-by-state analysis of whether implementation of the CDC Recommendations is consistent with state statutes. Furthermore, the literature uses an inaccurately broad understanding of opt-out testing rather than the specific CDC Recommendations for opt-out HIV screening. This has led to interpretive errors and inaccurate generalizations that state law is incompatible with implementation of the recommendations.

To offer policymakers and providers a comprehensive analysis, we performed a state-by-state review of all statutes pertaining to HIV testing and systematically assessed the compatibility of these laws with the new recommendations. We developed criteria for classifying state statutory frameworks as consistent, neutral, or inconsistent with the new recommendations, and evaluated the implications for implementation of the recommendations in these various legal contexts. We examined HIV testing statutes during the 2 years following release of the 2006 CDC Recommendations to capture new laws and legislative trends.

Methods

The 2006 CDC 'Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Healthcare Settings'¹ (CDC Recommendations) contain substantive changes to three components of the standard HIV testing process: 1) consent for testing, 2) pre-

and post-test counseling, and 3) method of offering screening to adults and pregnant women.

To enable a detailed assessment of state law consistency with the CDC Recommendations, we first recorded the key features of the Recommendations within each of these components, including the specific, CDC-provided definitions of terms such as 'opt-out screening', 'informed consent', and 'HIV-prevention counseling.'

Next, utilizing the legal search engines Lexis-Nexis and Westlaw, we systematically identified all state statutes pertaining to HIV testing in the 50 states and DC (see Appendix for search strategy). We performed a systematic survey of laws 6-, 12-, and 24-months after the September 2006 release of the Recommendations.

Following the survey, we reviewed the statutes for their relevance to each of the three testing components addressed by the CDC Recommendations. If a statute was deemed relevant, we assessed its language to determine to what extent the law permits, obstructs, or is silent on implementation of the testing component recommendation in question. We classified laws that permitted or promoted implementation as *consistent* with the testing component recommendation. We classified laws that were barriers to implementation as *inconsistent*. Laws that were silent about or neither conformed to nor conflicted with the testing component recommendation were classified as *neutral*.

To summarize a state's entire statutory framework, we developed criteria to classify it as consistent, neutral, or inconsistent with the CDC Recommendations. We classified a state statutory framework as consistent if any of its laws were consistent with either the consent, counseling, and/or prenatal provisions and it had no laws that were inconsistent with any one of these provisions. A state's statutory framework was classified as neutral if all of its laws were neutral on each of the three CDC provisions. A state's statutory framework was classified as

inconsistent if it had one or more laws that were inconsistent with one or more of the three provisions.

Results

Adult Consent for Testing

According to the Recommendations, a patient should be provided “oral or written information about the test and the opportunity to ask questions and to decline testing, and with such notification, consent for HIV screening should be incorporated into the patient’s general informed consent for medical care”. There was considerable variation in the statutory requirements for obtaining consent and in the degree to which statutes were consistent with the consent provision of the Recommendations (Table 1).

Pre- and Post-test Counseling

The Recommendations state that personalized and interactive HIV risk reduction counseling should not be required at the time of testing. Rather, such counseling should be offered to patients at high risk through referral. The Recommendations do require the provision of “pretest information”, a step considered a key component of, or sometimes entirely constitutive of, ‘pretest counseling’ by some state laws. The CDC defines “pretest information” as “oral or written information that includes an explanation of HIV infection and the meanings of positive and negative test results.” The Recommendations state that negative test results may be conveyed without direct personal contact between patient and provider and that post-test counseling is not required. For positive results, the Recommendations require communication of the result through personal contact along with efforts to ensure linkage to venues providing HIV care and counseling.

Statutory requirements for counseling are presented in Table 1.

Method of Offering Screening to Adults & Pregnant Women

The CDC defines ‘opt-out screening’ process as informing a patient orally or in writing that HIV testing will be performed unless they decline. Opt-out screening is intended for all patients, including pregnant women during prenatal care and at labor and delivery if the patient does not have a documented negative test. State consistency with these recommendations varied (Table 2).

Overall Consistency of Each State’s Statutory Framework

Consistency of each state’s statutory framework is depicted in Figure 1. In the 16 states that were inconsistent, implementation of one or more of the three new provisions of the Recommendations would not be possible without amendment of existing laws. Laws in the 20 states that were neutral neither promoted nor obstructed the 3 provisions. Among 15 states that were consistent, laws were in agreement with all 3 of the provisions in 9 states; they were in agreement with 1 or 2 of the provisions and neutral on the others in 6 states.

In the 2 years since release of the CDC Recommendations, 9 states had passed legislation moving them from the inconsistent to the consistent category and 2 other states moved from neutral to consistent. No state passed new legislation to move in a less consistent direction.

Discussion

In the national discussion about how best to perform routine HIV screening in accordance with CDC Recommendations, state law is often identified as a barrier to implementation. In this systematic review and analysis, we found that 35 states (including DC) have statutory frameworks that are consistent with or neutral to the CDC Recommendations. From a state statutory perspective, implementation of the Recommendations is permissible in these states.

Sixteen states have statutory frameworks that are inconsistent with the Recommendations and would require legislative amendment to fully implement them. The movement of 9 states from the inconsistent to consistent category indicates a trend toward enabling HIV screening in the spirit of the CDC Recommendations.

By performing a comprehensive state-specific survey of statutes pertaining to HIV testing and by analyzing the consistency of each law with new and corresponding provisions of the CDC Recommendations, to our knowledge, our findings are the first to provide policymakers and providers with information about their own legal context and to clarify the degree to which state law enables or obstructs routine HIV screening. The only other published literature on HIV testing statutes provides a general overview of how certain types of laws may impede routine HIV screening (15) or an appraisal limited to whether states require written informed consent (16). Public health students maintain a compendium of state HIV testing laws online (73) which, while useful, does not provide a consistency assessment of each state's statutory framework in relation to CDC Recommendations.

State implementation strategies for the CDC Recommendations might vary depending on the degree of statutory consistency. States with some inconsistent statutes may consider implementation of those provisions that do not have statutory barriers. State law in Alabama, for instance, requires written informed consent, but does not require counseling. Providers in Alabama may consider a routine opt-in HIV screening process that utilizes written consent but does not require counseling at the time of testing. Partial implementation of the Recommendations might still increase testing (74) and perhaps build support for amending obstructive statutes.

Apart from statutory consistency, a number of other issues must be considered before proceeding with implementation of the CDC Recommendations. State regulations, which are rules adopted by state agencies to interpret, implement, and enforce state laws (75), may also govern the HIV testing process by, for example, requiring written consent even when not called for by law. An analysis of state regulations is beyond the scope of our research, but public health officials and providers will also need to review state regulations prior to implementing the Recommendations. Similarly, judicial decisions about HIV testing should be examined.

Any opt-out screening process must adhere to the highest standards of medical ethics and human rights protections (17). Citing concerns about patient autonomy during opt-out screening and the impact of stigma and discrimination on patients diagnosed in the absence of adequate counseling, some human rights scholars and civil rights groups have expressed reservations about the new CDC Recommendations (11,13,14). They argue that, due to HIV-related stigma, the use of 'general consent', in which a patient authorizes a medical intervention without an explicit discussion about the risks and benefits of the intervention, is problematic (14).

Moreover, those who test positive must be offered effective linkage to care, requiring that care programs be adequately funded (17).

The CDC Recommendations, however, do in fact address many of the important concerns raised by critics, in some cases requiring even more protection for patients than state laws currently require. For example, the CDC does not endorse a typically understood opt-out and general consent process, as is done with other routine screening tests. Instead the Recommendations, while still using the term "opt-out screening," actually calls on providers to offer pretest information and ask patients whether they have questions and to inform them that they may decline the test. In this regard, the Recommendations may be more protective of patient autonomy than critics realize. In addition, for patients who test positive, the

Recommendations specifically require that the result be communicated confidentially through personal contact by a clinician or other skilled staff. The Recommendations also call for efforts to ensure that HIV infected patients are linked to clinical care and counseling at another provider, if not available at the screening site.

Meeting the standards for HIV screening under the CDC Recommendations first requires that providers understand the consistency of their state's HIV testing laws and regulations with these Recommendations. If implementation is permissible, providers should receive adequate information about the HIV opt-out screening and consent process, and about the importance of establishing referral mechanisms with HIV prevention and care providers. Each of these requirements is difficult to achieve and will require coordinated efforts of public health departments, provider groups, and other stakeholders.

Illustrating the challenge, the first published data on an opt-out HIV screening program based in an emergency department revealed that half of patients who tested positive did not establish care and were lost to follow-up (76). This screening program has since introduced a policy of having an infectious diseases physician see patients briefly while in the ER and arrange a clinic appointment within 24 hours. For settings without immediate access to infectious disease specialists, establishing formal collaborations with community-based HIV/AIDS organizations and clinical HIV/AIDS-care providers may be necessary to ensure linkage to care.

It is important not to lose sight of patient perspectives on and satisfaction with an opt-out HIV screening process. This is particularly important for vulnerable populations who may have limited access to healthcare services and are disproportionately at risk for HIV stigma and discrimination (77). To date, patient acceptability of opt-out HIV screening has only been examined by presentation of hypothetical scenarios through convenience sample surveying of

emergency room patients (78). Further research on patient perspectives is needed to tailor the screening process for different populations and to identify unintended consequences.

Finally, we note that the completeness of our review of statutory law depends on the efficacy of our search methodology as well as the accuracy of the legal search engines we used. It is possible that a few legislative developments were not captured. We sought to mitigate this by utilizing 2 different legal search engines and performing the systematic survey of laws at 3 different time points.

With more than a quarter million Americans unaware of their HIV positive status and 56,000 new HIV infections per year (79), it is incumbent on our health system to improve HIV screening rates. In addition to unknowingly transmitting the virus, individuals unaware of their positive status often already meet the criteria for AIDS by the time they test positive (80,81), which compromises long-term immune recovery even with appropriate antiretroviral therapy (82,83). In a national survey, 65% of respondents supported treating HIV testing like routine screening for any other disease (84). Multiple analyses indicate that HIV screening according to the CDC Recommendations are cost-effective (85-87). Misreading of the CDC Recommendations and inaccurate generalizations about state statutes should not derail implementation. Although many have voiced concern about potential statutory barriers, state statutes that govern HIV testing are in fact increasingly compatible with implementation of the CDC Recommendations.

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Table 1. State HIV testing laws pertaining to consent and counseling in healthcare settings*

Statute Element	Consistency w/ CDC Rec.	No. of States	States Identified by their Abbreviations
<i>Consent</i>			
Opt-out with general consent for medical care sufficient, if notified that HIV testing may be included	Consistent	9	AZ (18); CA (19); IL (20); LA (21); MD (22); ME (23); NH (24); NM (25); VA (26)
General consent for medical care sufficient, if notified that HIV testing may be included (opt-out not specified)	Consistent	3	IA (27); KY (28); TX (29)
Specific written consent required	Inconsistent	9	AL (30); HI (31); MA (32); MI (33); NE (34); NY (35); PA (36); RI (37); WI (38)
Specific consent required, verbal or written	Neutral	7	CT (39); DE (40); FL (41); IN (42); MT (43); OH (44); WV (45)
Specific consent required, method of consent not indicated	Neutral	4	CO (46); MO (47); OR (48); WA (49)
No statute on consent	Neutral	19	AK; AR; DC; GA; ID; KS; MN; MS; ND; NV; NJ; NC; OK; SC; SD; TN; UT; VT; WY
<i>Counseling</i>			
'Pre-test counseling' consisting of HIV pretest information required	Consistent	6	GA (50); IL (20); MD (22); NM (25); NY (35); PA (36)
'Post-test counseling' required, negative or positive result	Inconsistent	10	CT (39); DE (40); MI (33); MT (43); NH (51); NY (35); OH (44); PA (36); RI (52); WV (45)
'Pre-test counseling' required, content of counseling unspecified	Neutral	3	MI (33); MT (43); RI (37)
'Counseling' required, not specified whether pre-test or post-test	Neutral	1	WI (53)
Option to receive pre-test and/or post-test counseling must be provided	Neutral	1	HI (31)
No statute on counseling	Neutral	35	AL; AK; AZ; AR; CA; CO; DC; FL; ID; IN; IA; KS; KY; LA; ME; MA; MN; MO; MS; NE; NV; NJ; NC; ND; OK; OR; SC; SD; TN; TX; UT; VA; VT; WA; WY

*As of November 1, 2008.

Table 2. State HIV testing laws pertaining to screening and consent for pregnant women in healthcare settings*

Statute Element	Consistency w/ CDC Rec.	No. of States	States (identified by their abbreviations)
<i>Opt-out screening</i>			
Opt-out with general consent for medical care sufficient, if notified that HIV testing may be included	Consistent	14	AR (54); CA (55); FL (56); GA (57); IA (58); IL (59); LA (60); MD (61); NJ (62); NM (25); RI (63); TN (64); TX (65); VA (66)
Opt-out with specific consent required, method of consent not indicated	Neutral	2	MI (67); OR (68)
Opt-out with specific consent required, verbal or written	Neutral	1	CT (69)
Opt-out with specific written consent required	Inconsistent	1	IN (70)
<i>Opt-in screening</i>			
Opt-in with specific consent required, method of consent not indicated	Inconsistent	1	DE (71)
<i>Timing of screening</i>			
Prenatal and labor and delivery specified	Consistent	13	AR (54); CA (55); CT (69); FL (56); GA (57); IL (59); IN (72); LA (60); MD (61); MI (67); OR (68); TN (64); TX (65)
Prenatal only, labor and delivery not specified	Neutral	6	DE (71); IA (58); NJ (62); NM (25); RI (63); VA (66)
<i>No statute on screening of pregnant women</i>	Neutral	32	AL; AK; AZ; CO; DC; HI; ID; KS; KY; ME; MA; MN; MS; MO; MT; NE; NV; NH; NY; NC, ND, OH, OK; PA; SC; SD; UT; VT; WA; WV; WI; WY

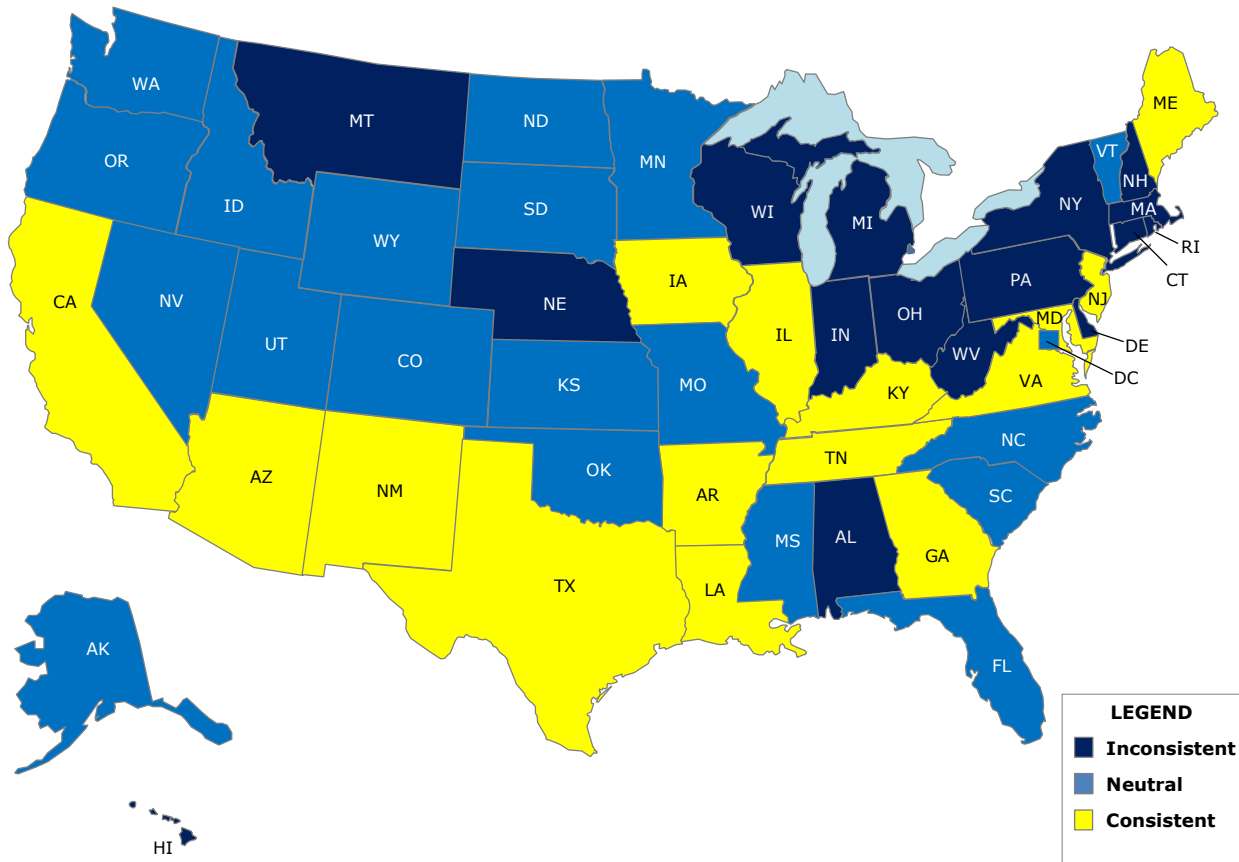
*As of November 1, 2008.

Figure 1. Consistency of state statutory frameworks with the CDC's Revised Recommendations for HIV Testing in Health Care Settings*

Inconsistent: 16 states (at least one law is a barrier to implementation)

Neutral: 20 states (laws are silent on or do not conform or contradict each of the provisions of the CDC Recommendations)

Consistent: 15 states (laws are consistent with one more provisions of the CDC Recommendations and no law is a barrier)



*As of November 1, 2008

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Appendix

Methodology of Identifying State Statutes Pertaining to HIV Screening

We used the legal research search engines of Lexis-Nexis and Westlaw to systematically identify all state statutes pertaining to HIV testing in each of the 50 states and the District of Columbia (DC). To ensure a comprehensive search, we utilized a set of search terms that would capture a wide range of laws that may pertain to HIV testing in healthcare settings.

Selecting 1 state at a time, we searched the state's entire set of statutes using each of the following search terms: "HIV testing", "HIV" and "test", "HIV" and "consent", "HIV" and "counseling", "HIV" and "pretest", "HIV" and "results", "HIV" and "prenatal", "HIV" and "pregnant", "test" and "pregnant", and "test" and "prenatal". If no laws were identified, "HIV" was replaced with "human immunodeficiency virus" or "acquired immunodeficiency deficiency syndrome" in the aforementioned search strings. Next, from the entire set of potentially relevant HIV testing statutes identified, we excluded those statutes that specifically related to HIV testing in community-based settings, in department of health funded voluntary counseling and testing programs, for insurance related matters, among incarcerated populations, among sex offenders, and for healthcare workers with potential occupational exposure. This methodology of identifying HIV testing statutes was utilized in both Lexis-Nexis and Westlaw and was repeated at the following 3 time points: April – May 2007, October – November 2007, and September – October 2008.