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Updated CDC Recommendations for the Management of Hepatitis B Virus–Infected Health-Care Providers and Students



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Updated CDC Recommendations for the Management of Hepatitis B Virus–Infected Health-Care Providers and Students

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Summary

This report updates the 1991 CDC recommendations for the management of hepatitis B virus (HBV)–infected health-care providers and students to reduce risk for transmitting HBV to patients during the conduct of exposure-prone invasive procedures (CDC. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. MMWR 1991;40[No. RR-8]). This update reflects changes in the epidemiology of HBV infection in the United States and advances in the medical management of chronic HBV infection and policy directives issued by health authorities since 1991.

The primary goal of this report is to promote patient safety while providing risk management and practice guidance to HBV-infected health-care providers and students, particularly those performing exposure-prone procedures such as certain types of surgery. Because percutaneous injuries sustained by health-care personnel during certain surgical, obstetrical, and dental procedures provide a potential route of HBV transmission to patients as well as providers, this report emphasizes prevention of operator injuries and blood exposures during exposure-prone surgical, obstetrical, and dental procedures.

These updated recommendations reaffirm the 1991 CDC recommendation that HBV infection alone should not disqualify infected persons from the practice or study of surgery, dentistry, medicine, or allied health fields. The previous recommendations have been updated to include the following changes: no prenotification of patients of a health-care provider's or student's HBV status; use of HBV DNA serum levels rather than hepatitis B e-antigen status to monitor infectivity; and, for those health-care professionals requiring oversight, specific suggestions for composition of expert review panels and threshold value of serum HBV DNA considered "safe" for practice (<1,000 IU/ml). These recommendations also explicitly address the issue of medical and dental students who are discovered to have chronic HBV infection. For most chronically HBV-infected providers and students who conform to current standards for infection control, HBV infection status alone does not require any curtailing of their practices or supervised learning experiences. These updated recommendations outline the criteria for safe clinical practice of HBV-infected providers and students that can be used by the appropriate occupational or student health authorities to develop their own institutional policies. These recommendations also can be used by an institutional expert panel that monitors providers who perform exposure-prone procedures.

Introduction

In 1991, CDC published recommendations to prevent transmission of bloodborne viruses from infected health-care providers to patients while conducting exposure-prone invasive procedures (1). These recommendations did not prohibit the continued practice of invasive surgical techniques by HBV-infected surgeons, dentists, and others, provided that the nature of their illnesses and their practices are reviewed and overseen

by expert review panels. Essential elements of the 1991 CDC recommendations relevant to HBV included that 1) there be no restriction of activities for any health-care provider who does not perform invasive (exposure-prone) procedures; 2) exposure-prone procedures should be defined by the medical/surgical/dental organizations and institutions at which the procedures are performed; 3) providers who perform exposure-prone procedures and who do not have serologic evidence of immunity to HBV from vaccination should know their HBsAg status and, if that is positive, also should know their hepatitis B e-antigen (HBeAg) status; and 4) providers who are infected with HBV (and are HBeAg-positive) should seek counsel from and perform procedures under the guidance of an expert review panel (1).

The 1991 recommendations also recommended that an HBV-infected health-care provider who performed exposure-prone procedures, broadly defined, should notify patients

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in advance regarding the provider's seropositivity. However, scientific data and clinical experience accumulated since 1991 demonstrate that the risk for HBV and other bloodborne virus transmission from providers in health-care settings is extremely low. In addition, improvements in infection control practices put into effect since 1991 have enhanced both health-care provider and patient protection from exposure to blood and bloodborne viruses in health-care settings.

This report is intended to guide the practices of chronically HBV-infected providers and students and the institutions that employ, oversee, or train them; it does not address those with acute HBV infection. This report is limited to the provider-to-patient transmission of HBV; it does not address infection control measures to prevent bloodborne transmission of HBV to patients through receipt of human blood products, organs, or tissues because these measures have been described elsewhere (2). Nor does this report provide comprehensive guidance about prevention of patient-to-health-care provider bloodborne pathogen transmission because this guidance also has been published previously (3,4). On the basis of a thorough literature review, reports of providers who experienced curtailed scope of practice, and expert consultation, CDC considered the following issues when developing these recommendations: 1) very rare or, for most types of clinical practice, no detected transmission of HBV from providers to patients; 2) nationally decreasing trends in the incidence of acute HBV infection in both the general population and health-care providers; 3) successful implementation and efficacy of policies promoting hepatitis B vaccination; 4) evolving and improving therapies for HBV infection; 5) guidelines in the United States and other developed countries that propose expert-based approaches to the risk management of infected health-care providers; 6) the adoption of Standard Precautions (formerly known as universal precautions) as a primary prevention intervention for the protection of patients and providers from infectious agent transmission; 7) the implementation of improved work practice and engineering controls, including safety devices; 8) the testing and vaccination of providers; 9) increasing availability of HBV viral load testing; and 10) instances of restrictions or prohibitions for HBV-infected providers and students that are not consistent with CDC and other previous recommendations.

Methods

To update recommendations for the risk management of HBV-infected health-care providers and students, CDC considered data that have become available since the 1991 recommendations were published. Information reviewed was obtained through literature searches both by standard search engines (PubMed) and of other literature reviews used in guidelines developed by

other professional organizations since 1991. Search terms used included "hepatitis B," "hepatitis B virus," or "HBV" with "healthcare," "health-care," "healthcare workers" or "providers" or "personnel"; "nosocomial" or "healthcare transmission"; and "healthcare worker-to-patient." However, these searches did not identify additional cases beyond the few already known to CDC and the experts consulted. To gather data on HBV transmission, CDC reviewed all hepatitis B outbreak investigations conducted by CDC and state officials since 1991. CDC national hepatitis surveillance data were examined for reports of acute HBV infection in persons with information about recent health care, as well as reports received regarding dismissal of HBV-infected health-care providers (i.e., surgeons) or prohibition from matriculation of medical, dental, and osteopathic students identified as HBV-infected after acceptance (see Actions Taken Against HBV-Infected Health Care Providers and Students).

Medical, dental, infection control, public health, infectious disease, and hepatology experts, officials, and representatives from government, academia, the public, organizations representing medical, dental and osteopathic colleges, and professional medical organizations were consulted.* Some were consulted at an initial meeting on June 4, 2011. All experts and organizations were provided draft copies of these recommendations as they were developed, and they provided insights, information, suggestions, and edits. In finalizing these recommendations, CDC considered all available information, including expert opinion, results of the literature review, findings of outbreak investigations, surveillance data, and reports of adverse actions taken against HBV-infected surgeons and students.

Major Trends in Regard to Providers with HBV Infection

Health-Care Provider-to-Patient Transmission of HBV

Since publication of the 1991 CDC recommendations (1), CDC has accrued substantial information about HBV-infected health-care providers and students. Many interventions, including the adoption of Standard Precautions (formerly known as universal precautions) and double-gloving during invasive surgical procedures, have eliminated almost completely the very low risk for transmission of HBV (as well as hepatitis C virus [HCV] and human immunodeficiency virus) during exposure-prone procedures. In developing these recommendations, CDC weighed the risk for HBV transmission based on the following:

*A list of the persons consulted appears on page 10.

1) documented cases of confirmed transmission of HBV from health-care providers to patients are rare (up to eight cases from one surgeon in the United States since 1994), 2) it has not been possible to conduct case-control or cohort studies that estimate the rate of such rare events, and 3) data are insufficient to quantify the strength-of-evidence or enable the grading of a recommendation (5).

Nonetheless, CDC and state authorities have been able to detect instances of patient-to-patient transfer of HBV (and HCV) from unsafe injection and dialysis practices, sharing of blood-glucose monitoring equipment, and other unsanitary practices and techniques (6). One report from an oral surgery practice documented patient-to-patient HBV transmission, although a retrospective assessment did not identify inappropriate procedures (7). However, despite detecting patient-to-patient transmission, there is only one published

report of health-care provider-to-patient transmission of HBV during exposure-prone procedures in the United States since 1994 (8). In that case, an orthopedic surgeon who was unaware of his HBV status and who had a very high level of HBV DNA (viral load >17 million IU/ml) (9) transmitted HBV to between two and eight patients during August 2008–May 2009 (10).

An international review of HBV health-care provider-to-patient transmissions in other countries in which the HBV DNA levels (viral load) of the providers were measured has determined that 4×10^4 genome equivalents per ml (GE/ml) (roughly comparable to 8,000 international units (IU)/ml) was the lowest level of HBV DNA in any of several surgeons implicated in transmission of HBV to patients between 1992 and 2008 (9–15; Table 1). This lowest measurement was taken >3 months after the suspected transmission event, so the relevance of the HBV DNA viral load to transmissibility

TABLE 1. Cases of surgeon-to-patient transmission of hepatitis B virus (HBV) in which the surgeon's HBV DNA was quantified

Location of reported case (yr)	Profession	HBV DNA (GE/ml)*	HBV e-antigen	Quantification technique	Time sample taken after transmission
United States (1992) [†]	Thoracic surgery resident	1.0×10^9	Positive	Semi-quantitative PCR dot-blot hybridization, with comparison serum containing 108 chimpanzee- infectious particles	4 mos
United Kingdom (1990–1997) [§]	Cardiothoracic surgeon	10^9	Positive	Semi-quantification by end-point dilution	6 mos
	General surgeon	10^8	Positive		>8 wks
	General surgeon	10^9	Positive		Unknown
	General surgeon	10^7	Positive		Unknown
	Cardiothoracic surgeon	10^5	Positive		Unknown
United Kingdom (1988, 1993–1995) [¶]	General surgeon	1.0×10^7	Negative	Liquid hybridization and enzyme-linked oligonucleotide assay	12 wks
	Gynecologist	4.4×10^6	Negative		Unknown
	Gynecologist	5.5×10^6	Negative		Unknown
	General surgeon	2.5×10^5	Negative		12 wks
United Kingdom (1999)**	Surgeon	1.03×10^6	Negative	Lightcycler PCR	Unknown
Netherlands (1998–1999) ^{††}	Surgeon	5.0×10^9	Positive	Limited dilution PCR	1 yr
United Kingdom (1988–1997) ^{§§}	Surgeon	1.12×10^8	Negative	Chiron Quantiplex Branched DNA assay and Roche Amplicor HBV DNA monitor assay	At least 3 mos after transmission in all surgeons
	Surgeon	2.55×10^5			
	Surgeon	6.72×10^5			
	Surgeon	6.35×10^4			
	Surgeon	4.20×10^8 ^{¶¶}			
	Surgeon	9.47×10^8			
United States (2008) ^{***}	Orthopedic surgeon	1.79×10^7	Positive	Versant 3.0 third generation branched DNA assay	14 wks

* GE/ml, genome equivalents/ml; generally, approximately five times comparable measurement of international units (IU)/ml.

[†] Source: Harpaz R, von Seidlin L, Averhoff AM, et al. Transmission of hepatitis B virus to multiple patients from a surgeon without evidence of inadequate infection control. *N Engl J Med* 1996;334:549–54.

[§] Source: Ngui SL, Watkins RPF, Heptonstall J, Teo CG. Selective transmission of hepatitis B after percutaneous exposure. *J Infect Dis* 2000;181:838–43.

[¶] Source: The Incident Investigation Teams and Others. Transmission of hepatitis to patients from four infected surgeons without hepatitis B e antigen. *N Engl J Med* 1997;336:178–84.

^{**} Source: Molyneaux P, Reid TM, Collacott I, McIntyre PG, Dillon JF, Laing RB. Acute hepatitis B in two patients transmitted from an e antigen negative cardiothoracic surgeon. *Commun Dis Publ Health* 2000;3:250–2.

^{††} Source: Spijkerman IJ, van Doorn LJ, Janssen MH, et al. Transmission of hepatitis B virus from a surgeon to his patients during high risk and low risk surgical procedures during 4 years. *Infect Contr Hosp Epidemiol* 2002;23:306–12.

^{§§} Source: Corden S, Ballard AJ, Ijaz S, et al. HBV DNA levels and transmission of hepatitis B by health care workers. *J Clin Virol* 2003;27:52–8.

^{¶¶} Lowest value in any transmitting surgeon; average of testing at two laboratories using the same (Roche) assay.

^{***} Source: Enfield KB, Sharapov U, Hall K, et al. Transmission of hepatitis B virus to patients from an orthopedic surgeon [Abstract no. 420]. Presented at the 5th Decennial International Conference on Healthcare-Associated Infections, Atlanta, Georgia; March 18–20, 2010. Available at <http://shea.confex.com/shea/2010/webprogram/Paper2428.html>.

is unclear. In general, those surgeons who transmitted HBV to patients appear to have had HBV DNA viral loads well above 10^5 GE/ml (or above 20,000 IU/ml) at the earliest time that viral load was tested after transmission (Table 1). However, the few studies conducted in nonhuman primates have reported different results regarding the correlation between HBV DNA levels in blood and infectivity. One study found a correlation (16), but another did not (17).

In addition to the rarity of surgery-related transmission of HBV since 1994 (one reported instance), the most recent case of HBV transmission from a U.S. dental health-care provider to patients was reported in 1987 (18,19). Since this event, certain infection control measures are thought to have contributed to the absence of detected transmissions; such measures include widespread vaccination of dental health-care professionals, universal glove use, and adherence to the tenets of the 1991 Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (20). Since 1991, no transmission of HBV has been reported in the United States or other developed countries from primary care providers, clinicians, medical or dental students, residents, nurses, other health-care providers, or any others who would not normally perform exposure-prone procedures (21).

National Trends in Acute Hepatitis B Incidence and Prevalence

Symptomatic acute HBV infections in the United States, as reported through health departments to CDC, have declined approximately 85% from the early 1990s to 2009 (22), following the adoption of universal infant vaccination and catch-up vaccinations for children and adolescents (23). If declining trends continue, an ever-increasing proportion of patients receiving health care and their providers will be protected by receipt of hepatitis B vaccination.

Patient-to-health-care provider transmission of HBV also has declined markedly. Reflecting this finding, the reported number of acute HBV infections among providers in the United States, not all of which reflect occupational exposure, decreased from approximately 10,000 in 1983 to approximately 400 in 2002 (24) and to approximately 100 by 2009 (22).

Treatments for Chronic Hepatitis B Infection

Medications for hepatitis B have been improving continually and are usually effective at reducing viral loads markedly or even to undetectable levels. Currently, seven therapeutic agents are approved by the Food and Drug Administration for the treatment of chronic hepatitis B, including two formulations of interferon (interferon

alpha and pegylated interferon) and five nucleoside or nucleotide analogs (lamivudine, telbivudine, abacavir, entecavir, and tenofovir). Among the approved analogs, both entecavir and tenofovir have potent antiviral activity as well as very low rates of drug resistance. Treatment with these agents reduces HBV DNA levels to undetectable or nearly undetectable levels in most treated persons (25–27). Virtually all treated patients, even those few still receiving older agents (e.g., lamivudine), can expect to achieve a reduction of HBV DNA viral loads to very low levels within weeks or months of initiating therapy (25). The newer medications are effective in suppressing viral replication, and it is expected that they will be used for a newly identified HBV-infected health-care provider who is performing exposure-prone procedures and who has HBV virus levels above the threshold suggested in this report (1,000 IU/ml [i.e., about 5,000 genome equivalents (GE)/ml]) or as adopted by his or her institution's expert review panel. However, clinicians caring for infected health-care providers or students who are not performing exposure-prone procedures and who are not subject to expert panel review should consider both the benefits and risks associated with life-long antiviral therapy for chronic HBV started at young ages (25).

Consistency with Other Guidelines

Recommendations for the management of HBV-infected health-care providers and students have evolved in the United States and other developed countries (Table 2). In 2010, the Society for Healthcare Epidemiology of America (SHEA) issued updated guidelines that recommended a process for ensuring safe clinical practice by HBV-infected health-care providers and students (28). These separate guidelines classify many invasive procedures and list those associated with potentially increased risk for provider-to-patient blood exposures (Category III procedures, in the SHEA guidelines). SHEA recommends restricting a provider's practice on the basis of the provider's HBV DNA blood levels and the conduct of certain invasive procedures considered exposure prone. The SHEA guidelines also address the current therapeutic interventions that reduce the viral loads and the infectiousness of HBV-infected personnel. For providers practicing certain exposure-prone procedures, SHEA recommends that they maintain HBV blood levels $<10^4$ GE/ml, i.e., depending on the assay used, approximately 2,000 IU/ml (exposure prone, Category III) procedures, or cease surgery until they can reestablish a viral load level below that threshold.

Restrictions based on the provider's HBV DNA blood levels also exist in guidelines published by some European countries and Canada (Table 2) (21,29–36). No guidelines from any developed country recommend the systematic prohibition of invasive surgical or dental practices by qualified health-care providers whose chronic HBV infection is monitored.

TABLE 2. Recommendations for the management of health-care providers (HCP) with hepatitis B virus (HBV) infection*

HBV-infected HCP	SHEA (2010)	ACS (2004)	Europe (2003) [†]	Canada (2000)	United Kingdom (2000)	United States (1991)
Screening	— [§]	All surgeons	All who do EPP and who do not respond to vaccination	—	All who do EPP	All who do EPP
Vaccination	—	All surgeons	All who do EPP	—	All who do EPP	All who do EPP
Management of HBV-infected HCP performing EPP						
Hepatitis B e-antigen	Not required to be negative	Not required to be negative	Required to be negative	Required to be negative	Required to be negative	Required to be negative
HBV DNA	<10 ⁴ GE/ml	—	Variable by country <10 ² –<10 ⁴ GE/ml	<10 ⁵ GE/ml initially and <10 ³ GE/ml on therapy	<10 ³ GE/ml	(test not available)
Frequency of monitoring	6 mos	—	3 mos if doing EPP; 12 mos for other HCP	—	12 mos	—
Expert panel	Yes	Yes	Yes	Yes	—	Yes

Abbreviations: ACS = American College of Surgeons; EPP = exposure-prone procedures; GE/ml = genome equivalents/ml (roughly equal to 5 International Units/ml depending on assay used); SHEA = Society for Healthcare Epidemiology of America.

* Sources: CDC. Recommendations for preventing transmission of HIV and HBV virus to patients during exposure-prone invasive procedures. *MMWR* 1991;40(No. RR-8); Henderson DK, Dembry L, Fishman NO, 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;31:203–32; American College of Surgeons. Statement on the surgeon and hepatitis. Available at http://www.facs.org/fellows_info/statements/st-22.html; Health Canada. Proceedings of the consensus conference on infected health care worker risk for transmission of bloodborne pathogens. *Can Commun Dis Rep* 1998;24(suppl 4):1–28. Available at <http://www.collectionscanada.gc.ca/webarchives/20071124025757/http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98vol24/24s4/index.html>; UK Department of Health. Hepatitis B infected healthcare workers: guidance on implementation of health service circular 2000/020. UK Department of Health. Hepatitis B infected healthcare workers and antiviral therapy. 2007. Available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073164; U.K. Department of Health. Health Services Guidelines HSG (93)40. Protecting health care workers and patients from hepatitis B. Available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4088384.pdf; Gunson RN, Shouval D, Roggendorf M, 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;27:213–30.

[†] Consensus conference included representatives from Austria, Belgium, France, Germany, Greece, Holland, Israel, Italy, Portugal, The Republic of Ireland, Sweden, the United Kingdom, and the United States.

[§] Issue not addressed in recommendation or guideline.

The generally permissive principles delineated in the CDC 1991 recommendations also have been reiterated in recent Advisory Committee on Immunization Practices (ACIP) recommendations on immunization of health-care personnel in the United States for HBV infection (37). ACIP recommends that HBV-infected persons who perform highly exposure-prone procedures should be monitored by a panel of experts drawn from diverse disciplines and perspectives to ensure balanced recommendations. However, the ACIP recommendations do not require that HBV-infected persons who do not perform such procedures have their clinical duties restricted or managed by a special panel because of HBV infection alone.

Prevention Strategies

Standard Precautions

Strategies to promote patient safety and to prevent transmission of bloodborne viruses in health-care settings

include hepatitis B vaccination of susceptible health-care personnel and the use of primary prevention (i.e., preventing exposures and therefore infection) by strict adherence to the tenets of standard (universal) infection control precautions, the use of safer devices (engineering controls), and the implementation of work practice controls (e.g., not recapping needles) to prevent injuries that confer risks for HBV transmission to patients and their providers. Public health officials in the United States base Standard Precautions on the premise that all blood and blood-containing body fluids are potentially infectious (3,4). Since 1996, CDC has specified the routine use of Standard Precautions (38,39) that include use of protective equipment in appropriate circumstances, implementation of both work practice controls and engineering controls, and adherence to meticulous standards for cleaning and reusing patient care equipment. For example, double-gloving now is practiced widely, and the evidence to demonstrate the feasibility and efficacy of this and other interventions is extensive (40–44).

Work Practice and Engineering Controls

Parenteral exposures are mainly responsible for HBV transmission in health-care settings. Work practice modifications in the past 20 years have been important in mitigating such exposures. Examples of such modifications include the practice of not resheathing needles, the use of puncture-resistant needle and sharp object disposal containers, avoidance of unnecessary phlebotomies and other unnecessary needle and sharp object use, the use of ports and other needleless vascular access when practical or possible, and the avoidance of unnecessary intravenous catheters by using needleless or protected needle infusion systems.

Testing and Vaccination of Health-Care Providers

Recommendations generated over the past 20 years, both in the United States and other developed countries, urge all health-care providers to know their HBV and other bloodborne virus infection status (21), especially if they are at risk for HBV infection (37,45). OSHA mandates that hepatitis B vaccine be made available to health-care providers who are susceptible to HBV infection and that they be urged to be vaccinated (Bloodborne Pathogens Standard [29 CFR 1910.1030 and 29 CFR 1910.030f]) These guidelines stipulate that the employer make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure and that postexposure evaluation and follow-up be provided to all employees who have an exposure incident.

Approximately 25% or more of medical and dental students (46,47) and many physicians, surgeons, and dentists in the United States have been born to mothers in or from countries in Asia (including India), Africa, and the Middle East with high and intermediate endemicity for HBV. CDC recommends that all health-care providers at risk for HBV infection be tested and that all those found to be susceptible should receive vaccine (37). Such testing is likely to detect chronically infected health-care providers and students. Recommendations to ensure safe practice of health-care providers identified as chronic carriers of HBV should have reasonable and feasible oversight by the relevant school, hospital, or other health-care facility.

Actions Taken Against HBV-Infected Health-Care Providers and Students

CDC is aware of several recent instances in which HBV-infected persons have been threatened with dismissal or actually dismissed from surgical practice on the basis of their HBV infection, and others have had their acceptances

to medical or dental schools rescinded or deferred because of their infection (Joan M. Block, Hepatitis B Foundation, Anna S. F. Lok, University of Michigan Medical Center, personal communications, 2011). Some of these instances have involved requirements that the infected provider, applicant, or student demonstrate undetectable HBV viral load or hepatitis B e-antigen negativity and, in at least one case, that this be demonstrated continuously by weekly testing. These actions might not be based on clear written guidance and procedures at the institutions involved (48,49).

Technical and Ethical Issues in Developing Recommendations

Monitoring HBV DNA Level and Hepatitis B e Antigen (HBeAg)

Whereas the 1991 recommendations assessed the infectivity of surgeons and others performing invasive procedures based on the presence of HBeAg, documented transmissions of HBV to patients from several HBeAg-negative surgeons (12,15,50) led to examination of correlations between HBeAg and HBV viral load. Some of these HBeAg-negative persons, despite high rates of viral replication, might harbor pre-core mutants of the virus: that is, loss of HBeAg expression might result from a single nucleotide substitution that results in a stop codon preventing transcription (51,52). Persons with such HBV strains who test HBeAg-negative might nonetheless be infectious (despite the mutation) and even have a high concentration of virions in their blood.

Recent guidelines from other bodies (Table 2) have recommended using HBV DNA serum levels in preference to HBeAg in determining infectivity. Several studies have documented numerous HBeAg-negative persons who have high circulating levels of HBV DNA, i.e., viral loads often 10^5 IU/ml or more by various commercial assays: 78 HBeAg-negative Australian patients with median HBV DNA of 38,000 IU/ml (determined by the Siemens Versant HBV DNA 3.0 assay) (53); 48 HBeAg-negative Greek patients with a median HBV DNA of 76,000 IU/ml (by Roche Amplicor HBV-Monitor) (54); 165 HBeAg-negative Korean patients with a mean HBV DNA of 155,000 IU/ml (by Roche COBAS TaqMan) (55); and 47 HBeAg-negative Chinese patients with median HBV DNA blood levels of 960,000 copies/ml (about 200,000 IU/ml) (by PG Biotech [Shenzhen, China] PCR) (56). On the basis of these data, monitoring quantitative HBV DNA levels provides better information to serve as a predictive indicator of infectivity than is provided by monitoring HBeAg status alone.

Assessing a Safe Level of HBV DNA

Review of information concerning six HBeAg-negative surgeons who had transmitted hepatitis B to patients and whose HBV DNA had been determined (using both Chiron Quantiplex Branched DNA assay and Roche Amplicor HBV DNA Monitor assay) showed the lowest value (at one laboratory) in one surgeon to be 40,000 copies/ml (approximately 8,000 IU/ml) (9). However, because this quantification was performed more than 3 months after the transmission had taken place, correlative relevance is uncertain.

In 2003, recommendations from the Netherlands set the level above which health-care providers should not be performing exposure prone procedures at HBV DNA levels 10^5 GE/ml or above (approximately 20,000 IU/ml). A larger European consortium set this restriction at HBV DNA levels $\geq 10^4$ GE/ml (approximately 2,000 IU/ml) (33) for persons who are HBeAg-negative. In 2010, this latter threshold, without a requirement for e-antigen negativity, was adopted in the U.S. SHEA Guidelines (28). U.K. guidelines for HBV-infected providers who are HBeAg-negative require these providers to achieve or maintain HBV DNA levels of $<10^3$ GE/ml (less than approximately 200 IU/ml) (31,57).

Although newer assays such as real-time polymerase chain reaction (PCR) tests are expected to reduce the level of detection for HBV DNA to 10–20 IU/ml, this level could be undetectable in some assays in use in the United States. The lower limit of detection for four assays currently in use are 200 IU/ml (qualitative assay); 30–350 IU/ml (branched DNA assay); 30 IU/ml (real-time PCR assay); and 10 IU/ml (real-time PCR assay). Thus, any requirement for demonstration of a viral load <200 IU/ml will need to specify the use of an assay (usually real-time PCR) that can detect loads well below that threshold.

Fluctuating HBV DNA Levels

Persons who achieve and maintain HBV DNA blood concentrations below some designated threshold level or attain an undetectable level might have HBV DNA that is transiently elevated and detectable but not necessarily transmissible. Such instances might represent infrequent detections of virus at very low levels despite long-term suppression of virus on therapy (58) but also could represent, especially for persons taking older therapies, breakthrough of antiviral-drug resistant HBV (59). As assays become increasingly sensitive (newer ones can detect circulating HBV DNA down to 20–30 IU/ml), such transient elevations will be recognized increasingly and will trigger more frequent follow-up. If such an elevation in detectable HBV DNA represents not spontaneous fluctuation (sometimes referred to as a blip) but rather therapeutic drug failure (i.e., breakthrough), then appropriate change in therapy may be considered.

Specifying Exposure-Prone Procedures

In general, three conditions are necessary for health-care personnel to pose a risk for bloodborne virus transmission to patients. First, the health-care provider must be sufficiently viremic (i.e., have infectious virus circulating in the bloodstream). Second, the health-care provider must have an injury (e.g., a puncture wound) or a condition (e.g., nonintact skin) that allows exposure to his/her blood or other infectious body fluids. Third, the provider's blood or infectious body fluid must come in direct contact with a patient's wound, traumatized tissue, mucous membranes, or similar portal of entry during an exposure-prone procedure. The vast majority of HBV-infected health-care personnel pose no risk for patients because they do not perform activities in which both the second and third conditions are met.

Beyond meeting these three basic conditions, defining exposure-prone invasive procedures that pose a risk for HBV transmission between infected provider and patient has been problematic in the development of all recommendations and guidelines; this process is made especially difficult by varying surgical techniques used by health-care providers doing the same procedure. More recent guidelines and published articles indicate that exposure-prone procedures can be defined broadly, and lists of potentially exposure-prone procedures have been developed (28,31,60). Principles cited are that exposure-prone procedures include those in which access for surgery is difficult (28) or those in which needlestick injuries are likely to occur (60), typically in very closed and unvisualized operating spaces in which double gloving and the skin integrity of the operator might be compromised (Box).

Defining exposure-prone procedures in dentistry and oral surgery has been particularly difficult. Many intra-oral procedures (e.g., injection or scaling) occur in a confined cavity and might lead to injuries to the operator (61), so some institutions have considered these procedures to be exposure-prone. However, no transmission of HBV from a U.S. dentist to a patient has been reported since 1987, and no transmission has ever been reported from a dental or medical student. Thus, Category I Procedures (Box) include only major oral surgery, and do not include the procedures that medical and dental students or most dentists would be performing or assisting.

In addition to these lists of specific procedures, an institutional expert review panel convened to oversee an HBV-infected surgeon or other health-care provider performing exposure-prone procedures may consult the classification of such procedures (Box) for guidance. Given the variety of procedures, practices, and providers, each HBV-infected health-care provider performing potentially exposure-prone procedures will need individual consideration. However, this

BOX. CDC classification of exposure-prone patient care procedures**Category I. Procedures known or likely to pose an increased risk of percutaneous injury to a health-care provider that have resulted in provider-to-patient transmission of hepatitis B virus (HBV)**

These procedures are limited to major abdominal, cardiothoracic, and orthopedic surgery, repair of major traumatic injuries, abdominal and vaginal hysterectomy, caesarean section, vaginal deliveries, and major oral or maxillofacial surgery (e.g., fracture reductions). Techniques that have been demonstrated to increase the risk for health-care provider percutaneous injury and provider-to-patient blood exposure include

- digital palpation of a needle tip in a body cavity and/or
- the simultaneous presence of a health care provider's fingers and a needle or other sharp instrument or object (e.g., bone spicule) in a poorly visualized or highly confined anatomic site.

Category I procedures, especially those that have been implicated in HBV transmission, are not ordinarily performed by students fulfilling the essential functions of a medical or dental school education.

Category II. All other invasive and noninvasive procedures

These and similar procedures are not included in Category I as they pose low or no risk for percutaneous injury to a health-care provider or, if a percutaneous injury occurs, it usually happens outside a patient's body and generally does not pose a risk for provider-to-patient blood exposure. These include

- surgical and obstetrical/gynecologic procedures that do not involve the techniques listed for Category I;
- the use of needles or other sharp devices when the health-care provider's hands are outside a body cavity (e.g., phlebotomy, placing and maintaining peripheral and central intravascular lines, administering medication by injection, performing needle biopsies, or lumbar puncture);
- dental procedures other than major oral or maxillofacial surgery;
- insertion of tubes (e.g., nasogastric, endotracheal, rectal, or urinary catheters);
- endoscopic or bronchoscopic procedures;
- internal examination with a gloved hand that does not involve the use of sharp devices (e.g., vaginal, oral, and rectal examination; and
- procedures that involve external physical touch (e.g., general physical or eye examinations or blood pressure checks).

evaluation should not define exposure-prone procedures too broadly; the great majority of surgical and dental procedures have not been associated with the transmission of HBV.

Notification of Patients of HBV-Infected Health-Care Providers

There is no clear justification for or benefit from routine notification of the HBV infection status of a health-care provider to his or her patient with the exception of instances in which an infected provider transmits HBV to one or more patients or documented instances in which a provider exposes a patient to a bloodborne infection. Routine mandatory disclosure might actually be counterproductive to public health, as providers and students might perceive that a positive test would lead to loss of practice or educational opportunities. This misperception might lead to avoidance of HBV testing, of hepatitis B vaccination (if susceptible), of treatment and management (if infected), or of compliance with practice oversight from an expert panel (if infected and practicing exposure-prone procedures). In general, a requirement for disclosure is accepted to be an insurmountable barrier to practice and might limit patient and community access to quality medical care.

Ethical Considerations

On July 18, 2011, the Consult Subcommittee of CDC's Public Health Ethics Committee reviewed these proposed recommendations. The reviewing team also included three external ethicists. The opinion of the Consult Subcommittee was that guidelines that allow providers with HBV to practice while requiring those doing exposure-prone procedures to be monitored to maintain low load strikes the right balance between protecting patients' interests and providers' rights. The Consult Subcommittee also noted that providers have an ethical and professional obligation to know their HBV status and to act on such knowledge accordingly (CDC Public Health Ethics Committee, personal communication, 2011). The Consult Subcommittee supported the new recommendation that mandatory disclosure of provider HBV status to patients was no longer warranted and that the 1991 recommendation for disclosure was discriminatory and unwarranted.

In addition, the Consult Subcommittee determined that there was no scientific or ethical basis for the restrictions that some medical and dental schools have placed on HBV-infected students and concluded that such restrictions were detrimental to the professions as well as to the individual students.

Guidance for Expert Review Panels at Institutions

HBV infection in health-care providers and students who do not perform invasive exposure-prone procedures should be managed as a personal health issue and does not require special panel oversight. However, for providers who perform exposure-prone procedures, all recent guidelines advocate the constitution of an expert panel to provide oversight of the infected health-care provider's practice (Table 2).

For HBV-infected providers performing exposure-prone procedures, expert review panels should evaluate the infected provider's clinical and viral burden status; assess his or her practices, procedures and techniques, experience, and adherence to recommended surgical and dental technique; provide recommendations, counseling, and oversight of the provider's continued practice or study within the institution; and investigate and notify appropriate persons and authorities (e.g., risk management or, if need be, licensure boards) for suspected and documented breaches (62) in procedure or incidents resulting in patient exposure. The panel should reinforce the need for Standard Precautions (e.g., double gloving, regular glove changes, and use of blunt surgical needles). Panels may appropriately provide counseling about alternate procedures or specialty paths, especially for providers, students, residents, and others early in their careers, as long as this is not coercion or limitation (perceived or actual) of the provider or student.

The members of the expert review panel may be selected from, but should not necessarily be limited to, the following: one or more persons with expertise in the provider's specialty; infectious disease and hospital epidemiology specialists; liver disease specialists (gastroenterologists); the infected providers' occupational health, student health, or primary care physicians; ethicists; human resource professionals; hospital or school administrators; and legal counsel. Certain members of the panel should be familiar with issues relating to bloodborne pathogens and their infectivity.

In instances when it is generally accepted (or thought) that a patient might have been exposed to the blood of an infected health-care provider, institutions should have in place a protocol for communicating to the patient that such an exposure might have occurred. The patient should receive appropriate follow-up including post-exposure vaccination or receipt of hepatitis B immune globulin and testing (i.e., similar to the reverse situation of prophylaxis for providers exposed to the blood of an HBV-infected patient).

The confidentiality of the infected provider or student should be respected. Certain expert review panels might elect to consider cases without knowledge of the name of the infected provider or student. However, awareness of the infected

provider's or student's identity might be unavoidable. In such cases, respect for the confidentiality of the person under review should be accorded as it is for any other patient.

Recommendations for Chronically HBV-Infected Health-Care Providers and Students

CDC recommends the following measures for the management of hepatitis B virus–infected health-care providers and students:

Practice Scope

- Chronic HBV infection in itself should not preclude the practice or study of medicine, surgery, dentistry, or allied health professions. Standard Precautions should be adhered to rigorously in all health-care settings for the protection of both patient and provider.
- CDC discourages constraints that restrict chronically HBV-infected health-care providers and students from the practice or study of medicine, dentistry, or surgery, such as
 - repeated demonstration of persistently nondetectable viral loads on a greater than semiannual frequency;
 - prenotification of patients of the HBV-infection status of their care giver;
 - mandatory antiviral therapy with no other option such as maintenance of low viral load without therapy; and
 - forced change of practice, arbitrary exclusion from exposure-prone procedures, or any other restriction that essentially prohibits the health-care provider from practice or the student from study.

Hepatitis B Vaccination and Screening

- All health-care providers and students should receive hepatitis B vaccine according to current CDC recommendations (37,45,63). Vaccination (3-dose series) should be followed by assessment of hepatitis B surface antibody to determine vaccination immunogenicity and, if necessary, revaccination. Health-care providers who do not have protective concentration of anti-HBs (>10 mIU/ml) after revaccination (i.e., after receiving a total of 6 doses) should be tested for HBsAg and anti-HBc to determine their infection status (37).
- Pre vaccination serologic testing is not indicated for most persons being vaccinated, except for those providers and students at increased risk for HBV infection (37), such as those born to mothers in or from endemic countries and sexually active men who have sex with men (64).

- Providers who are performing exposure-prone procedures also should receive prevaccination testing for chronic HBV infection. Exposure of a patient to the blood of an HBV-infected health-care provider, in the performance of any procedure, should be handled with postexposure prophylaxis and testing of the patient in a manner similar to the reverse situation (i.e., prophylaxis for providers exposed to the blood of an HBV-infected patient) (65).

Expert Panel Oversight Not Needed

- Providers, residents, and medical and dental students with active HBV infection (i.e., those who are HBsAg-positive) who do not perform exposure-prone procedures but who practice non- or minimally invasive procedures (Category II, Box) should not be subject to any restrictions of their activities or study. They do not need to achieve low or undetectable levels of circulating HBV DNA, hepatitis e-antigen negativity, or have review and oversight by an expert review panel, as recommended for those performing exposure-prone procedures. However, they should receive medical care for their condition by clinicians, which might be in the setting of student or occupational health.

Expert Panel Oversight Recommended

- Surgeons, including oral surgeons, obstetrician/gynecologists, surgical residents, and others who perform exposure-prone procedures, i.e., those listed under Category I activities (Box), should fulfill the following criteria:
 - Consonant with the 1991 recommendations and Advisory Committee on Immunization Practices (ACIP) recommendations (37), their procedures should be guided by review of a duly constituted expert review panel with a balanced perspective (i.e., providers' and students' personal, occupational or student health physicians, infectious disease specialists, epidemiologists, ethicists and others as indicated above) regarding the procedures that they can perform and prospective oversight of their practice (28). Confidentiality of the health-care provider's or student's HBV serologic status should be maintained.
 - HBV-infected providers can conduct exposure-prone procedures if a low or undetectable HBV viral load is documented by regular testing at least every 6 months unless higher levels require more frequent testing; for example, as drug therapy is added or modified or testing is repeated to determine if elevations above a threshold are transient.
 - CDC recommends that an HBV level 1,000 IU/ml (5,000 GE/ml) or its equivalent is an appropriate

threshold for a review panel to adopt. Monitoring should be conducted with an assay that can detect as low as 10–30 IU/ml, especially if the individual institutional expert review panel wishes to adopt a lower threshold.

- Spontaneous fluctuations (blips) of HBV DNA levels and treatment failures might both present as higher-than-threshold (1,000 IU/ml; 5,000 GE/ml) values. This will require the HBV-infected provider to abstain from performing exposure-prone procedures, while subsequent retesting occurs, and if needed, modifications or additions to the health-care provider's drug therapy and other reasonable steps are taken.

Institutional Policies and Procedures

- Hospitals, medical and dental schools, and other institutions should have written policies and procedures for the identification and management of HBV-infected health-care providers, students, and school applicants. These policies should include the ability to identify and convene an expert review panel (see Guidance for Expert Review Panels) aware of these and other relevant guidelines and recommendations before considering the management of HBV-infected providers performing exposure-prone procedures.

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