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Current Strategies for Managing Providers Infected with Bloodborne Pathogens

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Abstract

Background—In 1991 CDC issued guidelines to reduce risks for provider-to-patient transmission of bloodborne pathogens. These guidelines, unchanged since 1991, recommend management strategies for hepatitis B ‘e’ antigen-positive providers and for providers infected with human immunodeficiency virus (HIV); they do not address hepatitis-C-virus (HCV)-infected providers.

Objective—We summarize current state practices and surveyed state health departments to determine: 1) if state policies have been modified since 1991; 2), if state laws require prospective notification of patients and/or expert review panels to manage infected providers; 3) the frequency with which infected-providers issues come to the attention of state health departments; and 4) how state health departments intervene.

Methods—We reviewed all 50 states’ laws and guidelines to determine current practices and conducted a structured telephone survey of all state health departments.

Results—Whereas only 19 states require infected providers to notify patients of the providers’ bloodborne pathogen infection, these 19 states require notification under highly varied circumstances. Only ten of 50 state health department officials identified these issues as requiring significant departmental effort. No state law or guideline incorporates information about providers’ viral burdens as part of the risk assessment. Only 3/50 States have modified policies or laws since initial passage; and only 1/50 discusses the management of HCV-infected providers..

Conclusions—These results identify a need for incorporating contemporary scientific information into guidelines and also suggest that infected-provider issues are not occurring commonly, are not being detected, or that they are being managed at levels below the state health department.

INTRODUCTION

The optimal management of health care providers infected with bloodborne pathogens has long been the focus of controversy. Whereas the risk for provider to patient transmission of hepatitis B virus has long been recognized (1–8), and provider-to-patient transmission of

hepatitis C virus (HCV) has been an increasing concern over the past fifteen years (9–21), public interest in provider-to-patient transmission of bloodborne pathogens was galvanized by the occurrence of a cluster of HIV infection in the practice of a dentist in Florida in 1990 (22–27). The Florida cases dramatically increased both public and political interest in this issue (22), resulting ultimately in the 1991 publication of CDC guidelines, entitled, “Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures” (28). These guidelines asked as many questions as they answered and left many questions unresolved. These guidelines have not been updated since their initial publication (28).

The pivotal recommendation in these guidelines stated that, “healthcare workers who are infected with HIV or HBV and are “e” antigen positive should not perform exposure-prone procedures unless they have sought the counsel of an expert review panel and have been advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include notifying prospective patients of the healthcare worker’s seropositivity before they undergo exposure-prone invasive procedures” (28). This recommendation was controversial at the time and remains so to date. In addition, from an implementation perspective, the guidelines were equally as challenging. The guidelines assumed that a subset of invasive procedures could be classified as “exposure-prone,” a task that was initially daunting. Secondly, the guidelines required that an infected practitioner notify prospective patients of her/his infection status, an intervention that did not seem justified based on the estimated magnitude of risk. Third, the guidelines recommended the formation of an Expert Review Panel, a process that is fraught with legal and administrative implementation barriers. These guidelines were not uniformly embraced by the clinical community; some medical economists suggested that the resultant financial burden for physicians would be exorbitant (29); and many clinicians doubted the scientific rationale for the recommendations (29). The guidelines were found to be confusing and difficult to implement. To address the confusion over what would constitute an “exposure-prone invasive procedure”, shortly after publication of the guidelines in the early 1990’s CDC convened a working group to develop a list of such procedures, with the help of professional medical associations and professional societies, but no consensus was ever reached.

To compel states to act upon these guidelines, Congress passed Public Law 102-141 in 1991, mandating that states adopt these “CDC guidelines or their equivalent.” In 1992, the CDC Director, in a letter to health departments, noted that the states, not CDC, would certify equivalency and further stated that “...exposure-prone procedures are best determined on a case-by-case basis, taking into consideration the specific procedure, as well as the skill, technique, and possible impairment of the infected healthcare worker.” As a result, substantial variability exists among state guidelines, and the roles and compositions of the expert review panels are inconsistent among varied jurisdictions.

Despite the accumulation of nearly 20 years’ worth of new scientific knowledge about the epidemiology and pathogenesis of infection caused by these agents, despite substantial clinical experience with these agents in the healthcare setting over the past two decades, and despite substantial modifications of guidelines in other developed countries, the CDC guidelines have never been modified. We were interested in trying to determine how states

were managing these problems in 2010. We conducted a telephone survey of state health department experts, to determine if state policies have been modified since 1991 to incorporate new scientific information; second, to determine if state laws require prospective notification of patients and expert review panels to assist with the management of infected providers; third, to assess the frequency with which issues relating to infected providers come to the attention of the state health departments; and fourth, in instances in which these issues do surface at the state health department level, how often do they require departmental action, and how do the state health departments intervene.

METHODS

One of us (ST) contacted all 50 US state health departments by telephone, initially to identify the most knowledgeable health department staff from whom to obtain information about the management of providers infected with bloodborne pathogens and then subsequently to conduct the structured survey interview to obtain state-specific information from those individuals. Individuals interviewed self-reported their standing to respond to the interview. All interviews were conducted over the telephone by the same interviewer to reduce risk of inter-observer variability and were structured to provide consistency. Each respondent was assured that data provided would be used only in aggregate, and that the specific names or states of the respondents would not be disclosed. In addition, we reviewed The Center for HIV Law and Policy's electronic resource that details current state laws and guidelines for all 50 states (30) to confirm interview findings and to answer remaining legal questions.

In interviewing state health department officials, we used a brief, focused, structured, standardized questionnaire that included questions about: 1) the individual's familiarity with her/his state's law and guidelines; 2) whether or not the guidelines had been modified since the statute was initially passed; 3) respondents' awareness of any time in the last 5 years that the state policy was used to manage an infected provider situation; 4) in identified instances in which state health departments were engaged on the issue of infected providers, the extent to which existing state statutes and guidelines were followed in the management of the providers; and 5) whether the state health department had encountered any challenges or problems with their state's laws or guidelines? We also provided respondents with an opportunity for open ended, spontaneous comments about these issues.

We also evaluated whether we could identify a relationship between the state rank in terms of the cumulative number of AIDS cases reported in the preceding year and whether a state has had to address this issue in the last 5 years, using data from the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention State Profiles (31).

RESULTS

The job category of the respondents identified by state health department personnel as being most knowledgeable about providers infected with bloodborne pathogens is presented in Table 1. The most common job category was state epidemiologists (46%).

Although the overwhelming majority (82%) of these state experts were knowledgeable about the issue of healthcare workers infected with bloodborne pathogens, the risk of transmission of provider's infections to their patients, and their state guidelines concerning how to manage such an event, surprisingly, nearly 20% were not.

Most states incorporated the CDC guideline recommendation that expert review panels be convened to address the problem of infected health care providers into their state laws or guidelines; 84% of state policies mention the creation of an expert panel or committee as a means of managing infected healthcare workers, while 16% do not. The requirement that the infected healthcare worker should inform her or his patient of the provider's bloodborne pathogen infection status prior to treating the patient, (i.e., the issue of prospective notification), is not addressed in nine states' guidelines (18%). Although an additional 22 states' policies (44%) mention the possibility of retrospective notification, they either do not mention prospective notification or dismiss it entirely. The 19 states (38%) that have laws or guidelines that require infected healthcare workers to notify their patients of their bloodborne pathogen status require such notification under highly varied circumstances. For example, one state requires uniform prospective notification of all patients, with no distinction about the type of care that will be provided to the patient; another state requires that once healthcare workers have been shown to have transmitted their bloodborne infection to patient(s), they must disclose their infection status to future patients; and three states require prospective notification if the infected practitioner will be performing an exposure-prone procedure on the patient. An additional 14 states (28%) leave the possibility of prospective notification to the discretion of their expert review panel, expert advisory committee or state officials, on a case-by-case basis (30).

Respondents from only three states (6%) reported that their state has modified its initial state policies to incorporate new scientific information. Specifically, only one state had revised its policies to include hepatitis C as a bloodborne pathogen of interest with respect to this issue. In addition, no state has incorporated the healthcare providers' circulating viral burden as a means of assessing potential patient risks associated with their infections.

The majority of state health departments (32 states, 64%) have not addressed this issue in the past 5 years (Table 2). Only eighteen (36%) of state health departments reported having to engage on a case involving an infected provider in the past 5 years, and, of those, only nine applied their state laws or enforced their guidelines in dealing with an infected provider scenario. Interestingly, of the 32 state health departments that had not had to address a case involving an infected provider in the prior 5 years, respondents from only five noted that they would enforce existing state policies, should the issue ever reach them in the future. We could identify no apparent association between state rank in cumulative number of AIDS cases reported in 2008 and whether an individual state health department had to address this issue over the last 5 years (Wilcoxon/Kruskal-Wallis, $p = 0.74$).

In the open comment section of the interview, respondents most often spontaneously commented that the issue of health care workers infected with bloodborne pathogens is generally managed at the hospital or facility level and not by their state health department (38%). Some respondents (10%) commented in this segment of the interview that they

believed that current CDC/US Public Health Service guidelines increase stigma and hysteria, and are far too conservative. Another 10% opined that standard or universal precautions should suffice in the management of this population. To help explain why this issue may not arise at the state level very often, 6% considered departmental bureaucracy or the structure of state and local governments to be partly to blame, and only 4% criticized the lack of resources.

DISCUSSION

Substantial progress has been made with respect to our understanding of the risks for transmission of these bloodborne pathogens since the initial guidelines were issued in 1991. Our continued experience for the past twenty years demonstrates infrequent provider-to-patient transmission of HBV, rare HCV transmission and extremely rare instances of provider-to-patient HIV transmission (32). In addition, with respect to hepatitis B infection, 'e' antigen has been demonstrated to be unreliable as a marker for infectivity, as a direct result of the identification of the so-called 'pre-core' mutants of HBV that are genetically incapable of producing 'e' antigen. Several instances of provider-to-patient HBV transmission have been linked to providers who were infected with 'pre-core' mutants (6, 33). Thus, newly developed molecular tests that directly measure patients' circulating viral burdens with precision have effectively replaced 'e' antigen as surrogate markers for HBV infectivity. In addition, antiviral therapy for chronic HBV infection has become available since the guidelines were published. Anti-HBV treatment regimens have been developed that, in many instances, are capable of substantially reducing patients' HBV viral burdens and producing durable remissions, if not cures. To date, more than half a dozen agents have been approved for the treatment of chronic hepatitis B in the United States, with more under evaluation. With respect to hepatitis C, the past two decades have also witnessed the development of molecular diagnostic studies that accurately measure the circulating viral burdens of patients infected with HCV. In addition, as was the case for HBV, new therapeutic options have been developed for patients with either acute or chronic HCV infection (34–37), with even more exciting therapeutic options on the immediate horizon. Of particular significance are several studies that demonstrate that acute HCV infection can be treated with virtually 100% success (38–41). With respect to HIV, molecular tests have also been developed that accurately measure patients' circulating viral burdens, and the past two decades have witnessed the development of highly active antiretroviral therapy that can, in many instances, virtually suppress HIV replication. Thus, the past two decades have witnessed the continued definition of the epidemiology, pathogenesis, as well as novel approaches to the effective treatment of these three bloodborne pathogen infections. These data provide more clarity for the modification and fine-tuning of existing guidelines for managing providers with these infections.

Most existing state guidelines do not incorporate current relevant scientific information; most guidelines and regulations do not address hepatitis C as a pathogen of interest with respect to infected providers; and no guidelines yet advocate the use of providers' circulating viral burdens to assist with the risk assessment. Given the significant increase in knowledge about bloodborne pathogens, over the past twenty years [summarized in detail in

reference (42)], the fact that 47 of the 50 state guidelines have not been modified is discouraging.

Since only 18 states reported having had to deal with this issue in the last five years, problems with infected providers are either are not occurring commonly, not being detected, or are being managed below the level of state health departments. Although all 50 states have specific laws or guidelines addressing how to manage infected healthcare providers, health departments may not have been called upon to assist with the management of situations involving this issue. In addition, even in instances in which health departments were called on to intervene, fully half the time, the state guidelines or policies were not followed. [Table 2]

Whereas the US guidelines have not been modified since they were initially issued in 1991, other countries have published updated guidelines, and several manuscripts have been published that argue differing points of view about this complex issue (34, 43–53). The UK has revised its HBV guidelines based on the availability of molecular testing. HBV-infected providers who are ‘e’-antigen positive may not conduct exposure-prone invasive procedures and those who are ‘e’ - antigen negative, but have HBV DNA levels >1000 genome equivalents/mL also may not conduct exposure-prone invasive procedures. If an HBV-infected provider is ‘e’-antigen negative, and has HBV DNA levels <1000 genome equivalents/mL he/she may conduct exposure-prone invasive procedures, so long as the practitioner is retested at least every 12 months and remains below the threshold (45, 47, 48). A European consortium reached a different conclusion concerning HBV-infected providers, and recommended that: HBV-infected providers who are ‘e’ antigen positive, should not perform exposure-prone procedures, that HBV-infected providers who are ‘e’ - antigen negative, but have HBV DNA levels <10,000 genome equivalents/mL may conduct exposure-prone invasive procedures, but must be retested at least annually and maintain their respective viral burdens below that threshold, and that healthcare workers who have been shown to transmit HBV should not perform exposure-prone procedures (50). A group from the Netherlands recommended an even higher cutoff for HBV-infected providers, suggesting that HBV-infected providers who have HBV DNA levels <100,000 genome equivalents/mL be allowed to conduct exposure-prone invasive procedures, so long as they are retested at least annually and remain below that viral burden threshold (53).

In the UK, providers who have circulating HCV RNA may not conduct exposure-prone invasive procedures and trainees found to have circulating HCV RNA are restricted from starting training in exposure-prone invasive procedures (34, 48, 51). The European consortium could not reach consensus about HCV-infected providers and concluded, ““on balance it is not recommended that exposure-prone procedures be forbidden for HCV-infected healthcare workers” (50).

In the UK, HIV-infected providers may not conduct exposure-prone invasive procedures (46). Neither the European consensus group, nor the group from the Netherlands commented about HIV-infected providers.

Since only 18 states report that they have had to deal with this issue in the last 5 years, we conclude that issues relating to infected providers are not occurring commonly, are not being detected, or are being managed at levels below state health departments. In fact, as noted above, during the open comment section of our structured interview, more than 35% of state health department personnel commented that they believed that these problems were being managed at the institutional level.

Our study has several limitations. We may not have been able to identify the most knowledgeable state health department personnel for interview, although nearly half the time the state epidemiologist was the individual interviewed. Because the interviews were conducted over the telephone, the interviewer could not assess non-verbal communication cues. We did review the superb Center for HIV Law and Policy database (<http://www.hivlawandpolicy.org/resources/view/167>) for each of the 50 states to confirm our findings. In addition, the most knowledgeable individuals in the state may not have been included in the study, since 38% of interviewees spontaneously suggested that these problems were managed at the local or institutional level. Thus, despite the fact that the authority is placed at the level of the state, the problem may well be most commonly managed at the local level. Perhaps a logical next step in our inquiry should be focused at the institutional level. Finally, we cannot assure that these interviews actually mirror practices in each of the states – only that these results accurately depict what the interviewees reported as occurring.

Issues relating to the management of healthcare providers infected with bloodborne pathogens remain controversial for several complex reasons. First, American public opinion has consistently focused on achieving ‘zero-risk’ for provider-to-patient transmission of bloodborne pathogens, and despite the fact that risks for transmission are so small as to be currently unmeasurable, public sentiment still favors excluding infected providers from patient care (54). Second, whereas most guidelines have focused on practice restrictions for infected providers who conduct ‘exposure-prone’ procedures, a panel of experts convened by CDC was unable to come to consensus about which invasive procedures are exposure-prone, at least in part because of the substantial variability from provider to provider. Reitsma and colleagues from the University of Virginia provided a thoughtful detailed analysis of this latter issue (52). More recently The Society for Healthcare Epidemiology of America (SHEA) has provided a set of guidelines that include a similarly detailed, but significantly modified set of recommendations that draw heavily on the structure of the Table in the Reitsma paper (42). The main tenets of the SHEA recommendations are summarized in Table 3.

Policies regarding the management of providers infected with bloodborne pathogens are woefully out of date and vary substantially. Our results suggest a need for either state policy revisions (presumably with an eye toward harmonization and consistency) or for the development of a cogent national policy. In either event such policies must incorporate the clinical experience of the past two decades as well as what we have learned about the epidemiology, pathogenesis, and diagnosis of the relevant bloodborne pathogen infections since the previous guidelines were developed. The recently published SHEA guidelines offer a framework for the establishment of coherent regulations and policies.

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Table 1

Summary of survey results - 1

Respondents Identified as Most Knowledgeable	n	%
State Epidemiologist	23	46%
HIV/hepatitis branch chief/director	12	24%
HIV/hepatitis program coordinator	7	14%
HIV/hepatitis program manager	5	10%
HIV/hepatitis epidemiologist/specialist	3	6%
States Using Expert Review Panels	n	%
	42	84%
States Requiring Prospective Notification	n	%
	19	38%
States Modifying Policy Since Initially Enacted	n	%
	3	6%

Table 2

Enforcement of State Laws or Guidelines

	Did (or would) the State Enforce Existing Laws or Guidelines			
		YES	NO	TOTAL
Issue has arisen in last 5 years	YES	9	9	18 (36%)
	NO	5	27	32 (64%)
	TOTAL	14 (28%)	36 (72%)	50 (100%)

Table 3

SHEA recommendations for managing providers infected with bloodborne pathogens* (42) (Reprinted with Permission)

Virus	Circulating Viral Burden	Clinical Activities**	Recommendation	Testing
HBV	< 10 ⁴	Categories 1, 2 and 3	No Restrictions***	Twice Annually
	10 ⁴	Categories 1, 2	No Restrictions***	N/A
	10 ⁴	Category 3	Restricted#	N/A
HCV	< 10 ⁴	Categories 1, 2 and 3	No Restrictions***	Twice Annually
	10 ⁴	Categories 1, 2	No Restrictions***	N/A
	10 ⁴	Category 3	Restricted#	N/A
HIV	< 5 X 10 ²	Categories 1, 2 and 3	No Restrictions	Twice Annually
	5 X 10 ²	Categories 1, 2	No Restrictions	N/A
	5 X 10 ²	Category 3	Restricted##	N/A

* These recommendations provide a framework within which to consider such cases; however, each such case is sufficiently complex that each should be independently considered in context by the expert review panel (see text)

** See Reference 42 for characterization of clinical activities

*** No restrictions recommended, so long as provider is not detected as having transmitted infection to patients; obtains advice from an Expert Review Panel about continued practice; is followed routinely by Occupational Medicine, who tests the provider twice annually to demonstrate the maintenance of a viral burden of less than the recommended threshold (see text) as well as by a personal physician who has expertise in the management of her/his infection who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloves and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [e.g., placing sternal wires]) agrees to the information in, and signs, a contract or letter from the Expert Review Panel that characterizes her/his responsibilities.

These procedures permissible only when viral burden is < 10⁴

These procedures permissible only when viral burden is < 5 X 10²