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Clinical Procedure for Screening, Prevention and Management of Blood Borne Virus in Patients under the Care of UHB Renal Service. 2nd Edition

CATEGORY:	**Procedural Document**
CLASSIFICATION:	**Clinical**
PURPOSE	**This clinical procedure provides guidance for registered nurses and medical staff working within the renal specialty who perform blood borne virus (BBV) screening and manage patients requiring pre-dialysis, haemodialysis or peritoneal dialysis treatment. NB. This procedure is accompanied by Protocols for Screening, Prevention and Management of Blood Borne Virus in renal patients under the care of UHBFT, Renal Services 2nd Edition**
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Distribution: • **Essential Reading for:** • **Information for:**	**The registered nurses and medical staff who perform blood borne virus screening and care for patients with a blood borne virus under the care of UHBFT renal service** **All clinical staff working in the renal specialty.**

Contents

All appendices referenced in this procedure are available as numbered in:

Protocols for Screening, Prevention and Management of Blood Borne Virus in renal patients under the care of UHBFT, Renal Services

1. Introduction

Blood borne virus (BBV) screening and control is a critical aspect of the management of patients with renal failure treated by dialysis. It is necessary to screen for, prevent and control BBV infections including hepatitis B virus (HBV) hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

This current Trust procedure encompasses:

- The Department of Health's Good Practice Guidelines for Renal Dialysis/Transplantation Units - Prevention and control of blood-borne virus infection (2002)
- British Renal Association current guidelines on 'Blood Borne Virus' management in dialysis patients (2009)
- The Department of Health's Addendum Guidelines for Dialysis away from base (2010).
- Any significant change in any subsequent national guidance will be reviewed with addition of addendums to this procedure if required

Transmission of BBVs to staff or patients may occur as a result of percutaneous exposure to blood or body fluids. BBVs may also be transmitted directly via mucosal surfaces through droplets, via the hands or forearms of staff, or indirectly through contaminated equipment or supplies. The environment of a Renal Unit predisposes to blood borne viral cross infection. This document details the processes to be performed when caring for UHB patients whether within UHB renal services or partner organisations to minimise risk of harm to patients and staff from BBV. However it is also essential that the adoption and regular audit of universal precautions is maintained at all times to help prevent cross infection between patients and for the protection of the staff.

2. Blood Borne Virus Screening

Patients to be Screened for Blood Borne Viruses

The following patients must be offered BBV screening that includes testing for HBV, HCV and HIV,

- All UHB patients requiring haemodialysis (HD) under the care of UHB; to include patients receiving dialysis at QEHB, on the UHB home haemodialysis programme or at any satellite units managed by partner organisations under contract to UHB
- Patients who are receiving pre-dialysis care with an eGFR < 15mls/min/1.73m2.
- Patients who require acute haemodialysis
- Patients requiring peritoneal dialysis (PD).

- Patients that are pre-renal transplantation- at the time of transplant listing and again at the time of admission for renal transplant.

- Patients that require other extracorporeal treatments (eg lipid / plasma exchange) delivered by renal within UHB. Such patients will be initially BBV sampled and risk assessed re future BBV sampling requirements. This must be agreed with the Matron for ERF and lead BBV Chair and documented in the patients notes.

The protocol for Blood Borne Virus screening is set out in Appendix 1 and the regime in Appendix 2 in the accompanying document 'Protocols for blood borne virus screening, prevention and management of renal patients under the care of UHBFT renal services'.

Informed Consent for Blood Borne Virus Screening

Prior to the initial performance of BBV screening, informed consent must be obtained from the patient by a registered nurse or medical staff. This is to be obtained verbally and documented along with topics of discussion in the patient's dialysis records and UHB EPR. In addition, the patient must receive the patient information leaflet 'Hepatitis B, Hepatitis C and HIV testing for people with chronic kidney disease and on dialysis with receipt documented as above. This process of recording will be regularly audited.

As part of the consent process for BBV screening, the patient must be informed that if they have chosen to receive dialysis (PD or HD) or transplantation, they will be offered Hepatitis B immunisation (in the form of a course of injections, ideally administered before commencing their chosen renal replacement therapy).

For further information regarding consent and mental capacity, please refer to the following documents, which staff must be competent in delivering:

- Department of Health Reference Guide to Consent for Examination or Treatment 2nd Ed (2009)
- University Hospitals Birmingham NHS Foundation Trust's Policy and procedural document for consent to examination or treatment (2013).
- Mental Capacity Act (2005).

Any patient who does not agree to consent must be managed as though they are BBV infected (DH, 2002). For patients receiving haemodialysis, this requires dialysis on a dedicated machine in an isolation room.

Contraindications for the Blood Borne Virus Screening at UHBFT Renal Unit

BBV screening must not be undertaken if the patient:

- Refuses to consent for BBV screening (consent is verbal but must still be documented)
- Patients who lack capacity will be treated as per 'best interests'.

3. Management of Specific Groups of Patients

Patients starting on haemodialysis

Refer to Appendix 3– BBV management of patients starting on haemodialysis in the accompanying document 'Protocols for blood borne virus screening, prevention and management of renal patients under the care of UHBFT renal services'.

Patients returning from dialysis in Renal Units outside of the UK

Management and surveillance of these patients are outlined in Appendix 4. Management and surveillance are dependent on whether the patient has dialysed in a high or low risk area.

Low Risk Countries	High Risk Countries
UK/Ireland Belgium/France/Germany/Netherlands Italy/Spain/Portugal/Greece Sweden/Norway/Denmark/Luxembourg North America (USA and Canada) Japan Australia / New Zealand	All other countries not listed in the low risk group are considered 'high risk'

For patients, who have returned from dialysing in high risk areas, results must be recorded on the 'Holiday Returner Flowchart' - Appendix 5

Patients receiving other extra corporeal treatments provided by the renal team at UHBFT

Patients receiving other extra corporeal treatments such as lipid removal or plasma exchanges will also require initial BBV screening at the start of treatment plus three monthly screening as standard. Any visits to 'high risk' countries as above must be risk assessed accordingly, discussed with BBV lead and documented in the patient's notes.

Patients that require dialysis (and/or other extra-corporeal treatments) that already have positive BBV results from other hospitals, where there is no subsequent 'in-date' current negative result from UHBFT laboratories

In this case the patient and machine must be isolated on "for sole use only machine". If the repeat sample is then negative this must be discussed with the Matron for ERF and BBV Chair lead and a risk assessment performed to decide how and where the patient is to be treated.

4. Management of Blood Borne Virus Infected Patients

If a new positive result (suggesting active infection) is received - HBsAg positive, HCV Ab positive, HIV Ab positive, HCV RNA +ve, the patient must be referred immediately to a consultant nephrologist (and preferably the BBV lead consultant and matron for established renal failure) who will advise on further assessment, counselling and treatment as appropriate.

Where possible for patients with active BBV with an AVF/G requiring the insertion of fistula needles, best practice would be to use safety AVF needles (or blunt for button hole needling).

HBV Positive (HBsAg)

Patients infected with HBV must be segregated from non-infected patients. This must be managed using a single isolation room facility (or in exceptional circumstance, only after discussion with a consultant nephrologist, a separate area designated for HBV infected patients). This area should not be used as a walk through area or contain other shared equipment. A dedicated hepatitis B machine must be used for patients known to be infected with HBV and labelled as permanently isolated, according to the isolation and de-isolation processes (appendix 6-8). The dedicated machine must be clearly labelled for the purpose. This machine can be shared between patients known to be HBsAg positive.

If a HBV infected patient requires dialysis during the on-call service at UHBFT, where possible, a second nurse should support the delivery of this dialysis in the dedicated HBV (room 29 Ward 301 at Queen Elizabeth Hospital). Where this is not possible, an alternative plan must be discussed and agreed with the on-call consultant for a similar suitable environment. If the dedicated HBV room is not used, the area where the patient was dialysed must be thoroughly cleaned according to UHB policy, before being used by any other patient.

Only experienced, competent dialysis nurses (these are nurse with BBV training competencies in-date – within 12 months) with adequate immunity should treat HBV infected patients. Such staff should be allocated to care for the infected cohort of patients ONLY whilst on duty and must not **under any circumstances** care for non-infected patients during the same span of duty. Staffing levels on the unit should reflect this requirement.

HCV and HIV

Patients infected with HCV and HIV are to be cohort managed and ideally cared for by an experienced competent dialysis nurse assigned to only care for those infected patients during the same span of duty. Patients must be dialysed in a designated area separate from non-infected patients. There is no need for dedicated machine use for HCV and HIV patients, unless local custom states such infected patients are to be treated on dedicated

machines (as it is for patients treated within ward 301 at Queen Elizabeth Hospital). Where local decontamination of equipment policy is approved as adequate, (approved by UHB renal service), no dedicated HIV or HCV machines are necessary. This variance must be approved and documented by UHB Trust.

Patients considered High Risk (eg holiday returners/new emergency patients requiring haemodialysis)

These patients are considered extremely high risk due to their unknown and unpredictable status.
These high risk patients must be treated on a machine for their sole use, and dialysed separately from both infected and non-infected patients. Ideally this is within a single room cared for by experienced competent dialysis nurses who do not care for other non-infected patients during the same span of duty.

For all holiday returner patients classified as high risk: if the patient returns directly to their base unit, the base unit dialysis nurses must inform (by telephone and email) the Satellite Liaison Team (hdsatelliteteam@uhb.nhs.uk) and ward 301 acutes. This will ensure UHBFT are prepared should the patient suddenly require admission to QEH. Ward 301 and the acute Consultant on-call will risk assess all new to QEH, dependant on where they last dialysed.

Machine allocation for all haemodialysis patients

As UHB Renal services care for a large population of hepatitis B core antibody (HBcAb) positive patients (who may reactivate their Hepatitis B viraemia), and because health care professionals have no insight into the social activities of patients in-between their dialysis sessions, best practice is to reduce the number of patients that use any given machine and movement of machines around a clinic / ward. Ideally each dialysis machine should be shared between a maximum of 6 patients per week (for non-named / non-sole use machines) and a patient's dialysis should be performed on a maximum of two machines per month. This reduces exposure of patients to unknown infected patients.

When patients are not treated on their expected / allocated machine this must be logged with the reasons why and audited. A machine that is out of service, once ready for use, should be returned to the same dialysis station. A robust machine numbering system is necessary to assist in the easy identification of machines and their movement.

For patients known to renal services who undergo dialysis in ITU at QEHB, where possible the on-call machine or machine regularly used on this patient are the only machines that should be transferred to ITU. Once the treatment and disinfection is complete, this machine must be returned immediately to 301 machine store. Only if the patient is in strict isolation (preventing equipment being removed from the room) can the dialysis

machine stay by the bedside until it is safe to remove. In such cases of strict isolation, following external and internal disinfection the machine may remain in the room during the "chemical de-misting" process before returning to 301 machine store

Due to the unpredictability of inpatients requiring dialysis, ward 301 acutes are not able to comply to the same regular machine allocation. Thus every patient dialysis machine number, station number and nurse are recorded for audit purposes.

5. Isolation and de-isolation of dialysis machines used to treat patients considered to be High Risk

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Isolating the dialysis machine for the sole use of:

A dialysis machine must be isolated for sole patient use for any patient dialysing under the care of UHB (either in hospital or at a partner organisation satellite dialysis unit) for any of the following reasons:-

- There are no results for hepatitis B, C, or/and HIV within the last three calendar months
- The patient has just returned from a high risk country where they received dialysis or other medical treatment (if new to dialysis) (as listed in section 3 above)
- The patient's most recent BBV result is an equivocal positive BBV result whilst confirmatory testing is performed.
- The patient's lifestyle is assessed to be socially 'high risk', and considered potentially harmful to other patients and staff. (As agreed by the ward manager and consultant and documented in the patient's records and in MARSII)
- The patient is known Hepatitis B core Ab positive and bloods for Hepatitis B surface Ag are more than one calendar month out of date (appendix 9).
- The patient from another country requires haemodialysis within UHBFT or associated satellite units, and the last BBV results are within one month, but details of the patient's last dialysis are unknown.

Machine storage

Isolated machines must be stored separately from non-isolated machines.

- When a patient is considered to be high risk to the remaining dialysis population, a dialysis machine will require temporary isolation for the sole use of and appropriate labelling
  See appendix 6 and 8

- When a patient or infected cohort group is classified as requiring a permanently isolated machine (which must also be appropriately labelled)
  See appendix 7 and 8

6. Staff Competence

All new nursing staff, including those employed within partner organisation satellite dialysis units, will, during induction, receive training on BBV risks and care of patients as per this procedure and the accompanying protocol document. A learning pack and competency document must be completed and passed as evidence of their knowledge. This competency will be repeated annually by all nursing staff in a manner agreed by the BBV Standing Committee Chair and Matron for Established Renal Failure

Nurses dialysing high risk / cohort infected patients must be "experienced" dialysis nurses, who have achieved competencies in BBV risks and care within the last 12 months.

BBV screening may be performed by registered nurses or medical staff working within the renal specialty who have received the appropriate education and training as recognised by the Matron and Clinical Service Lead for Haemodialysis.

The registered nurse and medical staff must have a working knowledge of the UHB policy and procedural document for consent to examination and treatment (2013) or local consent policy.

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i. Evidence of competence must be provided and a copy kept in the registered nurse's personal file and in the ward or department where the skill is practised

ii. Registered nurses new to Trust / partner organisation caring for UHB dialysis patients, who have been performing the skill elsewhere, must read and understand this procedure and be signed off as competent before performing the skill. Evidence of appropriate education and competence must be provided and checked by the line manager before undertaking this procedure, including any agency or bank support staff

iii. In accordance with codes of professional practice, the registered nurse has a responsibility to recognise, and to work within, the limits of their competence. In addition, the registered nurse has a responsibility to practise within the boundaries of the current evidence based practice and in line with up to date Trust local and national policies and procedural documents. Where specified, annual competencies must be completed ideally before the staff's annual appraisal process, to ensure compliance with the role and to identify any learning needs.

iv. A list of the registered nurses competent to perform these skills must be kept by their line manager.

v. Training or competency shortfalls that could affect the safety of patient

care delivery must be highlighted to the Trust Clinical Service Lead for Haemodialysis and Matron for Established Renal Failure.

7 Audit of the Procedure and Protocols

For the Trust, the Professional Development Lead Nurse in renal will lead the audit of the procedure with support from the Practice Development Team. The dialysis care partner organisations will similarly audit procedure and adherence and present to the Trust when requested. Audit will include:

- Full adherence to the procedure and protocols and any other relevant Trust guidelines
- Full RCA of any untoward incidents or complaints.
- The number of registered nurses competent to perform BBV screening.
- Timely performance of Hepatitis B Vaccinations
- The numbers of RNs and dialysis health care assistants with in-date competencies in BBV risks and care

All audits will be logged with the Risk and Compliance Unit.

8. Clinical Incident Reporting and Management

Any untoward incidents and near misses should be dealt with by the appropriate management team (local management team, Trust consultant nephrologist, Lead for Haemodialysis, Matron for ERF, BBV Standing Committee Chair and Clinical Service Lead for Renal Services). An incident form must be completed and in addition the Risk Management Team must be notified by telephone of any Serious Incidents Requiring Investigation (SIRI).

9. Management of Unexpected BBV Sero-conversion on a Dialysis Unit

Unexpected BBV sero-conversion of an existing haemodialysis patient is a critical Serious Untoward Incident and should be notified immediately to consultant nephrologist responsible for the unit who should inform immediately the BBV Standing Committee Chair and Matron for Established Renal Failure.

Sequence of actions

i. Confirm result

Consultant to inform Renal BBV Standing Committee Chair, Clinical Service Lead (CSL) and Consultant Virologist.
Consultant Virologist to guide urgent reference laboratory confirmation on existing sample and request repeat sample sent for confirmation including EDTA samples for PCR.

ii. Lead Consultant (usually Renal BBV Standing Committee Chair or CSL) to lead investigation if a new episode or unexpected BBV seroconversion confirmed. The investigation must commence within 24 hours of the result being confirmed.

iii. Immediate actions

Communication Brief

i. CSL or nominated deputy to inform:

- Divisional Medical Director
- Divisional Director of Operations/Renal Business Manager
- Trust Clinical Governance
- Trust Medical Director
- Clinics manager and Medical Director of dialysis partner organisations
- UHB Consultant Nephrologists
- Senior Renal Nurses
- Clinical Directors of relevant Trusts, if BBV seroconversion occurs at a unit where patients from other Trusts have also dialysed.
- Director of Infection Prevention and Control who will inform Public Health England

ii. Incident Team to be formed by BBV Standing Committee Chair and should include:

- Clinical Service Lead
- Relevant Consultant Nephrologist
- Consultant Virologist
- Matron for Established Renal Failure
- Senior Renal Nurses

- Group Manager
- Trust Governance Lead
- Senior Nurses at relevant satellite units
- Dialysis Partner Organisation managerial staff (where relevant)
- Appropriate CCG
- Infection Control (where relevant) etc

- Designated Public Health England representative

iii. Close involved unit to new patient transfers until further notice (Action: Clinical Lead).

Identify all patients potentially exposed with most recent BBV status.

iv. Refer to Action plan and resources held in Renal Common Directory on management of unexpected BBV seroconversion.

v. Review relevant NHS England (DH) document and latest RA BBV control documents.

vi. Communicate information to potentially affected patients involving UHBFT Communication Team

10. Terminology used throughout the procedure

Dedicated / for sole use (machine) – this dialysis machine has been identified for the sole use of the patient as named on the machine label

Isolated – this is when a patient is treated in an area / room away from other patients. This area must also not be used as a walk-through. A physical barrier (walls / screens) must divide and separate clean from infected areas. An isolated patient tends to be treated / cared for alone eg side room.

Patient Cohort – this is when an identified group of patients are treated together in a group. This group of infected or high risk patients (of a specific BBV) should ideally have physical barriers to separate them from non-infected patients.

Cohort machine - this is when one identified dialysis machine is used for a specific identified group of patients.

Antigen - a foreign substance in the body such as the hepatitis B or C virus. The presence of antigen indicates the presence of an infection either new or old

Antibodies - a protein that the immune system makes in response to a foreign substance. For BBV, antibodies are produced in response to a vaccine or to an infection. Some antibodies can protect against future infections.

HBsAg (hepatitis B surface antigen) – this test identifies whether the HBV is present or not identifying whether a patient is currently infected and infective. This may be as an acute or chronic infection

HBcAb (hepatitis B core antibody) – this test identifies the patient has produced an antibody to the HBV from either a present or past infection. Whilst providing some "self" immunity these patients are very unpredictable and could sero-convert to again becoming HBsAg positive and thus infective without warning.

Anti-HBs (hepatitis B surface antibody) – this test tells us that the patient has either:

i. had a successful response to the Hepatitis B vaccination **OR**
ii. that the patient has recovered from an acute HB infection and produced their own immunity as protection to further infection

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University Hospital Birmingham NHS Foundation Trust *Protocols For Blood Borne Virus Screening, Prevention and Management of renal patients under the care of UHBFT, Renal Services (2014)*

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