

# Integrated guidance on health clearance of healthcare workers and the management of healthcare workers living with bloodborne viruses (hepatitis B, hepatitis C and HIV)

UK Advisory Panel for Healthcare Workers Living with Bloodborne Viruses (UKAP)

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lechyd Cyhoeddus Cymru Public Health Wales



Health clearance of healthcare workers and the management of healthcare workers living with bloodborne viruses

# Foreword

In July 2019 UK Advisory Panel for Healthcare Workers Living with Bloodborne Viruses (UKAP) published updated integrated guidance that described new recommendations on the monitoring and clearance of healthcare workers (HCWs) living with hepatitis B infection, and the investigation of situations where a HCW has been diagnosed with a bloodborne virus (BBV), based on the evidence base and experience from over 20 years of UKAP investigations.

Over the past 2 years this guidance has been embedded into practice and UKAP have received helpful feedback on its implementation. The 2020 update contained changes based on this feedback in order to clarify roles and responsibilities of stakeholders, and the settings in which the guidance should be applied. The 2021 update contained changes to the recommended monitoring time of HCWs living with hepatitis B. These changes, detailed in <u>section 7.2</u>, align with national practice (<u>1 to 2</u>) and other international (<u>3 to 5</u>) guidelines.

This 2022 update has new advice regarding reactivation of hepatitis B (rHBV) following immunosuppression. In cases with resolved hepatitis B, rHBV is becoming more common due to increasing use of therapeutic immunosuppression for other conditions. This advice is included in <u>section 6.4</u> and detailed in <u>section 7.2.</u>

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# What is new in this document

Changes in the document from 2019 include:

- removal of exposure prone procedure (EPP) restrictions, following effective antiviral therapy, and appropriate clearance, for healthcare workers (HCWs) living with hepatitis B (HBV) with high pre-treatment HBV DNA levels and or who are e antigen (HBeAg) positive
- updated guidance on the ongoing monitoring and associated reporting to UKAP Occupational Health Register (UKAP-OHR) of HCWs living with HBV cleared to perform EPPs
- updated guidance on the risk assessment and investigation required following the identification of healthcare workers found to be living with a bloodborne virus (BBV)
- updated wording on the roles and responsibilities of healthcare workers and their employing organisations including statements about disclosure of BBV status

Changes in the document from 2020 include:

- responsibilities when transferring monitoring to a new accredited specialist in occupational medicine
- responsibilities for HCWs moving from an exposure prone procedure (EPP) role to a non-EPP role
- clarifying the responsibility for maintaining records of procedures conducted by HCWs living with HBV and HIV
- a minor update to guidance on the roles and responsibilities of occupational health (OH) services before clearing a new HCW to perform EPPs
- revised guidance on hepatitis C virus (HCV) post-treatment cessation period from 6 months to 3 months
- clarifying the settings in which health clearance for dialysis procedures is advised
- confirming that the new specialist is suitably accredited in occupational medicine
- inclusion of UK crown dependencies and overseas territories

Changes in the document from 2021 include:

- changing the monitoring interval from every 12 months to every 6 months for HCWs living with hepatitis B who have HBV viral load below 200 international units per millilitre (IU/mL) and are not on antiviral treatment
- changing the monitoring interval from every 3 months to every 6 months for HCWs living with hepatitis B who are on antiviral treatment

 changing the requirements for resumption of EPPs in those who have ceased hepatitis B treatment from one test at the end of the 12 month EPP restriction period to 2 tests 6 months apart, the first being no less than 6 months after ceasing treatment

Changes in the document from 2022 include:

- 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
  - patients who do not start prophylactic treatment will need monitoring schedules to be agreed locally
  - routine treatment schedule such as 3 monthly monitoring is likely to be adequate
- recommendation that if HBV reactivation occurs, EPPs are ceased until viral load is suppressed and maintained in accordance to the clearance to perform EPP criteria

# How to use this document

The document should be used in electronic format to ensure the most recent guidance is being followed.

# **Chapter 1: introduction**

In the UK, the policy on the management of HCWs living with HBV, HCV and human immunodeficiency virus (HIV) was precautionary and conservative in the first instance (see <u>Appendix 4</u> for the evolution of UK policy on BBV in HCW).

Policies have evolved over time guided by emerging evidence on the risk of HCWs transmitting BBVs to their patients, experience of patient notification exercises (PNEs) and the recommendations of the Expert Advisory Group on AIDS (EAGA), the Advisory Group on Hepatitis (AGH) and the UK Advisory Panel for Healthcare Workers Living with Bloodborne Viruses (UKAP), who have regularly reviewed the policies for managing HCWs living with BBVs.

# 1.1 Objectives

This integrated guidance provides updated, evidence-based recommendations that are intended to:

- reduce the risk of HCW to patient transmission of BBVs
- reduce the future burden of PNEs
- retain HCWs in the workforce and reduce adverse social and professional impact on HCWs living with BBVs

The guidance is also intended to provide advice on key operational and service delivery issues that need to be addressed to ensure HCWs living with BBVs who perform EPPs are managed in a manner that safeguards their confidentiality and employment rights.

# 1.2 Target audience

The guidance is intended primarily for use by OH services who have the responsibility for dealing with all matters arising from, and relating to, the training and or employment of HCWs living with BBVs in the UK. This guidance may be applied to OH services in UK crown dependencies and overseas territories.

The guidance should also be brought to the attention of all HCWs working in the UK, in the NHS and other settings including independent contractors such as general dental and medical practitioners and relevant staff; independent midwives; students; locums and agency staff; and

visiting HCWs, providing a reminder of their responsibility to seek professional advice about the need to be tested if they have been exposed to BBVs.

The guidance is also relevant to NHS organisations who arrange for NHS patients to be treated by non-NHS health establishments in the UK; these organisations should ensure that HCWs who perform EPPs on NHS patients in these settings follow this guidance.

The preparation of the integrated guidance has been supported by UKAP and the clinical and public health networks represented by UKAP members.

# Part A: definition of key terms

# Chapter 2: exposure prone procedures (EPPs)

Provided appropriate infection prevention and control precautions are adhered to scrupulously at all times, the majority of clinical procedures (including many which are invasive) in the healthcare setting pose no risk of transmission of BBVs from a HCW to a patient and can safely be performed.

Those procedures where an opportunity for HCW-to-patient transmission of BBV does exist are described as EPPs, where injury to the HCW could result in the worker's blood contaminating the patient's open tissues. This is described as 'bleed-back' in this guidance.

EPPs include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times.

The definition of EPPs covers a wide range of procedures, in which there may be very different levels of risk of bleed-back. A risk-based categorisation of clinical procedures has been developed, including procedures where there is negligible risk of bleed-back (non-EPP) and 3 categories of EPPs with increasing risk of bleed-back.

It should be noted that the majority of HCWs do not perform EPPs.

The definitions and examples of categories 1, 2 and 3 are:

# Category 1

Procedures where the hands and fingertips of the worker are usually visible and outside the body most of the time and the possibility of injury to the worker's gloved hands from sharp instruments and or tissues is slight. This means that the risk of the HCW bleeding into a patient's open tissues should be remote.

Examples: local anaesthetic injection in dentistry, removal of haemorrhoids.

# Category 2

Procedures where the fingertips may not be visible at all times but injury to the worker's gloved hands from sharp instruments and or tissues is unlikely. If injury occurs it is likely to be noticed and acted upon quickly to avoid the HCW's blood contaminating a patient's open tissues.

Examples: routine tooth extraction, colostomy.

# Category 3

Procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages, and in which there is a distinct risk of injury to the worker's gloved hands from sharp instruments and or tissues. In such circumstances, it is possible that exposure of the patient's open tissues to the HCW's blood may go unnoticed or would not be noticed immediately.

Examples: hysterectomy, caesarean delivery, open cardiac surgical procedures.

A series of speciality-specific lists of the most common clinical procedures, classified into EPP category depending upon the relative risk of bleed-back, has been developed by UKAP and are available on the <u>UKAP webpage</u>.

### Non-exposure prone procedures

Non-EPPs are those where the hands and fingertips of the worker are visible and outside the patient's body at all times, and internal examinations or procedures that do not involve possible injury to the worker's gloved hands from sharp instruments and or tissues. These procedures are considered not to be exposure prone provided routine infection prevention and control procedures are adhered to at all times.

Examples are:

- taking blood (venepuncture)
- setting up and maintaining intravenous lines or central lines (provided any skin tunnelling procedure used for the latter is performed in a non-exposure prone manner)
- minor surface suturing

- the incision of external abscesses
- routine vaginal or rectal examinations
- simple endoscopic procedures

### Exposure prone environments

The exposure prone environment is 'an environment in which there is a significant intrinsic risk of injury to the HCW, with consequent co-existent risk of contamination of the open tissues of the patient with blood from the HCW'. Examples include emergency HCWs attending to road traffic collisions (RTCs), domestic, recreational or industrial accidents where sharp surfaces such as glass fragments, sharp metal or stone edges may lead to laceration of the skin of the HCW whilst in the process of attending to and or retrieving a casualty.

The risk of BBV transmission between a HCW and patient, in the pre-hospital emergency setting is not known. UKAP has received no reports of such transmission in this setting, and standard literature searches are inconclusive in quantifying this risk. Nevertheless, there is a theoretical risk of such a route of infection, requiring an approach to risk assessment and mitigation that is both proportionate and practical, and considers the role of the emergency HCW, and the environment in which pre-hospital emergency care is given.

Guidance on emergency and pre-hospital trauma care is available on the UKAP webpage.

# Part B: general principles

# Chapter 3: duties and obligations of HCWs who are, or may be, living with a BBV

All HCWs, including those who are self-employed or employed in the independent sector, are under ethical and legal duties to protect the health and safety of themselves and of others, such as colleagues and patients, and must have understanding of, and co-operate in health and safety matters.

The current statements of the General Medical Council (GMC), General Dental Council (GDC), the Nursing and Midwifery Council (NMC) and the Health and Care Professions Council (HCPC) about the ethical responsibilities of HCWs set out the expectations with regards to safeguarding the health of patients and minimising the risk of exposure to BBVs through the provision of care. These responsibilities are equally applicable to all other professional groups not covered by these regulatory bodies.

All healthcare professionals who have direct clinical care of patients, have a duty to keep themselves informed and updated on the codes of professional conduct and guidelines on infection with BBVs laid down by their regulatory bodies and any other relevant guidance issued.

All HCWs must meet the requirements for health clearance (screening for BBVs) at the appropriate stages of their career, including training and undertaking new roles which involve EPPs. HCWs applying for new posts should complete health questionnaires honestly.

HCWs who might perform EPPs also have a responsibility to seek advice and or a BBV test, either through clinical services (most commonly this would be via their GP or attending a sexual health clinic) or from an OH service, if they have any reason to believe that they may have been exposed to a BBV infection or have reactivation of their HBV infection, or be at risk of reactivation of HBV infection, regardless of whether this was in an occupational or personal setting.

Any HCW who may perform EPPs and who has been diagnosed with a BBV infection must seek expert OH advice to enable appropriate occupational health care to be provided, and any restriction of working practice (if required) to be implemented. HCWs who are self-employed or working as a locum via an agency should arrange to take advice from an accredited specialist

in occupational medicine (defined as someone who is on the specialist register for occupational medicine) independently if it is not provided by the locum agency or employer.

HCWs living with BBVs must not undertake procedures that are thought to be EPP whilst expert advice is sought or until they meet the appropriate criteria to recommence EPPs.

Any HCW who has concerns about another HCW's practice in relation to BBV infection should follow their local patient safety policies.

It is advisable, but not a requirement, that HCWs living with BBVs who are not carrying out EPPs seek support from occupational health. Employers should foster a supportive and nonstigmatising environment which encourages HCWs to access occupational health support and protects confidentiality. Occupational health providers should not share information about BBV status with any other staff member without the explicit consent of the HCW.

# Chapter 4: roles and responsibilities of organisations

# 4.1 Occupational health (OH) service

All matters arising from and relating to the training and or employment of HCWs living with BBVs should be co-ordinated through an accredited specialist in occupational medicine. Where a healthcare establishment's OH service does not have its own accredited specialist in occupational medicine, arrangements should be put in place for this advice to be sought from an accredited specialist in occupational medicine outside the establishment. Suitable arrangements must be in place for agency or locum staff, including dental staff, to ensure that they have access to a designated accredited specialist in occupational medicine.

While the specialist in occupational medicine has responsibility for occupational medical management and assessment, if a specialist in occupational medicine is not immediately available, HCWs may initially seek advice from occupational health nurses under the supervision of an accredited specialist in occupational medicine. The nurse should make every effort to arrange for the HCW to see the specialist in occupational medicine as soon as possible.

Occupational health services should adopt a proactive role in helping HCWs to assess if they have been at risk of BBV infection and encourage them to be tested, if appropriate. It is the responsibility of the OH service to ensure that new HCWs who intend to perform EPPs, have the necessary clearance to do so. OH services should explain the testing arrangements for health clearance and how BBV infection might affect continued performance of EPPs.

Before HCWs living with BBVs are cleared to perform EPPs, the OH service should also follow a standard practice of checking the HCW's previous EPP history; further details on investigation and risk assessment are provided in <u>Chapter 9</u>.

After testing, OH services should inform HCWs of the results of their tests and the implications for their working practice, including where appropriate any requirements for further follow up and monitoring. All HCWs living with BBVs should be given accurate and detailed advice on ways to minimise the risks of transmission in the healthcare setting and to close contacts. It is recommended that referral of HCWs living with BBVs to the appropriate physician for specialist clinical assessment (if this has not already taken place), should be made by the OH service, and not by self-referral.

Responsibility for the ongoing monitoring of HCWs living with HBV or HIV cleared to perform EPPs, in accordance with this guidance, rests with the accredited specialist in occupational medicine. The HCW's treating physician is responsible for providing the necessary regular care for the HCW with respect to managing their BBV infection.

As part of the process of ongoing monitoring, responsibility for maintaining accurate and contemporaneous local records relating to HCW monitoring, and communicating the outcome of the monitoring to UKAP secretariat using the templates (see <u>Chapter 7</u>), lies with the accredited specialist in occupational medicine. Delegated authority may also be given to specific named individuals within a given occupational health service to undertake these roles on behalf of the accredited specialist in occupational medicine. The responsibility for the assurance and management of the UKAP-Occupational Health Monitoring Register of Healthcare Workers Living with Bloodborne Virus (UKAP-OHR) lies with the UKAP secretariat.

### 4.2 Employers and commissioning bodies

All employers should ensure that new and existing staff (including agency and locum staff and visiting HCWs) are aware of this guidance and of the professional regulatory bodies' statements of ethical responsibilities. This may include issuing regular reminders. Commissioners may wish to stipulate this when placing service agreements with NHS organisations.

Providers using locums and agency staff are ultimately responsible for making sure that HCWs have the necessary health clearance to undertake EPP work.

# 4.3 Training establishments

Medical, dental, nursing and midwifery schools, colleges and universities should draw students' attention to this guidance and the relevant professional statements. Each training establishment should identify a nominated officer with whom students may discuss their concerns in confidence. In addition, all students should be appropriately trained in procedures and precautions to minimise the risk of occupational BBV transmission. All these issues should be addressed before there is clinical contact with patients.

<u>Guidance on health clearance and management of medical and dental students living with</u> <u>BBVs</u> is produced jointly by the Council of Heads of Medical Schools, the UK Health Security Agency (UKHSA), Public Health Scotland, the Association of UK Hospitals and the Higher Education Occupational Practitioners Group.

# Chapter 5: confidentiality concerning the healthcare worker living with a BBV

There is a general duty to preserve the confidentiality of medical information and records. Breach of this duty is very damaging for the individuals concerned, and it undermines the confidence of the public and of HCWs in the assurances about confidentiality that are given to those who come forward for examination or treatment.

Occupational health records are held separately from other hospital notes and can be accessed only by occupational health practitioners, who are obliged ethically and professionally not to release records or information without the consent of the individual.

Every effort should be made to avoid disclosure of the HCW's identity or information which would allow deductive disclosure. Any unauthorised disclosure about the BBV status of an employee constitutes a breach of confidence and may lead to disciplinary action.

The duty of confidentiality, however, is not absolute. Legally, the identity of individuals living with BBVs may be disclosed with their consent, or without consent in exceptional circumstances, where it is considered necessary for the purpose of treatment, the prevention of spread of infection or in the public interest where patients are, or may have been, at risk. Any such disclosure will need to be justified and based on a robust assessment of the risk to patient(s).

In balancing duty to the HCW living with a BBV and the wider duty to the public, complex ethical issues may arise. As in other areas of medical practice, a HCW disclosing information about another HCW will be required to justify their decision to do this. The need for disclosure must be carefully weighed and where there is any doubt the HCW considering such disclosure may wish to seek advice from his or her professional body.

The duties of confidentiality still apply even if the HCW has died or has already been identified publicly.

Further detailed advice on managing confidentiality when consulting UKAP can be found in Part E of this document.

# Part C: bloodborne virus health clearance

# Chapter 6: health clearance for hepatitis B, hepatitis C and HIV: New HCWs

Health clearance measures for new HCWs provide protection for patients from exposure in the clinical care setting to HBV, HCV and HIV. These measures are not intended to prevent those living with BBVs from working in the NHS, but rather to restrict them from working in those clinical areas where their infection may pose a risk to patients in their care. This is consistent with restrictions imposed on the working practices of those HCWs who are known to be living with a BBV.

The HCW also benefits from the health clearance arrangements personally (for example, earlier diagnosis may lead to curative or life-prolonging treatment and prevention of onward transmission), and professionally (for example, avoiding work activities that may pose a risk to their own health and making career choices appropriate to their infection status).

Employers should establish mechanisms, in conjunction with their human resources and occupational health services, to identify new HCWs and ensure that the necessary health checks are carried out.

The guidance does not apply to HCWs who are already employed in the NHS, with the exception of those moving to a post requiring the performance of EPPs for the first time in their career.

This guidance is supplementary to routine OH checks and immunisations for other infectious diseases (for example, for rubella and varicella). Guidance on health clearance for tuberculosis is not reproduced in these guidelines.

Guidance on the immunisation of HCWs is not reproduced in this document, as recommendations are continually under review by the Joint Committee on Vaccination and Immunisation. Current advice on immunising HCWs can be found in chapter 12 of Immunisation against Infectious Disease (commonly known as <u>The Green Book</u>).

# 6.1 Categories of new HCWs

For the purpose of this guidance, a new HCW is defined as an individual who has direct clinical contact with patients in the NHS or independent sector for the first time, whether as an employee or with the employer's agreement (for example, student placements, visiting fellows).

Existing HCWs who are moving to a post or training that involves EPPs for the first time in their career, are also considered as 'new'.

Returning HCWs may also be regarded as 'new', depending on what activities they have engaged in while away from the health service.

#### **Students**

#### Medical students

The practical skills required of medical students to obtain provisional <u>GMC registration</u> or of pre-registration foundation house officers (Foundation Year 1) to obtain <u>full GMC registration</u> generally do not include EPPs. Freedom from infection with BBVs is therefore not an absolute requirement for those wishing to train as doctors. This recognises that many career paths are available to doctors which do not require the performance of EPPs.

However, some components of the undergraduate medical curriculum may provide an opportunity for students to perform EPPs, (for example, obstetrics and gynaecology, trauma or surgical attachments). Additional health clearance is therefore recommended for those students who may find themselves in a position where the opportunity to perform an EPP may arise. Medical schools should ensure that their students do not perform EPPs as part of their training until there has been time to complete screening. Students found to be infectious carriers of BBVs will need to comply with OH supervision and guidance from the responsible head of course to ensure they do not perform EPPs until they meet the criteria set out in <u>Part D</u>.

<u>Guidance on health clearance and management of medical and dental students living with a</u> <u>BBV</u> is produced jointly by the Council of Heads of Medical Schools, the UKHSA, Public Health Scotland, the Association of UK Hospitals and the Higher Education Occupational Practitioners Group.

#### Nursing students

Additional health clearance is not necessary for nursing students, as performance of EPPs is not a requirement of the curriculum for pre-registration student nurse training.

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#### Dental, midwifery, and podiatric surgery students

Additional health clearance is recommended for all dental students (including dental hygienists and therapists but not nurses), midwifery and podiatric surgery (but not podiatry) students before acceptance onto training courses, because EPPs are performed during training and practice of these specialties.

#### Emergency healthcare students

Paramedic and ambulance technician students may require <u>EPP clearance</u> subject to the outcome of a risk assessment.

#### HCWs who are performing EPPs for the first time

HCWs moving into training or posts involving EPPs for the first time should also be treated as 'new', and additional health clearance is recommended. This will include, for instance, foundation house officers entering surgical or other specialties involving EPPs, qualified nurses wishing to train as midwives and post-registration nurses moving into work in operating theatres or accident and emergency for the first time.

#### HCWs moving to a new role who have previously performed EPPs

Healthcare workers who are moving from an existing post that involves EPPs to a new post that involves EPPs are not required to provide evidence of health clearance if they started practising EPPs before 2007.

Healthcare workers who are moving from an existing post that involves EPPs to a new post that involves EPPs should be able to provide evidence of their health clearance if they started practising EPPs after 2007. It remains the responsibility of the HCW to request evidence of their health clearance from their previous employer. If evidence of clearance is not provided then this HCW should be treated as 'new', and additional health clearance is recommended.

A suggested framework for establishing a HCW's EPP and health clearance history is outlined in <u>Appendix 2</u> for transfers to a new OH services or new EPP role, and <u>Appendix 3</u> for transfers to a non-EPP role. This process should also involve the employer who has a duty to provide the requested information to the HCW and or new OH services.

# HCWs who are returning to the NHS and who may have been exposed to serious communicable diseases

The need for additional health checks for any HCW who is returning to work in the NHS and who may have been exposed to BBVs while away should be based on a risk assessment and

will depend on what activities they have engaged in while away from the health service. This should be carried out by the OH service. The timing of any tests should take account of the natural history of the infections (the 'window period').

Some examples of HCWs who might be considered 'returners' include those returning from research experience (including electives spent in countries of high prevalence for BBVs), voluntary service with medical charities, sabbaticals (including tours of active duty in the armed forces), exchanges, locum and agency work or periods of unemployment spent outside the UK.

#### HCWs from locum and recruitment agencies

OH checks, to the same standard as applied to NHS employees, should form part of preemployment checks conducted by providers of temporary staff, regardless of whether they have worked previously in the NHS. Health clearance appropriate to HCWs' duties should be verified before the individual undertakes any clinical work. Whilst it is the responsibility of the agency to clear temporary staff for EPPs, the NHS employer has the responsibility to check they have been cleared. While working on NHS premises, responsibility for continuing occupational health and safety needs of temporary workers lies with the NHS employer, as covered by the Health and Safety at Work Act 1974. Agencies are responsible for supplying staff that are fit for the post they are being recruited into.

#### HCWs in the independent healthcare sector

NHS organisations that arrange for NHS patients to be treated by non-NHS hospitals or health establishments in the UK, including the independent sector, should ensure that the health clearance guidance is followed.

# 6.2 Standard BBV health checks for all new HCWs

Standard health clearance is recommended for all categories of new HCWs employed or starting training (including students) in a clinical care setting, either for the first time or returning to work in the NHS.

Standard health checks for non-EPP posts may be conducted on appointment; these should be completed before clinical duties commence. Declining to disclose BBV status on appointment should not affect the employment or training of HCWs who will not perform EPPs. HCWs may however, wish to disclose this information in confidence to their occupational health service, who can then ensure that appropriate OH advice and support is provided, including advising on suitability for a particular post or need for vaccination or other actions where appropriate.

#### Offer of hepatitis B immunisation: non-EPP HCWs

It is recommended that all HCWs, including students, who have direct contact with blood, blood-stained body fluids or patients' tissues, are offered immunisation against hepatitis B and tests to check their response to immunisation. Guidance on immunisation against hepatitis B, which includes information about dosage, protocols and supplies, is contained in chapter 18 of the <u>Green Book</u>.

Declining vaccination (whether contra-indicated or not), or non-response to vaccine, will not affect the employment or training of HCWs who will not perform EPPs.

#### Offer of testing for hepatitis C: non-EPP HCWs

All HCWs who are new to the NHS should be offered a pre-test discussion and an HCV antibody test (and if positive, an HCV RNA test), in the context of their professional responsibilities. During this discussion, they should be given a copy of the guidance from their professional regulatory body, if relevant. It would be helpful to remind them of the ways in which they might have been exposed to HCV.

Being HCV positive, or declining a test for HCV, will not affect the employment or training of HCWs who will not perform EPPs.

#### Offer of testing for HIV: non-EPP HCWs

All HCWs who are new to the NHS should be offered an HIV test with appropriate pre-test discussion, including reference to their professional responsibilities. During this discussion, they should be given a copy of the guidance from their professional regulatory body, if relevant. It would be helpful to remind them of the ways in which they may have been exposed to HIV.

Declining a test for HIV or having HIV will not affect the employment or training of HCWs who will not perform EPPs. In the event that a HCW discloses that they are living with HIV, accredited specialists in occupational medicine should consider the impact of HIV infection on the individual's susceptibility to other infections when advising on suitability for particular posts.

# 6.3 Additional BBVs health checks (testing for HBV, HCV and HIV) for new HCWs who will perform EPPs, and for existing HCWs who are new to EPPs

Additional health clearance is required for HCWs who will perform EPPs. It will obviously be to the advantage of HCWs to establish their BBV status early as they make their career choices.

HCWs have the right to decline to be tested for HIV, HBV and HCV, in which case, they will not be cleared for EPP work.

Practising HCWs who undertake EPPs or who perform clinical duties in renal units or any other settings involving renal dialysis are under a professional duty to seek medical advice on the need to be tested if they may have been exposed to HIV, HBV or HCV, occupationally or otherwise. If found positive, the HCW should obtain and follow appropriate clinical and OH advice.

The time for testing for new HCWs may vary depending upon the particular chosen career, but times considered appropriate are:

- junior doctors entering all surgical specialties, obstetrics and gynaecology, should be tested before their first foundation house officer post (this will include those posts in accident and emergency and trauma care where doctors may be called upon to perform EPPs)
- prospective dental students, hygienists and therapists should be tested before entry into dental school, as EPPs form an integral part of their training and in the work of dentists
- prospective midwifery students should be tested before embarking on midwifery courses
- nurses should be tested before they move to specialised areas of work where they
  may be required to perform EPPs, for example, operating theatre and accident and
  emergency nursing
- ambulance staff should be tested before they embark on training as paramedics or technicians
- podiatrists should be tested before they commence training in podiatric surgery

This list covers the major specialties but is not intended to be exhaustive. It is not possible to provide a definitive list of types or specialties of HCWs who perform EPPs, because individual

working practices may vary between clinical settings and between workers. Examples of EPPs are available on the <u>UKAP webpage</u>.

# 6.4 Health clearance for HCWs who will perform EPPs: Hepatitis B virus

#### Hepatitis B testing of HCWs who will perform EPPs

New HCWs who intend to perform EPPs or clinical duties in renal units or any other settings involving renal dialysis should:

- be tested for hepatitis B surface antigen (HBsAg) first with appropriate pre-test discussion, including reference to their professional responsibilities
- if negative for HBsAg, be offered vaccination (unless they have already received a course of vaccine) and have their response checked (anti-HBs)
  - to determine the immune status of HCWs who received Hep B vaccine as part of a childhood schedule, a challenge dose of Hep B vaccine can be used to determine the presence of vaccine-induced immunologic memory
  - where there is evidence that an HCW, who is known to have had a previous HBV infection that has cleared, now has natural immunity and immunisation is not necessary, but the advice of a local virologist or clinical microbiologist should be sought
  - healthcare workers for whom hepatitis B vaccination is contra-indicated, who decline vaccination or who are non-responders to vaccine (those with anti-HBs levels of less than 10 milli-international units per millilitre (mIU/mL) should be restricted from performing EPPs or clinical duties in renal units or any other settings involving renal dialysis, unless shown to be non-infectious, they should be tested annually for HBsAg

Testing for past, cleared, hepatitis B infection is not part of routine EPP clearance.

HCWs who have evidence of past cleared hepatitis B infection, or have a current infection and clearance for EPPs without antiviral therapy, may reactivate hepatitis B if immunosuppressed. Such reactivation may pose a risk to patients. Therefore where a HCW is immunosuppressed, testing for HBcAb is advised. For further information on additional clearance considerations regarding immunosuppression see Section 7.2.

All testing should be carried out by any accredited specialist virology laboratory that is experienced in performing such tests. Further guidance on laboratory testing for BBVs, including management of results from overseas laboratories, is provided in <u>Appendix 1</u>.

#### Initial health clearance for HBsAg positive HCWs who intend to perform EPPs or clinical duties in renal units or any other setting involving renal dialysis

HCWs initially testing positive for HBsAg, should be tested for hepatitis B viral load (HBV DNA). On the grounds of patient safety, HCWs who perform EPPs or undertake clinical duties in renal units will not be allowed to practice if they have an HBV DNA level at or above 200 IU/mL regardless of their treatment status. The cut off used historically 10<sup>3</sup> genome equivalents per millilitre (gEq/mL) to monitor HCWs living with HBV who have been cleared to perform EPPs, is equivalent to 200 IU/mL, as determined using a CE marked assay, which is standardised to the World Health Organisation (WHO) international standard for hepatitis B virus nucleic acid amplification techniques.

Initial clearance to perform EPPs requires 2 Identified and Validated Samples (IVS) taken no less than 4 weeks apart with both showing a viral load result below 200 IU/mL. An IVS is defined by the Association of NHS Occupational Physicians (ANHOPS) and the Association of NHS Occupational Health Nurses (ANHONS) as meeting the following criteria:

- 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
- the sample of blood should be taken in the occupational health department
- samples should be delivered to the laboratory in the usual manner, not transported by the healthcare worker
- 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

The decision to clear individual HCWs to undertake EPPs, or clinical duties in renal units or any other settings involving renal dialysis, is the responsibility of the accredited specialist in occupational medicine. UKAP may be consulted on the application of the policy, as required.

HCWs living with HBV should continue to be periodically monitored in line with UKAP-OHR requirements (see <u>Chapter 7</u>).

# 6.5 Health clearance for HCWs who will perform EPPs: hepatitis C virus

#### HCV testing of HCWs who will perform EPPs

New HCWs who intend to perform EPPs should be tested for HCV antibody with appropriate pre-test discussion, including reference to their professional responsibilities. Those who are positive should be tested for HCV RNA to detect the presence of current infection. Testing for HCV RNA should be carried out by an accredited specialist virology laboratory that is experienced in performing such tests.

The Advisory Group on Hepatitis (AGH) has assessed that the risk of transmission of HCV from a HCW of unknown HCV status through EPPs is low and therefore advised that existing HCWs doing EPPs should not be routinely tested for HCV. However, appropriate HCV testing should be conducted for existing HCWs who carry out EPPs who are aware that they may have been exposed to HCV infection, occupationally or otherwise.

HCWs who have antibodies to the HCV and are HCV RNA negative should be allowed to continue performing EPPs.

HCWs who have active, or current, infection (those who are HCV RNA positive) should be restricted from performing EPPs or commencing training for careers that rely upon performing EPPs.

HCWs living with HCV who have been treated with antiviral therapy and who remain HCV RNA negative for at least 3 months after cessation of treatment should be permitted to return to performing EPPs at that time. As a further check, they should be shown still to be HCV RNA negative 3 months after. Provided that these criteria are met, a return to EPPs is a local decision and does not need to be referred to UKAP (although UKAP is available to provide advice if required).

Testing for HCV RNA should be carried out by an accredited specialist virology laboratory that is experienced in performing such tests. Further guidance on laboratory testing for BBVs, including management of results from overseas laboratories, is provided in <u>Appendix 1</u>.

# 6.6 Health clearance for HCWs who will perform EPPs: HIV

#### HIV testing of HCWs who will perform EPPs

New HCWs who intend to perform EPPs should be tested for HIV infection with appropriate pre-test discussion, including reference to their professional responsibilities. The presence of HIV antibody should not automatically restrict HCWs from performing EPPs. Confirmation of HIV infection should be undertaken and plasma viral load measured. Vaccine Induced Sero-Reactivity (VISR) may be encountered when testing HCWs who have participated in HIV vaccine trials. Documentary evidence of the HCWs participation in a vaccine trial, with evidence of negative serum HIV p24 antigen and viral load (RNAor DNA) is sufficient to confirm the HCWs HIV negative infectious status. Detecting HIV antibody as a consequence of VISR should not prevent HCWs performing EPPs.

Guidance on laboratory testing for BBVs, including management of results from overseas laboratories, is provided in <u>Appendix 1</u>.

# Initial health clearance for HIV positive HCWs who intend to perform EPPs

HCWs living with HIV with a plasma viral load above 200 copies/mL should be restricted from performing EPPs.

Initial clearance to perform EPPs requires a HCW to be on effective combination anti-retroviral therapy (cART) and to have had 2 IVS test results taken no less than 12 weeks apart with both demonstrating a viral load below 200 copies/mL. For the purposes of initial health clearance, no less than 12 weeks apart is defined as between 12 and 16 complete calendar weeks. The decision to clear individual HCWs to undertake EPPs is the responsibility of the accredited specialist in occupational medicine. UKAP may be consulted on the application of the policy, as needed.

For HCWs currently restricted from EPPs who are already on cART and have a viral load below the clearance threshold, based on an IVS test result at 12 to 16 weeks since their last undetectable IVS viral load result is sufficient proof on which to grant clearance for conducting EPPs. If a HCW's viral load test is performed outside the UK, advice should be sought from UKAP.

HCWs performing EPPs who are living with HIV should continue to be periodically monitored in line with UKAP-OHR requirements (see <u>Chapter 7</u>).

## 6.7 Redeployment and retraining

Employers should assure HCWs living with BBVs that their status and rights as employees will be safeguarded so far as practicable. If for any reason, a HCW is unable to recommence EPP practice, employers should make every effort to arrange suitable alternative work and retraining opportunities, or where appropriate, early retirement, in accordance with good general principles of occupational health practice. With the opportunity for HCWs living with HIV or HBV to recommence EPPs once the criteria in this guidance have been met, it is anticipated that the number of HCWs requiring retraining will be small. There may, however, be a requirement for short term redeployment while the HCW commences antiviral treatment and until a point that their infection is cleared (for HCV), or their viral load is reduced below the level required to perform EPPs.

# Part D: management of healthcare workers living with bloodborne viruses

# Chapter 7: OH monitoring of HCWs living with BBVs

### 7.1 Monitoring roles and responsibilities

The model for allowing HCWs living with HBV or HIV to undertake EPPs whilst on therapy relies on continuing care and regular viral load monitoring by both their treating physician and accredited specialist in occupational medicine. Effective monitoring requires close working between these 2 parties to ensure that the policy is being adhered to appropriately, thus minimising the risk of transmission.

Where a healthcare establishment's OH service does not have its own accredited specialist in occupational medicine, arrangements should be put in place for this advice to be sought from such an individual outside the establishment. Suitable arrangements must be in place for agency or locum staff, including dental staff, to ensure that they have a designated accredited specialist in occupational medicine who is responsible for their monitoring, in accordance with this guidance.

All HCWs living with HBV or HIV who perform EPPs should have their viral load measured regularly using a blood IVS as described in this Chapter. Blood testing for this purpose will usually be carried out by the OH service, but where this would give rise to duplication of testing, local arrangements should be made between the treating physician and the OH service to ensure that blood drawn from HCWs for viral load measurements in genitourinary medicine (GUM) and sexual health or infectious diseases settings follows the principles of an IVS (see <u>Appendix 1</u>).

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.

UKAP-OHR currently records monitoring data on HCWs living with HIV; a phased introduction of HCWs living with HBV is ongoing. Details of this will be circulated to Occupational Health departments and appropriate clinical networks.

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 as a result of an increase in viral load should be reported using the register to record that 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.

Whilst it is important that UKAP should be called upon for advice on the application of the policy as needed, decisions to clear individual HCWs for EPP work remain the responsibility of the accredited specialist in occupational medicine.

The roles and responsibilities of the respective individuals involved in the monitoring process for HCWs living with BBVs who are performing EPPs are set out below:

#### A. Healthcare worker

The HCW must be under the care of a designated accredited specialist in occupational medicine. They must accept that it is a condition of undertaking EPPs that they consent to ongoing monitoring including:

- i. The registration of their details and monitoring data on the UKAP-OHR.
- ii. The release of viral load test results to the accredited specialist in occupational medicine if the treating physician undertakes monitoring. Some HCWs may have their viral load tested regularly as part of their clinical HIV care; in these situations, results can be shared with OH, with the HCW's consent, to avoid unnecessary repeat testing. The treating clinician must provide assurance that the sample meets criteria of IVS.

- iii. To attend the OH service (or other appropriate service) when arranged and to provide an IVS for viral load monitoring at the appointed times.
- iv. To seek advice if a change in health condition may affect their fitness to practise or impair their health or, in order to assess their risk of rHBV, if they start immunosuppressive treatment or develop an illness that compromises their immune system.
- v. To notify OH when they are changing their practice or their place of employment, including informing the new OH service of BBV status and monitoring (where EPPs are involved in new role). HCWs should keep their OH specialist informed of any change in role or place of work so that monitoring records can be updated, any new monitoring arrangements established and their clearance to practice maintained.
- vi. To notify their accredited specialist in occupational medicine and treating physician if there has been an interruption to therapy or sub-optimal adherence or if they are at risk of rHBV due to immumosuppresive therapy or any illness that may compromise their immune system.

Thus, HCWs must agree that by seeking to undertake EPPs, they are giving implied consent to i and ii, and they are undertaking to satisfy iii to vi.

It is recommended that the OH department puts in writing to the HCW, the requirements they must meet in order to continue practising EPPs.

If the HCW is moving to a new employer, they should liaise with their existing OH physician to ensure the transfer and sharing of necessary information about the monitoring of their viral load for ongoing EPP clearance to the OH service of their new employer (see Section 6.1).

#### B. Accredited specialist in occupational medicine

The accredited specialist in occupational medicine is responsible for the monitoring of the HCW, including:

- i. Ensuring that appointments are available for testing in accordance with the testing protocol, and timings are followed.
- ii. Reacting promptly to any alerts received via the UKAP-OHR.
- iii. Taking appropriate action when those who should present for tests do not do so, for example, notifying the relevant manager of the HCW's non-attendance and restriction from EPP practice.

- iv. Ensuring that IVS samples are collected and tested and results obtained in a timely manner.
- v. Interpreting the viral load results in relation to clearance to perform EPPs.
- vi. Notifying the HCW that they are cleared to perform EPPs.
- vii. Ensuring that the UKAP-OHR is updated within the specified time-frame.
- viii. Advising the employer if the HCW is no longer fit to perform EPPs (advising employer about clearance to practice should be on an 'exception' basis', meaning once cleared the employer is only updated if there is a change to this status).
- ix. Timely liaison with treating physicians when required.

The accredited specialist in occupational medicine should inform UKAP-OHR of any change of employer and provide contact details for the new OH service which will be taking over monitoring the HCW's infection.

#### C. Treating physician

The treating physician is responsible for:

- i. The clinical management and support of the HCW.
- ii. Advising and maintaining timely communications with the accredited specialist in occupational medicine responsible for monitoring the HCW.
- iii. Advising the HCW what constitutes a risk of therapy failure (for example, an interruption to therapy or sub-optimal adherence).
- iv. Notifying the accredited specialist in occupational medicine if there has been a risk of therapy failure.

#### D. Occupational health register (UKAP-OHR)

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.

#### E. Employers and commissioning bodies

It is the responsibility of the employer to maintain a record of procedures performed by HCWs living with HBV or HIV who are cleared to perform EPPs. EPP performing HCWs living with BBVs who are self-employed should be responsible for maintaining their own record of the procedures performed. Records should be captured and stored in line with appropriate information governance requirements.

# 7.2 Monitoring and ongoing clearance for HCWs who will perform EPPs: hepatitis B

#### Monitoring of HCWs who will perform EPPs

HCWs who are HBsAg positive should not be restricted from performing EPPs or clinical duties in renal units or any other settings involving renal dialysis if HBV DNA viral load is less than 200 IU/mL (either whilst on continuous antiviral therapy, from natural suppression, or after a minimum of 12 months after stopping a course of antiviral therapy during which time there must have been 2 HBV DNA tests 6 months apart, the first being no less than 6 months after ceasing treatment) and their HBV DNA levels are monitored every 6 months by their accredited specialist in occupational medicine.

Those who have ceased treatment need to show that they have a viral load that does not exceed 200 IU/mL at least one year after cessation of treatment before a return to unrestricted working practices can be considered, through 2 tests 6 months apart (see <u>Treatment issues</u>). Any health care worker living with HBV returning to unrestricted working practices would be subject to the same 6 monthly re-testing as recommended for other health care workers living with HBV.

The 6 month monitoring period should be taken from the date the previous IVS was drawn, and not from the date the result was received. Six-monthly viral load testing can be performed no earlier than 24, and no later than 28 complete calendar weeks after the date of the preceding specimen taken for occupational health monitoring purposes.

If a HCW's plasma viral load is equal to or above 200 IU/mL, they should be restricted immediately from performing EPPs until their viral load returns to being stable below 200 IU/mL (see <u>Resuming EPPs</u>). The significance of any increase in plasma viral load above the cut-off, identified through routine monitoring, should be assessed jointly by the accredited specialist in occupational medicine and treating physician with input from appropriate local experts (for example, consultant virologist or microbiologist).

The table below sets out the expected course of action for HBV DNA level test results below and above the level for EPP clearance, after the HCW has satisfied the initial clearance criteria.

Guidance on laboratory testing for BBVs, including management of results from overseas laboratories, is provided in <u>Appendix 1</u>.

Health clearance of healthcare workers and the management of healthcare workers living with bloodborne viruses

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 <u>Chapter 9</u> ) 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.	

#### Resuming exposure prone procedures

If a HCW does not attend for their monitoring appointment, then they should cease conducting EPPs. Six-monthly monitoring can be performed no later than 28 complete calendar weeks after the preceding IVS specimen taken for occupational health monitoring purposes.

If a HCW does not attend for the missed viral load test within this timeframe (for whatever reason) then resumption of EPPs requires 2 IVS taken no less than 4 weeks apart with both showing a viral load result below 200 copies/mL.

HCWs living with HBV who take a career break from performing EPPs or clinical duties in renal units or any other settings involving renal dialysis, may wish to continue monitoring during this period to facilitate a return to EPPs or clinical activities. Individuals with a break in their monitoring record must meet the criteria for initial clearance before returning to performing EPPs or clinical duties in renal units or any other settings involving renal dialysis.

#### **Treatment issues**

It is for the HCW to decide, in collaboration with their treating physician, whether they wish to take antiviral therapy for occupational health reasons when it is not clinically indicated, taking account of possible advantages and disadvantages.

Breakthrough infection, with increases in serum HBV DNA and in serum alanine aminotransferase (ALT) levels can be associated with the emergence of resistant virus. With successful oral antiviral treatment, the rate of viral replication in HCWs should be suppressed to levels where the risk of emergence of drug resistant strains is likely to be low. Early detection of the emergence of resistance through the 6 monthly monitoring can be achieved by using sensitive HBV DNA assays, as is recommended here, allowing consideration of an early change in antiviral therapy before patients have been put at appreciable risk.

If breakthrough infections occur due to the development of resistant strains, and HBV DNA levels rise above 200 IU/mL, then it is recommended that the HCW be restricted from performing EPPs (or clinical duties in renal units or any other settings involving renal dialysis) 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 200 IU/mL on 2 consecutive tests performed no less than 4 weeks apart.

HCWs should be advised by their treating physician of the importance of notifying them of missed doses, drug interactions, or other factors that might influence their viral load, as soon as is practicable and before further EPPs are performed.

It is recommended that if a HCW stops antiviral treatment for any reason, they should immediately cease to perform EPPs or clinical duties in renal units or any other settings involving renal dialysis and seek the advice of their treating physician if this has not already been obtained. The HCW should be restricted from performing EPPs for 12 months if they remain off antiviral therapy. To resume EPPs after this 12 month period, the HCW must demonstrate a viral load result of below 200 IU/mL through 2 consecutive IVS tests 6 months apart. The first test should be conducted at a minimum of 6 months after treatment cessation. Upon return to performing EPPs, the HCW should undertake 6 monthly testing as recommended in these guidelines.

#### Reactivation of HBV (rHBV)

There is a risk of reactivation of hepatitis B when a person becomes immunosuppressed. This is becoming more common due to the increased use of therapeutic immunosuppressive agents in organ transplants and inflammatory and autoimmune illnesses. Reactivation may occur in 2 main settings:

- in those who have current infection (HBsAg positive) but a low or negative HBV DNA level (viral load)
- in those with past, cleared, infection (HBsAg negative, hepatitis B core antibody [HBcAb] positive)

Such a reactivation increases HBV viral load and can create a risk of transmission. An increase in viral load in a previously HBsAg negative HBcAb positive individual, or the appearance of HBV DNA in a previously HBV DNA negative case or an increase of viral load above 200 IU/mL in a previously dectectable but below 200IU/mL individual may all indicate rHBV. However increase in viral load level may be due to other factors including rHBV and a case by case approach should be taken to determine if rHBV has occurred. In all cases a retest in 10 days is advised.

Testing for past, cleared, hepatitis B infection is not part of routine EPP clearance. HCWs may already be aware of past cleared hepatitis B infection, or may become aware as part of standard investigations pre-immunosuppression. Clinicians starting immunosuppressive treatment or diagnosing a condition conferring risk of rHBV should arrange to test for current and past hepatitis B infection.

UKAP recommend the following when there is a risk of hepatitis B reactivation:

 all EPP workers who are HBsAg positive but not on antiviral therapy for hepatitis B and EPP workers who are HBsAg negative and HBcAb positive should be advised by the clinician managing the immunosuppression and or the hepatologist they are under to inform the accredited specialist in occupational medicine responsible for their monitoring of the decision to start immunosuppressive treatment or of any illness that may compromise their immune system

- the accredited specialist in occupational medicine should liaise with the specialist starting the immunosuppressive treatment and hepatologist or virologist regarding options of starting prophylactic antiviral therapy and or more regular monitoring of HBV infection markers. There may need to be a period of stopping EPP until it is established that the virus has not reactivated
  - if the virus does reactivate, the HCW must not return to EPP until their viral load is stabilised and below 200 IU/mL in 2 IVS samples at least 4 weeks apart; further advice can be sought from UKAP
- HCW who are HBsAg positive but not on antiviral therapy should typically be offered antiviral prophylaxis before starting immunosuppressive treatment
  - the rationale and decision on management options should involve the HCW, the clinician managing the immunosuppression, the accredited specialist in occupational medicine and a hepatologist.

# 7.3 Monitoring and clearance for HCWs who will perform EPPs: hepatitis C

HCWs who have active, or current, infection (those who are HCV RNA positive), should be restricted from carrying out EPPs.

HCWs who have antibodies to HCV and are confirmed as having a sustained viral response (those who are HCV RNA negative), following treatment should be allowed to perform EPPs, subject to guidance in <u>Chapter 6</u>.

Guidance on laboratory testing for BBVs, including management of results from overseas laboratories, is provided in <u>Appendix 1</u>.

# 7.4 Monitoring and ongoing clearance for HCWs who will perform EPPs: HIV

#### Monitoring of HCWs who will perform EPPs

HCWs living with HIV must meet the following criteria before they can perform EPPs:

#### Either

- i. be on effective cART, and
- ii. have a plasma viral load less than 200 copies/mL

#### Or

iii. be an elite controller (defined as a person living with HIV who is not receiving antiretroviral therapy and who has maintained their viral load below the limits of assay detection for at least 12 months, based on at least 3 separate viral load measurements.)

#### And

- iv. be subject to plasma viral load monitoring every 12 weeks
- v. be under joint supervision of an accredited specialist in occupational medicine and their treating physician
- vi. be registered with UKAP-OHR

HCWs living with HIV who are cleared to perform EPPs are subject to viral load testing every 12 weeks while continuing to perform such procedures. The 12-week period should be taken from the date the previous IVS was drawn, and not from the date the result was received. Quarterly viral load testing can be performed no earlier than 10, and no later than 14 complete calendar weeks after the date of the preceding specimen taken for occupational health monitoring purposes.

If a HCW's plasma viral load rises above 1,000 copies/mL, they should be restricted immediately from performing EPPs until their viral load returns to being consistently below 200 copies/mL in at least 2 consecutive tests no less than 12 weeks apart. The significance of any increase in plasma viral load above 200 copies/mL and below 1,000 copies/mL should be assessed jointly by the accredited specialist in occupational medicine and treating physician with input from appropriate local experts (for example, consultant virologist or microbiologist).

The table below sets out the expected course of action for viral load test results below and above the level for EPP clearance, after the HCW has satisfied the initial clearance criteria.

Guidance on laboratory testing for BBVs, including management of results from overseas laboratories, is provided in <u>Appendix 1</u>.

Viral load test result	Action	
<50 copies/ml or below	No action. Retest in 12 weeks.	
≥50 but <200 copies/mL	A case-by-case approach based on clinical judgement should be taken which may result in no action (as above) or a recommendation 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 copies/mL but <1,000 copies/mL	A second test should automatically be done 10 days later on a new blood sample to verify that the viral load remains above the threshold.	
	If the count is still in excess of 200 copies/mL, the HCW should cease conducting EPPs until their count, in 2 consecutive tests no less than 12 weeks apart, is reduced to <200 copies/mL.	
	If the viral load was below 200 copies/mL then further action will 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.	
1,000 copies/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 1,000 copies/mL.	
	If the count is below 1,000 copies/mL further action will be informed by the test result as above.	

Viral load test result	Action
	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.
	If the count is still in excess of 1,000 copies/mL, a full risk assessment 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 further public health investigation and action (for example, patient notification) will be determined by a risk assessment on a case-by-case basis in discussion with UKAP.

#### Resuming exposure prone procedures

If a HCW does not attend for their monitoring appointment, then they should cease conducting EPPs. Twelve-weekly monitoring can be performed no later than 14 complete calendar weeks after the preceding IVS specimen taken for occupational health monitoring purposes.

If a HCW does not attend for the missed viral load test within 14 weeks from the date the previous IVS was drawn (for whatever reason) then resumption of EPPs requires demonstration of consistent viral load suppression to very low or undetectable levels, by 2 samples taken no less than 12 weeks apart demonstrating viral load below 200 copies/mL.

HCWs living with HIV who take a career break of more than 14 weeks from performing EPPs may wish to continue 12 weekly monitoring during this period to facilitate a return to EPPs. Individuals with a break in their monitoring record must meet the criteria for initial clearance before returning to EPP activities.

#### **Treatment issues**

HCWs should be advised by their treating physician of the importance of notifying them of missed doses, drug interactions, or other factors that might influence their viral load, as soon as is practicable and before further EPPs are performed.

If there is any suggestion that the HCW's infection is no longer controlled by their antiretroviral treatment, the treating physician overseeing the case may consider it appropriate that viral load tests are performed sooner than the next 12-week test. Advice on the management of suspected treatment failure or suboptimal response should be sought from the appropriate specialist team.

#### Elite controllers

Elite controllers comprise a small proportion (0.2 to 0.55%) of all people living with HIV, who are not receiving antiretroviral therapy and have maintained their viral load below the limits of assay detection for at least 12 months, based on at least 3 separate viral load measurements.

A HCW who meets the definition of being an elite controller can be cleared for EPP activities without being on treatment but must remain subject to 12 weekly viral load monitoring to ensure they maintain their viral load below 200 copies/mL and to identify any rebound promptly. Any such cases should be referred to UKAP for advice on a case-by-case basis.

# 7.5 Failure to attend or refusal to test (HBV, HIV and HCV)

All HCWs living with BBVs performing EPPs should be advised by their accredited specialist in occupational medicine and their treating physician of the importance of periodic monitoring of their viral load and the implications of not doing so.

Where a HCW does not attend for their appointments at the specified interval or attends but refuses to have their viral load tested, it is recommended that the accredited specialist in occupational medicine should inform the HCW's employer that they are no longer cleared to perform EPPs, until it has been established that the HCW has an up-to-date viral load which does not exceed the cut-off.

# 7.6 Patient notification exercises (PNEs)

Finding that a HCW has performed EPPs while living with HCV, or that the viral load of a HCW living with HIV or HBV has risen above the cut-off for performing EPPs would not, in itself, be an indication to trace, notify and offer testing to patients treated by the HCW (undertake a PNE).

The need for a PNE should be determined on a case-by-case basis taking into consideration a risk assessment of the HCW's practice and probity in relation to the risk of BBV transmission to EPP patients, the relative infectious window period, and significance of any viral load 'blip', in

line with the principles in existing guidance. UKAP should be consulted for advice on undertaking a PNE (see <u>Part E</u> for contact details).

### 7.7 Management of accidental exposure

There may be occasions when a HCW living with a BBV is aware of accidentally exposing a patient to their blood or body fluid. These incidents should be managed in accordance with local needlestick injury policies and in consultation with the local health protection team.

# Part E: risk assessment and investigation of potential exposures

# Chapter 8: the UK Advisory Panel on Healthcare Workers Living with Bloodborne Viruses (UKAP)

UKAP was set up originally under the aegis of EAGA in 1991 to consider individual cases of HCWs living with HIV. In 1993 its remit was extended to cover HCWs living with other BBVs, in particular HBV and more recently HCV. Advice for accredited specialists in occupational medicine arises from individual queries, cases or general issues which have been referred to the UKAP since its inception.

### 8.1 The role of UKAP

UKAP's remit is to:

- establish, and update as necessary, criteria on which advice on modifying working practices of HCWs may be based
- provide supplementary specialist occupational advice to treating physicians of HCWs living with BBVs, accredited specialist in occupational medicine and professional bodies
- advise individual HCWs or their advocates on how to obtain guidance on working practices
- advise those with the responsibility for managing incidents involving HCWs living with BBVs
- keep under review the literature on transmission of BBVs in healthcare settings

The current membership list and code of conduct for members, is available at the <u>UKAP</u> webpages.

### 8.2 When to consult UKAP

UKAP advises as a committee and may be consulted through its secretariat. The panel is available for consultation and for advice on the implementation of guidance for managing HCWs living with BBVs.

The panel works within the framework of government guidance concerning HCWs and BBVs and aims to interpret the guidance in relation to individual cases on a consistent basis.

Cases are considered by UKAP. Experts from other specialties not represented on the panel are co-opted to advise as necessary.

### 8.3 How to consult UKAP

Occupational health clinicians, consultants in communicable disease control or health protection (CCDC or CHP) and public health medicine (CPHM), medical directors and other physicians, Directors of Public Health, and others wishing to obtain the UKAP's advice should contact the UKAP secretariat by, email (<u>ukap@ukhsa.gov.uk</u>). Those seeking the advice of UKAP should ensure the anonymity of the referred HCW and should avoid the use of personal identifiers.

Each case reported to UKAP is assigned a unique UKAP case number which is used in all subsequent correspondence to maintain confidentiality. UKAP does not hold any named or identifiable information on the HCWs involved; investigating teams are advised to keep the number of people who know personal details of the affected HCW to a minimum.

The secretariat to UKAP is provided by staff at UKHSA (National Infection Service), and Public Health Scotland.

# Chapter 9: investigation of a HCW diagnosed with BBV, including risk assessment and consideration of patient notification exercise

### 9.1 Local risk assessment

Maintaining patient safety is paramount, therefore, UKAP recommends a formal, structured local risk assessment (involving occupational health, and public health as a minimum) is undertaken, to identify any factors that may impact on the HCW's ability to practise safely and or increase the risk of transmission from the HCW to patients. It is envisaged that in most situations, this would not be the case and that no further public health action or investigation would be required. In cases where other risks are identified, specific or tailored advice on further action will be provided by UKAP based on a case by case basis.

The process should follow local guidance and protocols, to assess the risk of transmission of a BBV from the HCW to the patient. The depth of the investigation should be proportional, considering the burden of work and the level of risk to patients. This process should involve as few people as possible, on a strictly confidential and need-to-know basis, in order to preserve the HCW's confidentiality and that of patients receiving treatment from the HCW.

#### Process for initial investigation (guided by UKAP proforma)

The <u>UKAP enquiry form</u> can be used to guide this initial investigation:

- i. If a HCW living with a BBV has been recognised as the source of transmission to a patient, the local investigating team should make a careful appraisal of the facts, seeking relevant specialist advice (for example occupational health, epidemiological and virological advice). This process should involve as few other people as possible, on a strictly confidential need-to-know basis, in order to preserve the HCW's confidentiality.
- ii. If there is no recognised transmission to a patient associated with the HCW, the local investigating teams should collect information to assess the following factors that would increase the risk of transmission from HCW to patient.
  - a. Details of the HCWs infections (for example, when acquired, treatment, viral load and so on).
  - b. Details of the HCWs practice (for example, types of procedures undertaken).

- c. Evidence of a confirmed or highly likely transmission. This would likely be identified from investigation of an index case of BBV infection where exposure by a named HCW is the only plausible risk factor.
- d. Poor infection prevention and control (IPC) practice or identified breaches that could have resulted in significant exposure to the blood or body fluids of the HCW for example, repeated needlestick injuries or observed poor IPC practice.
- e. Consideration of other elements of HCW's conduct or behaviour (that may have led to poor compliance with treatment of their BBV infection and or their compliance with good IPC practice).
- f. Any action or omission by occupational health or other departments that could be considered a breach of guidance or could have put patients at risk should also be considered and followed up according to trust policy.
- iii. If no 'risks' are identified, the proforma, alongside the details and conclusions of the local risk assessment, should be returned to UKAP and no further action is required.
- iv. If concerns about index case or transmission, poor IPC practices and or other factors affecting the HCW's practice are identified, the case should be discussed with the UKAP secretariat who will advise on further actions required. Actions may include reviewing specific EPPs undertaken, providing information to patients and offering testing for BBVs.

Previously, if a HCW who carried out EPPs was identified as having a BBV and the diagnosis had not been made in the context of a proven transmission event from the HCW to an index patient, a crossmatching exercise was advised to identify any transmissions that could then lead to wider patient notification action.

A review of the past 20 years of UKAP's experience of the investigation and management of HCWs with a BBV found that the risk of transmission of any BBV from HCW to patient is extremely low and the risk versus benefit (cost versus benefit) of undertaking large, resource-intensive lookback exercises does not support the routine use of this approach.

Therefore, the panel now advises that the initial local risk assessment following the identification of a HCW living with a BBV no longer requires a cross matching exercise be undertaken, however it may be recommended if concerns are identified. In addition, a patient notification exercise (PNE) will only be recommended if transmission is identified through an index case report, or if the local risk assessment identifies factors that increase the risk of BBV transmission from the HCW.

The advice from UKAP is based on clinical and public health risk; this does not preclude organisations undertaking their own investigation or lookback or consideration of notifying patients, but this would be outside the remit or scope of UKAP's work.

Following these changes in approach to local risk assessment and PNEs, UKAP will continue to monitor the number and nature of incidents where HCWs with BBVs may have been practising EPPs. This data will inform any future amendments to guidance.

# Part F: general principles of bloodborne virus infection control

The general principles and practices of infection prevention and control (IPC) are designed to protect HCWs and patients from infection caused by a broad range of pathogens including BBVs. These principles and practices must be followed when caring for all patients to minimise the risk of exposure to blood products and any associated BBVs.

Guidance for clinical HCWs on minimising the risk of exposure to blood products and any associated BBV can be found on the <u>Health and Safety Executive webpage</u> and has been reproduced below. The measures recommended will also minimise the risk of transmission from HCWs to patients and from patient-to-patient. The measures are:

- avoid contact with blood or body fluids
- take all necessary precautions to prevent puncture wounds, cuts and abrasions in the presence of blood and body fluids
- avoid use of, or exposure to, sharps (needles, glass, metal, and so on) when possible, and discard sharps directly into the sharps container immediately after use, and at the point of use
- take particular care in handling and disposal if the use of sharps is unavoidable; 'one use only' contaminated sharps must be discarded into an approved sharps container (this is generally safer and more practical than attempting to recycle contaminated items)
  - this must be constructed to BS 7320; 1990/ UM 3291, and used containers must be disposed of through a waste management company who will dispose of them safely as 'waste for incineration only'
- protect all breaks in exposed skin by means of waterproof dressings and or gloves; chain mail and armoured gloves are available to protect the hands when working with sharp instruments or exposed to bone splinters, and so on
- protect the eyes and mouth by means of a visor or goggles or safety spectacles and a mask when splashing is a possibility (this will also protect against bone fragments in orthopaedic surgery and post-mortem examination)
- avoid contamination of the person or clothing by use of waterproof or water resistant protective clothing, plastic apron, and so on
- wear rubber boots or plastic disposable overshoes when the floor or ground is likely to be contaminated
- apply good, basic hygiene practices, including handwashing, before and after glove use, and to avoid hand-to-mouth or eye contact
  - disposable gloves should never be washed and reused, as they may deteriorate during use and in washing

- if latex gloves are worn, powder-free, low-protein products should be chosen to help prevent latex allergy
- any disposable gloves should be CE marked for use with biological agents
- control surface contamination by blood and body fluids by containment and appropriate decontamination procedures
- dispose of all contaminated waste safely and refer to relevant guidance

# Part G: Links to guidance documents and webpages

# Regulatory bodies for statements on professional responsibilities

#### **General Medical Council**

Duties of a doctor: specifically, Domain 2: Safety and Quality.

#### **General Dental Council**

Standards for the dental team: specifically, standards 1, 6, 7, 8 and 9.

#### Nursing and Midwifery Council

The Code for nurses and midwives: specifically, standards 5, 8, 16, 17, 19 and 23.

#### Health and Care Professions Council

Standards of conduct, performance and ethics: specifically, standards 1, 6 and 7.

### UKAP guidance and documents

UK Advisory Panel for Healthcare Workers Living with Bloodborne Viruses (UKAP), including UKAP-OHR registration and guidance on categories of exposure prone procedures can be found at the <u>UKAP webpage</u>.

UKAP enquiry proforma

# Appendix 1. Laboratory testing arrangements for health clearance and monitoring

### Identified and validated samples (IVS)

Those commissioning tests to establish or monitor a healthcare worker's BBV status should ensure that IVS are used; that is, they should ensure that samples tested are from the HCW in question and not open to fraudulent submission of samples or tampering with samples or results. HCWs should not submit their own samples to a laboratory.

The standards for occupational health data recording have been agreed by the Association of NHS Occupational Physicians (ANHOPS) and the Association of NHS Occupational Health Nurses (ANHON) as the 2 relevant professional bodies. The standards are:

- laboratory test results required for clearance for undertaking EPPs, and ongoing monitoring thereafter must be derived from an IVS
- results should not be recorded in occupational health records if not derived from an IVS

An IVS is defined by ANHOPS and ANHONS as meeting the following criteria:

- the HCW should show a proof of identity with a photograph (for example trust identity badge, new driver's licence, some credit cards, passport or national identity card) when the sample is taken
- the sample of blood should be taken in the occupational health service
- samples should be delivered to the laboratory in the usual manner, not transported by the HCW
- 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 service, at the relevant time

Blood testing for the purpose of ongoing monitoring of HCWs living with HIV or HBV who perform EPPs will usually be carried out by the occupational health service but where this would give rise to duplication of testing, local arrangements should be made between the treating physician and the occupational health service to ensure that blood drawn from HCWs living with HBV or HIV for viral load measurements in GUM, sexual health or infectious diseases settings follows the principles of an IVS.

All samples sent for BBV testing for EPP clearance purposes should be accompanied by a request which contains as a minimum:

- forename
- surname
- date of birth
- purpose of testing 'clearance for EPP'
- information on whether the HCW is, or is not, taking antiviral therapy

For circumstances where coding is required or preferred, the accredited specialist in occupational medicine should liaise with the lead consultant microbiologist or virologist in the local laboratory to ensure a consistent coding system unique to that laboratory is used, and that serial samples from the same HCW are identifiable as such.

### **Testing arrangements**

Laboratories must be accredited to provide the assays used in healthcare clearance and monitoring for bloodborne virus infection and must use assays that comply with relevant national regulations and professional guidance. The turnaround time (TAT) for an HIV viral load test is subject to local agreement and will vary between laboratories. Accredited specialists in occupational medicine should consider the TAT of their local laboratory when scheduling appointments for occupational health monitoring to ensure viral load results are available no later than 14 complete calendar weeks after the date of the preceding specimen taken for occupational health monitoring purposes.

Such assays must also have performance characteristics demonstrating the necessary sensitivity and reproducibility inherently required by the thresholds defined in this integrated guidance.

The use of personal identifiers in requests for laboratory tests may be avoided and care taken to ensure that the number of people who know the HCW's identity is kept to a minimum. However, full person identifiers must always be used when sending results to the UKAP-OHR in the first instance.

Where coding is used, the accredited specialist in occupational medicine should liaise with the lead consultant microbiologist or virologist in the local laboratory to ensure a consistent coding system unique to that laboratory is used, and that serial samples from the same HCW are identifiable as such.

All tests for clearance and monitoring must be conducted by an accredited laboratory in the UK. Tests conducted outside the UK cannot be accepted for these purposes.

# Hepatitis B diagnostic cut-off and changes to designated laboratory status

The original guidance for HCWs living with HBV specified a cut-off of 10<sup>3</sup> genome equivalents/mL (gEq/mL), above which HCWs were not allowed to perform EPPs. HBV DNA testing was restricted to 2 designated laboratories, (the West of Scotland Specialist Virology Centre and the Public Health Laboratory Birmingham), who were able to benchmark HCW-derived samples against a WHO International Standard known to contain 10<sup>3</sup> gEq/mL.

In the years since issuance of that guidance, commercially available HBV viral load assays have been developed that use a WHO International Standard for Hepatitis B Virus Nucleic Acid Amplification Techniques. The International Standard and CE marked quantitative HBV DNA PCR assays calibrated to this standard are now widely available and it is now standard practice for HBV viral load assay results to be reported in international units per millilitre (IU/mL). Bioassays, including quantitative HBV DNA PCR (viral load) testing, use complex biological systems to test activity therefore are variable from test to test. By using a biological reference material or standard of known concentration, bioassay results can be compared and calibrated to give a consistent result, no matter when or where the bioassay is performed. The WHO international standards are calibrated in units of biological activity which are assigned following extensive studies involving multiple international laboratories.

Going forward, viral load testing can be undertaken by an accredited virology laboratory in the United Kingdom, provided a CE marked assay, which is standardised to the WHO international standard for hepatitis B virus nucleic acid amplification techniques, is used and HBV DNA levels are reported in international units per millilitre (IU/mL). The historical cut-off has been converted to IU/mL by dividing by a factor of 5 to approximate the conversion used in the most commonly used assays. Thus  $10^3$  gEq/mL = 200IU/mL, and this replaces the previous cut-off for performing EPPs.

Two cut-offs have been used historically for pre-treatment viral load. 10<sup>3</sup> gEq/ml is equivalent to 200 IU/mL; 10<sup>5</sup> gEq/ml is equivalent to 20,000 IU/mL. Where pre-treatment viral load was

measured before the introduction of this new guidance, viral loads reported as either gEq/mL or IU/mL are acceptable; results should not be converted between units. Previous and newlyissued guidance on hepatitis B diagnostic cut-offs for clearance of HCWs performing EPP are shown in the table below:

Item	Previous guidance	New guidance
Cut-off for clearance to perform EPP	<10 <sup>3</sup> gEq/mL	<200 IU/mL
Testing laboratory	One of 2 designated laboratories.	An accredited laboratory in the UK, using a CE marked assay standardised to the WHO international standard for hepatitis B virus nucleic acid amplification techniques, reported in IU/mL.
Specimen type	Identified and validated samples (IVS)	IVS

# Appendix 2. Process of transferring to another accredited specialist in occupational medicine: EPP role

When transferring OH monitoring a HCW living with a BBV to a new OH service or healthcare organisation, the current accredited specialist in occupational medicine should consider including in the transfer summary:

- approximate dates of employment and clearance
- consent of HCW to transfer UKAP-OHR registration
- confirmation that the UKAP-OHR team have been informed of the transfer
- UKAP-OHR reference number
- consent of HCW to transfer the HCWs EPP related health records
- medical and treatment history including medication changes and compliance testing history including points of note for example historical actions or tests needed
- confirmation that the new accredited specialist in occupational medicine is accredited in occupational medicine
- contact details of the treating doctor
- any other concerns or details necessary

# Appendix 3. Process of transferring to another accredited specialist in occupational medicine: non-EPP role

If a HCW subject to monitoring wishes to stop undertaking EPPs, for example because of moving jobs, they are recommended to formally inform their current accredited specialist in occupational medicine. HCWs should also consider providing the reason for halting monitoring and the date of stopping EPPs, including confirmation from the employer about their new non-EPP role. Those who are self-employed could provide a self-statement confirming their new non-EPP role. The accredited specialist in occupational medicine is advised to notify the HCW and UKAP-OHR when monitoring will cease.

# Appendix 4. Evolution of policy on the management of blood-borne viruses in healthcare workers

### HIV

The first guidance, published by the General Medical Council in 1988 addressed the duties of doctors living with HIV or who had developed acquired immune deficiency syndrome (AIDS). This stated:

"It is imperative, both in the public interest and on ethical grounds that any doctors who consider that they may have acquired HIV should seek appropriate diagnostic testing and counselling, and if found to be infected, should have regular medical supervision. They should also seek specialist advice on the extent to which they should limit their professional practice in order to protect their patients. They must act upon that advice, which in some circumstances would include a requirement not to practise or to limit their practice in certain ways. No doctors should continue in clinical practice merely on the basis of their own assessment of risk to patients." (<u>6</u>)

This was followed in 1988 with a recommendation from EAGA that HCWs who know or who suspect that they had acquired HIV and who ordinarily perform or assist in surgical invasive procedures, where blood to tissue contact can occur, must seek expert advice on whether there is a need to limit or modify their working practice.

These recommendations were made when there was no known case of HCW-to-patient HIV transmission. In making these recommendations, EAGA acknowledged the theoretical risk of such transmission based on existing knowledge of HBV transmission. Assessment of the magnitude of the risk was based on reports of occupationally acquired HIV. This evidence pointed to a low risk of transmission but grave consequences if such a transmission were to occur.

Worldwide, there have been 3 reports of healthcare associated HIV transmission from HCWs during EPPs; a Florida dentist (7), where the exact route of transmission was never established, a French orthopaedic surgeon (8), and a gynaecologist in Spain (9). In the last 2 cases, transmission occurred during category 3 EPPs. A further transmission has been reported involving a French nurse who was co-infected with HCV (10); this did not involve an EPP and the exact route of transmission remains unclear. Genetic relatedness of virus in the HCW and

patient(s) was demonstrated in all 4 cases. These 4 cases of transmission involved HCWs who were not undergoing antiretroviral therapy at the time of transmission.

In 1991, following the Florida dentist incident (<u>11</u>), EAGA strengthened its advice stating that:

"HIV infected HCWs should not perform invasive surgical procedures in which injury to the worker could result in blood contaminating a patient's open tissues." (<u>12</u>)

EAGA updated its guidance in 1993 (<u>13</u>), recommending that HCWs living with HIV should not perform exposure prone procedures (EPPs) (as defined in <u>Chapter 2</u>). Updated versions of the guidance were subsequently published in 1998 (<u>14</u>) and 2005 (<u>15</u>).

The risk of HIV transmission from a HCW to their patient was later reviewed by a Tripartite Working Group of EAGA, AGH and UKAP using data available from PNEs undertaken between 1988 and 2008. No cases of HCW to patient HIV transmissions were identified despite over 10,000 patients being tested (<u>16</u>). The group concluded that the risk of HIV transmission from an untreated HCW living with HIV to a patient during EPPs was extremely low for the most invasive procedures (category 3) and negligible for less invasive procedures (category 1); this risk could be reduced even further by cART, if the HCW's viral load is suppressed to a very low or undetectable level. Following this report, updated guidance was published in January 2014 which allowed HCWs living with HIV to undertake EPP if they were either on effective cART and had a plasma viral load less than 200 copies/mL or were an elite controller and subject to viral load testing every 3 months (<u>17</u>).

### Hepatitis **B**

As at the end of 2018, there had been 9 episodes of documented transmission of HBV from surgeons to patients in the UK since 1991, when HBV vaccination became widespread. There has also been transmission of HBV from a doctor to 2 patients which did not involve EPPs. Worldwide, since 1970 there have been more than 40 clusters where over 400 patients contracted hepatitis B from a HCW (<u>18 to 22</u>).

The policy on the management of HCWs living with HBV has evolved over time in light of epidemiological findings, the development of better laboratory tests and improved treatment options. The first guidance, issued by the Department of Health in 1993 (23), followed a number of documented outbreaks of HBV in patients who were operated on by HBV e-antigen (HBeAg) positive HCWs. Based on recommendations from AGH, these HCWs were restricted from performing EPPs. This guidance was later amended in 1996 to allow an HBeAg positive HCW

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who was successfully treated and whose HBeAg negative status was sustained 12 months after cessation of therapy, to be able to resume EPPs ( $\underline{24}$ ).

Further cases of HBV transmission were, however, subsequently reported in HCWs living with HBV who were HBeAg negative. These HCWs were found to have high HBV DNA levels and in 2000, guidelines were issued which restricted HBeAg negative HCWs who had HBV DNA levels above 10<sup>3</sup> gEq/mL from performing EPPs or clinical duties in renal units. The practice of HCWs with levels below 10<sup>3</sup> gEq/mL, was not restricted subject to annual testing of their HBV DNA levels (<u>19</u>). The 10<sup>3</sup> gEq/mL HBV viral load cut-off point was chosen because:

- it allowed a margin of safety to accommodate natural fluctuations in HBV DNA levels
- the lowest documented HBV DNA level at which transmission was reported was 104 gEq/mL

Following advice from AGH, further guidance was issued in 2007, allowing HCWs living with HBV who were HBeAg negative and who had pre-treatment HBV DNA levels between  $10^3$  and  $10^5$  gEq/mL to perform EPPs while on oral antiviral therapy, provided their viral load was suppressed to below  $10^3$  gEq/mL and were subject to HBV DNA level testing every 3 months (25).

Successful implementation and the efficacy of the policies for managing HCWs living with HBV has resulted in no detected transmission of HBV from HCWs to patients since the policy change in 2000.

In 2015, the UKAP Secretariat initiated a review of the evidence base on newer, more effective treatments for hepatitis B (such as Tenofovir and Entecavir) which are now standard care. The expert UKAP working group agreed in 2017 that the evidence was of a satisfactory quality and indicated that currently available antiviral therapies (unavailable at the time of the implementation of extant 2007 guidance), were far more effective in suppressing virus and far more resilient to resistance than predecessor therapies (such as Lamivudine). Thus in 2019, restrictions on EPP-performing HCWs living with hepatitis B with a high pre-treatment viral load (greater than 10<sup>5</sup> gEq/ml) and or who are e-antigen positive were lifted, subject to Tenofovir (first line) and Entecavir being used and an adequate response and strict monitoring in place (similar to UKAP-OHR for HIV).

In 2020, UKAP clarified that HCWs living with BBVs performing renal dialysis duties in any clinical setting are subject to OH clearance and monitoring as required.

# Hepatitis C

The first reported incident in the UK, of HCV transmission from a HCW to a single patient was in 1994 (<u>26</u>). Following this, the AGH recommended in 1995 that HCWs living with HCV associated with transmission of HCV to patients should no longer perform EPPs (<u>27</u>). Following 5 further incidents in the UK in which HCWs living with HCV transmitted HCV to 15 patients, DH published guidance in 2002 (<u>28</u>) introducing additional restrictions based on the advice from AGH.

As at the end of 2015, there had been 11 incidents of HCWs living with HCV transmitting the virus to 28 patients in the UK. With the exception of 2, all HCWs were surgeons and all but 3 of these transmissions have been in the highest category 3 EPP. The 3 exceptions occurred in non-EPPs; one involving a repair of a paraumbilical hernia, one from a midwife to a mother in a post-natal ward and the third from an anaesthetist to a patient. The route of transmission in these cases has never been identified (29 to 31).

Six documented international cases involving surgeons have also been described in the literature, resulting in the acquisition of HCV in 23 patients (32, 33). In addition there have been 3 cases involving anaesthesiology HCWs who transmitted HCV to 9 patients, with 2 of these HCWs having initially acquired their infection from a patient (34 to 36).

Recent reviews have highlighted the issue of substance misuse by HCWs, resulting in the transmission of HCV to large numbers of patients. In these cases, the HCWs were addicted to injectable anaesthetic opioids and in some cases, it was established that the HCW would partly inject themselves with the opioid before injecting the patients, resulting in subsequent transmission of the virus (drug diversion) (<u>37</u>).

The guidance restricts HCWs who are known to be living with HCV (HCV RNA positive) from carrying out EPPs. HCWs living with HCV who have a sustained viral response to therapy, that is those who remain HCV RNA negative 3 months after the course of treatment has ended, are allowed to return to performing EPPs at that time and are subject to a further check 3 months later.

#### Health clearance for new HCWs

The 2002 guidance for managing HCWs living with HCV was also the first to recommend testing of HCWs who were about to start careers or training that would rely on the performance of EPPs. This principle of screening HCWs for BBVs was further developed and expanded to include HIV and HBV in the guidance on health clearance for HCWs new to the NHS published in 2007 (<u>38</u>). This guidance aimed to identify, and consequently restrict, all new HCWs living

with BBVs from working in clinical areas where their infection may pose a risk to patients in their care. The guidance did not apply to HCWs already employed in the NHS, with the exception of those moving to a post requiring the performance of EPPs for the first time in their career, who were considered to be under an ongoing obligation to seek professional advice about the need to be tested if they had been exposed to a serious communicable disease.

# **Appendix 5. Previous guidance documents**

The previous publications have provided important guidance for all HCWs and their employers. Their development across the years, however, has resulted in relevant information being contained across a number of documents.

In October 2017, consolidated guidance was published which brought together all existing guidance documents into a single comprehensive guidance that clarified the duties of HCWs, their medical advisers and employers, and described i) the BBV health clearance measures for new HCWs (this guidance does not cover the checks for tuberculosis disease or immunity), ii) the follow-up and management of HCWs living with HIV and or HBV who perform EPPs and iii) procedures that should be followed if a PNE is being considered.

The 2017 guidance combined and replaced the following:

# General

Department of Health. <u>Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare</u>. March 2007. (The bloodborne virus sections of this guidance only; the document should still be used for guidance on clearance for tuberculosis. The consolidated guidance does not include recommendations on health clearance for new HCWs for tuberculosis; <u>current guidance is, however, available</u>.)

# HIV

Public Health England. <u>The management of HIV infected healthcare workers who perform</u> <u>exposure prone procedures: updated guidance.</u> January 2014

# Hepatitis B

Department of Health. <u>'Hepatitis B infected healthcare workers and antiviral therapy'</u>. March 2007

Department of Health. <u>'Hepatitis B infected healthcare workers'. Health Service Circular, HSC</u> 2000/020. 23 June 2000 Health clearance of healthcare workers and the management of healthcare workers living with bloodborne viruses

Department of Health. <u>'Hepatitis B infected healthcare workers: guidance on implementation of Health Service Circular, HSC 2000/020</u>'. 2000

Department of Health. <u>'Protecting healthcare workers and patients from hepatitis B:</u> recommendations of the Advisory Group on Hepatitis'. August 1993

Department of Health. <u>'Protecting healthcare workers and patients from hepatitis B'. Health</u> service guidelines on heptatitis. HSG(93)40. 18 August 1993

Department of Health. Addendum to HSG(93)40: 'Protecting healthcare workers and patients from hepatitis B' EL (96) 77. 26 September 1996

Department of Health. <u>Addendum to HSG(93)40: 'Protecting health care workers and patients</u> <u>from hepatitis B'.</u> April 2004

# Hepatitis C

Department of Health. <u>'Hepatitis C infected healthcare workers'. Health Service Circular, HSC</u> 2002/010. 14 August 2002.

Department of Health. <u>'Hepatitis C infected healthcare workers'</u>. August 2002.

# References

1. National Institute for Health and Care Excellence (NICE). '<u>Hepatitis B (chronic): diagnosis</u> and management'. 2017 (accessed 27 October 2021)

2. European Association for the Study of the Liver (EASL). '<u>EASL 2017 Clinical practice</u> guidelines on the management of hepatitis B virus infection'. Journal of Hepatology 2017: volume 67, issue 2, pages 370 to 398

3. Ogunremi T and others. '<u>Preventing transmission of bloodborne viruses from infected</u> <u>healthcare workers to patients: summary of a new Canadian guideline</u>'. Canada Communicable Disease Report 2019: volume 45, issue 12

4. Centers for Disease Control and Prevention (CDC). '<u>Updated CDC recommendations for the</u> <u>management of hepatitis B virus–infected health-care providers and students</u>'. 2012 (accessed 27 October 2021)

5. The Society for Healthcare Epidemiology of America (SHEA). '<u>Management of healthcare</u> <u>personnel living with hepatitis B, hepatitis C, or HIV in UK healthcare institutions</u>'. Infection Control and Hospital Epidemiology 2020

6. General Medical Council. 'HIV infection and AIDS: the ethical considerations'. 1988

7. Ciesielski C and others. 'Transmission of human immunodeficiency virus in a dental practice'. Annals of Internal Medicine 1992: volume 116, pages 798 to 805

8. Lot F and others. 'Probable transmission of HIV from an orthopedic surgeon to a patient in France'. Annals of Internal Medicine 1999: volume 130, pages 1 to 6

9. Mallolas J and others. 'Transmission of HIV-1 from an obstetrician to a patient during a caesarean section'. AIDS 2006: volume 20, pages 285 to 299

10. Goujon C and others. 'Phylogenetic analyses indicate an atypical nurse-to-patient transmission of human immunodeficiency virus type 1'. Journal of Virology 2000: volume 74, pages 2,525 to 2,532

11. Centers for Disease Control and Prevention (CDC). '<u>Update: Investigations of patients who</u> have been treated by HIV-infected health-care workers'. 1992. (accessed 27 October 2021)

12. UK Health Departments. 'AIDS-HIV infected health care workers – occupational guidance for health care workers, their physicians and employers'. 1991

13. UK Health Departments. 'AIDS/HIV Infected health care workers: guidance on the management of infected health care workers'. 1993

14. UK Health Departments. 'AIDS/HIV infected health care workers: guidance on the management of infected health care workers and patient notification'. 1998

15. UK Health Departments. 'HIV infected health care workers: guidance on the management and patient notification'. 2005

16. The Expert Advisory Group on HIV and AIDS, the Advisory Group on Hepatitis and the UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses. 'The report of the Tripartite Working Group, Management of HIV-infected healthcare workers'. 2011

17. Public Health England. 'The management of HIV infected healthcare workers who perform exposure prone procedures: updated guidance'. 2014

18. Smellie MK and others. 'Hospital transmission of hepatitis B virus in the absence of exposure prone procedures'. Epidemiology and Infection 2006: volume 134, issue 2, pages 259 to 263

19. Department of Health. 'Health service circular 2000/ 020 Hepatitis B infected health care workers'. 2000

20. Department of Health. 'Health service circular 2000/ 020 Hepatitis B infected health care workers: guidance on the implementation of health service circular 2000/ 020'. 2000

21. Gunson RN and others. 'Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in health care workers (HCWs): guidelines for prevention of transmission of HBV and HCV from HCW to patients'. Journal of Clinical Virology 2003: volume 27, pages 213 to 230

22. Lewis JD and others. 'Hepatitis B in healthcare workers: transmission events and guidance for management'. World Journal of Hepatology 2015: volume 7, pages 488 to 497

23. UK Health Department. 'Health Service Guidelines HSG(93)40: Protecting health care workers and patients from hepatitis B'. 1993

24. UK Health Department. Addendum to HSG(93)40: 'Protecting health care workers and patients from hepatitis B'. 1996

25. UK Health Department. 'Hepatitis B infected health care workers and antiviral therapy'. 2007

26. Duckworth GJ and others. 'Transmission of hepatitis C virus from a surgeon to a patient'. Communicable Disease and Public Health 1999: volume 2, pages 188 to 192

27. Communicable Disease Surveillance Centre (CDSC). 'Hepatitis C virus transmission from health care worker to patient'. Communicable Disease Report CDR Weekly 1995: volume 5, page 121

28. Department of Health. 'Hepatitis C infected health care workers'. 2002

29. Public Health England. Personal communication. 2015

30. Muir D and others. 'Transmission of hepatitis C from a midwife to a patient through nonexposure prone procedures'. Journal of Medical Virology 2014: volume 86, issue 2, pages 235 to 240

31. Mawdsley J and others. 'Anesthetist to patient transmission of hepatitis C virus associated with non exposure-prone procedures'. Journal of Medical Virology 2005: volume 75, issue 3, pages 299 to 401

32. Hatia RI and others. 'Nosocomial hepatitis C virus transmission from tampering with injectable anesthetic opioids'. Hepatology 2015: volume 62, issue 1, pages 101 to 110

33. Cardell K and others. 'Nosocomial hepatitis C in a thoracic surgery unit; retrospective findings generating a prospective study'. Journal of Hospital Infection 2008: volume 68, issue 4, pages 322 to 328

34. Cody SH and others. 'Hepatitis C virus transmission from an anesthesiologist to a patient'. Archives of Internal Medicine 2002: volume 162, pages 345 to 350

35. Ross RS and others. 'Transmission of hepatitis C virus from a patient to an anesthesiology assistant to 5 patients'. New England Journal of Medicine 2000: volume 343, pages 1851 to 1854

36. Stark K and others. 'Nosocomial transmission of hepatitis C virus from an anesthesiologist to 3 patients – epidemiologic and molecular evidence'. Archives of Virology 2006: volume 151, issue 5, pages 1025 to 1030

37. Schaefer MK and Perz JF. 'Outbreaks of infections associated with drug diversion by US health care personnel'. Mayo Clinical Proceedings 2014: volume 89, issue 7, pages 878 to 887

38. Department of Health. 'Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: new healthcare workers'. 2007

# About the UK Health Security Agency

The <u>UK Health Security Agency</u> is an executive agency, sponsored by the <u>Department</u> <u>of Health and Social Care</u>.

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