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For use in:	Workplace Health and Wellbeing
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For:	All healthcare staff, other agency/contracted workers and students
Division responsible for document:	Corporate
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If Yes - does the strategy/policy deviate from the recommendations of NICE? If so why?	N/A

Trust Guideline on Protection from Occupational Exposure to Hepatitis B Virus

This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

Version and Document Control:

Version Number	Date of Update	Change Description	Author
6		Amended to national guidance, key people amended, exposure prone environment added, UKAP- OHR section added	Hilary Winch
7	14/12/2022	Added recommendation that HCWs with current or with past, cleared, HBV infection, who are not receiving anti-viral therapy, inform OH of any decision to start immunosuppressive treatment or of any illness that compromises their immune system and consider prophylactic treatment in line with national guidance update. (sections 7.7 and 9.10)	Hilary Winch

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Contents

1. Quick Reference Guideline 1

1.1 General Information on the Hepatitis B protection of Health Care workers

The primary protection against exposure to blood borne viruses (hepatitis B, HIV and hepatitis C) is adherence to safe working practices. In addition, all HCWs who are potentially exposed to blood and body fluids should be immunised prior to / on commencement of their posts and antibody level determined to ensure they are immune against Hepatitis B virus. Where immunity cannot be achieved advice will be given by Workplace Health and Wellbeing.

All HCWs who undertake Exposure Prone Procedures (EPPs) must provide evidence that they are not a hepatitis B infection risk and must provide proof of antigen and antibody level **before** being allowed to perform EPPs in compliance with UK Health Security Agency (UKHSA) (2021) guidance. All documentation must be identity verified.

1.2 Hepatitis B Immunisation procedure – Primary course, boosters and titres

Hepatitis B protection is recommended for Health Care Workers (HCWs) who may have:

- Exposure to blood by patient contact.
- Contact with blood samples or specimens.
- Contact with equipment or articles contaminated with blood.
- Contact with used needles or other sharp objects.
- Contact with blood-stained body fluids (the following fluids should also be handled with same precautions as blood; cerebrospinal, peritoneal, pleural, pericardial, synovial, amniotic, vaginal secretions and breast milk.)
- Risk of exposure to human bites which cause bleeding.
- Contact with biological waste.

The primary course of immunisation consists of three injections. The second dose is given at one month and the third six months after the first dose (0, 1, and 6). On advice from the Joint Committee on Vaccination and Immunisation (JCVI), Public Health England (2018) indicated that the 5 yearly boosters will no longer be required in healthy, immunocompetent adults who have completed a primary course of vaccine, this includes healthcare workers who are known responders. In special circumstances (e.g. if a staff member has not been immunised and has a blood exposure incident or if a staff member starts employment involving a high level of EPPs or in area that is considered high risk for hepatitis B, and has no immunity) an accelerated course may be used (0, 1, 2, 12 months – the 4th dose (12 months) being given to reinforce immunity), following consultation with the duty virologist as necessary.

One to two months after the third dose, the HCW should attend Workplace Health and Wellbeing for a blood test to measure their antibody response to the vaccine (anti-HBs titre). The significance of the results and actions required (DoH recommendations) are as follows:

Response level >100 mIU/mL. No further action required*.

Response level 10-100 mIU/mL. An additional booster dose is required at the time. In immunocompetent individuals a further titre is not required and there is no additional booster dose required. *

Non-responder (<10 mIU/mL). Tests for Hepatitis B Surface Antigen (HBsAg) and Hepatitis B Core Antibody (Anti-HBc) should be taken as markers for current or past infection. If these are negative, a repeat course of immunisation (3 vaccines) followed by a titre at 1-2 months is indicated. If the level remains at <10 mIU/mL then the individual is defined as a non-responder. If the level is >10 mIU/mL then future actions would be taken as per their response level.

Non- responders are advised in writing by Workplace Health and Wellbeing that they are not protected against Hepatitis B infection and in the event of an exposure they must inform Workplace Health and Wellbeing as they may require Human Hepatitis B Specific Immunoglobulin (HBIG) following consultation with the duty Virologist. They must be particularly vigilant with universal precautions and self-protection from exposure to blood and body fluids.

*Any healthcare worker who is immunocompromised (e.g., has had a transplant, taking a disease modifying agent) may need to be monitored in terms of their antibody level. This will be done on a case-by-case basis according to their condition and medication.

HCWs who have previously been immunised but have no record of immunity status should have an anti-HBs titre taken and if indicated be given a booster dose of vaccine. Dependent upon length of time since primary immunisation a challenge dose of Hepatitis B vaccine may be advised prior to the anti-HBs titre being taken.

2. Quick Reference Guideline 2

2.1 Exposure Prone Procedures (EPPs)

Definition of Exposure Prone Procedure (EPP)

EPPs are defined as those procedures where there is a risk that injury to the worker may result in the blood of the worker contacting the patient's open tissues. EPPs include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space, and where the hands or fingertips may not be visible at all times.

An Exposure Prone Environment is defined as "an environment in which there is a significant 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 HCW"

In addition, it is a requirement to screen all staff undertaking clinical work in renal units from a Hepatitis B perspective to the same requirements as EPP workers.

New HCWs who will perform EPPs or undertake clinical work in renal units will be tested for HBsAg, before immunisation. This process will help identify individuals who have current HBV infection.

"True Non-responders" performing EPP procedures, will be tested for HBsAg every 12 months to ensure that they have not acquired Hepatitis B infection. These will need to be IVS samples

Poor responders already performing EPP procedures require a single HBs Ag test to exclude the possibility of Hepatitis B carriage (a current or previous test will be acceptable if it has been confirmed as an IVS).

2.2 Identified Validated Sample (IVS)

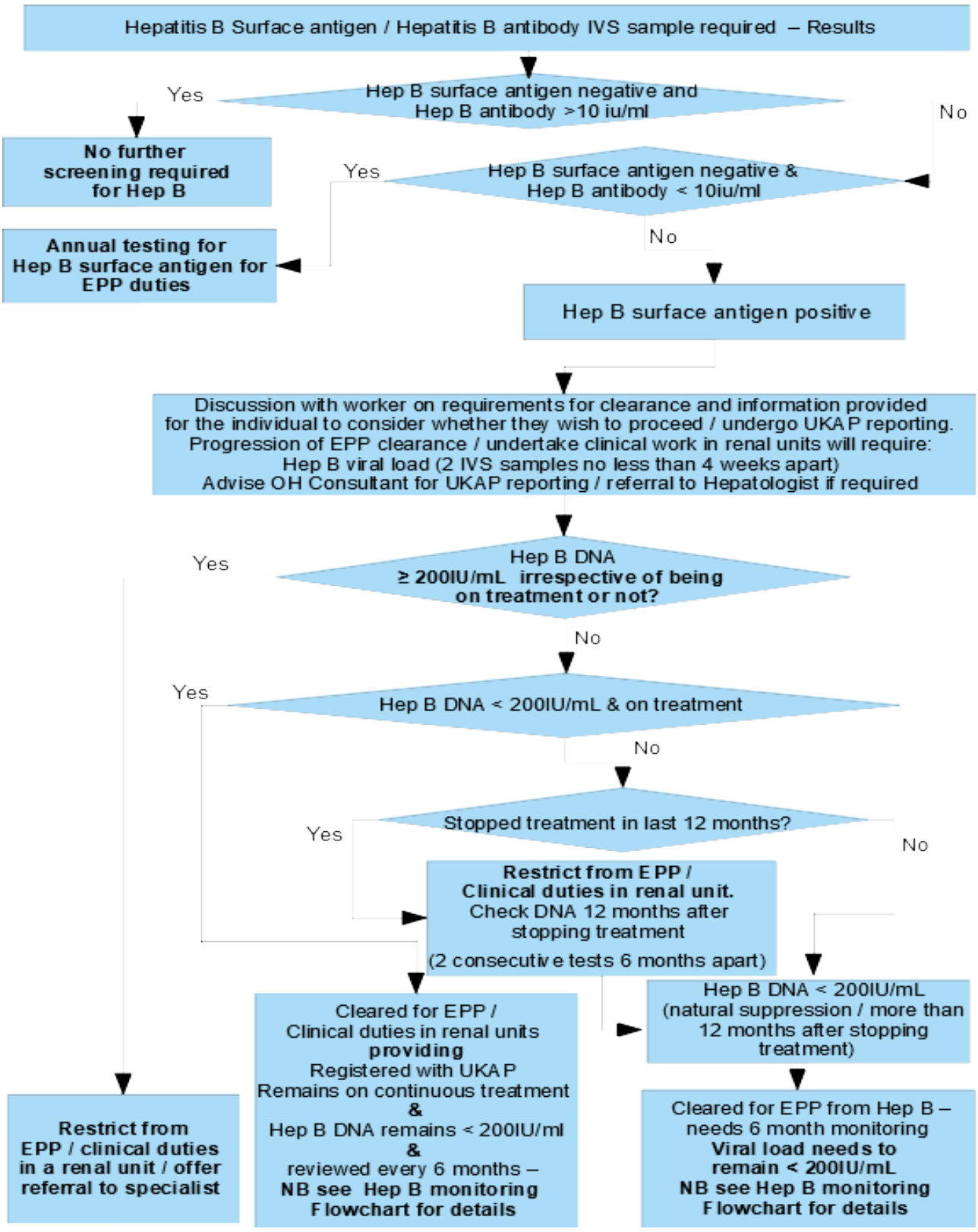
HCWs who undertake EPPs or undertake clinical work in renal units and have previously been immunised will need to provide UK laboratory or documentary evidence from a UK OH department of the necessary hepatitis B serology results, which must be from an identified validated sample (IVS).

An IVS is defined according to the following criteria:

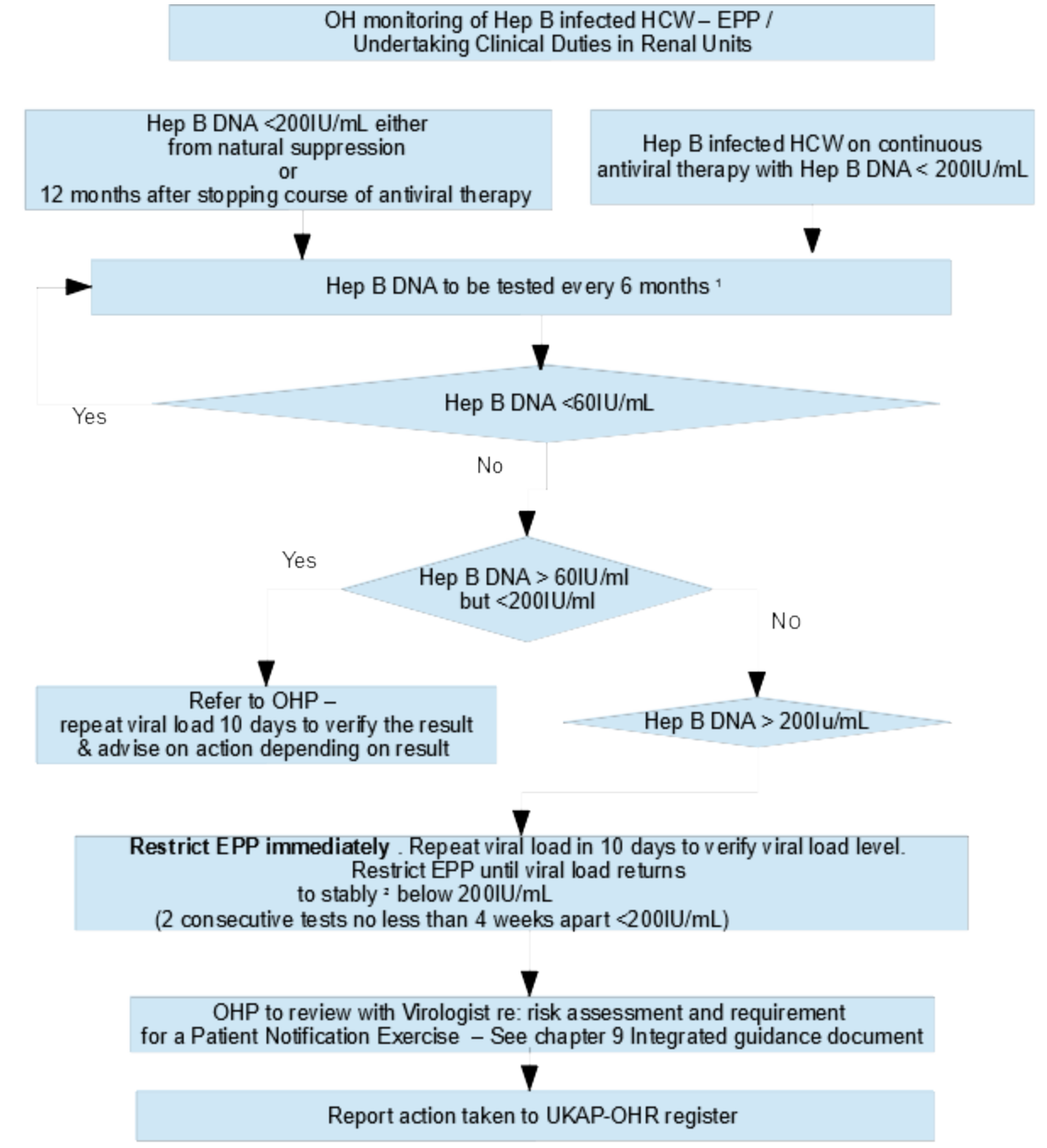
- The healthcare worker should show proof of identity with a photograph – NHS trust identity badge, photographic driving licence, passport or photographic national identity card – this photographic ID should be checked when the sample is taken and evidence of this recorded on the laboratory or test report.
- The sample of the blood must be taken in Workplace Health and Wellbeing or another occupational health department.
- Samples must be transported by hospital transport and are not to be delivered to the laboratory by the healthcare worker.
- When results are received from the laboratory, WHWB will check that they have sent the blood and then record the result in the employee's occupational health records.

3. Quick Reference Guideline 3 EPP and Hepatitis B Infected Health Care workers (see section 11 for detail)

3.1 Hepatitis B Screening Clearance requirement



3.2 Hepatitis B monitoring requirements for Hepatitis B Infected Health Care Worker whose role involves Exposure Prone Procedures (EPP)



NB:

1. 6 monthly viral load testing can be performed no earlier than 24 weeks and no later than 29 complete calendar weeks after the date of the preceding specimen taken for OH monitoring purposes

2. Resumption of EPP activities following a period of interruption requires at least two IVS Hep B DNA < 200IU/mL no less than 4 weeks apart.

HBV DNA Level	Action
<60 IU/mL	No action. Retest in 6 months.
>60 but < 200 IU/mL	A case-by-case approach based on clinical judgement should be taken which may result in no action (as above) or recommending that a second test should be done 10 days later to verify the viral load remains below the threshold. Further action will be informed by the test result.
200 IU/mL or above	The HCW should cease conducting EPPs immediately. A second test must be done on a new blood sample 10 days later to verify the viral load remains above 200 IU/mL. If the viral load is still in excess of 200 IU/mL, the HCW should cease conducting EPPs until their viral load, in 2 consecutive tests no less than 4 weeks apart, is reduced to <200 IU/mL. If the viral load is below 200 IU/mL then further action should be informed by the test result as above. If test results are unexpected (for example, from very high viral load to low viral load) then seek further advice from a local virologist or UKAP secretariat. A full risk assessment (see Chapter 9) should be triggered to determine the risk of HCW to patient transmission. At a minimum, this will include discussion between the accredited specialist in occupational medicine and the treating physician on the significance of the result in relation to the risk of transmission. The need for public health investigation or action (for example, patient notification) will be determined by a risk assessment on a case by case basis in discussion with UKAP.

3.3 UKAP- OHR

To support and monitor implementation of the policy and to ensure patient safety, all HCWs living with HBV or HIV including locum staff, who wish to perform EPPs (and for HCWs living with HBV, clinical duties in renal units or any other settings involving renal dialysis), and who meet the criteria for clearance, must be monitored locally and registered on the UKAP-OHR, a central confidential register, managed by UKHSA (on behalf of Public Health Scotland, Public Health Wales, and the Public Health Agency for Northern Ireland) and overseen by UKAP (United Kingdom advisory Panel on Healthcare Workers Living with bloodborne Viruses). The UKAP-OHR team will register HCWs on the database and provide regular reports to Occupational Health departments on the monitoring status of HCWs under their care. The OHR team is not responsible for the clearance of HCWs.

Each HCW must be registered onto the UKAP-OHR by their designated accredited specialist in occupational medicine. Their ongoing viral load monitoring data should be reported to UKAP-

OHR by the accredited specialist in occupational medicine periodically in line with this guidance. Action taken because of an increase in viral load should be reported using the register to record those restrictions on EPP performance are put in place appropriately and, where necessary, risk assessments and patient notification exercises are carried out.

The UKAP-OHR is a secure and confidential system. Access to the individual records of the HCWs on the register is limited to the designated accredited specialist in occupational medicine responsible for the care, monitoring, management and EPP clearance of the HCW. Delegated authority may also be given by the accredited specialist in occupational medicine to specific named individuals within a given OH service to undertake these roles on behalf of the accredited specialist in occupational medicine. Limited access will also be given to a small number of individuals who manage the register on behalf of UKAP.

4. Objectives

To ensure the Trust complies with UK Health Security Agency (UKHSA) guidance in implementing protection from hepatitis B virus (HBV) infection for health care workers.

To ensure the best possible standards of hepatitis B immunity are achieved for HCWs who are at risk of exposure to blood and body fluids.

To ensure all staff appointed to new posts, which involve participation in exposure prone procedures (EPPs), have their carrier status determined in order to advise the appointing officer of their fitness to undertake EPPs before their appointment is confirmed (**See Trust Guideline for the immunisation of new and existing health care workers)**

5. Rationale

Hepatitis B virus can be transmitted by sexual intercourse, blood to blood contact or by perinatal transmission. It may cause an acute illness, but in the majority of adults infected the acute infection is asymptomatic. Up to 5% of adults develop chronic infection (defined as persistence of HBsAg > 6 months). This can lead to cirrhosis, hepatic decompensation and hepatocellular carcinoma. Hepatitis B infection can be prevented by immunisation.

The Control of Substances Hazardous to Health (COSHH) 1995 amended in 2002 requires employers to risk assess, control and protect against exposure to hazard substances. Consequently, all HCWs who are potentially exposed to blood and body fluids should be trained in appropriate working procedures when dealing with body fluids. They should operate methods of safe working and also be offered hepatitis B vaccine or have their hepatitis B immunity status reviewed and updated as necessary.

These guidelines are in response to Integrated Guidance on health clearance of healthcare workers and the management of healthcare workers infected with Blood borne Viruses (2021)

This guidance should be read in conjunction with the:

- Trust Guideline for the immunisation of new and existing health care workers Trustdocs Id: 8105
- Trust Policy for the prevention (and investigation) of needlestick and sharps injuries within the Trust. Trustdocs Id: 585

- Trust Guideline for the management of incidents which have the potential to transmit blood borne viruses CA4003. Trustdocs Id: 1260

6. Broad Recommendations

Refer to the following quick reference page:

- Quick Reference Guide 1:
  - General Information on the hepatitis B protection of health care workers (HCWs) when hepatitis B protection is recommended.
- Quick Reference Guide 2 – EPP
  - The definition of Identified Validated Sample (IVS).
- Quick reference Guide 3
  - Hepatitis B Screening Clearance requirement for EPP
  - Hepatitis B monitoring requirement for Hepatitis B infected Health care worker whose role includes EPP.

7. Responsibility of the Trust

To ensure the health and safety of patients is not compromised by exposure to a HCW infected with hepatitis B.

To ensure that the status and the rights of an infected HCW are safeguarded so far as is reasonably practicable. If necessary, suitable alternative work will be identified and retraining opportunities considered in accordance with good general principles of occupational health and management practice.

To ensure that all staff who are at risk of exposure to blood and body fluids have access to the necessary protection (appropriate Personal Protective Equipment as well as immunisation)

8. Responsibility of Managers

To undertake a COSHH risk assessment in areas where HCWs may be exposed to biological agents. To ensure measures have been introduced to protect HCWs and others who may be exposed to these risks.

To ensure all new HCWs have undergone the necessary health clearance checks required as part of the pre-employment process and to ensure all HCWs have been advised about the communicable disease health risks of their work. **(See Trust Guideline for the immunisation of new and existing health care workers).**

To ensure all new and existing staff have protection against hepatitis B virus if they are identified as being at risk of exposure to blood and body fluids.

9. Responsibility of managers for HCWs who undertake EPPs

To ensure all new HCWs who undertake EPPs have undergone checks (EPP clearance) in line with Trust Guideline for the Immunisation of new and existing healthcare workers. To ensure that HCWs do not undertake EPPs until they have been cleared by Workplace Health and Wellbeing.

To be aware of any staff member who needs their EPP screening reviewed (expiry date on fitness certificate) and ensure that they attend the relevant screening with Workplace Health and Wellbeing prior to that date.

Redeployment may have to be considered if a HCW is diagnosed with hepatitis B and is restricted from undertaking EPPs.

To advise a HCW whose work involves EPPs that refusal to comply with this guideline will result in them being restricted from carrying out EPPs.

10. Role of Workplace Health and Wellbeing

To advise the Trust, in liaison with virology, on all aspects of the prevention and protection of HCWs from occupationally acquiring hepatitis B.

To provide a hepatitis B immunisation programme in line with UKHSA guidance.

To inform managers on HCWs' fitness to perform EPPs, prior to and during employment with the Trust.

To maintain confidential computerised hepatitis B immunisation records in order to identify and inform HCWs who are due for recall for further hepatitis B serology and/or immunisation.

To provide advice and support for any HCW (whether EPP worker or otherwise) who becomes infected with hepatitis B.

To ensure any infected HCW is referred to an appropriate practitioner for advice and treatment options (e.g., hepatologist/ general practitioner).

To ensure any worker who is living with Hepatitis B is monitored in accordance with this guidance and registered with the UKAP-OHR this includes:

- Ensure that appointments are available for testing in accordance with the timings / requirements
- Reacting promptly to any alerts received via UKAP-OHR
- Taking action if the HCW does not attend for tests – e.g., notifying manager and restrict from EPP practice/ clinical duties in renal units
- Ensure IVS samples are taken
- Interpreting the viral load results in relation to EPP clearance / clinical duties in renal units

- Notifying the HCW of the results and if there is any implication for continued EPP practice / clinical duties in renal units
- Ensuring the UKAP-OHR is updated within the specified timeframe.
- Ensuring the HCW is aware of the risk of reactivation of Hepatitis B if they were to become immunosuppressed and the requirement for informing WHWB if at any time they become immunosuppressed through treatment or illness.

11. Role of the Health Care Worker

To undertake all necessary health clearance checks as requested **(See Trust Guideline for the immunisation of new and existing health care workers** Trustdocs Id: 105

It is a legal and professional responsibility of all HCWs to report a blood exposure incident in the workplace in line with the Trust Guideline for the Management of incidents which have the potential to transmit a Blood Borne Virus.

Any HCW, particularly those involved in exposure prone procedures (EPPs), who believe that they may have been exposed to hepatitis B virus outside of the workplace, must seek advice from Workplace Health and Wellbeing and have appropriate serology undertaken and if necessary be assessed by an occupational physician. They must not rely on their own assessment of the possible risks to patients.

HCW who are working in EPP or Renal Units who is living with Hepatitis B must comply with the required monitoring in accordance with this guidance and be aware that they will be registered with the UKAP-OHR. Failure to do so will result in immediate cessation of EPP.

Physicians, nurses and others, who are aware that a hepatitis B-infected HCW has not followed advice to refrain from EPPs and modify his/her practice, must advise Workplace Health and Wellbeing and the Trust's Medical Director or Chief Nurse, having informed the HCW of their intention to do so. In addition, for those HCWs who are aware that they have Hepatitis B and are moving to a role where EPP (Trustdocs Id: 13321) or renal unit clearance is required, should highlight this to their prospective manager as they may not be able to fulfil all duties required. This is a legal and professional responsibility.

HCWs identified as performing EPPs are required to retain documented evidence of having received hepatitis B vaccination, their antibody status and recall date (where applicable). They also have a personal responsibility (under COSHH 2002) to ensure that their vaccination programme is maintained according to local and national guidelines.

12. Hepatitis B infected HCWs

If a blood sample collected from a HCW contains HBsAg, the HCW will be tested for Hepatitis B DNA Viral load to ascertain risk of infectivity. They will be restricted from EPP or Clinical work in Renal Units until the viral load level has been established.

If the Hepatitis B DNA viral load level is ≥ 200IU/ml they should not be allowed to perform exposure prone procedures (EPP) or undertake clinical duties in Renal Units.

If the Hepatitis B DNA viral load level is < 200IU/ml then initial clearance to perform EPP or clinical work in Renal Units requires 2 IVS samples to be taken no less than 4 weeks apart both showing a viral load result of < 200IU/ml

If a HCW has been aware of this infection but has stopped treatment – then they need to be restricted from EPP or Clinical duties in a Renal Unit for a period of 12 months from stopping treatment and demonstrate a viral load level of < 200IU/ml on 2 consecutive tests 6 months apart.

Hepatitis B infected HCWs wishing to perform EPPs whilst on antiviral treatment need to be under the continuing care of a consultant OH physician and a consultant who has expertise in treating chronic hepatitis B infections and be subject to 6 monthly monitoring (no earlier than 24 and no later than 28 weeks after the date of the preceding specimen was taken for occupational monitoring purposes).

If at any point the levels increase above 200IU/mL then the worker should be withdrawn from EPP. Any period of interruption requires at least two IVS Hep B DNA viral load results of less than 200IU/mL no less than 4 weeks apart.

If staff discontinue treatment for hepatitis B infection, they must immediately cease to perform EPPs.

If staff fail to attend their appointments for blood tests whilst on antiviral treatment, they are to be immediately excluded from EPPs.

If a patient is accidentally exposed to the blood of a hepatitis B infected healthcare worker, it is recommended that the incident 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.

There is a risk of reactivation of hepatitis B when a person becomes immunosuppressed. Any HCW who are HBsAg positive or HBcAb (core antibody) positive and are cleared to undertake EPP must inform the OH of a decision to start immunosuppressive treatment or of any illness that may compromise their immune system

13. Special Groups undertaking Exposure Prone Procedures (EPP)

13.1 Medical Locums and visiting clinicians

The immune status of medical locums involved in EPPs will be reviewed by Workplace Health and Wellbeing, who will advise the appointing officer of their fitness to undertake EPPs before work commences. The authorisation will be for a maximum of 12 months, with a review if they remain in post.

- Verified proof of immunisation and IVS blood test documentation must be provided to Workplace Health and Wellbeing. NB UKSHA (2021) Appendix A indicates that laboratory test results required for clearance for undertaking
- EPPs and ongoing monitoring thereafter MUST be derived from an IVS sample.
    - ‘Non-responders’ (< 10 mIU/mL) must provide a negative HBsAg result from within the last 12 months.

- Responders (10–100 mIU/mL) must provide evidence of any previous negative HBsAg result.

In addition, consideration will need to be given to other EPP requirements in line with Hepatitis C Infection in Health Care Workers (Trustdocs Id: 1271) and the Immunisation for new and existing Health care workers (Trustdocs Id: 8105).

Medical Staffing will inform the manager responsible for the department when EPP clearance has been given. If at any stage they are able to work but not undertake EPP procedures, then this will be clearly communicated from WHWB to the clinical director of that area. The clinical director will need to ensure that EPP procedures are NOT undertaken in the course of their work.

14. Staff of other employers.

Those staff identified as being at risk of infection because of their work should follow the same immunisation programme as Trust employees. Their organisations should make provision for immunisations to be undertaken.

15. Confidentiality

HCWs who contract a communicable disease will receive the same rights to confidentiality as any other individual seeking or receiving Workplace Health and Wellbeing advice and support.

Personal information will not be released to the employer or another agency or person without the written consent of the HCW.

To maintain confidentiality, Workplace Health and Wellbeing is responsible for ensuring hepatitis B immunisation and post-vaccination immunity screening programmes.

HCWs infected with hepatitis B have a right to confidentiality. There are rare occasions when an occupational physician may need to advise the Medical Director or Chief Nurse that there is a change to EPP clearance. , However, the hepatitis B status of a HCW will not normally be disclosed without the HCW's consent. The Trust will make every effort to arrange suitable alternative work, should this be necessary. When patients are, or have been, at risk it will be necessary, in the public interest, for the Medical Director and the Director of Public Health to have access to this confidential information.

All staff serology results are held confidentially and are not available to view on ICE by anyone other than authorised occupational health team members.

16. Audit

Workplace Health and Wellbeing will assess the following standards as part of the rolling audit programme:

- All staff members who have a hepatitis B positive infectivity status will be reviewed by Workplace Health and Wellbeing.
- All new EPP workers within the Trust will be assessed and activity restricted until full clearance has been given by Workplace Health and Wellbeing.

17. Process of Development and Dissemination

This policy was drafted by the authors listed above. It reflects UK Health Security Agency and HSE national guidance and has been agreed by Trust consultant virologists and clinical staff in the Workplace Health and Wellbeing.

This Policy will be held by Risk Management, and will be available on the Trust's Intranet: Clinical Guidelines - Workplace Health and Wellbeing

18. References/Source documents

1. Health and Safety Executive (2002) Control of Substances Hazardous to Health Regulations.
http://www.hse.gov.uk/healthservices/index.htm

2. Department of Health (2006) Immunisation Against Infectious Disease 3rd edition, ("Green Book") Immunisation against infectious disease - GOV.UK

3. UK Health Security Agency (2021) Integrated Guidance on health clearance of healthcare workers and the management of healthcare workers infected with blood borne viruses (November 2021)
BBVs in healthcare workers: health clearance and management - GOV.UK (www.gov.uk)

4. Public Health England (2018) Plan for phased re-introduction of hepatitis B vaccine for the lower priority groups in 2018
https://www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints

5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4621464/
(Successful vaccination is documented by an antibody response of more than 10 mIU/mL and is achieved in about 95% of the immune-competent population.)

6. https://academic.oup.com/cid/article/53/1/68/492859
(Vaccine efficacy studies have demonstrated virtually complete protection against acute and chronic hepatitis B in immunocompetent people, with post-immunization anti-HBs levels of ≥10 mIU/mL. Therefore, seroprotection against HBV infection was defined as having an anti-HBs level of ≥10 mIU/mL after having received a complete immunisation schedule.)

Trust Guideline for the immunisation of new and existing health care workers
Trustdocs Id: 8105

Trust Policy for the prevention (and investigation) of needlestick and sharps injuries within the Trust Trustdocs Id: 585

Trust Guideline for the management of incidents which have the potential to transmit blood borne viruses CA4003. Trustdocs Id: 1260

Guideline for the immunisation of new and existing health care workers Trustdocs Id: 105

EPP Areas and Immunisation Requirements Trustdocs Id: 13321

Hepatitis C Infection in Health Care Workers (Trustdocs Id: 1271)

Immunisation for new and existing Health care workers (Trustdocs Id: 8105)