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SHEA

SHEA White Paper

Management of healthcare personnel living with hepatitis B, hepatitis C, or human immunodeficiency virus in US healthcare institutions

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Introduction

Significant advances have occurred in the clinical care of persons living with hepatitis B virus (HBV), hepatitis C virus (HCV), and/or human immunodeficiency virus (HIV) since the publication of the 2010 "Society for Healthcare Epidemiology of America (SHEA) Guideline for Management of Healthcare Workers Who Are Infected With Hepatitis B Virus, Hepatitis C virus, and/or Human Immunodeficiency Virus."[1] Only 5 instances of healthcare personnel (HCP)-to-patient transmission of HBV (n = 2), HCV (n = 3), or HIV (n = 0) have occurred since this guideline was published, underscoring the low risk for these events. In addition, interventions have been developed to reduce risks for occupational exposures and injuries, rendering the healthcare environment less risky for both patients and HCP. Effective antiretroviral therapy can now fully suppress HIV, rendering the person noninfectious to others through sexual contact. Antivirals effectively suppress the viral load and slow the progression of HBV, and direct-acting antivirals (DAA) have made HCV a curable disease in almost all patients. Here, we examine this progress and address how the additional 10 years of experience and advances in medical progress necessitate modulation of the recommendations made in the 2010 SHEA guideline.[1]

Issues related to the management of HCP who are living with bloodborne pathogens have been challenging and controversial. In 1991, the Centers for Disease Control and Prevention (CDC) published guidelines designed to prevent HCP-to-patient transmission of hepatitis B virus (HBV) and human immunodeficiency virus (HIV).[2]

> This set of guidelines stated that HCP, "... who are infected with HIV or HBV (and are HBeAg positive) should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include the facility's notifying a prospective patient of the HCP's seropositivity before the patient undergoes exposure-prone invasive procedures."[2]

SHEA has long been engaged on this matter, issuing a position paper regarding the management of HCP living with bloodborne pathogens in 1990,[3] followed by a more extensive updated guidance in 1997,[4] and a detailed set of recommendations in 2010.[1]

Since all of these documents were published, the medical community has gained additional experience with the management of HCP living with bloodborne pathogens as well as additional insight into the factors that contribute to the risks for healthcare-associated transmission of these pathogens. Considerable progress has been made in the management of HBV, HCV, and HIV infection, in the development of sensitive molecular tests designed to measure viral load, and in the sophistication of that measurement. Additionally, clinical scientists have developed a variety of interventional strategies to reduce occupational risk, which has also reduced patient risk in the healthcare setting.

In 2012, CDC issued updated recommendations for the management of HCP and students living with HBV.[5] These guidelines controverted the 1991 guidelines (at least for HCP living with HBV), specifically noting,

> "There is no clear justification for or benefit from routine notification of the HBV infection status of an HCP to his or her patient with the exception of instances in which an HCP transmits HBV to one or more patients or documented instances in which an HCP exposes a patient to a bloodborne infection."[5]

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In addition, on CDC's website at the top of the online location of the previously published 1991 guideline, a statement now reads that the "guidance related to HIV infection is retired" and that the "guidance for hepatitis B has been superseded."[2,5] In 2013, the CDC Advisory Committee on Immunization Practices (ACIP) issued updated guidance about the assessment of immunity to HBV in HCP, including postexposure management strategies.[6]

More recently, the Communicable Disease Network of Australia (CDNA) published updated guidelines for managing HCP living with bloodborne pathogens,[7] the Public Health Agency of Canada (PHAC) published an exhaustive guideline for the prevention of transmission of bloodborne viruses from HCP to their patients.[8] The United Kingdom published guidance in July 2019 on the health clearance and management of HCP living with a bloodborne pathogen,[9] and CDC issued testing and follow-up information for HCP potentially exposed to HCV.[10]

The following section summarizes the changes involved in the management and treatment of these pathogens since 2010.

Hepatitis B virus (HBV)

The use of hepatitis B vaccine has had a profound effect on the frequency with which HCP acquire HBV infection. Consonant with the US Department of Labor's Occupational Safety and Health Administration (OSHA)'s Bloodborne Pathogen Standard,[11] all HCP must be offered the complete vaccination series. The current CDC guidelines[5] recommend that prevaccination testing not be routinely conducted, except for HCP who are at increased risk for HBV infection, such as HCP born to mothers from endemic countries and sexually active men who have sex with men.[12] The 2012 CDC guidelines[5] also recommend that the HBV vaccination series be followed by assessment of post-vaccination immunity (ie, determination of hepatitis B surface antibody [anti-HBs]). If the anti-HBs determination is negative, CDC recommends revaccination.[5] If the second course of vaccination does not produce protective levels of anti-HBs, CDC recommends that HCP be tested for hepatitis B surface antigen (HBsAg) and hepatitis B core antigen (anti-HBc) to determine infectivity. A recent report has documented 4 instances of chronic HBV infection in HCP who failed to respond to 2 courses of vaccination.[13]

The availability of antiviral therapy has changed the landscape for HCP living with hepatitis B. A substantial pharmacologic armamentarium has been developed to suppress hepatitis B viral load substantially, including 7 US Food and Drug Administration (FDA)–approved agents: tenofovir, entecavir, lamivudine, telbivudine, adefovir, interferon α, and pegylated interferon. Since the publication of the previous guidance, only 2 instances of HCP-to-patient transmission of HBV have been reported in the literature.[14,15] In both instances, neither HCP (an orthopedist and a gynecologic surgeon) was aware of the hepatitis B infection, and, thus, neither was on treatment. Both HCP had viral loads $>10^8$ (ie, ~2.0×10^7 IU/mL).[14,15] Several clinical studies have demonstrated that antiviral treatment can lower circulating HBV DNA levels in most patients, often to undetectable or nearly undetectable levels.

Hepatitis C virus (HCV)

The less effective and poorly tolerated interferon-plus-ribavirin therapies used since the 1980s for treatment of HCV infection have been replaced in the past decade by the development and FDA approval of >10 drugs or drug combinations that act directly on the hepatitis C virus (direct-acting antivirals, or DAA). The use of DAAs has resulted in sustained virologic response (SVR) rates of nearly 100%, in most cases curing HCV infection.[16-18] Since the publication of the 2010 SHEA guideline, with the exception of cases linked to substance use disorders among healthcare professionals engaged in recreational intranasal or intravenous drug use, including drugs diverted from appropriate medical use,[19-27] only 3 instances of HCP-to-patient HCV transmission have been documented in the literature.[28-30] Each of these reports is notable because the individuals implicated in HCV transmission did not participate in exposure-prone procedures with the individuals who were identified as acutely infected; one case was associated with hemodialysis, another with postpartum care, and another with home care.[28-30] In each of these 3 cases, which occurred in Europe, the possibility of substance use disorder was neither entertained nor discussed.

Over the past decade, the importance of substance use disorder among HCP resulting in transmission of hepatitis C to patients has become even more apparent.[19-27] In light of the significant expansion of the opioid epidemic in the United States, consideration should always be given to the possibility of substance use disorder when HCP-to-patient transmission of a bloodborne pathogen is detected. Curiously, in a 2013 review of HCP-associated outbreaks (including those caused by bloodborne pathogens), substance use was not discussed as a possible contributor to these outbreaks.[31] Similarly, in other more recent reports outside the United States, substance use was not discussed as a potential contributing factor.[29,32,33] Importantly, HCP substance use is a well-recognized, treatable illness, and SHEA emphasizes the importance of access to effective treatment for healthcare workers who are diagnosed with this illness.

Human immunodeficiency virus (HIV)

Antiretroviral therapy (ART) has markedly changed both the prognosis for persons living with HIV as well as the risk of transmission to others. Over the past decade, new drugs and combinations of drugs have rendered ART less toxic, better tolerated, and more efficacious. These drugs can fully suppress HIV viral load to undetectable levels in most persons. In addition, studies have demonstrated that persons living with HIV with undetectable viral loads do not transmit HIV sexually, even during unprotected sex, leading to the conclusion that "undetectable equals untransmittable (U = U)" by sexual routes.[34,35] Since the magnitude of risk for a single unprotected sexual encounter approximates the magnitude of risk for occupational infection following a parenteral occupational exposure (eg, needlestick exposure to blood from a person living with HIV in the pre-antiretroviral era), these data are highly relevant. In addition, in the 10 years since the publication of the 2010 SHEA guideline, the authors were unable to identify any new reports of HCP-to-patient transmission of HIV.

Intended Use

Here, we examine progress in the management of bloodborne pathogens and how 10 years' experience and the medical advances described above necessitate a change in the recommendations made in the 2010 SHEA guideline.[1] It updates the expert guidance presented in the previous 3 SHEA documents and attends to issues that were not addressed directly in the prior SHEA documents.

This white paper builds on the evidence summaries and grading of recommendations contained within the 2012 CDC,[5] the 2018 Australian guidelines,[7] the 2019 Canadian (PHAC) guidelines[8] and the 2019 UK guidelines.[9] Specifically, this white paper covers

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topics unique to the United States audience as well as practical considerations that may not be addressed due to the paucity of information available about the factors that influence the risk for HCP-to-patient transmission. The recommendations contained herein are best characterized as expert opinion and consensus within the context of the literature available.

No guideline, expert guidance, or white paper can anticipate all situations, and this document is not meant to be a substitute for individual judgment of qualified professionals or oversight panels. In addition, since laws vary from state to state in the United States, we have not made an effort to address the differences in state laws and regulations. Both HCP and those involved in the oversight of HCP living with HBV/HCV/HIV should be aware of state and local laws governing these issues.

Methods

This document was developed by a multidisciplinary panel of experts in infectious disease, HIV, hepatology, surgery, occupational health, and ethics. As noted, unlike the SHEA expert guidance format, this document is not based on a systematic literature search and review but builds on recent evidence-based guidelines to provide practical recommendations important to healthcare practice. This document was reviewed by the SHEA Guidelines Committee (GLC), the SHEA Publications Committee, the Infectious Diseases Society of America (IDSA) Standards and Practice Guidelines Committee (SPGC), the HIV Medicine Association (HIVMA), and the Surgical Infections Society (SIS). This white paper has been endorsed by SHEA, IDSA, HIVMA, and SIS.

Authors

The authors consist of authors of the 2010 SHEA guideline, current and past members of the SHEA Guidelines Committee, members of the SHEA Board, experts in the epidemiology and management of these bloodborne infections, and individuals representing HIVMA and IDSA. All authors are involved at their respective institutions in the development of policies relevant to management or treatment of bloodborne pathogens, either directly or in an advisory role.

For convenience, we also include a direct web link to the 2010 SHEA guideline.

Questions and Answers

Epidemiology and pathogenesis of HCP-to-patient transmission

Question: What factors contribute to the pathogenesis and risk for transmission of HIV, HCV, and HBV from HCP to patients?
Answer: Virtually no new information has surfaced about the healthcare-associated epidemiology, pathogenesis, or transmission of HBV, HCV, and HIV since the publication of the 2010 SHEA guideline. As noted in the introduction, with the exception of cases linked to HCP substance use,[19-27] literature reports documented no new cases of HIV, 3 cases of HCV,[28-30] and 2 cases of HBV transmission from HCP to patients.[14,15] The contribution of HCP substance use to HCP-to-patient HCV and HBV cases should not be overlooked. When transmission is documented, HCP substance use must be considered and excluded. In addition, staff should be made aware of institution-based HCP substance use detection programs.[36] Nonetheless, with perhaps the exception of the relatively new issue of the opioid epidemic involving HCP, the few instances of transmission provided limited new insights about the factors that influence transmission.

The 5 factors identified by the 2010 SHEA guideline as contributors to the pathogenesis and transmission risk for HBV, HCV, and HIV remain:

1. The intrinsic transmissibility of a specific pathogen
2. The frequency with which HCP sustain injuries that may present a risk for transmission of bloodborne pathogens to HCP
3. The frequency of occupational exposure events resulting in injuries that might present a risk for bloodborne pathogens transmission from HCP to their patients
4. The viral load in HCP living with HBV, HCV, and/or HIV and
5. The magnitude of risk of transmission of bloodborne pathogens following various types of exposure events.

Additionally, several procedural and technological interventions introduced to the healthcare environment (eg, blunt-tipped suture needles, needleless connectors, self-sheathing needles, etc) were designed to decrease risks for any kind of occupational exposures and, therefore, HCP-to-patient exposures. Although the precise efficacy of each of these interventions on HCP-to-patient transmission risk cannot be estimated, their net effect is likely to have made the healthcare environment safer, thereby decreasing the frequency of any occupational exposure.[37,38] Finally, with respect to an HCP's viral load, improvements in the therapy of these infections have significantly lowered viral loads in HCP living with HBV or HIV, which has resulted in the cure of HCV in nearly all individuals, thereby reducing risk for transmission in the unlikely event of a patient exposure.

Terminology and measurement

1. Viral load thresholds

Question: Given the medical progress made in the treatment or cure of these viral infections over the past decade, what modifications for determining viral load thresholds for any restrictions on HCP practice are advisable? Should these thresholds, if any, consider fluctuations in viral loads ("blips") that are known to occur?
Answer: The issue of viral nucleic acid quantification for HBV, HCV, and HIV remains challenging because different assay methodologies provide differing results. No uniform agreement exists about the conversions of genome equivalents per milliliter (GE/mL) to international units for HBV, HCV, or HIV. However, similar to the methods used by the authors of the PHAC guideline,[8] the authors of this manuscript recommend using the following thresholds:

- For HBV, 1,000 IU, using the World Health Organization (WHO) conversion for GE/mL to international units (5 GE/mL = 1 IU/mL). This threshold, which was arbitrarily set in the SHEA 2010 guidance[1] at 10^4 GE/mL has now been modified to 1,000 IU (ie, ~5×10^3 GE/mL), consonant with the Canadian guidelines.[8]
- For HCV: 'HCV RNA undetectable' (ie, implying a SVR, or cure, defined in the following section). Effective, and most often curative, therapy is now available.
- For HIV: 'suppressed viral RNA.' In the United States, viral suppression typically means an HIV viral load <200 copies/mL. Suppressive therapy is now widely available.

The question of how to manage the extremely small subset of HCP living with HCV for whom therapy can suppress viral loads but cannot achieve SVR is complex. This set of circumstances occurs

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rarely; most persons living with HCV (99%) experience a sustained virologic response to DAA therapy and are cured. Furthermore, those who do not experience a sustained virologic response rarely have their viral loads suppressed, and most rebound to pretreatment levels. For the unusual set of circumstances in which an HCP living with HCV has not achieved an SVR, each such case should be managed individually in collaboration with an oversight panel. No definitive threshold exists for a transmission risk, and different assays generate slightly disparate results. Conversion rates for genome equivalents (copies) to international units vary from ~2.5–5 GE/mL per IU. The HCV threshold from the SHEA 2010 guidance was initially arbitrarily set at 10^4 GE/mL. In this update, we have modified this threshold to 2,000 IU/mL (ie, ~5×10^3 to 1×10^4 GE/mL) for such cases. Again, we emphasize that each case should be assessed by an oversight panel.

Similarly, for HCP living with HIV whose viral loads are suppressed but not to undetectable levels, each case must be assessed individually by an oversight panel. In the 2010 SHEA guideline, we arbitrarily set this threshold at 5×10^2 GE/mL.[1] Both the Australian guidelines[7] and the UK guidelines[9] set this threshold at 200 copies/mL. To our knowledge, transmission has never been documented from a source HCP whose viral load was <1,000 copies/mL. In one instance, transmission was documented from an HCP who was shown to have a viral load of 1,500 copies/mL; however, the sample documenting the index HCP's viral load was not obtained until >7 months after the transmission event occurred.[39,40] Thus, this value may not represent the viral load at the time of the exposure.

Another issue relevant to HCP living with HIV is that 1%–2% of these individuals are capable of immunologically suppressing viremia, so-called 'elite controllers.'[41-43] As is the case for individuals who are on suppressive ART, elite controllers have infrequent fluctuations in viral loads associated with occasional detectable levels of viremia, generally <500 copies/mL. Importantly, no clinical or other decisions should be based on a single viral-load determination; results should always be validated by a second viral-load test, which is the standard of care for persons living with HIV.[44]

Low-level viremic fluctuations are generally thought to have limited clinical relevance.[45,46] For persons living with HIV on ART, the clinical data available to date suggest that such low-level fluctuations occur in 10%–23% of persons who have sustained virologic suppression,[47,48] although in the past few years (with more potent drugs), the prevalence of such fluctuations may be lower. These fluctuations are generally not sustained, and, based on the data relating to absence of sexual transmission during these fluctuations, likely do not present a risk for HCP-to-patient transmission.[34,35] Rarely, elite controllers and persons on effective ART may experience low-level fluctuations in their viral loads. In such instances (and especially for those experiencing higher viral loads >500 copies/mL), repeat viral load testing in 1–2 weeks is recommended to assure that they are not losing virologic control. HCP who experience fluctuations in viral loads must be managed individually in close consultation with the oversight panel.

2. Exposure-Prone Procedures

Question: Should institutions continue to characterize procedures as category II or III, or should these procedures be called "exposure-prone procedures"? How should they be managed?

Answer: Whereas occupational exposures can occur during both category II and III procedures (summarized in detail in the previous SHEA guidance[1]), the likelihood of such an exposure occurring is much higher for category III procedures. The distinction between category II and III can also be practitioner dependent (ie, occasionally the practitioner, and not the procedure, may be "exposure-prone"). The oversight panel should determine the precise procedures for which permission is sought, the historical risks for HCP-to-patient bloodborne pathogen transmission associated with these procedures in the literature and as reported in their facility, the HCP's experience with such procedures, and the likelihood of patient exposure to HCP blood during these procedures. Thus, the list of exposure-prone procedures may be best determined for each practitioner in conjunction with the oversight panel. The panel should also gather evidence regarding the HCP's skills, practices, and adherence to infection prevention procedures (particularly with respect to standard precautions) while making every effort to assure privacy and confidentiality. Also, with the HCP, the panel should investigate and discuss the availability of safer devices that may mitigate the risk for patient exposures.[1] Additional issues related to the functioning of the oversight panel are addressed below.

We also emphasize that the surgical environment continues to evolve. One can be assured that the list of category III procedures will continue to change over time, and oversight panels must be aware of such modifications in the surgical environment.

As noted below, the general recommendation for practice restrictions in this document addresses category III/exposure-prone procedures as defined by Reitsma et al.[49] We offer these recommendations as general guidance and note that institutions are encouraged to individualize their own processes to address local circumstances, including state and local statutes.

Responsibilities of healthcare organizations

1. Academic institutions and professional schools

Question: What are academic institutions' and professional schools' responsibilities for education, training, and management of students and trainees regarding the prevention of HCP-to-patient transmission of bloodborne pathogens?

Answer: Professional schools should provide the following for trainees and students:

1. Counseling students and trainees who will be participating in exposure-prone procedures to inform them that they have an ethical obligation: (1) to know their HBV, HCV, and HIV infection statuses; (2) to be vaccinated with HBV vaccine if they are working in a healthcare institution; (3) to seek appropriate treatment for HBV, HCV, and HIV if found to be infected; and (4) to inform the appropriate supervising individual according to institutional procedures (eg, at a minimum, the occupational medicine program, in order to facilitate the establishment of an oversight panel).
2. Detailed training and education about the bidirectional risks for exposure to, and infection with, bloodborne pathogens, including meeting the Occupational Safety and Health Administration's requirement for annual bloodborne pathogen education for healthcare workers
3. Access to and education about the efficacy of HBV immunization
4. Annual testing for serological signs of HBV infection for HCP who conduct exposure-prone procedures who elect not to be immunized or for HBV vaccine nonresponders. The Canadian guidelines[8] and the UK guidelines recommend annual and postexposure testing.

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5. Comprehensive exposure management and follow-up protocols, including postexposure immuno- and chemoprophylaxis, when appropriate, for exposed staff, students, and trainees
6. Career counseling to those planning to conduct exposure-prone procedures who are identified as living with a bloodborne pathogen(s) about the advances in the suppressive treatment or cure of these infections. Trainees and students have an obligation to provide notice of active infections to their institutions if they are planning to conduct exposure-prone procedures, and to participate in ongoing follow-up for these infections according to the standard of care.
7. Career counseling for students, trainees, and faculty whose viral loads cannot be consistently suppressed concerning their ability to conduct exposure-prone procedures and potential effects on their subsequent careers
8. Mechanisms and processes for oversight of HCP living with a bloodborne pathogen who perform exposure-prone procedures. Oversight can be provided by a state expert review panel, an institutional expert review panel, or a more informal oversight team that includes, at a minimum, the clinician providing care for the HCP and an independent occupational medicine physician who is not directly involved in the care of the HCP (discussed in detail in the following section).

2. Hospitals and healthcare facilities

Question: What policies and procedures should institutions have in place to provide guidance to HCP living with HBV, HCV, and/or HIV?

Answer: In addition to the suggestions for institutions and professional schools, healthcare facilities should do the following:

1. Assure that HCP living with HBV, HCV, and/or HIV who do not perform category III/exposure-prone procedures are not prohibited from participating in patient-care activities solely on the basis of their infection(s)
2. Ensure that all HCP follow all recommended and applicable infection prevention precautions
3. Ensure that all HCP have the necessary training, personal protective equipment and safer devices and equipment to be able to avoid transfers of blood or other potentially infectious materials
4. Ensure that all HCP who perform or participate in category III/exposure-prone procedures are aware of the ethical obligation to know their HBV, HCV, and HIV serologic/infection statuses
5. Provide all HCP who have potential for exposure to blood in the healthcare workplace with an HBV vaccine series and assure that vaccination has been successful, as measured by an anti-HBs response
6. Provide HCP who either refuse to be vaccinated or fail to develop an anti-HBs response after a second immunization series with access to additional testing to assess the HCP's HBV status (eg, HBsAg or anti-HBc)[6]
7. Ensure that HCP who perform category III/exposure-prone procedures and who have not been, or cannot be, immunized with the HBV vaccine are aware that they should undergo annual testing for HBV to assure they are not infected. The Canadian guidelines[8] and the UK guidelines[9] recommend annual and postexposure testing
8. Create postexposure management protocols for follow-up testing for potential or known exposures to HBV, HCV, and HIV that occur during the provision of healthcare
9. Confirm suspected HCV or HIV infection among HCP with virus-specific RNA testing; confirm suspected HBV infection with HBsAg and/or HBV DNA testing
10. Establish an oversight panel for appropriate tracking and management of any HCP who conduct category III/exposure-prone procedures and is identified as living with HBV, HCV, and/or HIV.

Question: Should a patient who has an exposure to an HCP with a viral load that is undetectable (ie, HBV, HCV, or HIV) receive postexposure prophylaxis and/or follow-up?

Answer: Institutions should have a defined protocol for managing patient exposures to HCP blood or other potentially infectious fluids. For exposures to blood or other potentially infectious fluids from an HCP with HIV, even if the viral load is undetectable, this plan should include notifying the patient about the exposure and offering postexposure chemoprophylaxis, following current postexposure prophylaxis recommendations.[50] Importantly, if the HCP has an undetectable viral load, in which case the risk for transmission is likely vanishingly small, postexposure prophylaxis should be administered out of an abundance of caution. HCP who had HCV and who have been treated with DAA and are cured present no risk for transmission. Management of potential hepatitis B or hepatitis C exposures should follow current CDC recommendations.[5,10]

Question: Should the management recommendations be altered if an HCP living with HBV, HCV, and/or HIV with a previously undetectable viral load becomes substantially immunocompromised due to a concurrent comorbidity or therapy?

Answer: Persons living with HIV who remain on their antiretroviral regimens generally maintain viral suppression even during periods of immunosuppression. Conversely, HBV reactivation occurs commonly in the face of certain comorbidities or causes of immunosuppression. The management of such an immunocompromised HCP living with HBV, HCV, and/or HIV should be individualized, and the individual should be monitored more closely (ie, with more frequent viral load testing) for possible reversion to higher viral loads. Definitive data relevant to immunosuppression and recrudescence for persons living with HCV and achieved sustained virologic response (SVR) to DAAs are not yet available. The overwhelming majority of patients attaining an SVR are completely cured of the disease.

Question: When an HCP, student, or trainee who is living with a bloodborne pathogen moves to another institution, what are the responsibilities of both the HCP and the institution to assure that this information is shared with the receiving institution?

Answer: The HCP and the home institution should provide the following:

1. When an HCP living with a bloodborne pathogen who conducts exposure-prone procedures moves to a new institution, the individual HCP has the responsibility of notifying the new institution's occupational medicine physician or, alternatively, may grant permission for their current oversight panel to inform the occupational medicine physician at the receiving institution. With the concurrence of the HCP, this communication can often be facilitated/coordinated by the hospital epidemiologist or occupational medicine office. Once at the new institution, the HCP living with a bloodborne pathogen should assist with the establishment of an oversight as described below.
2. When students living with bloodborne pathogens move into training programs, the responsibility for notifying the new

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institution or training program lies with the individual student, with the support and assistance of the oversight panel.

Management of HCP living with HBV

Question: How should institutions provide guidance for HCP living with HBV?
Answer:

1. HCP living with HBV should seek an initial evaluation from a physician who has expertise in HBV management to characterize the serologic and virologic aspects of infection.
2. HCP living with HBV should seek optimal medical management, including, when appropriate, treatment with effective antiviral agents.
3. HCP living with HBV who do not perform category III/exposure-prone procedures should not be prohibited from participating in patient-care activities solely on the basis of their HBV infection.
4. Consonant with the most recent set of guidelines from CDC concerning the management of HCP living with HBV,[5] there is no justification for, nor benefit gained from, routine notification of patients with regard to HCP living with HBV who are being managed through the institution's oversight panel.
5. For HCP living with HBV who perform category III/exposure-prone procedures:

    a. HCP living with HBV and who, despite appropriate treatment, have circulating viral loads ≥1,000 IUs should not perform category III/exposure-prone procedures.
    b. HCP living with HBV whose circulating viral loads can be consistently suppressed to <1,000 IUs can perform category III/exposure-prone procedures, as long as the individual

        i. Has not been previously identified as having transmitted infection to patients while on appropriate suppressive therapy
        ii. Obtains advice from the oversight panel (discussed in more detail below) about recommended practices to minimize risk of exposure events
        iii. Is followed by a personal physician who has expertise in the management of HBV infection and who is allowed by the HCP to participate in or communicate with the oversight panel about the individual's clinical status
        iv. Is monitored on a periodic basis (eg, every 6 months) to assure that the viral load remains <1,000 IUs, with results shared with the oversight panel and
        v. Agrees, in writing, to follow the recommendations of the oversight panel.

Management of HCP living with HCV

Question: How should institutions manage HCP living with HCV?
Answers:

1. HCP living with HCV should seek an initial evaluation from a physician who has expertise in HCV management to characterize the serologic and virologic aspects of infection.
2. HCP living with HCV should seek optimal medical management, including treatment with effective antiviral agents to achieve cure of the infection.
3. HCP living with HCV who do not perform category III/exposure-prone procedures should not be prohibited from participating in patient-care activities solely on the basis of their HCV infection.
4. Consonant with the most recent set of guidelines from CDC concerning the management of HCP living with HBV,[5] there is no justification for, nor benefit gained from, routine notification of patients of HCP living with HCV, who are being managed by the institution's oversight panel.
5. For HCP living with HCV who perform category III/exposure-prone procedures:

    a. HCP living with HCV and who, despite appropriate antiviral treatment, continue to have detectable circulating HCV RNA > 2,000 IU/mL should not perform category III/exposure-prone procedures (see the discussion in the previous section).
    b. HCP living with HCV who received treatment resulting in 'undetectable' circulating HCV-RNA levels can perform category III/exposure-prone procedures, as long as the individual

        i. Has not been previously identified as having transmitted infection to patients following definitive therapy resulting in an SVR
        ii. Provides the oversight panel with records and laboratory results (or permits the HCP's personal physician to provide records and laboratory results) confirming receipt of treatment and SVR
        iii. Has achieved SVR by remaining HCV RNA negative for 12 weeks following the completion of therapy.

Management of HCP living with HIV

Question: How should institutions provide guidance for HCP living with HIV?
Answer:

1. HCP living with HIV should seek an initial evaluation from a physician who has expertise in HIV management to characterize the serologic, virologic, and immunologic aspects of infection.
2. HCP living with HIV should seek optimal medical management, including treatment with effective combination antiretroviral agents to suppress viral replication.
3. HCP living with HIV who do not perform category III/exposure-prone procedures should not be prohibited from participating in patient-care activities solely on the basis of their HIV infection.
4. Consonant with the most recent set of guidelines from the CDC,[5] there is no justification for, nor benefit gained from, routine notification of patients with regard to HCP living with HIV who are being managed with the guidance of an oversight panel.
5. For HCP living with HIV who perform category III/exposure-prone procedures,

    a. HCP living with HIV and who, despite appropriate antiretroviral treatment, have a confirmed viral load >200 copies/mL should not perform category III/exposure-prone procedures until they have achieved virologic suppression.

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b. HCP living with HIV whose confirmed viral load is below 200 copies/mL can perform category III/exposure-prone procedures, so long as the HCP

   i. Has not been previously identified as having transmitted infection to patients while receiving appropriate suppressive therapy
   ii. Obtains advice from an oversight panel (discussed in more detail below) about recommended practices to minimize risk of exposure events
   iii. Is followed by a physician who has expertise in the management of HIV infection and who is allowed by the individual to participate in or communicate with the oversight panel about the individual's clinical status
   iv. Is monitored on a periodic basis (eg, every 6 months) to assure that the HIV RNA remains below the level of detection, with results provided to the oversight panel
   v. Is followed closely by their physician and the oversight panelIn instances in which fluctuations in HIV viremia occur,including appropriate retesting as discussed above to reevaluate the HCP's viral load and
   vi. Agrees, in writing, to follow the recommendations of the oversight panel.

Oversight of HCP living with Bloodborne Pathogen

Question: Have expert review panels been effective in providing oversight for HCP living with HBV, HCV, and/or HIV? How should oversight panels be assembled and how should they function?

Answer: The concept of expert review panels assisting in the management of HCP living with bloodborne pathogens was initially described in the now retired 1991 CDC guidelines.[2] These guidelines noted the following:

> "The review panel should include experts who represent a balanced perspective. Such experts might include all of the following: a) the HCW's personal physician(s), b) an infectious disease specialist with expertise in the epidemiology of HIV and HBV transmission, c) a health professional with expertise in the procedures performed by the HCW, and d) a state or local public health official(s). If the HCW's practice is institutionally based, the Expert Review Panel might also include a member of the infection control committee, preferably a healthcare epidemiologist. HCWs who perform exposure-prone procedures outside the hospital/institutional setting should seek advice from appropriate state and local public health officials regarding the review process. Panels must recognize the importance of confidentiality and the privacy rights of infected HCWs."[2]

The 2010 SHEA guidance extended these recommendations as follows:

> "The review panel should include, but not necessarily be limited to, individuals who have expertise in the HCP's specialty or subspecialty, Healthcare Epidemiology, Infectious Diseases or Hepatology (specifically, with expertise in the bloodborne pathogen[s] being discussed), Occupational Medicine, and/or hospital administration; the infected HCP's physician; a public health official (in states in which this issue is managed at the state level); a human resources professional; and, perhaps, an individual who has legal and/or ethics expertise."[1]

Some experts in the field have raised concerns that having a large number of individuals involved in these deliberations is unnecessary and may place the index HCP's medical privacy and confidentiality at risk. The United Kingdom has created a UK Advisory Panel. All HCP who are living with a bloodborne pathogen and who are performing exposure-prone procedures must be followed by a specialist in occupational medicine who will enroll the HCP in the UK Advisory Panel's Occupational Health registry.[9] The Australian guidelines also allow for direct oversight by the HCP's primary physician, but they encourage the HCP's physician to interact with the relevant area of the jurisdictional health department public health authorities if management issues arise.[7] The Australian guidance also requires the HCP to certify that testing occurs annually at the time of recertification. Australia also has a national expert review panel. The recently published Canadian guidelines allow oversight procedures to be decided at the provincial or territorial level.[8]

SHEA continues to recommend that oversight is an appropriate component of the management of HCP living with bloodborne pathogens who perform exposure-prone procedures. Because concern has been raised about the challenges of maintaining medical privacy and confidentiality of HCP living with a bloodborne pathogen when a broader expert review panel is convened, we recommend that oversight include the HCP's treating physician and an occupational health physician who has expertise in managing these risks and, ideally, has knowledge of the job roles and requirements of the HCP. These issues are most frequently managed at the institutional level; thus, some institutions already have panels in place that include the hospital epidemiologist and a practitioner who has expertise or understanding of the job roles/requirements of the HCP living with a bloodborne pathogen. SHEA continues to support this approach, but underscores that the number of panel members should be kept as small as is practical, both to provide optimal guidance while assuring medical privacy and confidentiality of the HCP.

Irrespective of the number of people recommended for inclusion on the oversight panel, the requirement that every member of the panel understands and commits to protecting the privacy and confidentiality of the HCP is an ethical imperative. To the extent possible, discussions and any written reports or summaries should avoid using names or other identifiers, and all reports should be kept under double lock and key (ie, in a locked file cabinet in a locked office with restricted access).

The now-retired 1991 CDC guidelines charged the states with the responsibility of deciding how to provide guidance to HCP living with bloodborne pathogen.[2] Two states (Minnesota and North Carolina) decided to manage these cases at the state level. North Carolina's salutary collective experience has been described.[51] The authors suggest that the state-based standardized management of HCP living with either HIV or HBV has proven successful, noting that HCP living with bloodborne pathogen experienced neither loss of employment nor inappropriate patient notification requirements. The authors conclude that their state-based process for investigating and mitigating risk of transmission from HCP living with HIV or HBV provides a reasonable balance between the protection of the public health and the maintenance of privacy, confidentiality, and the livelihood of the HCP.[51] Similarly, the oversight panels proposed in this white paper are designed to offer expertise, experience, and a balanced perspective to the decision-making process. As demonstrated in a survey of state health programs in 2011, most of these issues appear to be handled effectively at the institutional level.[52]

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