

REVIEW

Clinical and occupational health management of healthcare workers living with chronic hepatitis B: UK policy and international comparisons

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Abstract

Hepatitis B virus (HBV) is a highly infectious bloodborne virus, which remains endemic in large geographic areas and represents a major global healthcare challenge. HBV transmission from healthcare workers, who perform exposure prone procedures (EPP), to patients is a recognized transmission risk, which varies widely globally. Although the risk is small in developed countries, it increases significantly in high-prevalent, low-resource countries, representing a major challenge to these healthcare systems and underlining the necessity for robust guidance to be in place. The HBV landscape has evolved as a result of global vaccination programs, implementation of standard precautions and the advent of new generation antiviral agents (3rd generation nucleos(t)ide analogues). In light of the progress in the field, the UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses (UKAP) recently issued updated guidance, which essentially removes past barriers, restricting healthcare workers from performing EPPs solely on the basis of HBV DNA level, regardless of hepatitis B 'e' antigen and/or treatment status. Although the current recommendations remain conservative compared to those of other developed healthcare systems, UK practice is now in line with other high-income countries, while ensuring patient safety remains paramount, without unduly restricting HCWs from clinical practice. The current article presents the latest UKAP guidance, considers its implications for HCWs and compares it with the guidance from major international scientific societies and governing bodies.

KEYWORDS

health policy, hepatitis B, public Health, viral hepatitis

Significance statement

The risk of HBV transmission from healthcare workers (HCW) to patients is well-recognized. UKAP has endorsed the recent developments in the field of viral hepatitis and issued updated guidance on the management of HCWs living with bloodborne viruses. Patient safety has always been at

Abbreviations: anti-HBs, Hepatitis B surface antibody; BBV, Blood-borne virus; CHB, Chronic hepatitis B; EASL, European Association for the Study of the Liver; EPP, Exposure prone procedures; ETV, Entecavir; HBsAg, Hepatitis B surface antigen; HBV, Hepatitis B virus; HCW, Healthcare worker; SHEA, Society for Healthcare Epidemiology of America; TAF, Tenofovir alafenamide; TDF, Tenofovir disoproxil fumarate; UKAP, UK Advisory Panel for Healthcare Workers infected with Bloodborne Viruses; WHO, World Health Organization.

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the centre of UK policy and the latest guidance maintains this, while simultaneously removing unnecessary restrictions for HCWs. In view of the UK's revered track record in public health policy, we believe the present article may act as a springboard for health policymakers to consider issuing relevant guidance, especially in low-resource countries where recommendations are lacking.

1 | INTRODUCTION

Hepatitis B virus (HBV) is a highly infectious bloodborne virus that remains endemic in large geographic areas, with a third of the global population estimated to have been exposed to the infection at some point in their lives. For a healthcare worker (HCW) to transmit HBV to a patient, it is accepted the HCW must be sufficiently viraemic and there must be direct contact between the HCWs body fluids and/or blood and the patient's tissues or mucous membranes. At a population level, risk of transmission in the context of healthcare will depend upon the population prevalence of HBV, the use of standard precautions during procedures and the provision of an occupational health policy for HCWs. The risk of transmission to patients in a developed, low-prevalence nation is low. Nonetheless, minimizing this risk to patients is an important role for occupational health physicians, and an ethical duty for all healthcare workers to ensure their patients is not put at undue risk. In areas with high HBV prevalence, often coupled with limited healthcare resources and challenging environments to maintain appropriate infection prevention and control, the problem of transmission from HCW to patient and vice versa as well as patient-patient transmission constitutes an area of public health concern.

Guidance and support for the management of healthcare workers living with blood-borne viruses in the United Kingdom are provided by an independent advisory committee called the UK Advisory

Panel for Healthcare Workers infected with Bloodborne Viruses (UKAP). In 2020, UKAP issued updated guidance on the management of HCWs living with bloodborne viral infections. Importantly, a significant change was made to the guidance, in light of the availability of more effective treatments for HBV infection that removed restrictions on practice, provided the HCW living with HBV is compliant with certain clearance conditions.¹ The recent UKAP's key recommendations are summarized in Table 1.

2 | CURRENT UK CLINICAL AND OCCUPATIONAL HEALTH GUIDANCE FOR HEALTHCARE WORKERS LIVING WITH HEPATITIS B

Healthcare workers in the UK are offered screening for HBV serology as part of occupational health clearance. Testing for hepatitis B surface antigen (HBsAg) is mandatory for those wishing to perform exposure prone procedures (EPPs). Individuals that are negative for HBsAg are offered immunization with subsequent assessment of hepatitis B surface antibody (anti-HBs) titre. HCW for whom HBV vaccination is contra-indicated, who decline vaccination, or who are non-responders to vaccination (i.e. anti-HBs <10 mIU/mL) is restricted from performing EPPs unless shown to be non-infectious with regular ongoing

TABLE 1 Summary of the UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses (UKAP) guidance on health clearance and the management of healthcare workers living with hepatitis B, who intend to perform exposure prone procedures or clinical duties in renal units or any other settings involving renal dialysis

Hepatitis B serology	UKAP recommendations
HBsAg negative	<ul style="list-style-type: none"> - offer vaccination, unless already vaccinated or acquired natural immunity through past HBV infection - assess response to vaccination (anti-HBs) - in case vaccination is contra-indicated, HCWs decline vaccination or are non-responders (anti-HBs <10 mIU/mL), annual HBsAg assessment is required in order to give clearance for performance of relevant duties
HBsAg positive	
HBV DNA ≥200 IU/mL	- restrict from relevant duties, regardless of treatment status
HBV DNA <200 IU/mL [†]	<ul style="list-style-type: none"> - allow relevant duties and: <ol style="list-style-type: none"> a. monitor HBV DNA levels 12 weekly, in cases where HCWs are on continuous antiviral therapy[‡] b. monitor HBV DNA levels 12 monthly, in cases where viral load is <200 IU/ml, either because of natural suppression or 12 months after stopping a course of antiviral therapy[§]

Abbreviations: Anti-HBs, Hepatitis B Surface Antibody; HBsAg, Hepatitis B Surface Antigen; HBV DNA, Hepatitis B Viral Load; HBV, Hepatitis B Virus; HCW, Healthcare Worker; UKAP, UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses.

[†]Two identified and validated samples taken no less than 4 weeks apart.

[‡]The HCW, in collaboration with the treating physician, is responsible to decide whether to take antiviral therapy for occupational health reasons, when it is not clinically indicated.

[§]Monitoring intervals to be reviewed by UKAP in 2021.

monitoring. Importantly, there is no restriction on HCWs with HBV performing non-exposure prone procedures, regardless of the degree of viraemia.¹

The exposure prone environment is defined as 'an environment in which there is a significant intrinsic risk of injury to the healthcare worker, with consequent co-existent risk of contamination of the open tissues of the patient with blood from the healthcare provider'. Healthcare workers who are likely to perform invasive procedures in an exposure prone environment, for example packing a deep wound in a body cavity or performing a thoracotomy/ thoracocentesis requiring a finger sweep, would require health clearance for EPP. An EPP is defined as a procedure in which there is an opportunity for injury to a HCW, which could result in the worker's blood contaminating the patient's open tissues, referred to as 'bleed-back'. EPPs are further risk-stratified into three categories based on the type of procedure being performed, but in the UK restrictions to perform EPPs apply equally across all categories. Healthcare staff with responsibility for haemodialysis are subject to the same restrictions as HCWs performing EPPs. Although not an EPP per se, the repetitive bloodstream access that is a key part of this treatment is deemed to increase the risk of transmission from HCW to patient in comparison with other non-EPP clinical duties. Also, of note, some routine dental procedures are included in the UK definition of EPP.¹

HBsAg-positive HCWs, similar to any individual with chronic hepatitis B (CHB), should be referred for specialist management. In 2019 and more recently in 2020, UK restrictions on EPP-performing HCWs living with hepatitis B with a high pre-treatment viral load and/or who are hepatitis B e antigen (HBeAg)-positive were lifted, subject to tenofovir disoproxil fumarate (TDF) or entecavir (ETV) being prescribed with strict monitoring in place. In essence, UKAP recommends that HCWs who perform EPPs or work in a clinical role involving dialysis should be restricted from practising their duties only if HBV DNA level is equal to or higher than 200 IU/mL, regardless of their HBeAg or treatment status.¹ This change in UKAP guidance considered the efficacy of currently available antiviral agents. In a report published in 2015, 77% of confirmed or suspected HBV transmission from HCW to patients were from HBeAg-positive individuals.² The lowest measured viral load was 2.5×10^5 copies/mL in an HBeAg-negative surgeon from the UK, reflecting the fact that infectivity is best measured using molecular tests rather than using HBeAg status as a surrogate. However, the incidence of transmission via needlestick was reported as 2% from HBeAg-negative and 19% from HBeAg-positive HCWs.³ To date, all reported cases of HBV transmission associated with EPPs have occurred at HBV DNA levels $>10^5$ geq/mL ($>2 \times 10^4$ IU/mL), with the exception of one possible case, the validity of which has been challenged, because the sample was taken from the provider more than 3 months after the presumed transmission occurred.⁴ The conservative cut-off of 200 IU/mL, however, is believed to allow for some undetected fluctuations in viraemia within a safe buffer zone.

A more contentious issue relates to the restrictions placed on HBeAg-negative HCWs with a pre-treatment viral load $>20,000$ IU/mL, regardless of whether stable viral suppression on treatment is achieved. Although in the UK these restrictions, first implemented in

2007, were recently lifted, this may remain relevant in other health-care systems, especially in low-resource settings. These recommendations originally stem from concerns over viral rebound in the context of emergent viral resistance or poor adherence to antiviral therapy. Concerns over antiviral resistance originate from the era of 1st and 2nd generation nucleo(s)tide analogues such as Lamivudine, Adefovir and Telbivudine, which historically were the standard of care, but are characterized by a relatively low genetic barrier to resistance.⁵ In low-income healthcare systems, these drugs may still be prescribed. In particular, Lamivudine remains the first-line (or only available) antiviral therapy for hepatitis B in many low-income countries and adherence to guidance to restrict practice of those with a high pre-treatment viral load would be prudent in this context. However, TDF and ETV are now widely used as first-line antiviral agents in many countries. They have a potent antiviral effect with a high genetic barrier to resistance; notably, TDF resistance is reported in case series only.⁶ Resistance to ETV can occur, particularly in the context of prior exposure to Lamivudine.⁵ However, ETV may be chosen over TDF if there are concerns over renal risk factors or bone disease. More recently, this has been superseded by a new preparation of tenofovir [tenofovir alafenamide (TAF)], shown to be less nephrotoxic in clinical trials.⁷ However, TAF is not widely available in many countries, primarily owing to its cost.

To provide assurance to the Department of Health and Social Care that EPP-performing HCWs are meeting clearance requirements, UKAP introduced a mandatory requirement for HBV-positive HCWs to be registered on a secure, confidential central database with data uploaded regularly by the nominated occupational health physician for a HCW. This prospective dataset will also facilitate evidence-based decisions pertaining to the appropriate management of the HBV-positive HCW to maintain patient safety with the least restrictive occupational health recommendations. This register has been in place for 8 years for HIV-positive HCWs performing EPP, and there have been no breaches in practice that have resulted in transmission to patients (Unpublished, UKAP).

While patient safety must remain the paramount concern of any public health guidance, policy makers are obligated to consider developments in the field to ensure the delivery of a safe service and concurrently minimize restrictions on HCWs. With the recommended 12-weekly monitoring schedule and a low threshold to suspend duties involving EPP, UKAP contends that patient safety would not be compromised with the lifting of the aforementioned restrictions. This has also been endorsed by the Chief Medical Officers of the United Kingdom (Communication to UKAP, June 2018).

3 | THE IMPACT OF PREVENTIVE MEASURES ON REDUCING RISK OF HBV TRANSMISSION FROM HEALTHCARE WORKERS TO PATIENTS

Over the last two decades, there has been significant progress in implementing 'Standard Precautions' to minimize the risk of bloodborne

virus transmission in clinical practice, including but not limited to the use of protective equipment, double-gloving, wider use of single-use equipment and more effective cleaning standards.^{8,9} In combination with a robust occupational health policy, these measures have been highly effective in reducing the risk of HCW-to-patient transmission of HBV. In the UK, there have been no cases of HBV transmission from HCW to patient since 2007.

The reported risks of HBV transmission from a HCW to a patient, calculated from published lookback exercises in countries of low HBV prevalence, ranged from 0.2% to 13.19% with an average risk of 2.96% per EPP the HCW performed.¹⁰ In a further paper, Lewis *et al* summarized all published cases of confirmed, probable and possible HCW-to-patient transmission from 1969 onwards and it is notable that a decline has been documented over this timeframe.² Early cases were associated with a lack of standard prophylactic measures in a minority of cases. For example, gloves were not standard practice for dentists or oral surgeons before the 1980s; double-gloving only became a standard recommendation in the early 2000s.² In the United States, since 1994, there has been only one case published, where an orthopaedic surgeon unaware of his infection status transmitted HBV to between two and eight patients between August 2008 and May 2009.¹¹

4 | INTERNATIONAL COMPARISONS TO UK GUIDANCE

The UK guidance on restriction of practice of HCW with HBV is more stringent than that of the United States, Canada, Europe and Australia. While there is broad international agreement on what constitutes an EPP, albeit with some differences in interpretation of the principle of EPP to clinical practice, US recommendations do not count routine dental work as EPP, only major oral surgery, which is in contrast to UK guidance. Similarly, clinical work involving haemodialysis is not restricted on the basis of HBV status in the United States or Australia.^{10,12,13}

The latest Society for Healthcare Epidemiology of America (SHEA) guidance restricts HCW with HBV from performing EPP solely on the basis of HBV DNA level (on or off antiviral treatment) and not on HBeAg status, and adopts a cut-off level of equal to or higher than 1,000 IU/mL. This is in recognition that HBV DNA is a more sensitive marker of infectivity than the presence or absence of HBeAg.¹³ As previously discussed, UK-based HCWs with CHB are restricted from performing EPP if HBV DNA level is equal to or exceeds 200 IU/mL. This is more cautious than the 1,000 IU/mL SHEA cut-off, the cut-off of 10⁴ geq/mL (2,000 IU/mL) proposed by the European Consensus Group and the cut-off of 10⁵ geq/mL in the Netherlands.^{4,13,14} According to data published in 2008, it was estimated that this lower threshold would have restricted practice of 58% of HBV-positive HCWs in the UK and >94% in the Netherlands, if adopted.¹⁵ Notably, guidelines from the United States and the European Association for the Study of the Liver (EASL) do not restrict HCW on antiviral therapy from performing EPP based on the pre-treatment viral load.⁵

The UK with its longstanding track record in patient safety and occupational health has always sought to adopt the most stringent guidance with patient safety being paramount. The HBV field is now on the cusp of major change with multiple new therapeutic agents to achieve functional cure (sustained HBsAg loss) in the developmental pipeline. Therefore, these are timely changes to the UK guidance to ensure patients are protected from viral transmission through EPP, which in some cases could be catastrophic. Combined with the drive to eliminate HBV, the latest guidance will protect patients, but will not be overly restrictive on HCWs who can still make a major contribution to the NHS. Importantly, given the relatively small numbers of HBV-infected HCWs in the UK, the changes in policy have not overburdened occupational health departments.

In areas of high population prevalence of HBV, the risk of transmission from patient to HCW is significant and possibly even greater than the risk to the patient, given that the risk of infection from patient to HCW is not limited to the context of EPP and percutaneous exposure is common.^{12,16} Patient-to-patient transmission is also more common in areas with limited health-care resource, due to the lack of standard infection control precautions. The World Health Organization (WHO), alongside other international societies, recommends that all HCWs are vaccinated against HBV and have highlighted the need for improved safety of blood transfusions and infection control policy, particularly injection safety.¹⁷ Despite this, in sub-Saharan Africa the reported rates of HBV immunization in healthcare workers were suboptimal with 4.6%–64.4% of those 'ever vaccinated' completing the recommended vaccination course to give protective immunity, while hepatitis B core antibody (anti-HBc) positivity was as high as 41%–92%.^{18,19} South African guidelines recommend that HBsAg-positive HCW with HBV DNA $\geq 2,000$ IU/mL should commence TDF / ETV prior to performing EPP, with restrictions in place until HBV DNA <2,000 IU/mL or ideally an undetectable HBV DNA.²⁰ Unfortunately, formal guidelines and established occupational health policy are lacking in many of these geographic regions, where the risk of HBV transmission in healthcare settings is greatest.

5 | CONCLUSIONS

WHO recommended improved infection control measures, blood safety and widespread vaccination to limit HBV transmission from HCW to patient, patient to HCW and patient to patient, but implementation can be challenging in areas with limited healthcare resource. Such measures are effective and transmission of HBV from HCW to patient is now exceedingly rare in high-resource settings due to standard prophylactic measures, immunization of HCWs against HBV and restricting highly viraemic HCWs from performing EPPs. The current antiviral therapies, which have been standard of care in high-income countries for many years, achieve high rates of viral suppression and are characterized by their

high barrier to HBV resistance. Furthermore, many novel antiviral agents are in the developmental pipeline with the therapeutic goal of functional cure, thus the future of HBV treatment appears promising.

As it stands, UK guidance is conservative compared to that of other nations with lower thresholds for restricting HCW from performing EPP. Moreover, what is designated EPP in UK guidance is also restrictive compared to that of other high-income nations, including HCW performing dialysis procedures and routine dental work. Similar to the current UK policy that permits HIV-infected HCW on antiretroviral therapy to perform EPPs with appropriate monitoring, the changes in policy for HBV-infected HCWs performing EPPs in the UK recommended by UKAP have recently been adopted and integrated into clinical practice. Consequently, UK guidance is now in line with that of other high-income nations without compromising patient safety. Furthermore, in the long term, patients will benefit from an increase in staffing from a small but appreciable number of HCWs, who previously were restricted from being able to perform EPP. Based on current evidence, the recent changes to UK guidance will ensure that patient safety remains paramount, without unduly restricting HCWs from clinical practice.

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CONFLICTS OF INTEREST

None declared for this article.

AUTHOR CONTRIBUTIONS

Grace E. Dolman: Preparation of the manuscript, drafting the article and final approval of the version to be submitted; **Apostolos Koffas:** Preparation of the manuscript, drafting the article and final approval of the version to be submitted; **Emily Phipps:** Conception and design of the study, critical revision and final approval of the version to be submitted; **Patrick T.F. Kennedy:** Conception and design of the study, critical revision and final approval of the version to be submitted. **All authors** agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

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