Blood-Borne Viruses in the Haemodialysis, CAPD and Renal Transplantation Setting

2013

Foreword

In 2005 the Department of Health and Children (DOHC) published *The Prevention of Transmission of Blood-Borne Diseases in the Healthcare Setting* in which chapter 5 contained guidance specific to; haemodialysis (HD) continuous ambulatory/cycling peritoneal dialysis (CAPD/CCPD) and transplantation units. In 2008 the National Standing Advisory Committee for Blood-Borne Diseases, following submissions from interested parties, convened a sub-group to review the recommendations advised for HD, CAPD/CCPD and transplant units. See Appendix 1 for subgroup membership. The revised guidelines were published on-line in 2010 (http://www.hpsc.ie/hpsc/A-Z/Hepatitis/BloodborneVirus/).

The guidelines were further revised to:

- **Clarify guidance regarding the dialysis of patients who are HCV RNA positive.**
- **Include guidance regarding dialysis of patients who are currently undergoing anti-viral treatment or those individuals who have had a sustained virological response (SVR) to anti-viral treatment (defined as HCV RNA not detected 24 weeks following cessation of treatment).**
- **Reduce the number of HCV PCR investigations required from two to one for patients prior to dialysis in the multi-bedded unit.**

Key amendments in 2013:

1. It is not recommended that patients be further cohorted based upon a HCV viral load threshold. However, emphasis should be placed upon the importance of procedures to prevent cross infection, especially if any patient has a very high HCV viral load.
2. Patients who attain a SVR to anti-viral treatment should be regarded as having resolved HCV infection and in accordance with the "Blood borne viruses in haemodialysis, CAPD and renal transplantation 2010" they can be dialysed in the multi-bedded unit but tested monthly for HCV antigen.
3. Patients who are HCV RNA negative (HCV RNA not detected) at the end of treatment (ETR) can be either:
    - Dialysed in isolation, if facilities available, until an SVR is confirmed.

      Or

    - Dialysed in the multi-bedded unit but tested for HCV Ag **EVERY TWO WEEKS** until SVR.

    If HCV Ag or HCV RNA (>50 IU/ml) is detected any time within the 24 weeks following end of treatment, the patient should be cohorted with the HCV RNA positive patients, as above. The results should be discussed with the patient's hepatologist.

In these cases HCV genotyping should be performed to out-rule re-infection with another HCV genotype. This situation does not automatically require a "look back" of patients in the multi-bedded unit. This should be discussed with the Consultant Nephrologist and relevant microbiologists, virologists and public health physicians.

1.0 Introduction

End stage kidney disease (ESKD) requires a variety of treatment options including HD, CAPD and transplantation, procedures where infection control is of paramount importance. Chronic HD patients are at high risk of infection because the process of HD requires repeated vascular access for prolonged periods. Such patients are susceptible to person-to-person transmission of infectious agents, directly or indirectly, via contaminated devices, equipment and supplies, environmental surfaces or the hands of personnel.

For many years, viral hepatitis was recognised as a hazard for HD patients and staff.[1] In 1972, guidelines were issued in the UK for the prevention and control of hepatitis B virus (HBV) in renal and transplant units.[2] In the US, recommendations for the control of HBV in HD centres were first published in 1977.[3] By 1980, their widespread implementation was associated with a sharp reduction in incidence of HBV infection among both patients and staff members. In 1982, hepatitis B vaccination was recommended for all susceptible patients and staff members.[3] Hepatitis C virus (HCV) and human immunodeficiency virus (HIV) were later identified.

1.1 Hepatitis B Vaccination

Recombinant vaccines are available against HBV. Compared with adults with a normal immune status, the proportion of HD patients who develop a protective antibody response after vaccination (with higher doses) is lower.[3] For those who receive the three-dose schedule, the median is 64 per cent (range: 34-88 per cent), and for those who receive the four-dose schedule, the median is 86 per cent (range: 40-98 per cent). Some studies have demonstrated that higher antibody response rates could be achieved by vaccinating patients with chronic kidney disease (CKD) before they become HD dependent.[3] HD patients who mount a good response to vaccine appear unable to maintain high antibody levels[2]. Hepatitis B immunoglobulin (HBIG) may provide passive protection post-exposure. For further discussion about vaccine efficacy, serological response rates, antibody persistence, response to revaccination and different protocols, please refer to the current US and UK renal HD guidelines.[3, 4] Further information can also be sourced in the Immunisation Guidelines for Ireland 2008.[5]

1.2 Transmission of Blood-Borne Viruses (BBV) in HD Units

Outbreaks of both HBV and HCV infections continue to occur among chronic HD patients, mainly outside Ireland.[3,4] Investigations in other countries have indicated significant deficiencies in infection control practices along with failure to vaccinate HD patients against HBV. Factors that have been demonstrated to contribute to HBV outbreaks include: use of

multi-dose vials of drugs, failure to nurse HBV infected patients as a cohort and lapses in infection control practices. Two factors are consistently reported to be associated with increased prevalence of HCV infection in HD patients: the number of blood transfusions received and the length of time on HD. Studies show that HCV can be transmitted to HD patients by nosocomial transmission in HD units. There is evidence that dialysing HCV infected patients in a separate room or area in a HD unit reduces the risk of transmission to other patients.[4] There have been only a few reports of transmission of HIV in HD units, with many studies failing to show transmission of the virus.[3,4]

1.3 Prevention of Transmission

Currently, there is a low prevalence of BBV infections in renal units in Ireland. However, rigorous adherence to the protocols and recommendations proposed in this guideline is imperative to prevent transmission of these viruses. Implementation of Standard Precautions which are a group of infection control practices designed both for the protection of staff and patients are the cornerstone of infection prevention and control. Patients with CKDCKD or acute renal failure should be considered as potentially infectious until they have been fully tested. Regular testing of patients must be part of their subsequent management within the renal unit. Staff must be continually educated and brought up to date on BBV developments.

2.0 Haemodialysis

Prior to commencing HD, the patient should be asked about a past history of BBV infection. GPs and other physicians should inform the consultant nephrologists if they know of a past history of BBV infection in the patient.

All patients should be screened for evidence of HBV (Section 2.1), HCV (Section 2.2) and HIV (Section 2.3) infection. Informed consent to BBV testing must be obtained and those who withhold consent should be managed as though they were BBV infected. Infected patients should not be denied HD; however, every effort should be made to conform to the screening and management protocols that are outlined in this guideline.

Patients should be dialysed in an isolation room on a dedicated HD machine until negative results are obtained. HD units should ensure that arrangements are in place to obtain results rapidly from an accredited testing laboratory.

2.1 Hepatitis B

2.1.1 Pre-HD

Pre-HD testing for HBV should include hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), and hepatitis B surface antibody (anti-HBs) (Figure 1).

2.1.2 Regular testing while on HD

Weak positive HBsAg can occur immediately after HBV vaccination. Therefore HD patients should not be screened for HBsAg for at least 7 days after HBV vaccination.

1. HBV susceptible patients (i.e. unvaccinated or non-responders to vaccine) should have HBsAg tested monthly (Table 1).

2. Patients who have shown an initial good response to vaccination (anti-HBs ≥ 100 mIU/ml) should be tested for anti-HBs annually and for HBsAg three monthly. Refer to Section 6 to further information on HBV vaccination.

3. Patients who have shown an initial low level response to vaccination (anti-HBs 10-99 mIU/ml) should be tested for anti-HBs annually and for HBsAg three monthly. Refer to Section 6 to further information on HBV vaccination.

4. Patients who are anti-HBc positive and HBsAg negative should have monthly HBsAg testing.

   If these patients are immunosuppressed* or likely due to treatment to become immunosuppressed:

   - Test HBsAg weekly during period of immunosuppression, and for two months after completion of immunosuppressive treatment. Thereafter revert to monthly HBsAg.
   - Consider referral to Hepatologist/Gastroenterologist/Infectious Disease physician for advice regarding need for HBV anti-viral chemoprophylaxis and subsequent monitoring of HBV DNA.

2.1.3 Interpretation of the HBV results and management of the patient

- **HBsAg negative/anti-HBc negative:**

  No evidence of current or past HBV infection: HD in a multi-bedded unit provided no evidence of HCV (Section 2.2) or HIV (Section 2.3) infection. Proceed with HBV vaccination, if not already carried out (Section 6.0).

- **HBsAg positive/anti-HBc positive:**

  Evidence of acute or chronic HBV infection and the patient is infectious. The patient should be referred to a hepatologist or infectious diseases physician for on-going assessment and management. HD must be undertaken in an isolation room on a dedicated machine with dedicated HBV immune staff. See Figure 1 and Section 7.3 for management of an HBsAg positive patient.

* Immunosuppressed patient (e.g. HIV with CD4 count < 200/mm^3, TNF-α antagonist , high-dose systemic steroids, immunosuppressive chemotherapy, haematopoietic stem cell transplant recipients, other immunosuppressants such as azathioprine, cyclosporine, methotrexate, cyclophosphamide, leflunomide either alone or in combination with low doses of steroids, patients who received a solid organ transplant and are on immunosuppressive treatment currently, genetic conditions causing primary immunodeficiency, and as defined by attending consultant).

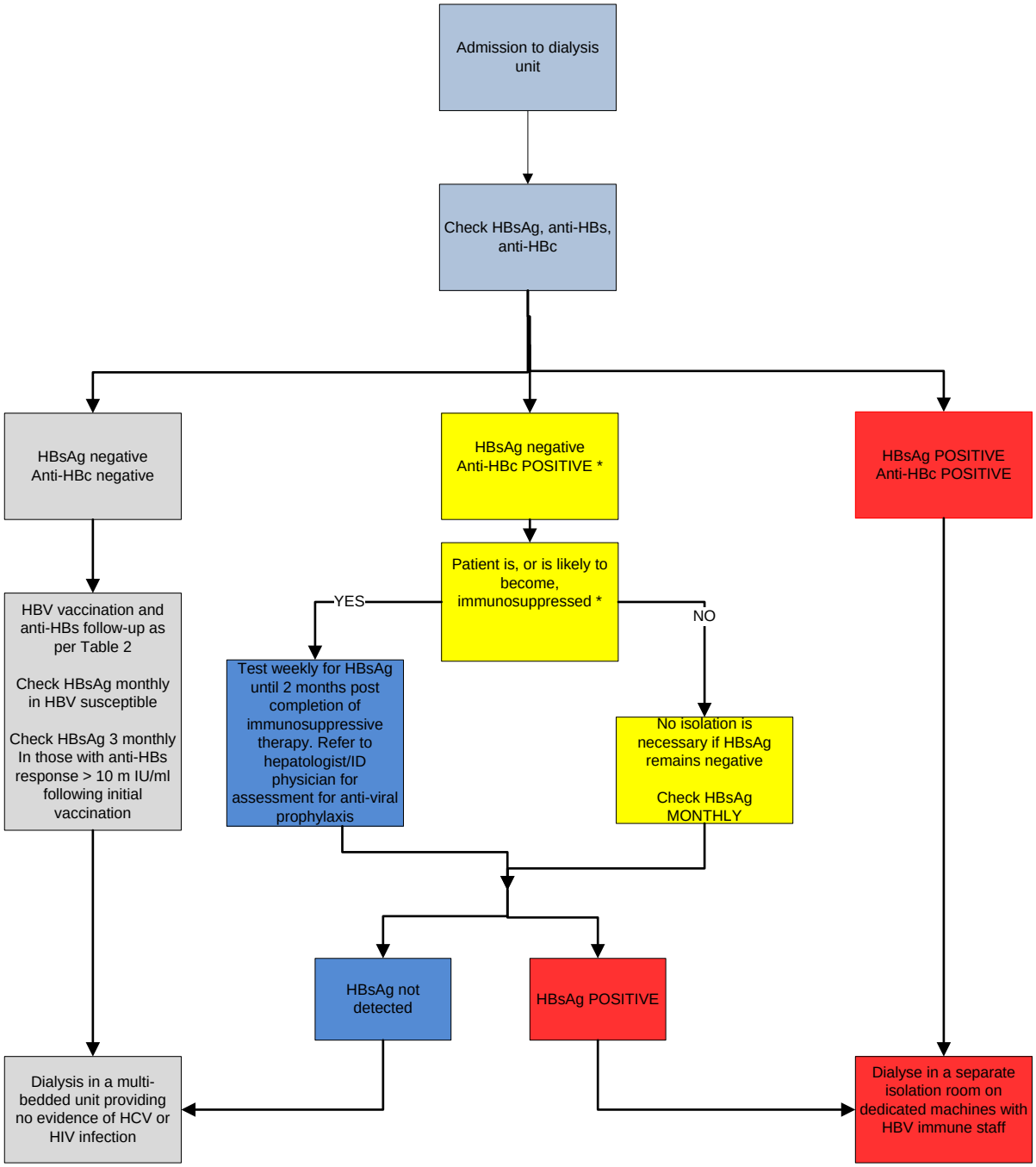
- **HBsAg negative/anti-HBc positive, in a patient who is not immunosuppressed*:**

  Evidence of past infection: No isolation is necessary if HBsAg remains negative. Carry out monthly HBsAg testing. However, please note intravenous immunoglobulin (IVIG) may contain anti-HBc; therefore an anti-HBc positive result should be reviewed in conjunction with the date of IVIG administration.

- **HBsAg negative/anti-HBc positive in an immunosuppressed* patient:**

  Evidence of past HBV infection but there is a risk of viral reactivation (i.e. reappearance of HBsAg): HD in a multi-bedded unit provided HBsAg remains negative. Test HBsAg weekly during period of immunosuppression, and for two months after completion of immunosuppressive treatment. Thereafter revert to monthly HBsAg. Consider referral to hepatologist/gastroenterologist/Infectious Disease physician for advice regarding need for HBV anti-viral chemoprophylaxis and subsequent monitoring of HBV DNA. If HBsAg is detected, the patient should be managed as infectious.

Figure 1: Schedule for testing for hepatitis B virus (HBV) infection



*Immunosuppressed patient (e.g. HIV with CD4 count < 200/mm^3, TNF-α antagonist , high-dose systemic steroids, immunosuppressive chemotherapy, haematopoietic stem cell transplant recipients, other immunosuppressants such as azathioprine, cyclosporine, methotrexate, cyclophosphamide, leflunomide either alone or in combination with low doses of steroids, patients who received a solid organ transplant and are on immunosuppressive treatment currently, genetic conditions causing primary immunodeficiency, and as defined by attending consultant).

2.2 Hepatitis C

2.2.1 Pre-HD

Testing for HCV should include antibody to hepatitis C (anti-HCV), hepatitis C antigen (HCV Ag) (Abbott Architect PCR for HCV RNA (HCV RNA), and alanine aminotransferase (ALT) (Table 1).

2.2.2 Regular testing while on HD

1. **Patients who are anti-HCV negative, HCV Ag (Abbott Architect) negative, and pre-HD HCV RNA negative:**

    - 3 monthly HCV Ag (Abbott Architect) and anti-HCV testing.
    - Monthly ALT.
    - Providing that investigation for HCV Ag (Abbott Architect) is undertaken 3 monthly for all patients, including immunosuppressed, and HCV RNA was not detected pre-HD,it is not necessary to have an annual HCV RNA.

2.2.3 Interpretation of HCV results and management of patients

Anti-HCV negative, HCV Ag (Abbott Architect) negative and HCV RNA negative patients: No evidence of HCV infection.

- **Patients who are not classified as immunosuppressed*:** May have HD in a multi-bedded unit when anti-HCV and HCV Ag (Abbott Architect) negative results are available provided there is no evidence of HBV (section 2.1) or HIV (section 2.3) infection (i.e. it is not necessary to wait for a HCV RNA negative result before HD in a multi-bedded unit).
- **Patients who are immunosuppressed*** (including those on immunosuppressive therapy for a renal transplant) may only have HD in the multi-bedded unit when anti-HCV, HCV Ag (Abbott Architect) and a negative HCV RNA result are available provided there is no evidence of HBV (section 2.1) or HIV (section 2.3) infection. Thereafter they should be followed up as described in Table 1.

Anti-HCV positive, HCV Ag (Abbott Architect) negative, ALT within normal limits and HCV RNA negative (including patients who have an SVR following treatment) (Figure 2)

This profile is consistent with resolved HCV infection. This patient may be dialysed in a multi-bedded unit. However, ongoing monitoring is essential. **Monthly HCV Ag** (Abbott Architect) and ALT should be undertaken.

*

Anti-HCV positive and HCV Ag (Abbott Architect) and or HCV RNA positive (Figure 2)

There is serological or molecular evidence of HCV infection and the patient is considered infectious: Patients should be segregated/cohorted or located in an isolation room for HD but a separate machine is not required(Section 7.3). HCV positive patients should be referred to a hepatologist or an infectious diseases physician for assessment and management.

It is not recommended that patients be further cohorted based upon a HCV viral load threshold. However, emphasis should be placed upon the importance of procedures to prevent cross infection, especially if any patient has a very high HCV viral load.

HCV infected individuals who are receiving anti-viral treatment

An increasing number of HCV infected patients are receiving anti-viral therapy to eradicate HCV infection. The aim is for the patient to be persistently HCV RNA negative after cessation of treatment. There are a number of stages regarding the anti-viral responses and these are listed below;

End of Treatment Response (ETR): Undetectable HCV RNA (<50 IU/ml) at the cessation of anti-viral treatment.

Sustained Virological Response (SVR): Undetectable HCV RNA (<50 IU/ml), 24 weeks after end of anti-viral treatment.

Relapse after treatment: Re-appearance of HCV RNA (> 50 IU/ml) between cessation of anti-viral treatment and before 24 weeks has elapsed.

Re-infection: Re-infection with HCV of the same or another genotype in an individual who has cleared HCV infection (HCV RNA not detected) either spontaneously or having achieved a SVR following anti-viral treatment.

1. Patients who attain a SVR to anti-viral treatment should be regarded as having resolved HCV infection and in accordance with the "Blood borne viruses in haemodialysis, CAPD and renal transplantation 2010" they can be dialysed in the multi-bedded unit but tested monthly for HCV antigen.

2. Patients who are HCV RNA negative (HCV RNA not detected) at the end of treatment (ETR) can be either:

    - Dialysed in an isolation room, if the facilities available, until a SVR is confirmed

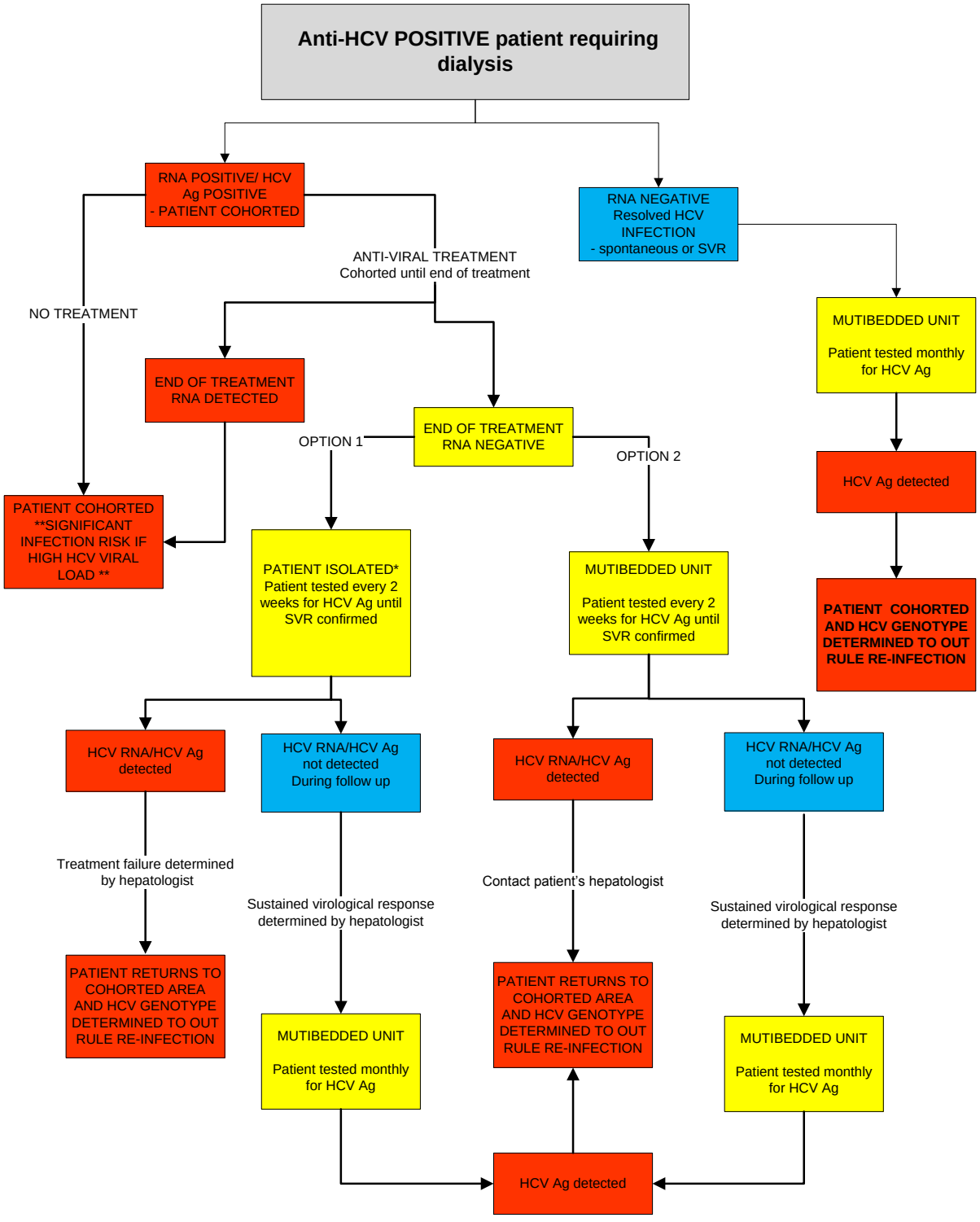
or

- Dialysed in the multi-bedded unit but tested for HCV Ag **EVERY TWO WEEKS** until SVR.

If HCV Ag or HCV RNA (>50 IU/ml) is detected any time within the 24 weeks following the end of treatment, the patient should be cohorted with the HCV RNA positive patients, as above. The results should be discussed with the patient's hepatologist.

In these cases HCV genotyping should be performed to out-rule re-infection with another HCV genotype. This situation does not automatically require a "look back" of patients in the multi-bedded unit. This should be discussed with the consultant nephrologist and relevant microbiologists, virologists and public health.

Figure 2: Management of HCV infected HD patients



* In an isolation room to prevent HCV re-infection

2.3 HIV

2.3.1 Pre- HD

Pre HD screening should be carried out to detect HIV infection using a combined antigen and antibody (Ag/Ab) test (Table 1).

2.3.2 Regular screening for HD patients

Annual HIV Ag/Ab testing (Table 1).

2.3.3 Interpretation of HIV results and patient management

HIV Ag/Ab negative:

No evidence of HIV infection: HD can be undertaken in a multi-bedded unit provided no evidence of HBV (Section 2.1) and HCV (Section 2.2) infection.

HIV Ag/Ab positive:

Evidence of HIV infection and the patient is infectious. Patients should be segregated/cohorted or located in an isolation room for HD (Section 7.3). HIV positive patients should be referred to an infectious diseases physician for assessment and management.

2.4 Management of Patients who have Received HD in another Unit

2.4.1 Transfer from a unit within the Republic of Ireland

Patients who have had HD in a unit in the Republic of Ireland do not require BBV investigation on admittance to another unit before commencement of HD provided a print copy of BBV laboratory results, originating from an accredited laboratory in accordance with the testing schedule (Table 1), is available to the receiving unit.

2.4.2 Transfer from a unit outside the Republic of Ireland

Units accepting patients from a unit outside the Republic of Ireland (e.g. for holidays or a long term transfer) should receive a print copy of BBV laboratory results, originating from an accredited laboratory, in accordance with the testing schedule (Table 1) before HD. Provided this print copy reveals HBsAg, anti-HCV, HCV Ag (Abbott Architect), HCV RNA and HIV Ag/Ab negative, the patient can be dialysed in a multi-bedded unit. Refer to section 7.3 for management of BBV positive patients. On admission repeat BBV testing should be undertaken in accordance with Table 1.

2.4.3 Haemodialysis abroad for a period of 2 weeks or less

Re-admitted patients who have been dialysed abroad for a period of 2 weeks or less should be tested for HBsAg, HCV Ag (Abbott Architect), anti-HCV and HIV Ag/Ab

before their first HD session on return but it is not necessary to have negative results before commencing HD. Due to the incubation period for HBV, HCV and HIV, infection is unlikely to be detected in the first sample post HD abroad if the patient has been away for two weeks or less.

2.4.4 Haemodialysis abroad for a period of 2 weeks or more

For re-admitted patients who have been dialysed abroad for 2 weeks or more, a negative HBsAg, HCV Ag (Abbott Architect), anti-HCV and HIV Ag/Ab must be available before HD in the multi-bedded unit.

2.4.5 Schedule of follow up testing following HD treatment abroad

To determine the ongoing testing protocol a risk assessment of the HD unit must be carried out based upon:

- Whether the unit currently dialyses patients infected with BBVs and what their isolation/decontamination practices are.
- Recent BBV transmission incidents within that unit.

An example of a questionnaire requesting this information is presented in Appendix 2.

If there is a significant risk of infection the patient should be tested for HBsAg, HCV Ag (Abbott Architect), HCV Ab and HIV Ag/Ab weekly for 3 months. **There is no need to segregate the patient and isolate the machine for this 3 months period providing the results remain negative.**

2.5 Abnormal Liver Function

Any patient who develops abnormal liver function tests should be screened for HBV (HBsAg) and HCV (anti-HCV & HCV Ag (Abbott Architect)) infection as appropriate depending on previous test results.

Table 1: Schedule for routine testing for HBV, HCV and HIV infections for haemodialysis patients

Patient status	On admission	Fortnightly	Monthly	3 Monthly	Annual
All patients	HBsAg, anti-HBc, anti-HBs, anti-HCV, HCV Ag (Abbott Architect), HCV RNA HIV Ag/Ab ALT				
HBV susceptible (unvaccinated and non-responders to vaccine)			HBsAg		
Vaccinated – good response (anti-HBs ≥100 mIU/ml)				HBsAg	Anti-HBs
Vaccinated – low level response (anti-HBs 10-99 mIU/ml)				HBsAg	Anti-HBs
Anti-HBc positive, HBsAg negative*			HBsAg*		
Anti-HCV negative, HCV Ag/HCV RNA negative			ALT	Anti-HCV, HCV Ag (Abbott Architect) **	HCV RNA**
Anti-HCV positive, HCV Ag/HCV RNA negative (including SVR attained)			HCV Ag ALT		
Anti-HCV positive, HCV Ag/HCV RNA negative (after anti-viral treatment but before SVR attained)		HCV Ag			
HIV Ag/Ab negative					HIV Ag/Ab

* See section 2.1.3 for management of immunosuppressed patients

** Annual HCV RNA investigation is not necessary provided that at baseline HCV RNA is not detected and the patient is tested for HCV Ag (Abbott Architect) every 3 months.

4.0 BBV Investigations for CAPD/CCPD

4.1 Pre CAPD/CCPD

Before starting CAPD/CCPD patients should be screened for BBVs as follows: HBsAg, anti-HBc, anti-HBs, Anti-HCV, HCV Ag (Abbott Architect), HCV RNA and HIV Ag/Ab.

4.2 Regular testing on CAPD/CCPD

Annual HBsAg, anti-HCV, HCV Ag (Abbott Architect) and HIV Ag/Ab

5.0 Renal Transplant Patients

- Consideration should be given to testing all renal transplant patients on a one-off basis for the following at 3 months post- transplant:

  a. Anti-HCV and HCV RNA or HCV ag

  b. HIV Ag/Ab

  c. HBsAg , anti-HBc

- For patients transplanted before the introduction of above: it is advisable that all patients currently with a functioning kidney transplant, unless known to be HCV infected, be tested on a one-off basis for anti-HCV and HCV RNA, to out-rule the possible acquisition of HCV infection through past treatment for renal failure.

6.0 Hepatitis B Vaccination

All long term HD and CAPD/CCPD patients should be immunised against HBV. Patients with CKD should be offered hepatitis B vaccination at the earliest opportunity, ideally before reaching the stage of requiring HD/CAPD/CCPD or transplantation (e.g. GFR < 25mls/min). For further information please refer to the latest edition of the RCPI National Immunisation Committee's Immunisation Guidelines for Ireland. [5]

Immunisation for HBV is best carried out in the CKD clinic, primary care setting or, for patients commenced on HD, in the dialysis unit. Local arrangements should be put in place.

The basic HBV vaccination schedule consists of three doses of vaccine at 0, 1 and 6 months. However, many renal patients will require more rapid protection, therefore an accelerated schedule (e.g. 0, 1, 2, 12 months or 0, 1, 2, 6 months) should be used.

There are two HBV vaccines currently available for patients with renal insufficiency, HBvax PRO ™ (40 mcg) and Fendrix™ (20 mcg). These vaccines are not interchangeable and therefore once a course has been initiated with one vaccine it cannot be completed using the other vaccine.

Post-vaccination testing after initial course (Table 2): Anti-HBs should be checked 2 months after the course of vaccine has been completed:

- **Anti-HBs ≥ 100 mIU/ml:** This is considered a good response. If the patient is on HD, anti-HBs should be tested annually and HBsAg three monthly. If anti-HBs drops below 10 mIU/ml, a booster dose of vaccine should be given and annual testing for anti-HBs continued. Retesting after the booster dose is not necessary.

- **Anti-HBs 10-99 mIU/ml:** An immediate booster should be given and anti-HBs retested at 2 months using 2 assays; if ≥ 10 mIU/ml is detected in both assays, this indicates an adequate response. If the patient is on HD, anti-HBs should be tested annually and HBsAg every 3 months. If anti-HBs drops below 10 mIU/ml, a booster dose of vaccine should be given and annual anti-HBs testing continued.

- **Anti-HBs < 10 mIU/ml**: This is considered non-response. Repeat a course of vaccination (a different brand of vaccine may be considered) and retest at 2 months post completion. HBsAg should be tested monthly during re-vaccination. The frequency of subsequent testing will be determined by the response to the repeat course of vaccination.

- **Anti-HBs < 10 mIU/ml after repeat vaccination:** the patient should be regarded as susceptible to HBV infection and tested for HBsAg on a monthly basis. However, if the patient is no longer on HD, HBsAg investigation is not required.

Previously vaccinated patients should be tested for anti-HBs on commencement of HD. Follow up testing and booster doses should be based on the anti-HBs level (both current and initial response taken 2 months after the original vaccination course) as per Table 2.

Table 2: Post-hepatitis B vaccination anti-HBs testing

Anti-HBs (mIU/ml)	Interpretation	Follow-up
≥ 100	**Good response**	**Test for HBsAg 3 monthly if on HD. Re-check anti-HBs annually. If anti-HBs < 10 mIU/ml, give booster dose of vaccine.**
10-99	**Give booster dose of vaccine. Check anti-HBs 2 months later using 2 different assays. Adequate response if both ≥ 10 mIU/ml.**	**Test for HBsAg 3 monthly if on HD. Re-check anti-HBs annually. If anti-HBs < 10 mIU/ml, give booster dose of vaccine.**
< 10	**Non-response. Repeat vaccination course (different brand). Check anti-HBs 2 months later. If anti-HBs < 10 mIU/ml, susceptible to HBV infection.**	**Test for HBsAg monthly if on HD.**

Note: IVIG and other blood products may contain anti-HBs. Therefore the anti-HBs result should be reviewed in conjunction with the date of administration of these products.

7.0 Infection Prevention and Control in a HD and CAPD/CCPD Setting

7.1 Environmental/design considerations

- Adequate layout and light is essential.
- There should be adequate space between patients' stations. UK guidance is included below for illustrative purposes. The relevant professional and technical staff should consider published guidance documents in the design of these units. [6-8]

The Department of Health (UK) recommends:

- 900 mm (3ft) minimum between haemodialysis stations.
- 1-2 isolation rooms (negative pressure ventilation) per 12 station units.
- One hand basin between two HD stations, with one for each isolated or segregated area.

7.2 Standard Precautions

Standard precautions are a group of infection prevention and control practices and measures that apply to all patients/clients at all times regardless of suspected, confirmed or presumed infectious status, in any setting in which healthcare is delivered. Standard precautions apply to: blood, all body fluids, secretions and excretions except sweat, regardless of whether or not they contain visible blood; non-intact skin; and mucous membranes.[9] Due to the infection risks associated with HD, additional measures (to standard precautions) have been recommended in international evidence-based HD guidelines, and have been included in this guideline. [3.4, 23]

Each unit should, in conjunction with the local infection prevention and control team, develop and update infection prevention and control guidelines.

Standard precautions consist of 15 infection prevention and control practices and measures (Table 3).

Table 3: Standard precautions infection prevention and control practices and measures

Occupational health programme
Patient placement
Patient movement and transfer
Hand hygiene
Personnel protective equipment (PPE)
Patient care equipment/instruments/devices
Environmental decontamination
Dishes and eating utensils
Management of spillages
Management of needle stick injuries and blood and body fluid exposure
Management of healthcare waste (non-risk and risk waste) including sharps
Management of linen and laundry
Respiratory hygiene and cough etiquette
Safe injection practices
Infection control practices for special lumbar puncture procedures

7.2.1 Occupational health programme

All HCWs should be assessed by an occupational health team prior to commencing work. The recommendations in the following documents should be followed:

- Immunisation Guidelines for Ireland 2008. [5]
- Department of Health and Children. Prevention of Transmission of Blood-Borne Diseases in the Healthcare Setting. Department of Health and Children; 2005.[10]

7.2.2 Patient placement

See Section 7.3 for patient placement for BBV positive patients .

7.2.3 Patient movement and transfer

The following information should be forwarded to the receiving unit.

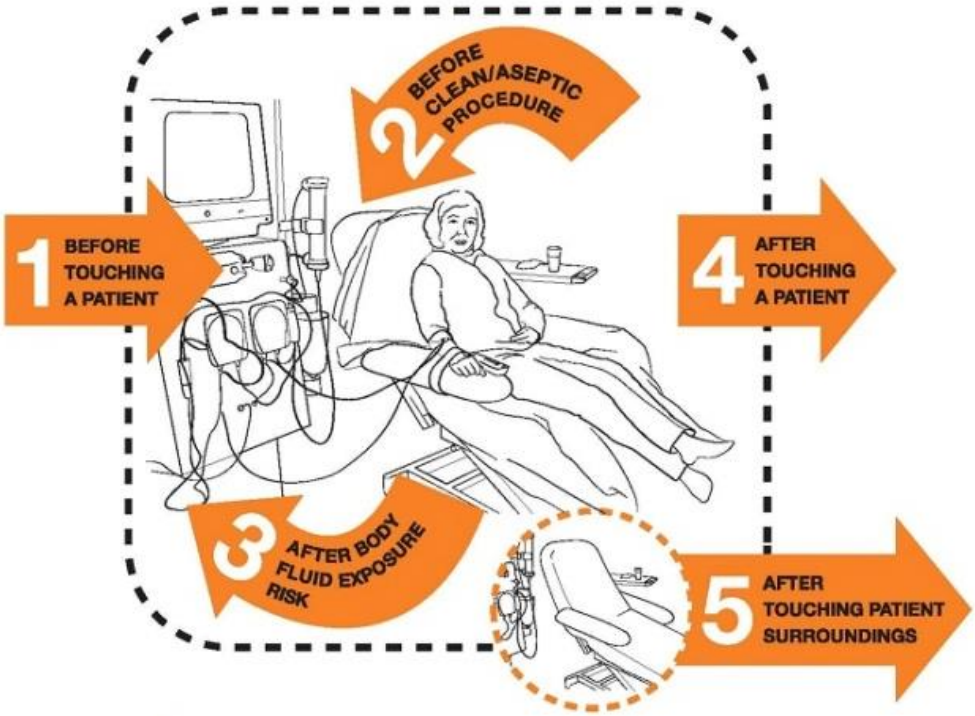
- Patient history.
- Up to date BBV laboratory results (Section 2.0 and Table 1).
- Information on any BBV transmission in the previous six months in the referring unit.

7.2.4 Hand hygiene

Hand hygiene is the single most important measure to prevent the transmission of microorganisms in HD and CAPD settings.
Hands should be decontaminated as per the WHO '5 Moments of Hand Hygiene'

- Before touching a patient.
- Before aseptic/clean procedure.
- After body fluid exposure risk.
- After touching a patient.
- After touching patient surroundings.

Figure 3: WHO 5 moments of hand hygiene in HD units



Hands should be decontaminated by adhering to the correct technique and using: [11]

- An alcohol based hand rub/gel if hands are physically clean.
- Plain or antiseptic liquid soap and water.

Alcohol hand solution (rub/gel/foam) is the preferred hand hygiene agent except in the following circumstances, when liquid soap must be used:

- When hands are visibly soiled.
- After caring for a patient where *Clostridium difficile* infection is suspected or confirmed. *Local guidelines may recommend that soap and water is used for all patients with diarrhoea.*

Patients should be educated on the importance of hand hygiene and advised to decontaminate their hands:

- Before eating.
- After toileting, sneezing or coughing.
- On entering the unit.
- Before cannulation.
- Immediately after a HD treatment especially if they applied digital pressure to needle exit sites. This is advised to reduce the risk of contamination to surfaces or equipment (e.g., weighing scales).
- Before leaving the unit.
- Before connecting and disconnecting CAPD/CCPD lines.
- Before undertaking exit site care.
- After handling peritoneal waste.

For additional information refer to the recommendations in the SARI Guidelines for Hand Hygiene in Irish Health Care Settings 2005 [11] and the World Health Organisation (WHO) Hand Hygiene Guidelines in Healthcare 2009. [12]

7.2.5 Personal protective equipment (PPE)

PPE is worn to protect the HCW from exposure to blood or body fluids and consists of gloves, face protection and aprons/gowns.
HCWs should select the appropriate PPE based on a risk assessment including the following:

- The nature of the anticipated procedure.
- The risk of exposure to blood, body fluids, mucous membranes and non-intact skin.
- The risk of contamination of the skin or clothing.

The external surface of the HD machines are frequently contaminated with blood, therefore gloves should worn for contact with a HD machine until the machine is cleaned and disinfected post treatment.
The use of gloves does not replace hand hygiene. Gloves should be removed and hand hygiene performed, when an indication occurs while wearing gloves (e.g., before and after touching a patient, before a clean/aseptic procedure, after body fluid exposure risk and after touching patient surroundings).

Aprons/gowns should be removed when contaminated by blood or body fluids and after each patient.
Face protection should be discarded between patients or if reusable, cleaned and disinfected between uses as per manufactures' instructions.

7.2.6 Patient-care equipment/instruments/devices

All healthcare facilities must develop policies and procedures for transporting, handling and decontamination of all reusable patient care equipment, instruments and devices. Medical devices designated as 'Single Use Only' must not be reprocessed or reused even for the same patient under any circumstances. The recommendations in the following documents should be followed:

- Health Service Executive. Code of Practice for Decontamination of Reusable Invasive Medical Devices 2007.[13]
- Creutzfeldt-Jakob Disease Infection Control Committee on behalf of the Scientific Advisory Committee of the HPSC and the National Creutzfeldt-Jakob Disease Committee DoHC. Guidelines on Minimising the Risk of Transmissible Spongiform Encephalopathies in Healthcare Settings in Ireland 2004.[14]

HD machines and equipment

- The external surface of each HD machine should be cleaned and disinfected after each treatment according to the manufacturer's instructions. Use a disinfectant with virucidial activity against BBV. Special attention should be paid to frequently touched areas on the machine (e.g. control buttons).
- The HD fluid pathway should be disinfected after each patient and following a blood leak in accordance with the manufacturer's instructions.
- Venous and arterial transducers should be protected with a disposable single use filter during every treatment.
- If there is evidence of the filters being contaminated by fluid (e.g. blood or saline) during a treatment, inspect the filter. If fluid is visible on the side of that faces the transducer, replace the filter. If breakthrough has occurred the machine components that may have become in contact with the blood should be replaced or decontaminated by qualified personnel according to a protocol that incorporates the manufacturers' instructions before the machine is used again.
- Should a blood spill occur on a HD machine, the machine should be removed from use after the treatment, checked for blood seepage (e.g. under external casing or in the dialysate tubing connectors) and appropriately cleaned and disinfected as per manufacturer's instructions.
- Any article brought to a patient's station must not be returned, used or unused, to the clean area where injections are drawn up or used on another patient without cleaning and disinfection.
- Clamps should be disposable or washed and disinfected (chemical or heat) after each treatment.
- Items brought to the treatment area, which are difficult to clean thoroughly such as; blood pressure cuffs, tourniquets, adhesive tape, ear phones etc should be single use items or dedicated as single patient use only.

- Glucometers should be either single patient use (i.e. the patient's personal glucometer) or dedicated to an individual patient for each HD session. Following the HD session and before use on another patient the glucometer should be cleaned and disinfected as per manufacturer's instructions. Glucometer boxes/trays with supplies (lancets etc) for multiple patients should not be used in HD units.
- Refer to Section 7.3 for the management of HD equipment and treatment area used for BBV infected patients.

7.2.7 Environmental decontamination

Routine environmental cleaning is essential to minimise the risk of infectious agents contaminating the environment.

- Cleaning (with a neutral detergent) is the first step in environmental cleaning, followed by disinfection if necessary (e.g. soiled with blood or body fluids). Local guidelines should be followed for the use of dual-action products (i.e. products that contain both detergent and disinfectant). Follow manufacturer's instructions for dilutions and contact time.
- Each treatment couch/bed, locker, bed table etc should be cleaned with detergent and water before use for another patient, and a hypochlorite solution (1,000ppm) used after cleaning if visible blood is present.
- Cleaning frequencies should reflect that HD and CAPD units are classified as high risk areas for environmental cleaning.
- Further information can be sourced from the Cleaning Manual for Acute Hospitals (2006).[15]

7.2.8 Dishes and eating utensils

Dishes and utensils should be washed in a dish washer or hand washed using warm water with detergent.

7.2.9 Management of blood spillages

A record of large blood spillages should be maintained in the unit. Blood spillages should be attended to immediately.

- HCWs should wear appropriate PPE.
- Decontaminate all blood spills with a chlorine based disinfectant (e.g., powder, granules or liquid containing 10,000ppm available chlorine as per local guidelines).
- Wipe up the spillage with disposable paper towels or scoop and discard into a healthcare risk bag or rigid container.
- Wash the area with a general purpose neutral detergent and water.
- Discard gloves and apron into healthcare risk waste.
- Perform hand hygiene after discarding PPE.

7.2.10 Management of needle stick injuries and blood and body fluid exposure

All healthcare facilities must have a local policy on the management of needle stick and other sharps-related injuries, human bites and blood and body fluid exposures (i.e. contamination of mucous membranes or conjunctiva).
Further information can be sourced from Guidelines on the Emergency Management of Injuries 2012.[16]

7.2.11 Management of healthcare non-risk, risk waste and sharps

Healthcare risk and non-risk waste
The recommendations in the following guideline should be followed: Health Services Executive; Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste, 2010.[17]

Sharps

Where there is a risk of sharps injuries, employers must consider the following based on a risk assessment: [18, 19]

- Eliminating the unnecessary use of sharps by implementing changes in practice where this is possible.
- The provision of medical devices incorporating safety engineered protection mechanisms which are safe to use, based on risk assessment. Prior to introducing any needle stick injury prevention device, HCWs should thoroughly evaluate devices to ensure their suitability for use and to ensure they do not create any other hazard to the patient or to the HCW.
- Needle stick injury prevention devices include needles that retract into the syringe after use, those that have a protective shield over the needle and systems that do not use needles.
- Where these devices are provided HCWs must be trained in their correct use.
- Where sharps cannot be eliminated, safe systems of work should be implemented to minimise the risk of injury.
- HCWs are personally responsible for the safe use and disposal of sharps, needles, scalpels and other sharp instruments/devices they use.

Disposal of sharps

- Sharps bins should be assembled correctly before use.
- Sharps bins should be securely stored that enables safe disposal by all members of staff but out of reach from patients, visitors and children.
- Discard used sharps into a designated sharps bin at the point of use.
- Syringes and needles should be disposed of as a single unit.
- Needles should never be re-capped, bent, broken or disassembled.
- Do not overfill the sharps bin, securely seal bin when ¾ full.
- Dispose of sharps bins according to healthcare risk waste guidelines. [17]

7.2.12 Management of laundry and linen

The recommendations in following document should be followed: Society of Linen Services and Laundry Managers; Hospital Laundry Arrangements for Used, Foul and Infected Linen, 2008.[20]

7.2.13 Respiratory hygiene and cough etiquette

The recommendations in following document should be followed: Standard precautions in healthcare settings. HPSC 2009.[21]

7.2.14 Safe injection practices

- An aseptic technique must be used to avoid contamination of sterile injection equipment.
- Needle, syringes and cannulae are sterile, single-use items and must not be reused for another patient or to access a medication or solution that might be used for a subsequent patient.
- The preparation of injections should **not** be undertaken within the patient treatment rooms.
- Each unit should have a dedicated room (clean utility room) adjacent to but physically separate from the patient treatment areas where medications are stored and prepared, and where clean and sterile stores are stored.
- Any article brought to a patient's station must not be returned, used or unused, to the clean utility room or used on another patient before cleaning and/or disinfection.
- No handling or storing of unclean supplies, equipment, or blood samples should occur in the clean utility room.
- Multi-dose vials MUST ONLY be used for single patient use or discarded after every use.
- Do not use bags or bottles of intravenous fluids as a common source of supply for multiple patients.

7.2.15 Practices for special lumbar puncture procedures

The recommendations in following document should be followed: Standard precautions in healthcare settings. HPSC 2009.[21]

7.3 Management of BBV Infected Patients

In addition to standard precautions (Section 7.2), the following should be applied for all BBV positive patients:

- Staff should not care for BBV positive patients and BBV negative patients at the same time including the period when HD is being discontinued on one patient and commenced on another.

- The external surface of the HD machine should be cleaned with detergent and water and disinfected using a disinfectant advised by the manufacturers after each use. Use a disinfectant with virucidial activity against BBVs. Special attention should be paid to frequently touched areas on the machine (e.g. control buttons).
- The fluid pathways of the HD machine should be disinfected after each treatment (heat and/or chemical, as per manufacturer's instructions).
- Reusable medical equipment such as blood pressure monitoring equipment, trays, stethoscopes and glucometers should be cleaned and disinfected as per manufacturers' instructions before use on another patient.
- Patients should be educated on prevention of transmission of infection in the home and in other settings.

7.3.1 HBsAg positive patients

- HBsAg positive patients should be dialysed in a separate isolation room on dedicated machines with HBV immune staff dedicated for that dialysis shift.

- There is a significant risk of HBV being transmitted via environmental surfaces and therefore a dedicated machine should be used for HBV infected patients.

- The room and patient care equipment (bed, couch, chair etc) can be returned to general use, if it is no longer used for an HBsAg positive patient, provided that it is cleaned with detergent and disinfected thoroughly using hypochlorite 1000 pmm.

- In accordance with the UK[4], CDC [3] and Australian guidelines [23] machines used to dialyse HBsAg positive patients, which are no longer required to dialyse HBsAg positive individuals, can be used for HBV susceptible patients providing that they are meticulously cleaned and disinfected in accordance with protocols that incorporate the manufacturers' instructions. In addition, replace the internal dialysate fluid circuit including the external tubing and fixings and venous and arterial transducers. There should be a clear audit trail for these actions.

- HBV positive patients should not have HD at the same time and in the same segregated area/isolation room with patients positive for either HCV or HIV.

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7.3.2 HCV Ag or RNA positive patients

- It is NOT necessary to have a dedicated machine provided that disinfection processes are properly carried out between patients according to a protocol that incorporates the manufacturers' instructions.

- It is not recommended that patients be further cohorted based upon a HCV viral load threshold. However, emphasis should be placed upon the importance of procedures to prevent cross infection, especially if any patient has a very high HCV viral load.

- HCV Ag or RNA positive patients should be either segregated/cohorted in an area portioned or physically separate from susceptible patients during HD or have HD treatment in an isolation room

- Patients who attain a SVR to anti-viral treatment should be regarded as having resolved HCV infection and in accordance with the "Blood Borne Viruses in Haemodialysis, CAPD and Renal Transplantation 2010" they can be dialysed in the multi-bedded unit but tested monthly for HCV antigen.

- Patients who are HCV RNA negative (HCV RNA not detected) at the end of anti-viral treatment (ETR) can be either;

    - Dialysed in an isolation room, if facilities available, until an SVR is confirmed.

      Or

    - Dialysed in the multi-bedded unit but tested for HCV Ag EVERY **TWO WEEKS** until SVR.

  If an SVR is not subsequently attained the patient should be cohorted with the HCV RNA positive patients, as above. In these cases HCV genotyping should be performed to out-rule re-infection with another HCV genotype. This situation does not automatically require a "look back" of patients in the multi-bedded unit. This should be discussed with the Consultant Nephrologist and relevant microbiologists, virologists and public health

- HCV positive patients should not have HD at the same time and in the same segregated area with patients positive for either HBV or HIV.

- The room/segregated area and patient care equipment (bed, couch, chair etc) can be returned to general use after a HD treatment provided that they are cleaned with detergent and disinfected thoroughly using hypochlorite 1000 pmm.

7.3.3 HIV positive patients

- It is NOT necessary to have a dedicated machine provided that disinfection processes are properly carried out between patients according to a protocol that incorporates the manufacturers' instructions.
- HIV positive patients should be either segregated/cohorted in an area portioned or physically separate from susceptible patients during HD or have HD treatment in an isolation room.
- HIV positive patients should not be dialysed at the same time and in the same segregated area with patients positive for either HBV or HCV.
- The room/segregated area and patient care equipment (bed, couch, chair etc) can be returned to general use after a HD treatment provided that they are cleaned with detergent and disinfected thoroughly using hypochlorite 1000 pmm.

7.3.4 Patients infected with more than one BBV

Patients co-infected with different BBV infections should not be dialysed in a segregated area at the same time with patients susceptible to the BBV.

7.3.5 BBV positive patients treated by CAPD/CCPD

Patients on CAPD/CCPD who are infected with BBVs do not need isolation. Standard precautions should be sufficient to avoid cross-contamination.

CAPD/CCPD fluid waste

Local arrangements should be made to manage CAPD/CCPD waste fluids known to be contaminated with BBVs.

7.3.6 BBVs and patients with CKD but not on HD

Standard Precautions should be observed for all patients with CKD who are not on HD.

8.0 Surveillance and record keeping

Each unit should develop and maintain a database for all patients to record HBV vaccination status, results of serological and molecular tests for BBV and adverse events such as blood leaks and spills, HD machine cleaning and disinfection and malfunctions.

Each unit should record, for each treatment, the machine number, station number occupied and staff connecting and disconnecting the patient.

Results of testing for BBVs and HBV vaccination status should be recorded in an accessible manner in individual patients' medical notes.

9.0 Audits

Yearly infection control audits in relation to preventing the transmission of BBVs in HD units should be undertaken jointly by renal and infection prevention and control teams.

10.0 Management of HCWs and carers in the HD setting

Staff working in HD units in contact with patients, machines or materials used in HD should be immunised against HBV and their response to vaccine checked. Non-responders or poor responders should be tested annually for HBsAg. Guidelines for exposure prone procedures (EPPs) should be followed.[10] HBV non-immune staff should not care for HBsAg positive patients during a HD treatment.

- Staff members who are either HBeAg positive or are HBeAg negative with an HBV DNA level exceeding 10^4 copies/ml should not undertake clinical procedures in the HD unit. Such procedures would include direct contact with the HD process. Such restrictions need not be applied to staff that have no patient contact or whose clinical duties do not involve direct contact with patients' body fluids, vascular access lines/ports or other relevant equipment. Decisions regarding the fitness for duty of a clinical health-care worker in this context should be informed by competent risk assessment with attention to individual factors, e.g. no existing skin disease.

- Unless performing EPPs there is no need to screen for HCV or HIV infection in current or prospective staff of renal units, either routinely at pre-employment health assessment or periodically. However, those known to be at risk of acquiring infection or known to be infected should seek advice from an Occupational Health Physician.

- The following points should be clearly documented in the Occupational Health Department in relation to staff members with BBV infection:

    1. That the infected health-care worker fully understands Standard Precautions and the implications for patients (and others) should they be breached at any time.

    2. That the definition of exposure-prone procedures is understood.

    3. That the individual does not suffer from an exudative skin disorder (e.g. psoriasis or eczema).

- It is important that renal units should have easy access to Occupational Health Departments and infection prevention and control expertise when dealing with outbreaks of BBVs and staffing matters relevant to the acquisition of BBVs.

Carers

- Carers who assist during the HD treatment of patients should be offered HBV vaccination and, if they do not respond, should be offered HBsAg and anti-HBc testing.

11.0 Infection control training and education

Staff members

Training and education for all employees at risk from occupational exposure to blood should be provided at least annually, and given to new employees before they begin working in a unit. Details of this training should be documented. At the minimum, the training should include information on the following topics:

- Hand hygiene technique
- Use of personal protective equipment
- Modes of transmission for blood-borne viruses, pathogenic bacteria and other micro-organisms as appropriate
- Infection prevention and control practices as recommended for HD units and how they differ from Standard Precautions recommended for other health care settings
- Proper handling and delivery of patient medication
- Rationale for segregating HBV positive patients in an isolation room, and segregation of their machines, instruments, supplies, medications and staff members
- Proper-infection control techniques for initiation, care and maintenance of access sites
- Housekeeping to minimise transmission of micro-organisms, including methods to clean and disinfect equipment and environmental surfaces

Training and education of patients

Training and education of patients (or family members for patients unable to be responsible for their own care) regarding infection prevention and control practices should be given on admission to the HD unit and at least annually thereafter. This should address the following topics:

- Personal hygiene and hand-washing techniques
- The patient's role in preventing infection at the access site, and recognition of signs of infection. This education and training should be reviewed each time the patient has a change of access type.
- Recommendations for vaccination.

12.0 Management of a previously unidentified case of BBV infection in a HD patient

The guidance below is primarily for HBV infected patients. Where the guidance differs for HCV or HIV infection, this is indicated in italics.

1. Consultant microbiologist/laboratory director to inform the consultant nephrologist and notify the Director of Public Health immediately.

2. **Management of the hepatitis B virus surface antigen (HBsAg) *(or HCV or HIV)* positive patient**

   The infected patient should be informed of the HBsAg *(HCV/HIV)* positive result, counselled as appropriate and referred for specialist assessment. Family members and other close contacts should be offered HBV vaccination as appropriate.

   If the patient is infected with HBV they should be dialysed in a separate isolation room, using a dedicated machine, with dedicated HBV immune staff. Staff should not care for HBV positive and negative patients at the same time. ***If the patient is HCV or HIV infected they should be segregated and cohorted if possible but a dedicated machine is not necessary (see section 7.6).***

   The source of the infection should be investigated. This should include review of the patient's recent medical history (e.g. blood transfusion, hospitalisation), history of high risk behaviour (e.g. injecting drug use, sexual activity), and unit practices and procedures.

   Blood from the infected patient should be sent to the local virology laboratory or the NVRL for further serological investigation and to determine the viral load. The consultant virologist/microbiologist will advise on the need for and timing of additional testing.

3. **Notification to the Director of Public Health**

   HBV, HCV and HIV infections are notifiable under the Infectious Diseases Regulations. Details regarding the infected patient should be sent to the Director of Public Health by both the Laboratory Director and the clinician.

4. **Identification of the exposed cohort**
   The exposed cohort is defined as all patients who have shared a HD machine or HD session with the infected patient since that patient was last negative for markers of HBV, HCV or HIV infection.

   If the infected patient has been dialysed in another HD unit in the last 3 months, the other unit must be informed of the incident. Patients in this other unit will therefore be part of the exposed cohort and need to be managed as such.

   If patients from the exposed cohort have been transferred to another HD unit, the director of this unit should be informed. The transferred patients should be managed and followed-up as the exposed cohort.

5. Management of the exposed cohort

Patients belonging to the exposed cohort should be informed of the incident and counselled as appropriate. A risk assessment should be performed based upon the source patient viral load and risk of transmission.

HBV: HBsAg, anti-HBc and anti-HBs testing should be carried out immediately on all patients in the exposed cohort. Details of hepatitis B virus (HBV) vaccination history for the exposed cohort should be reviewed and documented.

Thereafter, management of patients is dependent on their anti-HBs titres:

(a) Anti-HBs titre <100 mIU/ml + history of HBV vaccination:

- Test HBsAg weekly for 3 months
- Give a booster dose (40 mcg) of hepatitis B virus (HBV) vaccine
- Consider HBIG for non-responders to HBV vaccine (anti-HBs never ≥ 10 mIU/ml) and for those whose anti-HBs has fallen below 10 mIU/ml.

(b) Anti-HBs titre ≥100 mIU/ml + history of HBV vaccination:

- These patients are protected – therefore no further action is necessary.

(c) No history of HBV vaccination.

- Test HBsAg weekly for 3 months.
- Commence accelerated course of HBV vaccine (dose: 40mcg) immediately.
- Consider HBIG as appropriate.

HCV: *HCV Ag (Abbott Architect) and HCV antibody should be performed immediately and then weekly on all the exposed cohort for a period of 3 months.*

HIV: *HIV Ag/Ab assays should be performed immediately and then tested weekly on all the exposed cohort for a period of 3 months*

6. Communication

The Consultant Nephrologist in the unit where the new case has been identified should alert the following:

- Relevant staff in the HD unit
- If the infected patient was dialysed in another unit in the past 3 months, the Consultant Nephrologist in this unit should be informed

- The Consultant Nephrologists in other HD units, to which members of the exposed cohort have been transferred
- Consultant Microbiologist /Virologist
- Consultant Occupational Health Physician
- Hospital infection prevention and control team
- Hospital Chief Executive or Deputy
- Hospital Director of Nursing
- Director of Public Health, who will inform the Health Protection Surveillance Centre and the Assistant National Director responsible for Health Protection/National Medical Officer of Health.

7. Incident Control Teams

A local incident team should be set up in the hospital, to manage the incident within that hospital. The team should include the Director of Public Health and at least one expert in infectious diseases external to the situation concerned. The chairperson of the committee should be the hospital chief executive officer or a nominated deputy. A national incident team should be set up by the Assistant National Director responsible for Health Protection/National Medical Officer of Health and led by the HPSC to coordinate the incident nationally. National coordination is essential as incidents in HD units generally have national implications. The national team should include the Director of Public Health of the local incident team.

8. Identification of exposed staff

HBV vaccination history and anti-HBs titres of staff members who have had contact with the infected patient since that patient was last HBsAg negative should be reviewed.

Staff members with a history of HBV vaccination and anti-HBs titres ≥ 100 mIU/ml are protected and no further action is necessary.

Staff members with a history of HBV vaccination and anti-HBs titre < 100 mIU/ml, should be given a booster dose of vaccine.

Those with no vaccination or incomplete vaccination should be commenced on an accelerated course of HBV vaccine and HBIG considered, as appropriate. For non responders to HBV vaccine (anti-HBs titre never ≥ 10 mIU/ml), HBIG should be considered, as appropriate. The need for further HBsAg testing should be guided by conducting a risk assessment.

The investigation for infection in staff members who have had contact with the HCV or HIV infected patient should be guided by risk assessment.

Table 3 : KEY ACTION POINTS

Prevention and control of BBV infection in HD units is dependent on:

- Strict implementation of infection prevention and control procedures
- Infection prevention and control training and education
- Use of HBV vaccine for susceptible patients and staff
- Isolation of HBV infected patients and equipment
- Segregation and cohorting of HCV and HIV infected patients. Dedicated equipment is not required
- Routine serological investigation for HBV, HCV and HIV, and molecular investigation when required

Before commencing HD

Laboratory screening

- All patients should be tested for HBsAg, anti-HBc, HCV Ag (Abbott Architect), anti-HCV, HCV RNA, HIV Ag/Ab and ALT

HBV Vaccination

- All susceptible patients should be offered HBV vaccination before HD. A vaccination dose suitable for patients with CKD should be used. All carers who assist during haemodialysis treatments should be offered HBV vaccination.

Vaccination follow-up

- Anti-HBs response should be investigated 2 months after the HBV vaccine course has been completed

On HD

Laboratory Screening

HBV

- HBsAg negative/anti-HBc positive: HBsAg to be tested **monthly**
- Immunosuppressed HBsAg negative /anti-HBc positive**: HBsAg to be tested weekly until 2 months after immunosuppressive therapy discontinued.** Thereafter, monthly HBsAg testing. Consider referral to Hepatologist/Gastroenterologist/Infectious Disease physician for advice regarding need for HBV anti-viral chemoprophylaxis and subsequent monitoring of HBV DNA.
- Unvaccinated and vaccine non-responders: HBsAg to be tested **monthly**
- Vaccinated with good response (anti-HBs ≥ 100 mIU/ml): **HBsAg every 3 months and anti-HBs to be tested annually.**
- Vaccinated with low response (anti-HBs 10-99 mIU/ml): **HBsAg every 3 months and anti-HBs to be tested annually.**

HCV

- ALT monthly, 3 monthly HCV Ag (Abbott Architect), anti-HCV. If HCV Ag (Abbott Architect) is being performed, annual HCV RNA in not required for any patient provided that HCV RNA was not detected during initial laboratory screening.
- Resolved HCV infection (section 2.2): HCV Ag and ALT monthly.
- It is not recommended that patients be further cohorted based upon a HCV viral load threshold. However, emphasis should be placed upon the importance of procedures to prevent cross infection, especially if any patient has a very high HCV viral load.
- Patients who attain a SVR to anti-viral treatment should be regarded as having resolved HCV infection and in accordance with the "Blood borne viruses in haemodialysis, CAPD and renal transplantation 2010" they can be dialysed in the multi-bedded unit but tested monthly for HCV antigen.
- Patients who are HCV RNA negative (HCV RNA not detected) at the end of treatment (ETR) can be:
    - Dialysed in isolation , if facilities available, until an SVR is confirmed

- Dialysed in the multi-bedded unit but tested for HCV Ag **EVERY TWO WEEKS** until SVR.

If an SVR is not subsequently attained the patient should be cohorted with the HCV RNA positive patients, as above. In these cases HCV genotyping should be performed to out-rule re-infection with another HCV genotype. This situation does not automatically require a "look back" of patients in the multi-bedded unit. This should be discussed with the Consultant Nephrologist and relevant microbiologists, virologists and public health

HIV

- Annual HIV Ag/Ab

Infection Control

HBsAg positive/ anti-HBc positive: This patient should be dialysed in a separate isolation room on dedicated machines, with dedicated HBV immune staff

HBsAg negative/anti-HBc positive: No isolation is necessary if HBsAg remains negative.

HCV/HIV infected: The patient should be segregated from the main unit and cohorted. There is NO need to have dedicated machines.

Key amendments in 2013

1. It is not recommended that patients be further cohorted based upon a HCV viral load threshold. However, emphasis should be placed upon the importance of procedures to prevent cross infection, especially if any patient has a very high HCV viral load.

2. Patients who attain a sustained virological response (SVR) to anti-viral treatment should be regarded as having resolved HCV infection and in accordance with the "Blood borne viruses in haemodialysis, CAPD and renal transplantation 2010" they can be dialysed in the multi-bedded unit but tested monthly for HCV antigen

3. Patients who are HCV RNA negative (HCV RNA not detected) at the end of treatment (ETR) can be:

    - Dialysed in isolation , if facilities available, until an SVR is confirmed
    - Dialysed in the multi-bedded unit but tested for HCV Ag **EVERY TWO WEEKS** until SVR.

    If an SVR is not subsequently attained the patient should be cohorted with the HCV RNA positive patients, as above. In these cases HCV genotyping should be performed to out-rule re-infection with another HCV genotype. This situation does not automatically require a "look back" of patients in the multi-bedded unit. This should be discussed with the Consultant Nephrologist and relevant microbiologists, virologists and public health

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Appendix 1

Membership and terms of reference of sub-group

Terms of reference:

To review and update the recommendations in chapter 5 of the Prevention of Transmission of Blood-Borne Diseases in the Healthcare Setting 2005

Membership:

Dr. Jeff Connell (chair), Assistant Director, National Virus Reference Laboratory.

Dr. Liam Casserly, Consultant Nephrologist, Mid Western Regional Hospital Limerick.

Professor Peter Conlon, Consultant Nephrologist, Beaumont Hospital.

Dr. Brendan Crowley, Consultant Microbiologist with a special interest in virology, St James's Hospital/ National Virus Reference Laboratory.

Ms. Sheila Donlon, Infection Prevention and Control Manager, Health Protection Surveillance Centre.

Dr. George Mellotte, Consultant Nephrologist, Adelaide and Meath Hospital, incorporatingthe National Children's Hospital.

Dr. Lelia Thornton, Specialist in Public Health Medicine, Health Protection Surveillance Centre.

Appendix 2
Sample Questionnaire

Information from a HD unit outside the Republic of Ireland prior to patient transfer or referral to that unit

This form should be completed by a member of the medical or nursing staff.

Name of unit _____

Address _____

Section A: Management of all patients

1	Is the internal fluid pathway of the dialysis machine disinfected after each patient**?**	**Yes**	**No**
2	Is the external surface of the dialysis machine cleaned and disinfected after each patient?	**Yes**	**No**
3	Is the equipment in the bed space (e.g., chair, locker, bed table etc) cleaned after each patient?	**Yes**	**No**
4	Are patients tested for BBV routinely in the unit?	**Yes**	**No**

If yes, please provide details:

BBV	Type of test	Frequency
HBV		
HCV		
HIV		

Section B: Management of BBV positive patients

Hepatitis B

4	Are patients infected with hepatitis B (HBsAg positive) dialysed in the unit?	**Yes**	**No**
If no, proceed to Question 8			
5	Are dedicated machines used for HBsAg positive patients?	**Yes**	**No**
6	Are HBsAg positive patients dialysed in an isolation room?	**Yes**	**No**
If No, are HBsAg positive patients cohorted/segregated from HBsAg negative patients?		**Yes**	**No**
7	Do staff care for HBsAg positive and HBsAg negative patients at the same time?	**Yes**	**No**
8	Has any patient HBsAg negative on admission to your unit, tested HBsAg positive in the past 2 years?	**Yes**	**No**

Hepatitis C

9	Are patients infected with hepatitis C (HCV) dialysed in the unit?	**Yes**	**No**
If no, proceed to Question 11			
10	Are HCV infected patients cohorted/ segregated from HCV negative patients?	**Yes**	**No**
11	Has any patient HCV negative on admission to your unit, tested positive for HCV in the past 2 years?	**Yes**	**No**

HIV

12	Are patients infected with HIV dialysed in the unit?	**Yes**	**No**
If no, no proceed to Question 14			
13	Are HIV infected patients cohorted/ segregated from HIV negative patients?	**Yes**	**No**
14	Has any patient HIV negative on admission to your unit, tested HIV positive the past 2 years?	**Yes**	**No**

Thank you for providing this information