Joint Trust Guideline for the Management of: Prevention and Control of Blood Borne Virus Infection in the Renal Dialysis / Transplantation Unit

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A clinical guideline recommended for use

For Use in:	The Nephrology Directorate, NNUH.
By:	All Medical and Nursing Staff who have contact with patients either potentially or currently undergoing haemodialysis treatment (this includes Medical and Nursing students). All healthcare professionals who have contact with the above patients should be aware of these guidelines.
For:	Patients either potentially or currently undergoing haemodialysis treatment and staff who care for these patients. Patients who are active on the Kidney or Kidney/Pancreas transplant list.
Division responsible for document:	Medical Division (Including Emergency)
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Name of document author:	Owen Brooks NNUH, Samir Dervisevic NNUH
Job title of document author:	Nephrology Matron, Consultant Virologist
Name of document author's Line Manager:	Calum Ross NNUH
Job title of author's Line Manager:	Consultant Nephrologist
Supported by:	Calum Ross - Consultant Nephrologist supporter from JPUH, Workplace Health and Wellbeing
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This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

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The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.

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Version and Document Control:

Version Number	Date of Update	Change Description	Author
4	09/08/2022	Additional staff responsibilities and section on initial health clearance for HIV positive added.	Owen Brooks

This is a Controlled Document

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Rationale for the recommendation

This guideline was written as a response to the document 'Good Practice Guidelines for Renal Dialysis/Transplantation Units: Prevention and Control of Blood Borne Virus Infection' (Department of Health, 2002) where several recommendations were made to change the way that the prevention and control of Blood Borne Virus (BBV) infection is managed on Renal Dialysis/Transplantation Units.

The recommendations are largely precautionary and build upon previous recommendations from the Rosenheim Report (Department of Health, 1972), which focused on the management of Hepatitis B Virus (HBV) infection in Renal Units.

However, the advent of new viruses, especially Hepatitis C Virus (HCV) and the Human Immunodeficiency Virus (HIV) have necessitated the issue of new guidance for all members of staff caring for this patient group.

Broad Recommendations

- All patients undergoing haemodialysis treatment must be immunised against HBV.
- All staff in clinical contact with haemodialysis patients, blood samples, used equipment (including sharps, clinical waste) must be immunised against HBV.
- All nurses and medical staff who undertake Exposure Prone Procedures (EPP) must have EPP clearance from Occupational Health. NB Dialysis procedures are not classed as EPP but Public Health England recommends that the possibility of transmission cannot be entirely ruled out because renal patients having haemodialysis have repeated bloodstream access. Therefore the guidance recommended to test all those with 'clinical contact with this patient group (i.e. are concerned directly with the haemodialysis process)' for HBsAg (2017).
- All carers of home haemodialysis patients should be offered immunisation against HBV.
- Patients undergoing haemodialysis must be tested 3 monthly for HBV and HCV. All patients must be tested for HIV at the beginning of their treatment. Those who decline testing must be deemed high risk.
- HIV testing after the initial result is only necessary if:
  - Patient is deemed to have undertaken a high risk activity.
  - Patient is going to or returning from a holiday in another unit.
  - Patient is active on the cadaveric transplant waiting list.
- Haemodialysis patients who are leaving the unit for a holiday must be tested prior to leaving and retested on their return to the main unit for HBV, HCV and HIV infection.
- All temporary holiday dialysis patients visiting this unit must have had a negative serology report four weeks prior to transfer for all three BBVs before they are accepted for treatment.
- Immunise patients if:

- CRF with creatinine > 300 µmol/L.
- ESRF on HD or PD.
- Seroconversion is more likely/successful at an earlier stage in progressive renal disease (40% success after three doses and 60% after four doses in ESRF).

- Do not immunise patients if:
  - HBsAg + ve.
  - If patient demonstrates satisfactory immunity against HBV infection (e.g. Anti-HBs level is >100mIU/mL), or is naturally immune (e.g. Anti-HBc positive and HBsAg negative).
  - Known sensitivity or patient refusal.

- Please refer to Renal Association – Blood Borne Virus infection Guidelines BBV 5.1-5.8 (2011).

Procedure for control and prevention of BBV infection

Blood Testing

1. For staff immunization and testing, refer to Trust Guideline 'Hepatitis B protection for HCW from occupational exposure to Hepatitis B Virus Trust Docs ID:1226.
2. Carers, who have direct contact with haemodialysis patients throughout their treatment (i.e. those caring for patients on home haemodialysis), should be offered testing for HBV with a view to vaccination. Those who are negative should be offered a course of immunisation. Poor and true non-responders should be allowed to continue to care for their friend or relative during dialysis, but should be advised to continue having three-yearly boosters at their GP surgery. Those who are HBV positive should be advised of the risk of transmission and the precautions necessary to prevent this.
3. All virology testing must be done with informed consent following discussion with the patient.
4. Pre-dialysis patients must be tested for HIV infection within six months of the potential start date for their treatment. Proper procedure must be followed with regard to counselling pre-testing and the patient's consent to HIV testing must be documented in the patient's notes and annotated on the laboratory request form. The HIV testing information sheet (Appendix A) must be given before all first HIV tests. These patients must also be tested for HBsAg, Anti-HBc and HCV antibody.
5. When pre-dialysis patients begin their dialysis treatment, they should be retested for HBsAg, HCV and HIV, unless their previous testing was within six weeks.
6. Patients who are HCV antibody negative, but have either undergone transplantation, are immunosuppressed, or are transferring from a unit where there is known HCV transmission, will be tested for HCV RNA. They should be dialysed in isolation until these results are available.

7. Patients returning from holiday dialysis outside of the UK will be retested for HBsAg, HIV, HCV antibody and HCV RNA, and dialysed in isolation until these test results are available. This will include home dialysis patients.
8. Risk assessments will be undertaken on all patients who have travelled abroad, and they should be dialysed as per high risk patients. Enhanced surveillance for HBsAg and HCV RNA at monthly interval for three months should be conducted.
9. All hospital haemodialysis patients will be tested for HBsAg monthly, and HCV antibodies every three months. Repeat HIV testing will be done on a risk assessment basis (except for the circumstances outlined previously with regards to holidays and those patients on the transplant waiting list).
10. All patients undergoing haemodialysis in their own homes will have HBsAg and HCV monitoring annually.

Hep B/C Testing in Unconscious Patients

11. In exceptional circumstances, where an acutely unwell patient is admitted to hospital requiring emergency dialysis and is unable to give consent for virology testing, testing for hepatitis B and hepatitis C may be carried out if it is to be deemed in the patients "best interests", as long as it has not been refused in advance in a valid and applicable advance directive.

    For further details on advance directives, refer to the Trust's 'Shared Decision Making Policy (formerly Consent Policy)' Trust Docs ID: 980, and the national 'Reference guide to consent for examination or treatment' (Department of Health, 2009).

    Testing should be clearly documented in the patient's medical notes by medical staff, and the patient must be informed of this testing as soon as their conscious state permits. No other person has the right to give consent; therefore this should not be sought from family members. In addition, if consent cannot be obtained from the patient due to mental incapacity (temporary or permanent), the laboratory will only agree to testing if it is on the authority of a "named officer" - in this case the Consultant in charge. This officer must be clearly documented on the request form, and in the patient's medical notes.

HIV Testing in Unconscious Patients

12. It is extremely rare that a situation will occur where it is valid to take blood for HIV without consent from the patient. In this situation, the patient should be treated as if they are HIV positive until they are able to give an informed consent and a negative result has been received. If this situation is likely, advice must be sort from the Trust's legal team.

Routine Precautions

1. On initiation to dialysis the three monthly risk assessment of patients and infection

control procedures (adhering to Trust guidelines) must be adhered to reduce the incidence of cross infection.

2. All members of staff must adopt universal precautions (Appendix B) in all patient care situations.
3. Staffing must be adequate (1:4 nurse ratio is recommended) to ensure infection control procedures are not compromised.

In addition to the above, local action to be taken in the event of an outbreak (suspected transmission of a virus between patients) of BBV.

1. Inform the local Infection Control Team immediately on ext 5847 or bleep 0600.
2. Report as Serious Untoward Incident (SUI). Refer to the Trust's 'Incident Management and Investigation Policy and Procedure' Trust Docs ID:15736.
3. Dialyse infected patients in isolation.
4. Enhanced virology surveillance (as per Appendix C).
5. All patients who have shared a dialysis machine or dialysis session with a newly infected patient should be tested for HBsAg. Those patients who have not demonstrated an Anti-HBs titre of greater than 100 mIU/mL in the preceding 12 months, should be retested weekly for three months, and be given a booster dose of vaccine. Hepatitis B Immunoglobulin (HBIg) should be considered for those true non-responders (i.e. HBsAg and Anti-HB core negative) with titres of Anti-HBs less than 10 mIU/mL.
6. Where HCV or HIV transmission is suspected or confirmed, the local duty Consultant in Virology should be informed. Investigations in such case should involve testing by polymerase chain reaction (PCR) analysis on blood samples collected from all patients who have shared a machine/session with the infected patient. This test should be repeated at two weekly intervals for three months.
7. Further prophylactic immunisation against HBV should be given where appropriate.
8. An outbreak control team should be set up (co-ordinated by Consultant Virologist).

Management of BBV Infected Patients

1. It is essential that patients infected with **HBV** should be dialysed in isolation. Those infected with **HCV** should be dialysed in isolation where possible. The need for isolation for those infected with HIV should be based on local risk assessment. National guideline states: "HCV or HIV do not need to be dialysed in a segregated area, providing infection control and universal precautions can be properly adhered to."
2. Patients with different BBV infections should not be dialysed in a single segregated area at the same time.
3. In order to achieve segregation of BBV infected patients, full consideration should be given to the use of all available side rooms, and where necessary changing

patients dialysis schedules.

4. Where possible staff should work with either infected or non-infected patients during a shift. If this is not possible, risk assessment should be used to assign nurses with appropriate experience to relevant areas.
5. Separate machines should be used for patients infected with HBV, HCV and HIV. (An alert card needs to be placed in the patient's dialysis treatment folder denoting the isolated machine number).

Equipment

1. All equipment used for dialysis is for single use only. The transducer of the venous line should be replaced if contaminated with blood. If the transducer ruptures, a renal technician, according to manufacturer's instructions should carry out appropriate decontamination of internal machine parts. If this is not possible, the machine should be taken out of use whilst the manufacturer's advice is sought.
2. The dialysis fluid pathway should be decontaminated by an approved manufacturer's method between each patient. Surfaces of machines should be cleaned also between patients with Actichlor. Following use by infected patients, surfaces should be cleaned with Actichlor as per Trust policy. Trust Docs ID 9695.
3. All contaminated waste should be disposed of as clinical waste (i.e. in a yellow bag/sharps container) by incineration.

Staff

1. All staff should follow universal precautions (see Appendix B).
2. Sharps injuries must be reported to the Workplace Health and Wellbeing on ext 3035 as soon as they occur. Out of hours, a risk assessment form should be completed. For further information, refer to the Trust guideline for 'Management of Incidents Which Have the Potential to Transmit Blood Borne Viruses' Trust Docs ID: 1260.
3. Staff members who have eczema (or similar skin conditions) should seek advice from Occupational Health whilst they have active lesions or breaks in the skins surface (especially on their hands and arms).
4. Staff must demonstrate that they are immune to HBV. If a blood sample collected from a HCW contains HBsAg, the HCW will be tested for anti-HBc, anti-HBc IgM, and e-markers (HBeAg and anti-HBe) to ascertain risk of infectivity.
5. If they are e-antigen (HBeAg) positive, they should not be allowed to perform clinical duties in a renal department.
6. 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.

(Please refer to the latest guideline by UK Health Security Agency: "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) November 2021

7. If at any point the levels increase above 200IU/mL then the worker should be withdrawn from haemodialysis duties. Any period of interruption requires at least two IVS hepatitis B DNA viral load results of less than 200IU/mL no less than 4 weeks apart.
8. If staff discontinue treatment for hepatitis B infection, they must immediately cease to perform haemodialysis duties.
9. Individuals whose treatment concludes will be considered on a case by case basis by the Consultant in Occupational Medicine and advised accordingly on ability to undertake haemodialysis duties.
10. If staff fail to attend their appointments for blood tests whilst on antiviral treatment they are to be immediately excluded from haemodialysis duties.

It is the responsibility of the member of staff to inform the Workplace Health and Wellbeing Department if they know they have been exposed to or are infected with HIV or HCV.

11. All staff will be trained in safe working practices with regard to infection control. This will be done on induction to employment and on an annual basis. Appropriate documentation must be completed and filed in the staff member's personnel file.

Quality Measures

Staff on the unit will undertake continuous quality monitoring to ensure that the above guidelines are being adhered to and these will be fed back to the Clinical Governance meeting annually.

Workplace Health and Wellbeing are robust in their assessment and monitoring of the efficacy of the staff vaccination programme.

References

Department of Health (1972), '*Report of Rosenheim Advisory Group Hepatitis and the Treatment of Chronic Renal Failure'*. London: Department of Health and Social Security.

Department of Health (2002), '*Good Practice Guidelines for Renal Dialysis/Transplantation Units. Prevention and Control of Blood Borne Virus Infection'*. London: Department of Health.

Renal Association Clinical Guidelines on the management of blood borne viruses within the renal unit, 2008.

Department of Health (2018), '*Addendum: Guidelines for dialysis away from base (DAFB)'*. London: Department of Health.

Norfolk and Norwich University Hospital NHS Trust (2017). *'Shared Decision Making Policy (formerly Consent Policy)*'.

Department of Health (2009), *'Reference guide to consent for examination or treatment (*2nd ed.)

Norfolk and Norwich University Hospital NHS Trust (2018)- Guideline for Cleaning and Disinfection (ID 9695)

Integrated guidance for the health clearance of HCWs and the management of HCWs infected with BBVs: October 2017
Ref: PHE publications gateway number: 2017365

Integrated guidance on health clearance for healthcare workers and the management of healthcare workers infected with bloodborne viruses (hepatitis B, hepatitis C and HIV)", Quick reference guide PHE publications gateway number: 2017365

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.

Appendix A

HIV TEST

INFORMATION and ADVICE FOR PATIENTS

Guidelines from the Department of Health now instruct us that all patients on dialysis must be offered testing for HIV, either prior to or on starting dialysis treatment. In addition, we are required to HIV test all patients who are transferring to another unit, who are going away on holiday, who wish to be considered for transplantation and in some additional circumstances (see below).

What is HIV?

This is a virus that some people can have for many years without any symptoms. It is the virus that can eventually lead to AIDS (Acquired Immune Deficiency Syndrome). The virus can damage the body's immune system, which is the system which helps fight off infection. HIV could make it difficult for people to fight off infections that would not normally harm someone who did not have HIV.

How is HIV transmitted?

It can be passed on through infected body fluids, such as blood, semen and vaginal secretions. This can happen during sex; sharing unclean needles if injecting drugs; having tattoos or body piercing; through blood transfusions (especially unscreened blood abroad - all UK blood has been screened since 1985); infected women can pass the virus onto their babies during pregnancy, at birth or through breast milk.

How long does it take for the virus to show up in the blood?

HIV can be detected in the blood weeks after the risk exposure. However, It can take up to three months to detect antibody against HIV after infection.

What does the test involve?

A blood sample will be taken from your arm (if not on haemodialysis), or through your dialysis line.

Why have the test?

Because you are receiving treatment in an area where you may be exposed to blood, it is important that we are aware of all patients HIV status in order that we can minimise the risk for everybody. If you have not exposed yourself to known high-risk activity, having a negative test will give you peace of mind, and you will know that you cannot infect anyone else. If the test is positive, treatment can be given at an early stage before any serious symptoms appear. It is well accepted that, as treatment for HIV is so good, you are more

likely to die of an age related cause than you are from HIV. We can also further minimise the infection risk to other patients if we know that someone is HIV positive.

If however, you are concerned that you have been exposed to a risk, either from having unprotected sex with someone, using IV drugs or having had an unscreened blood transfusion, and would like further information, please either talk to your named nurse or alternatively you can contact your own GP or the local Integrated Contraception and Sexual Health (iCaSH) service on 0300 300 3030.

Patients wishing to be considered for transplantation must also agree to an HIV test before they can be added to the transplant list. The drugs that you take after a transplant are very powerful and could make you very ill if you were HIV positive. Also live donors wishing to donate to a family member or friend must also be tested to avoid accidental transmission.

Any patient has a right to refuse a blood test that is offered. However, without a result that is either positive or negative, we are instructed by the Department of Health that these patients must be "presumed positive" until a negative test result is obtained. This will not prejudice the treatment you receive on the Renal Unit at the Norfolk and Norwich University Hospital, though it may mean that you are dialysed in isolation.

Does having a test done affect my insurance?

If your test is negative it will not affect your insurance, current or future. People who are HIV positive may find it difficult to get life insurance, as with any other potential life-limiting illness. The results of any testing will not be passed on without your permission.

How and when will you get the result?

The multidisciplinary team will provide you with the test results.

If you have any further questions, please do not hesitate to ask any of the doctors or nurses involved in your care, or the Integrated Contraception and Sexual Health (iCaSH) service on 0300 300 3030.

Appendix B

Infection control checklist

Standard precautions underpin safe protection and should be used at all times with every patient. Use the following checklist to guide you.

Have you washed your hands?

Hand washing is the single most important step in reducing the spread of disease. Use the six-step technique before direct contact with patients and after any activity that contaminates the hands. Dry thoroughly afterwards, using disposable towels.

Do you need to use personal protective equipment?

Carry out a risk assessment if potential contamination by blood or body fluid is likely. Use disposable gloves, aprons, masks, goggles or visors to protect yourself and your patient from these risks of cross-infection, and when handling hazardous chemicals and some pharmaceuticals.

Are you preventing sharps injuries?

Keep handling to a minimum and never re-sheath. Dispose of sharps carefully in a special container at the point of use.

Are you disposing of waste safely?

Ensure that you have been instructed in how to dispose of waste safely, including the colour coding of bags used for different types of waste.

Do you deal promptly with spillages?

Spillages must be dealt with quickly, using appropriate chemical disinfectants as necessary. Ensure you have a thorough knowledge of chemical disinfectants.

Do you scrupulously decontaminate equipment?

Meticulously clean, disinfect and sterilise re-usable equipment, as appropriate, to ensure it is safe for future use.

Are you maintaining a clean environment?

Ensure your workplace has a regularly planned, written and monitored cleaning schedule, which details both the items and environments to be cleaned and how often this should happen.

Do you know what to do in the event of an accident?

Attend the injury, washing it well in cold running water. If bodily fluids have splashed into eyes, irrigate with cold water. If they have splashed into a mouth, do not swallow and rinse out several times with cold water. Report the incident and seek expert advice.

And finally, do you know your workplace's procedures?

Ensure that you understand and follow your workplace's written policies and procedures on all aspects of infection control.

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Appendix C

ACTION FOLLOWING TRANSMISSION OF A BLOOD-BORNE VIRUS

If transmission of HBV, HCV or HIV is suspected within the unit, measures must be taken to prevent further spread. An incident reporting form must be filled out immediately reporting the virus transmission as a Serious Untoward Incident (SUI).
Refer to the Trust's 'Incident Management and Investigation Policy and Procedure' Trust Docs ID:15736.

1. Infected patient(s)

- Should be dialysed in a segregated area with designated staff.
- If the transmitted virus is HBV, the patient should be dialysed with a dedicated machine while he/she is infectious.
- Patients infected with HBV or HCV should be referred to an hepatologist. Patients infected with HIV should be referred to the GU physicians.
- Patients should have no contact with any non-essential staff, carers and visitors

2. Other patients

- Elective transfers out of the unit should be stopped. If transfer is essential, the receiving unit must be informed about the outbreak.
- Patients should have no contact with any non-essential staff, carers and visitors
- If any patients were transferred in the incubation period, the receiving unit will be informed.
- Patients who have shared a dialysis machine or a dialysis session with the infected patient since the infected patient(s) last routine test for the virus concerned will be informed and will be screened as part of increased surveillance as follows:

HBV

- HBsAg (marker of active hepatitis B infection).
- Patients who have not had an Anti-HBs level equal to or greater than 100mIU/mL in the previous 12 months, should be tested weekly for HBsAg for three months after their last exposure to the index case.
- Patients who have previously responded to HBV vaccine should be given a booster.
- HBIg should be offered to for non-responders i.e. those whose Anti-HBs <10mIU/mL.

- HBIg and an accelerated course of vaccine will be offered to those who have not been immunised.
- Any patient who becomes infected with HBV will be referred to a Hepatologist.

HCV

- HCV RNA by PCR at two-weekly intervals for three months after last exposure to the index case.
- Consider monitoring ALT.
- Any patient who becomes infected with HCV should be referred to a hepatologist.

HIV

- Undertake a risk analysis.
- Consider HIV RNA by PCR at two-weekly intervals for three months after last exposure to index case.
- Any patient who becomes infected with HIV, advice will be taken from virology. Patients will be referred to iCASH and their GP informed.

3. Staff and other carers

- Staff and carers who have had contact with the infected patient will be offered screening for HBsAg, HCV or HIV as appropriate according to Trust policies.
- HBV vaccine will be offered where appropriate.

4. Management of the incident

The Service Director of the unit should be alerted as soon as possible following the incident. The following should be informed of the incident:

- Renal Unit Staff (Nursing and Medical).
- Director of Infection Control and Infection Control Team (ext 5847 or 4588).
- Consultant Virologists if not already involved (ext 4531).
- Risk Manager (ext 6623).
- Chief Executive (ext 3420).
- CCDC (Tel. working hours 01603 307317, out of hours 01493 452452 and ask to speak to the duty public health doctor).
- Regional Epidemiologist (01223 762037).
- HPA Communicable Disease Surveillance Centre (Tel: 020 8200 6868).

An outbreak control team should be established to investigate and manage the incident and to review arrangements to prevent transmission of BBV infection.