Hepatitis B Infected Health Care Workers and Oral Antiviral Therapy

Consultation paper on implementing expert advice about a limited relaxation of restrictions on hepatitis B infected health care workers

July 2004
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| **Document Purpose** | Consultation/Discussion |

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| **Title**            | Hepatitis B Infected Health Care Workers and Oral Antiviral Therapy |

| **Author**           | Department of Health/General Health Protection |

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| **Target Audience**  | PCT CEs, NHS Trusts CEs, SHA CEs, Medical Directors, Directors of PH, Directors of Nursing, Directors of HR, Allied Health Professionals, occupational physicians and nurses, consultants in communicable disease control |

| **Description**      | This document seeks views on the implementation of expert advice that, under specified conditions, hepatitis B infected health care workers should be allowed to perform exposure prone procedures whilst taking oral antiviral drug therapy |

| **Cross Ref**        | Health Service Circular 2000/020: Hepatitis B infected health care workers (June 2000) |

| **Superseded documents** | N/A |

| **Action required**   | Comments are requested on the consultation questions contained in the document |

| **Timing**            | Deadline for response is 22 October 2004 |

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Executive summary

1. This consultation paper seeks views on the practicability of implementing advice from the Advisory Group on Hepatitis (AGH) that, under specified conditions, health care workers infected with hepatitis B should be allowed to return to unrestricted practice whilst taking oral antiviral treatment provided that they are carefully monitored. Comments are sought on the general principle of the proposal and its implementation, and upon a number of specific questions set out in paragraph 14 below. The list of consultees is at Appendix C.

2. All comments should be sent to Mrs Helen Hamlet, Department of Health, Health Protection Division, Room 631B Skipton House, 80 London Road, London SE1 6LH or by e-mail to Hepatitis_B_Info@doh.gsi.gov.uk

3. The deadline for comments is 22 October 2004.
4. Current guidelines on the management of health care workers infected with hepatitis B restrict their working practices where it is felt that patients may be put at risk of infection. The guidelines do not permit such workers to return to unrestricted working practices whilst taking antiviral therapy. Any return depends upon a favourable and durable response to treatment 12 months after cessation. This is likely to benefit only a small proportion of those restricted.

5. The proposal being consulted upon, based upon expert advice from the Advisory Group on Hepatitis (AGH), is that, under certain specified circumstances and subject to careful and frequent monitoring, health care workers infected with hepatitis B should be allowed to return to unrestricted working practices if their infection is adequately controlled whilst taking continuous oral antiviral therapy.

Background

Restrictions on hepatitis B infected health care workers

6. Following outbreaks of hepatitis B among patients of health care workers infected with hepatitis B, guidelines issued by the Department of Health in August 1993\(^1\) routinely restricted those health care workers infected

with hepatitis B thought to be most infectious (i.e. those who carried the e-antigen) from performing exposure prone procedures. In these guidelines, the e-antigen was chosen as an indicator of high infectivity rather than the measurement of viral load because:

- at that time, all reported outbreaks in which the e-markers had been determined, had involved hepatitis B infected health care workers with the e-antigen;
- there were problems with the standardisation of tests to measure viral load; and
- viral loads at which transmission between health care workers and their patients was likely to occur were unknown.

7. However, subsequent to these guidelines, further health care worker-to-patient transmissions of hepatitis B were documented involving health care workers who did not carry the e-antigen but who were shown to have higher viral loads (HBV DNA levels). Also, newer and more sensitive tests that allowed viral load to be determined more reliably became available. Therefore, in further guidelines issued in June 2000, the restrictions were extended to include hepatitis B infected health care workers who were e-antigen negative but had HBV DNA levels above $10^3$ genome equivalents/ml (as measured by the Roche Amplicor assay). Health care workers with HBV DNA levels at $10^3$ or below are not restricted from performing exposure prone procedures but are subject to annual testing. Those workers whose viral load rises above $10^3$ have to stop performing exposure prone procedures.

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ii 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. These procedures occur mainly in surgery, obstetrics and gynaecology, dentistry and midwifery.

Possible return to exposure prone procedures

8. These guidelines do not permit hepatitis B infected health care workers to continue to perform exposure prone procedures whilst on interferon or antiviral therapy, but allow a return to be considered for those whose viral load does not exceed $10^3$ genome equivalents/ml 1 year after cessation of therapy, also subject to annual testing. Early studies using lamivudine for treatment of hepatitis B had reported high rates of drug resistant strains emerging whilst on prolonged therapy, although such studies usually involved only patients with high viral loads. Expert advice is that resistance is much less likely to develop in patients with lower baseline viral loads, and it has been shown that should breakthrough infections occur, the ensuing rise in viral load does not exceed pre-treatment levels while treatment is maintained.

9. Given the greater experience that has now accrued with oral antiviral agents active against hepatitis B in patients who are hepatitis B e-antigen (HBeAg) negative, and the development of newer drugs for the treatment of chronic hepatitis B infection, the AGH (which provides the Department of Health with expert advice on the prevention and control of hepatitis B) has recently reconsidered this issue. The AGH has advised that, under certain circumstances, HBeAg negative infected health care workers should be allowed to return to exposure prone procedures whilst taking antiviral treatment, provided that their HBV DNA levels are suppressed to $10^3$ genome equivalents/ml or below. Individual health care workers should remain under the close supervision of a consultant in occupational medicine, in collaboration with a consultant physician experienced in treating hepatitis B infection.

10. In formulating its advice the AGH noted that:
   • should resistant strains emerge, viral load would rise slowly and this would be readily detectable by routine 3-monthly monitoring of HBV DNA levels
given that whilst treatment is maintained the viral load would not rise above pre-treatment levels, if only those health care workers with a pre-treatment viral load no greater than $10^5$ were treated, any rise in HBV DNA levels during this period should not put patients at appreciable risk.

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

Recommendations from the Advisory Group on Hepatitis (AGH)

12. The AGH’s advice, with further background information and a number of practical considerations for the implementation of this proposal, is attached at Appendix A. In brief, the proposal is that:

- hepatitis B infected health care workers who are e-antigen negative and who have pre-treatment HBV DNA levels between $10^3$ and $10^5$ genome equivalents/ml (likely to be a significant proportion of those restricted by current guidelines) should be allowed to return to exposure prone procedures on oral antiviral suppressive therapy, if they so wish, if their viral load is suppressed to $10^3$ or below;

- such health care workers should have their HBV DNA levels monitored at regular 3-monthly intervals; and that

- they would be under a professional ethical obligation to cease performing exposure prone procedures within 48 hours should they stop treatment for any reason.
Health care workers infected with other blood-borne viruses

13. **Appendix B** explains why our advisory committees have recommended that health care workers infected with hepatitis C or HIV should not be allowed to return to exposure prone procedures whilst on antiviral therapy.

Purpose of consultation

14. Comments are sought concerning the general principle of this proposal and, in particular, upon how it might be implemented.

Specific questions to be considered should include:

- How practicable would it be for occupational health departments to implement such a policy?

- What are the benefits to the NHS and patients likely to be, and do they outweigh any risks associated with possible non-compliance with antiviral drug therapy by health care workers?

- Does the recommended relaxation of restrictions strike the right balance between protecting patients from the risk of infection and not imposing unnecessary restrictions on hepatitis B infected health care workers (i.e. restrictions that prevent them pursuing their chosen career)?

- Could adequate occupational health arrangements be made to monitor locum or agency staff not otherwise in regular employment?

- What arrangements could be made for health care workers in primary care (e.g. dentists) who may wish to take antiviral therapy?

15. Please send any comments to Mrs Helen Hamlet, Department of Health, Health Protection Division, Room 631B Skipton House, 80 London Road, London SE1 6LH or by e-mail to Hepatitis_B_Info@doh.gsi.gov.uk by 22 October 2004.
The Advisory Group on Hepatitis (AGH)

Statement of Advice

HEPATITIS B e-ANTIGEN NEGATIVE INFECTED HEALTH CARE WORKERS – RETURN TO UNRESTRICTED WORKING PRACTICES WHILST TAKING PROLONGED ORAL ANTIVIRAL THERAPY

Introduction

1. When drawing up recommendations for the management of hepatitis B infected health care workers on which HSC 2000/020 was based, the Advisory Group on Hepatitis (AGH) advised that infected health care workers should not be allowed to return to unrestricted practice whilst taking antiviral therapy. At that time, the only oral antiviral agent licensed for use against hepatitis B was lamivudine.

2. Studies had shown that treatment with lamivudine resulted in reduction in viral load, but that short courses were unlikely to result in a sustained response, with viral load rising in most cases on discontinuation of treatment (Dienstag et al. 1995; Santantonio et al. 2000). Prolonged treatment with this drug was associated with the emergence of high levels of drug resistant strains (10-20% per year)(Lai et al. 2003), resulting in a rise in HBV DNA titres. HBV DNA levels would also rise if there were a failure to comply adequately with continuous treatment. Further, the health consequences of prolonged treatment were unknown.
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3. Given greater experience of the use of oral antiviral agents active against hepatitis B in patients who are HBeAg negative, and the emergence of newer drugs, the AGH has recently reconsidered this question. The AGH’s view is now that it may be possible to allow some existing hepatitis B e-antigen negative infected health care workers to return to unrestricted practice whilst taking antiviral therapy, provided their HBV DNA levels are suppressed and remain below $10^3$ genome equivalents/ml, and the individual health care worker remains closely monitored by occupational health (see paragraphs 17 and 18).

Oral antiviral therapy for chronic hepatitis B infection

4. Research has shown that a number of oral antiviral agents, either currently licensed i.e. lamivudine (Hadziyannis et al. 2000) and adefovir (Hadziyannis et al. 2003) or at the clinical trials stage – e.g. entecavir (Lai et al. 2002), can suppress viral replication in patients with e-antigen negative chronic hepatitis B and result in reductions in viral load on sustained therapy. However, rises in viral load may occur if therapy is stopped (Gilson et al. 1999), or if mutations of the hepatitis B virus occur making it resistant to these agents (Papatheodoridos et al. 2002).

Drug resistance

5. Pre-treatment factors that may affect the emergence of lamivudine resistant strains include high rates of viral replication (HBeAg positivity and high HBV DNA levels) (Mutimer et al. 1999; Lai et al. 2003), and the particular virus subtype, the risk of lamivudine resistance being higher in $adw$ carriers than for $ayw$ carriers (Zollner et al. 2002). Factors predicting resistance during lamivudine therapy appear to relate to the degree of viral suppression and the speed with which it occurs. One study has reported an increased risk when HBV DNA levels remain above $10^3$ genome equivalents/ml (Amplicor HBV Monitor Assay) 6 months after commencing treatment; 62.3% of such patients subsequently developed resistance as compared to 13% of those with HBV DNA levels below $10^3$.
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genome equivalents/ml (Yuen et al. 2001). Another study following up renal transplant patients at 12-15 months showed that lamivudine resistance occurred in patients who had detectable virus levels of $10^3$–$10^5$ HBV DNA genome equivalents/ml after 3 months of treatment, but did not develop within the observation period in those who had no HBV DNA detectable by quantitative polymerase chain reaction (PCR) assay after 3 months of treatment (Puchhammer-Stockl et al. 2000).

6. When treated with lamivudine (or other viral suppressive agents), individuals with HBV DNA levels between $10^3$ and $10^5$ are very likely to have their viral loads suppressed sufficiently to fall below $10^3$ genome equivalents/ml and possibly below the lower range of the current quantitative assays. Continuous treatment with antiviral therapy of health care workers with HBV DNA levels within this range should reduce viral replication to levels where the risk of emergence of resistance is likely to be low. If resistant strains emerged, HBV DNA levels should not rise above the pre-treatment levels at which the risks of transmission are small.

7. Adefovir is active against lamivudine resistant strains.

8. The emergence of hepatitis B strains resistant to adefovir have recently been reported (Angus et al. 2003; Villeneuve et al., 2003). However, adefovir resistance appears to emerge slowly, a recent study showing rates of 0%, 2% and 3.9% after 1, 2 and 3 years of treatment, respectively (Qi et al. 2004). Adefovir resistant strains remain susceptible to lamivudine therapy.

Patient safety issues

9. In the interest of patient safety, the AGH recommends that only hepatitis B e-antigen negative health care workers with pre-treatment HBV DNA levels between $10^3$ and $10^5$ should be allowed to return to exposure prone procedures whilst on oral antiviral treatment, provided their HBV DNA levels fall to $10^3$ or below. It is the view of the AGH that, with successful oral antiviral treatment, the rate of viral replication in such health care 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 emerge, 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. Of the eight transmission incidents associated with e-antigen negative health care workers which have been reported in the UK, only one health care worker had an HBV DNA level below $10^5$ genome equivalents/ml.

10. When drug resistance develops there is a slow rise in HBV DNA, but whilst 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 $10^3$ or below by viral suppressive treatment. However, the emergence of resistant strains in such cases could result in a return of viral load to levels where transmission of infection has occurred. Therefore, the AGH recommend that only health care workers whose baseline viral loads do not exceed $10^5$ genome equivalents/ml should be eligible to return to exposure prone procedures provided there was satisfactory viral suppression. Health care workers with baseline viral loads above $10^5$ genome equivalents/ml would be ineligible to return to unrestricted working practices. This question will be reviewed if a form of viral suppressive therapy becomes available that is not associated with viral breakthrough.

Cessation of treatment

11. If a health care worker decided to stop taking antiviral therapy for any reason, they should, within 48 hours, cease to perform exposure prone procedures and seek prompt medical advice, as viral loads could quickly return to pre-treatment levels. Health care workers would be under a professional obligation to follow this advice. If HBV DNA levels remained at $10^3$ genome equivalents/ml or below 12 months after cessation of treatment, these health care workers could return to exposure prone procedures subject to a test 6 months later, and then annual monitoring as for other health care workers with viral loads at $10^3$ or below as set out in current Department of Health guidance.
**Health care worker safety issues**

12. Recent guidelines from the US (Lok *et al.* 2001) and Europe (EASL Jury 2003) have suggested that patients with chronic hepatitis B infection who are HBeAg negative and have viral loads of $10^5$ and above should be considered for antiviral treatment. Treatment is not usually offered to patients with HBV DNA levels below $10^3$ in the absence of other evidence of hepatic dysfunction. Hence, health care workers with viral loads between $10^3$ and $10^5$ could be embarking upon treatment purely in an attempt to return to unrestricted practice and not, in general, because treatment was deemed clinically necessary.

13. Lamivudine has been in use for several years, and so far appears to have a good safety record. However there have been reports of hepatitis B reactivation following discontinuation of treatment with lamivudine (Honkoop *et al.* 2000; Lim *et al.* 2002). There is less experience with adefovir. A study comparing the effects of 10 mgs and 30 mgs of adefovir in the treatment of patients with HBeAg positive chronic hepatitis B reported mild reversible nephrotoxicity with the 30 mgs dose but not with the 10 mgs dose (Marcellin *et al.* 2003). More severe nephrotoxicity has been reported with the high dose used to treat HIV. The long-term health consequences of taking these agents is not known.

14. Given the uncertain clinical benefits, the AGH recommend that it should be for individual health care workers, together with their treating physician, to weigh up the possible benefits and risks of long-term antiviral therapy for occupational reasons.
Practical considerations

Which health care workers should be considered?

15. The AGH recommend that only health care workers who are e-antigen negative and have pre-treatment HBV DNA levels between $10^3$ and $10^5$ genome equivalents/ml should be eligible to return to performing exposure prone procedures whilst on oral antiviral treatment provided their HBV DNA levels fall below the permitted threshold. A return to exposure prone procedures should not be considered for health care workers with pre-treatment levels above $10^5$ genome equivalents/ml.

Decisions about treatment

16. It will be for individual health care workers (and their treating physician) to weigh up the advantages and possible disadvantages for their health that might result from prolonged antiviral therapy before embarking on such treatment. The choice of drug(s) to use in a particular case will be a decision for the treating physician (and may change as new drugs become available and licensed).

Who should monitor health care workers?

17. Hepatitis B infected health care workers who return to exposure prone procedures whilst on antiviral therapy should be under the continuing care of a consultant physician experienced in treating patients with chronic hepatitis B with antiviral therapy, and of a consultant in occupational medicine.

Monitoring HBV DNA levels

18. Health care workers performing exposure prone procedures whilst taking antiviral therapy for hepatitis B should have their HBV DNA levels checked at least every 3 months (the period should be taken from the
date the previous blood sample was drawn, and not from the date the result was received). For the purpose of monitoring health care workers taking antiviral therapy, a single blood sample at each 3-monthly test is sufficient. Currently, tests should only be performed at one of the two laboratories designated in HSC 2000/020.

When can a health care worker recommence exposure prone procedures?

19. Hepatitis B infected health care workers taking oral antiviral therapy may recommence exposure prone procedures when their HBV DNA levels have been at or below $10^3$ genome equivalents/ml on two consecutive tests performed 1 month apart. HBV DNA levels should then be measured at 3-monthly intervals thereafter.

Discontinuation of therapy

20. If a health care worker stops antiviral treatment for any reason, they should cease to perform exposure prone procedures within 48 hours (and seek the advice of their treating physician if this has not already been obtained). If the HBV DNA level of a health care worker stopping antiviral therapy remains at or below $10^3$ genome equivalents/ml 1 year after cessation of treatment, a return to exposure prone procedures would be permitted at that time, subject to a further test 6 months later and annual testing thereafter, as is recommended in current guidelines.

Breakthrough infections

21. If breakthrough infections occur due to the development of resistant strains, and HBV DNA levels rise above $10^3$, then the health care worker should be restricted from performing exposure prone procedures until such time as they have re-stabilised on different oral antiviral drugs. (i.e. the HBV DNA level should be at or below $10^3$ on two consecutive tests 1 month apart).
Patient notification exercises

22. The finding, at a 3-monthly test, that an infected health care worker’s HBV DNA level had risen above $10^3$ genome equivalents/ml would not, in itself, be an indication to notify patients.

Accidental blood exposures

23. If a patient is accidentally exposed to the blood of a hepatitis B infected health care worker, 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.
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References


Appendix B

Health care workers infected with other blood-borne viruses

**Hepatitis C infected health care workers (Advisory Group on Hepatitis (AGH) advice)**

1. The AGH has advised that hepatitis C infected health care workers should not be allowed to return to exposure prone procedures whilst taking currently available treatments. Such treatments have an overall success rate of 55% after 6 or 12 months’ therapy, depending on genotype. It would not be appropriate for health care workers to return to exposure prone procedures whilst taking this medication (either during the recommended course or if given continuously) because of the severe side effects that can be experienced with interferon which may impair performance.

**HIV infected health care workers (Expert Advisory Group on AIDS (EAGA) advice)**

2. EAGA has recommended that HIV infected health care workers should not be allowed to return to performing exposure prone procedures even if their viral load (HIV RNA) is undetectable on combination antiretroviral therapy and they are closely monitored. EAGA’s arguments against allowing HIV infected health care workers to return to unrestricted practice are as follows:

   • HIV viral load can fluctuate over time (inter-current infection, lapse in medication, failing therapy) and it would be necessary to retest viral load very frequently to ensure that it was undetectable on a particular day.
• Routine viral load assessments do not measure pro-viral DNA that would be in circulating lymphocytes in infected people. This genomic material could potentially re-activate virus replication.

• The phrase ‘viral load undetectable’ is assay dependent, and virus clade dependent, and only measures cell-free virus circulating in the blood. Different methods notoriously give different values and all methods have a cut-off below which the viral load is ‘undetectable’. This is not the same as being non-infectious. A ‘safe’ viral load has not been defined.

• If a change in policy were to be contemplated, there would need to be a clear agreement about assay selection and cut-off level, to give the word ‘undetectable’ some rigour. (However, the definition of ‘undetectable’ is not stable; it will change over time as methodologies are refined.)

• If a return to exposure prone work on treatment were to be permitted for HIV infected health care workers, this could create a conflict for the health care worker and his/her physician. Recent trends have been to delay therapy, but a health care worker might opt to begin therapy in order to return to work, possibly compromising their long-term health interests.
List of consultees

Chief Executives, Primary Care Trusts
Chief Executives, NHS Trusts
Chief Executives, Strategic Health Authorities
Chief Executives, Workforce Development Confederations
Directors of Human Resources via
Directors of Public Health, Strategic Health Authorities e-mail
Directors of Public Health, Primary Care Trusts bulletin
Medical Directors, NHS Trusts

African and Caribbean Medical Society
Ambulance Service Association
Ambulance Whitley Council (Staffside Secretary)
Anglo-Asian Odontological Group
Association of Medical Microbiologists
Association of NHS Occupational Health Nurse Advisers
Association of NHS Occupational Physicians
Association of Occupational Health Nurse Practitioners
British Association for the Study of the Liver
British Dental Association
British Infection Society
British International Doctors Association
British Liver Trust
British Medical Association
British Society of Gastroenterology (Liver Section)
Commission for Racial Equality
Community Practitioners and Health Visitors Association
Council of Heads of Medical Schools
Deans of Medical/Dental Schools in England
Faculty of Dental Surgery
Faculty of General Dental Practitioners
Faculty of Occupational Medicine
Faculty of Public Health Medicine
General Dental Council
General Dental Practitioners Association
General Medical Council
Health Protection Agency
Hepatitis Specialist Nurses Forum
Independent Health Care Association
Muslim Doctors and Dentists Association
NHS Trusts Association
NHS Confederation
Nursing and Midwifery Council
Patients' Association
Patient Advice and Liaison Services Development Group
Patients' Forum
Public Health Medicine Environmental Group
Regional Directors of Public Health
Regional Epidemiologists
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Ophthalmologists
Royal College of Pathologists
Royal College of Paediatrics and Child Health
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons
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Society of Chiropodists and Podiatrists
Society of Occupational Medicine
UK Advisory Panel for Health Care Workers Infected with Blood-borne Viruses (UKAP)
UNISON
Universities UK (Health Committee)
The consultation criteria

The criteria for all UK public consultations by government departments and agencies are set out in the Code of Practice on Consultation published by the Cabinet Office. These are:

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.

2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.

3. Ensure that your consultation is clear, concise and widely accessible.

4. Give feedback regarding the responses received and how the consultation process influenced the policy.

5. Monitor your department’s effectiveness at consultation, including through the use of a designated consultation co-ordinator.

6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

Web address: www.cabinet-office.gov.uk/regulation/consultation/code.htm