

Hepatitis B infected healthcare workers and antiviral therapy



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Introduction

1. These new guidelines, based upon recommendations from the Advisory Group on Hepatitis (AGH),¹ provide advice on the criteria and arrangements for allowing certain healthcare workers infected with hepatitis B to perform exposure prone procedures² while taking continuous oral antiviral therapy.

1 www.advisorybodies.doh.gov.uk/agh/

2 Exposure prone procedures are those invasive procedures where there is a risk that injury to the worker may result in the exposure of the patient's open tissues to the blood of the worker. Such procedures occur mainly in surgery (including some minor surgery carried out by GPs), obstetrics and gynaecology, dentistry and some aspects of midwifery. Most nursing duties do not involve exposure prone procedures; exceptions include A&E and some aspects of theatre nursing. Further guidance and examples of exposure prone procedures can be found in HIV infected healthcare workers: guidance on management and patients notification – www.dh.gov.uk/assetRoot/04/11/64/16/04116416.pdf

Background

Previous guidance

2. Health Service Circular (HSC 2000/020) issued in June 2000³ recommended that hepatitis B infected healthcare workers, who were e-antigen negative but had hepatitis B virus (HBV) DNA levels above 10^3 genome-equivalents/ml (geq/ml) measured in two designated laboratories, should be restricted from performing exposure prone procedures. This guidance did not recommend that restrictions be placed upon healthcare workers who were e-antigen negative with HBV DNA levels at 10^3 geq/ml or below, but did recommend that they be subject to annual testing, and that those workers whose viral load rose above 10^3 geq/ml should stop performing exposure prone procedures for as long as their viral load remained above that level.
3. HSC 2000/020 also advised that hepatitis B infected healthcare workers should not perform exposure prone procedures while on interferon or oral antiviral therapy; but that a return to exposure prone procedures could be considered for those whose viral load did not exceed 10^3 geq/ml one year after cessation of therapy. However, this may not be a common outcome.

AGH's recommendations and consultation exercise

4. Given the greater knowledge and experience about oral antiviral agents active against hepatitis B infected individuals who are hepatitis B e-antigen (HBeAg) negative, and the development of newer drugs for the treatment

3 Health Service Circular HSC 2000/020: Hepatitis B infected healthcare workers – www.dh.gov.uk/assetRoot/04/01/22/57/04012257.pdf and www.dh.gov.uk?assetRoot/04/05/75/38/04057538.pdf

of chronic hepatitis B, in July 2004 the Department of Health consulted on further advice from the AGH. This advice was that, subject to certain conditions, including regular monitoring, hepatitis B infected healthcare workers, who were HBeAg negative, could be allowed to perform exposure prone procedures while taking continuous oral antiviral therapy if their infection were adequately controlled (ie HBV DNA levels no higher than 10^3 geq/ml).

5. The majority of respondents to the consultation exercise supported the principles of the AGH advice, but this was heavily qualified, with recognition that there could be significant problems associated with implementing this advice. Based upon the responses to this exercise, the Department decided not to ask the NHS to implement the AGH's advice because of concerns that the necessary monitoring arrangements could not be put in place locally across the whole of the NHS and that patients may be put at risk of infection.⁴
6. Since then, the Department has explored ways to establish suitable monitoring arrangements to permit implementation of the AGH's advice. Under these arrangements, it is recommended that only consultant occupational physicians and a small network of designated clinicians with expertise in the management of chronic hepatitis B infection should have responsibility for assessing and monitoring individual hepatitis B infected healthcare workers who wish to perform exposure prone procedures while taking continuous oral antiviral therapy.
7. The main AGH recommendations underpinning this guidance are as follows:
 - hepatitis B infected healthcare workers who are HBeAg negative and who have pre-treatment HBV DNA levels between 10^3 and 10^5 geq/ml (likely to be a significant proportion of those restricted from performing exposure prone procedures) could be allowed to perform exposure prone procedures on oral antiviral therapy, if their viral load is suppressed to below 10^3 geq/ml;

4 www.dh.gov.uk/Consultations/ResponsesToConsultations/ResponsesToConsultationsDocumentSummary/fs/en?CONTENT_ID=4119983&chk=4Oeflg

- healthcare workers with baseline viral loads above 10^5 geq/ml should be ineligible to perform exposure prone procedures while taking oral antiviral therapy on the grounds of patient safety. The rationale for this limitation is explained in **Annex A**;
- hepatitis B infected healthcare workers performing exposure prone procedures while on oral antiviral therapy should have their HBV DNA levels monitored at regular three-monthly intervals. Samples should be sent for testing at one of the two designated laboratories specified in the guidelines issued in 2000 (see paragraph 2);
- healthcare workers should cease to perform exposure prone procedures if their HBV DNA levels rise to greater than 10^3 geq/ml while on or after treatment;
- healthcare workers would be under a professional and ethical obligation to immediately cease performing exposure prone procedures should they stop treatment for any reason;
- if a patient were accidentally exposed to the blood of a hepatitis B infected healthcare worker, such exposures should be assessed as soon as possible by designated local staff and managed in accordance with existing guidance, including consideration of the need for post-exposure prophylaxis.

Implementation

8. In line with these recommendations, individual hepatitis B infected healthcare workers may be allowed to undertake exposure prone procedures while taking oral antiviral therapy, provided that the necessary safeguards are in place to ensure patient protection.

Case-by-case assessment by consultant occupational physician

9. Employers should undertake a risk assessment on a case-by-case basis, taking account of the factors and recommendations set out below. It is anticipated that the risk assessment will normally be carried out by the consultant occupational physician.
10. The consultant occupational physician would be responsible for advising the healthcare worker's employer of their fitness to perform exposure prone procedures. All NHS employers should have access to appropriate advice from a consultant occupational physician through their occupational health arrangements. If the employer has no such arrangement, the Association of NHS Occupational Physicians (ANHOPS) may be able to assist in identifying suitable local contacts.⁵

5 For ANHOPS advice, contact the Chairman whose contact details are on the Association's website: www.anhops.com

Monitoring arrangements

11. It is recommended that hepatitis B infected healthcare workers wishing to perform exposure prone procedures while taking antiviral treatment are under the continuing care of a consultant occupational physician and one of the clinicians with expertise in treating chronic hepatitis B infection designated in **Annex B**. Where a Trust does not have its own consultant occupational physician, arrangements should be put in place for this advice to be sought from such a consultant outside the Trust (see paragraph 10).
12. It is recommended that referral of hepatitis B infected healthcare workers to the clinicians designated in Annex B be made by the employee's local occupational health service, and not by self-referral.
13. The model for allowing hepatitis B infected healthcare workers to undertake exposure prone procedures in these circumstances relies on continuing access and monitoring. Suitable arrangements for supervision should be in place for agency or locum staff in accordance with this guidance.
14. As an essential part of the monitoring arrangements, it is recommended that, with the healthcare worker's permission, the consultant occupational physician and the designated clinician involved in a particular case liaise on the management of that case.
15. Occupational physicians will be responsible for:
 - ensuring that the testing protocol and timings are followed (see paragraphs 17–21);
 - assessing the results of the HBV DNA levels (see paragraphs 17–21);
 - advising the healthcare worker and the employer, in the usual way and on an ongoing basis, whether the healthcare worker is fit to perform exposure prone procedures.

Funding issues

16. It is for local NHS organisations to consider funding for antiviral treatment of hepatitis B infected healthcare workers and the provision of occupational health supervision, eg if there is not a consultant occupational physician available in the organisation in which the healthcare worker is employed.

Practical considerations

Occupational health and patient safety issues

17. **Only** healthcare workers who are **e-antigen negative and have pre-treatment HBV DNA levels between 10^3 and 10^5 geq/ml** are eligible to return to performing exposure prone procedures while on oral antiviral treatment provided their HBV DNA levels fall to 10^3 geq/ml or less (see paragraph 7 and Annex A).
18. It is recommended that hepatitis B infected healthcare workers taking oral antiviral therapy could commence exposure prone procedures when their HBV DNA levels have been at or below 10^3 geq/ml on two consecutive tests performed no less than one month apart.

Monitoring of HBV DNA levels

19. Once a hepatitis B infected healthcare worker taking antiviral therapy has been cleared to start exposure prone procedures, it is recommended that they should have their HBV DNA levels checked every three months (the period should be taken from the date the previous blood sample was drawn, and not from the date the result was received). Identified and validated

samples (IVS)⁶ should be taken in the occupational health department, which will be responsible for arranging for them to be tested and for informing the treating clinician of the results in a timely manner. If the healthcare worker's HBV DNA level is greater than 10^3 geq/ml, then they should cease exposure prone procedures and be referred to their hepatologist for assessment (see also paragraphs 24–25).

20. For the purpose of monitoring healthcare workers taking antiviral therapy, a single blood sample at each three-monthly test is sufficient. Tests should be performed at one of the two laboratories designated in HSC 2000/020. The laboratory request form should be clearly marked **single sample for monitoring antiviral treatment**.

Failure to attend appointments or those who refuse to be tested

21. Where a healthcare worker does not attend for their regular appointments with the occupational health physician or the treating clinician, or attends but refuses to have their HBV DNA tested, it is recommended that the occupational health physician should inform the worker's employer that they are no longer cleared to perform exposure prone procedures, until it has been established that the healthcare worker is continuing with oral antiviral treatment and an up-to-date HBV DNA level not greater than 10^3 geq/ml has been obtained.

6 An IVS is defined by ANHOPS and the Association of NHS Occupational Health Nurses (ANHONS) as meeting the following criteria (a) the healthcare worker should show a proof of identity with a photograph – Trust identity badge, new driver's licence, some credit cards, passport or national identity card – when the sample is taken; (b) the sample of blood should be taken in the occupational health department; (c) samples should be delivered to the laboratory in the usual manner, not transported by the healthcare worker; (d) when results are received from the laboratory, the clinical notes should be checked for a record that the sample was sent by the occupational health department, at the relevant time.

Treatment issues

Decisions about treatment

22. Currently it would be unusual to offer antiviral treatment to patients who are HBeAg negative and have viral loads below 10^5 geq/ml unless there was evidence of an active hepatitis. Hence, hepatitis B infected healthcare workers wishing to take advantage of this change in policy could be embarking upon long-term antiviral treatment purely in an attempt to be allowed to perform exposure prone procedures rather than because such treatment was deemed clinically necessary. It would be for the individual healthcare worker, in collaboration with their treating physician, to weigh up the advantages and possible disadvantages to their health from such treatment.

Discontinuation of therapy

23. It is recommended that if a healthcare worker stops antiviral treatment for any reason, they should immediately cease to perform exposure prone procedures (and seek the advice of their treating physician if this has not already been obtained). If the HBV DNA levels of healthcare workers stopping antiviral therapy remains below 10^3 geq/ml a year after cessation of treatment, it may be appropriate for the employer to permit a return to exposure prone procedures at that time, subject to a future test six months later and annual testing thereafter as is recommended in the earlier guidelines.

Breakthrough infections

24. If there is any suggestion that a breakthrough infection⁷ has developed, the clinician overseeing the case may consider it appropriate that HBV DNA tests are performed sooner than the next three month test.

⁷ The emergence of strains of the virus resistant to these antiviral agents is usually associated with a breakthrough infection with increases in serum HBV DNA and (later) in serum alanine aminotransferase (ALT) levels. Early diagnosis of the emergence of resistance can be achieved by using sensitive HBV DNA assays, as is recommended here, allowing consideration of an early change in antiviral therapy.

25. If breakthrough infections occur due to the development of resistant strains, and HBV DNA levels rise above 10^3 , then it is recommended that the healthcare worker be restricted from performing exposure prone procedures until such time as they have been re-stabilised on different oral antiviral drugs. This would be demonstrated by HBV DNA levels of less than 10^3 geq/ml on two consecutive tests performed no less than one month apart.

Accidental blood exposures

26. As mentioned above, if a patient is accidentally exposed to the blood of a hepatitis B infected healthcare worker, it is recommended that such exposures should be assessed as soon as possible by designated staff and managed in accordance with existing guidance, including consideration of the need for post-exposure prophylaxis.

Confidentiality

27. It is extremely important that hepatitis B infected healthcare workers receive the same right of confidentiality as any patient seeking or receiving medical care. Occupational health staff, who work within strict guidelines on confidentiality, have a key role in this process. It is recommended that occupational health departments are closely involved in revising local procedures for managing hepatitis B infected healthcare workers who are taking antiviral therapy. Occupational health notes are separate from other hospital notes. Occupational health staff are ethically and professionally obliged not to release information without the consent of the individual. There are occasions when an employer may need to be advised that a change of duties should take place, but hepatitis B status itself will not normally be disclosed without the healthcare worker's consent. Where patients are, or have been, at risk, however, it may be necessary in the public interest for the employer to have access to confidential information.

Duties of other healthcare workers

28. Healthcare workers who know or have good reason to believe (having taken steps to confirm the facts as far as practicable) that a hepatitis B infected healthcare worker has not complied with this guidance or followed advice to modify their practice, should inform an appropriate person in the healthcare worker's employing or contracting authority (eg a consultant occupational health physician, Trust medical director or director of public health) or, where appropriate, the relevant regulatory body. Healthcare workers may wish to seek advice from their regulatory and professional bodies before passing on such information. Such cases are likely to arise very rarely. Wherever possible, the healthcare worker should be informed before information is passed to an employer or regulatory body.

Patient notification exercises

29. It is recommended that the finding, at a three-monthly test, that an infected healthcare worker's HBV DNA level has risen above 10^3 geq/ml would not, in itself, be an indication to trace, notify and offer hepatitis B testing to patients treated by the healthcare worker. Advice on the need for patient notification is available from the UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses (UKAP). UKAP's contact details are as follows:

Dr Fortune Ncube
Medical Secretary, UKAP
Tel: 020 8327 6423
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Administrative Secretary, UKAP
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Annex A

Rationale for recommendation that healthcare workers with baseline viral loads above 10^5 genome equivalents/ml (geq/ml) should be ineligible to perform exposure prone procedures while taking oral antiviral therapy

1. The AGH has recommended that only hepatitis B e-antigen negative healthcare workers with pre-treatment HBV DNA levels between 10^3 and 10^5 should be allowed to perform exposure prone procedures while on oral antiviral treatment provided their HBV DNA levels fall below 10^3 .
2. It is the view of the AGH that with successful oral antiviral treatment the rate of viral replication in such healthcare workers should be suppressed to levels where the risk of emergence of drug resistant strains is likely to be low. Also, if such resistant strains were to occur, HBV DNA levels should not rise above the baseline level and, with frequent monitoring, should be detected early and before patients were put at appreciable risk.
3. When drug resistance develops, there is a slow rise in HBV DNA, but while on continued treatment this does not usually rise above the baseline level. The viral loads in individuals with baseline levels well in excess of 10^5 genome equivalents/ml may also be suppressed to below 10^3 by viral suppressive treatment. However, the emergence of resistant strains in such cases could result in a return of viral load to levels where transmissions of infection are known to have occurred.
4. On grounds of patient safety, the AGH agreed that only healthcare workers whose baseline viral loads did not exceed 10^5 geq/ml would be eligible to perform exposure prone procedures, provided there was satisfactory viral suppression. This question will be reviewed if a form of viral suppressive therapy emerges that is not associated with viral breakthrough.

Annex B

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