



What Is the Moral Responsibility of Health Care Providers to Report HBV or HCV Status if They Perform Invasive Procedures?

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Performing certain invasive procedures, sometimes referred to as “exposure-prone procedures” poses a risk of transmission of blood-borne infections, although the risk across procedures is not equal (Table 1). While there has been much focus on patient-to-provider and patient-to-patient transmission of blood-borne infections, provider-to-patient transmission has also received attention. When a provider has known hepatitis B (HBV) or hepatitis C (HCV) viral infections, what is the provider’s moral responsibility to report his or her infected status if they perform invasive procedures? To whom should they report their infection? Do providers infected with HBV or HCV have a duty to disclose their infected status to their patients prior to any invasive procedures?

Risk of Viral Transmission From Provider to Patient

In 1991, the Centers for Disease Control and Prevention (CDC), acting in response to concerns over the possibility of hepatitis B transmission from providers to patients, issued guidelines for the management of HBV infection in health care providers and students.¹ Among these recommendations were requirements that infected health care providers should know their HBV disease status (namely their surface antigen [HBsAg] and e antigen [HBeAg] status), that providers with HBeAg-positive HBV notify and be guided by a clinical practice expert review panel at their local institution, and that HBV-infected providers who performed exposure-prone procedures should be required to disclose their status to patients prior to performing any procedure.¹ There were no specific recommendations made regarding HCV-positive providers, because data was too limited at that time. The first documented US cases of provider-to-patient HBV and HCV infection were reported in the mid-1990s.^{2,3} Since that time, there have been a total of approximately 500 documented cases of provider-to-patient transmission of HBV worldwide and

approximately 400 documented cases of HCV.⁴ It is worth noting that 275 of these cases were linked to a single Spanish anesthesiology provider, where injection drug use, drug diversion, and reinjection of patients after use of intravenous needles by the provider was suspected.

In 2012, the CDC issued new guidance regarding the management of HBV-infected providers, though again, they offered no guidance for HCV-infected providers.⁵ These and other guidelines note that there is a clear professional and ethical duty for providers who perform exposure-prone procedures to know their HBV, HCV, and HIV status.^{3,5} For providers known to be infected with these viruses *and* who perform exposure-prone procedures, a multidisciplinary expert panel should provide oversight of the infected provider’s practice (Table 3).^{3,5} Additional guidelines published over the years have provided similar guidance, but, in the most recent guidelines, the CDC reversed its policy on routine mandatory disclosure, citing the low risk of infection and possibility of harm to both providers and patients.

Right to Privacy Versus Patient Safety

With respect to the ethical responsibility of a provider to routinely disclose infected status to patients, there are several competing ethical principles at stake: the provider’s right to privacy and freedom from unjust discrimination due to their medical condition and the patient’s right to be protected from harm and to make an informed decision regarding medical procedures. From the provider’s perspective, routine mandatory disclosure to patients represents a breach of confidentiality that can functionally result in a restriction of practice, loss of privacy, and discrimination, even if risk of transmission is extremely low. Multiple medical societies both in the United States and internationally have *not* required mandatory disclosure because the risk to the patient is so low, even with exposure-prone procedures, that it does not outweigh the

Abbreviations: CDC, US Centers for Disease Control and Prevention; HBV, hepatitis B virus; HCV, hepatitis C virus.

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TABLE 1 Categories of Procedures According to Level of Risk for Provider-to-Patient Bloodborne Pathogen Transmission

Category	Examples of Procedures* [†]
Minimal to no risk	<ul style="list-style-type: none"> • Routine history and physical examination • Routine dental exam, including gloved oral exam with mirror and/or tongue depressor or probe • Routine rectal or vaginal exam with gloved hand • Minor suturing • Lower gastrointestinal tract procedures (ie, colonoscopy and sigmoidoscopy)
Theoretical risk but unlikely	<ul style="list-style-type: none"> • Elective peripheral phlebotomy • Upper gastrointestinal endoscopic procedures • Bronchoscopy • Minor local procedures (eg, abscess drainage, biopsy) under local anesthesia when provider's hands remain outside a body cavity • Central vein and arterial line insertion, maintenance, and drug administration • Laparoscopic and thoracoscopic procedures • Endotracheal intubation
Definite risk; "Exposure-prone procedures"	<ul style="list-style-type: none"> • Most forms of major surgery, including general, orthopedic, neurosurgery, oral surgery, cardiothoracic • Obstetrical and gynecologic surgery, including cesarean section, vaginal deliveries, forceps delivery, episiotomy and any procedure involving hand-guided sharps • Transplant surgery (except skin and corneal transplantation) • Any procedure where there is digital palpation of needle tip in a body cavity or where provider's fingers and needle, sharp instrument, or object (eg, bone fragment) are in poorly visualized or confined anatomic spaces • Interactions with violent or seizing patients where the risk of patient biting a provider is high

Adapted from Henderson et al³ and Centers for Disease Control and Prevention Guidelines.⁵

*This list is not exhaustive. For the complete list, see Henderson et al³ and Centers for Disease Control and Prevention.⁵

[†]All procedures and physical examinations listed assume proper Standard Precautions are utilized, including use of gloves where appropriate.

TABLE 2 Comparison of Recommendations for Management of Health Care Providers With HBV and HCV Infection Who Perform Exposure-Prone Procedures

Requirements*	CDC (2012) ⁵	SHEA (2010) ³	Europe (2003) ¹⁰
HBV Monitoring			
HBe Ag	Not required to be negative	Not required to be negative	Required to be negative
HBV DNA	<1000 IU/mL	<~2000 IU/mL	<~2000 IU/mL
Frequency	<ul style="list-style-type: none"> • Providers with HBV DNA at or below cutoff without treatment: every 6 months • Patients on treatment may require more frequent monitoring 	<ul style="list-style-type: none"> • Providers with HBV DNA at or below cutoff without treatment: every 6 months • Patients on treatment may require more frequent monitoring 	<ul style="list-style-type: none"> • HbeAg-positive or treated providers with HBV DNA below cutoff: every 3 months[†] • Providers with HBV DNA at or below cutoff without treatment: annual testing
Mandatory Disclosure Requirements			
To patients	No [‡]	No	No
To expert panel	Yes	Yes	Yes
HCV Monitoring			
HCV RNA	NA	<~2000 IU/mL [§]	-
Frequency	NA	every 6 months	-
Disclosure requirements			
To patients	NA	No	No ^{††}
To expert panel	NA	Yes [§]	No ^{††}

*Requirements for performing exposure-prone procedures without restrictions.

[†]For providers on treatment, monitoring may be more frequent.

[‡]Exceptions include providers who have had prior transmission of viral infection to patients and instances where a blood exposure has or is suspected to have occurred. In this latter instance, all guidelines recommend notifying the patient.

[§]All providers with positive HCV levels should report to their expert review panel and be guided by panel recommendations regarding ability to perform of exposure-prone procedures, frequency of monitoring, and use of infection-control interventions.

^{††}Recommendations not made based on lack of evidence.

Abbreviations: CDC, Centers for Disease Control and Prevention; SHEA, Society for Healthcare Epidemiology of America.

provider's right to confidentiality (Table 2). This is particularly true given Health System that mandatory disclosure would likely result in limitation of practice, if not outright loss of all health care practice.^{3,4}

Patients, however, perceive that a right to know such risks is important. Surveys have shown that a large majority

(>80%) of patients want to know when their health care providers are infected with bloodborne viruses and that a substantial percentage (~34%) believe that infected providers should not practice at all.⁶ However, the patient's perceived risk of infection may not match the actual risk. The institution of Standard Precautions, routine double-

**TABLE 3** Guidance for Responsibilities of Institutional Expert Review Panels

Only infected providers who perform exposure-prone procedures (see Table 1) should have panel oversight. Providers who do not perform exposure-prone procedures should be managed as a personal health care issue

Expert review panels should evaluate infected providers':

- Clinical and viral burden status
- Practices, procedures, techniques, and experience
- Adherence to recommended procedural technique

Expert review panels should also:

- Provide oversight of infected provider's continued practice, recommendations, and counseling as needed
- Investigate and notify appropriate persons and authorities (such as medical licensing boards or risk management) in the event of a patient exposure or suspected or documented breach in procedure
- Reinforce Standard Precautions
- Provide noncoercive counseling regarding alternate procedure or specialty paths
- Develop a written contract with the provider, detailing provider and panel responsibilities*

Composition of the panel should be multidisciplinary and could include, but is not limited to, members from the following:

- Persons with expertise in the provider's specialty
- Liver disease specialist
- Infectious disease specialist
- Infected provider's primary care physician
- Human resource personnel
- Occupational health
- Ethicists
- Hospital administrators/hospital director
- Hospital clinical affairs/risk management personnel

A protocol should be in place to communicate to patients when a provider-to-patient exposure has or may have occurred.

Patients with possible or confirmed exposures should be offered appropriate follow-up including postexposure vaccination and treatment (ie, hepatitis B immune globulin and follow-up testing for HBV exposure)

Confidentiality of the infected provider should always be respected, as with any patient

Compiled from Henderson et al.³ and Centers for Disease Control and Prevention.⁵ In cases where a provider is not based in a single institution, city, county, or state-level panels should be created. A minimum of two yearly meetings, either face-to-face or via conference call, is suggested, but meetings could be called more frequently as need requires.³

*A sample contract and description of contract elements can be found in Henderson et al.³ Because state law differs in what aspects of the contract are required, panels should consult with relevant legal experts.

gloving during invasive procedures, widespread hepatitis B vaccination, attention to infection control guidelines, and more effective treatments for both HBV and HCV have all worked together to decrease the already low risk of provider-to-patient transmission.⁷ In fact, there has been only one reported instance of HBV infection from provider to patient in the United States since 1996 and no cases of HCV transmission in the United States from exposure-prone procedures since 2001.^{4,5,8,9} The most recent HBV case occurred in 2009 and involved an HBV-infected surgeon who had been previously vaccinated but had, unbeknownst to the surgeon, not achieved sufficient levels of HBsAb to warrant protection from infection.⁸ There have been several reports of provider-to-patient HCV transmission in the United States since 2000, but these have been found to be

largely due to drug diversion in providers with opioid addiction.⁹

Because of this extremely low risk of transmission, guidelines now advocate against routine mandatory disclosure of infected status to patients, arguing that this is an unethical and unnecessary breach of the provider's right to privacy. In addition, mandatory disclosure may be harmful to patients as well as providers because it could lead to a reluctance to be tested for viral infection and to be guided by an expert panel for oversight of practice. Mandatory disclosure could also lead to an unnecessary limitation in access to medical care due to overzealous restrictions in practice.⁵ In other areas of medical practice where providers are or have been impaired (such as medical, psychiatric, or substance abuse issues), mandatory disclosure is not required and practice is not restricted, provided the health care worker is under treatment for the condition and does not pose a risk to patient safety. In a similar manner, infected providers with viral loads above recommended levels (Table 2) can and should be treated to reduce the viral load to lower levels, *before* the provider performs exposure-prone procedures. In addition, patients who are infected with HBV or HCV are not required to disclose this to providers and, even in the case of a patient-to-provider bloodborne infection exposure, can decline to be tested for viral infections. To impose mandatory patient disclosure requirements on HBV- or HCV-infected providers would be a double standard that is difficult to justify in the face of existing evidence.

There are exceptions to nondisclosure to patients, however; in cases where there has been documented transmission from an infected provider to a patient or when a provider with a viral load above recommended levels (Table 2) will be performing an exposure-prone procedure, informed consent should be provided prior to the procedure.^{3,5} When an infected provider has exposed a patient to a bloodborne infection, patients should be notified that the exposure has occurred and offered appropriate follow-up, treatment, and counseling, in a similar manner as when exposure from an infected patient to a provider or from one infected patient to another patient occurs. In these cases, the provider's confidentiality should be maintained as much as possible.

Conclusions

To protect patients, providers have a moral and professional obligation to follow Standard Precautions (formerly known as universal precautions), including double-gloving for exposure-prone procedures, knowing their infection status with respect to HBV, HCV, and HIV, and obtaining hepatitis B vaccination. For those providers known to be infected who perform exposure-prone procedures, their status should be disclosed to an expert review panel to help determine if and when scope of



practice should be restricted based on their viral load status (Table 3). For infected providers whose viral loads are above recommended levels, antiviral therapy can be used to reduce viral loads before a provider performs exposure-prone procedures. Mandatory routine disclosure to patients, however, should not be required because the risk of infection is too low to warrant overriding provider confidentiality. ■

References

1. Centers for Disease Control and Prevention. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. *MMWR Morb Mortal Wkly Rep* 1991;40(no. RR-8).
2. Harpaz R, Seidlein Von L, Averhoff FM, Tormey MP, Sinha SD, Kotsopoulou K, et al. Transmission of hepatitis B virus to multiple patients from a surgeon without evidence of inadequate infection control. *N Engl J Med* 1996;334:549-554.
3. Henderson DK, Dembry L, Fishman NO, Grady C, Lundstrom T, Palmore TN, et al. SHEA guideline for management of healthcare workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol* 2010;31:203-232.
4. Carlson AL, Perl TM. Health care workers as source of hepatitis B and C virus transmission. *Clin Liver Dis* 2010;14:153-168.
5. Centers for Disease Control and Prevention. Updated CDC recommendations for the management of hepatitis B virus-infected health-care providers and students. *MMWR Morb Mortal Wkly Rep*. 2012;61(no. RR-3):1-12.
6. Tuboku-Metzger J, Chiarello L, Sinkowitz-Cochran RL, Casano-Dickerson A, Cardo D. Public attitudes and opinions toward physicians and dentists infected with bloodborne viruses: results of a national survey. *Am J Infect Control* 2005;33:299-303.
7. Michelin A, Henderson DK. Infection control guidelines for prevention of health care-associated transmission of hepatitis B and C viruses. *Clin Liver Dis* 2010;14:119-136.
8. Enfield KB, Sharapov U, Hall KK, Leiner J, Berg CL, Xia G-L, et al. Transmission of hepatitis B virus from an orthopedic surgeon with a high viral load. *Clin Infect Dis* 2013;56:218-224.
9. Hatia RI, Dimitrova Z, Skums P, Teo EY-L, Teo C-G. Nosocomial hepatitis C virus transmission from tampering with injectable anesthetic opioids. *Hepatology* 2015;62:101-110.
10. Gunson RN, Shouval D, Roggendorf M, Zaaizer H, Nicholas H, Holzmann H, et al. Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in health care workers (HCWs): guidelines for prevention of transmission of HBV and HCV from HCW to patients. *J Clin Virol* 2003; 27:213-230.

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