Worcestershire Acute Hospitals NHS Trust

Prevention and Control of Blood-borne Virus (BBV) Infections In the Haemodialysis Unit

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

INTRODUCTION

Patients receiving haemodialysis are a particularly high risk group for blood-borne virus (BBV) infections. This is because of repetitive access to the vascular system. Since the Rosenheim Advisory Group issued good practice guidelines to prevent the transmission of hepatitis B in 1972, new BBV's have emerged such as hepatitis C (HCV) and human immunodeficiency virus (HIV). This has since prompted further investigation into understanding such diseases in order to develop effective evidence based systems and protocols to reduce the transmission of all health care associated infections (HCAI) to patients and staff

THIS GUIDELINE IS FOR USE BY THE FOLLOWING STAFF GROUPS:

Although this guideline was developed for staff and patients within the haemodialysis environment, the detail enclosed can be utilised in most all environments where there is a risk of BBV transmission. Doctors, students, relatives, visitors and any person visiting or working within the haemodialysis environment are responsible for following all infection prevention policies and likewise must adhere to this guideline.

Lead Clinician

Liz Wittich	Lead Nurse – Renal Services
Approved by Renal Specialty Meeting on:	27th February 2023
Review Date: This is the most current document and is to be used until a revised version is available	27th February 2026

Key amendments to this guideline

Date	Amendment	By:
27.03.12	Extended for three years. No changes made.	Dr M Ferring
06/08/15	Document extended for 12 months as per TMC paper approved on 22nd Jul 2015	TMC
17/08/16	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
August 2017	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
December 2017	Sentence added in at the request of the Coroner	
June 2018	Document extended for 3 months as per TLG recommendation	TLG
January 2020	Document extended for 3 months whilst undergoing approval process	Dr Martin Ferring
15th December 2021	Document extended for 6 months to allow for thorough review	Specialist Medicine Divisional Governance
17th March 2022	Document extended until the end of the year to allow for thorough review	Dr Jasper Trevelyan
Dec 2022	Document reviewed and no amendments required	

Prevention and Control of Blood Borne Virus Infections in the Haemodialysis Unit
(Guideline)

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INTRODUCTION

Patients receiving haemodialysis are a particularly high risk group for blood-borne virus (BBV) infections. This is because of repetitive access to the vascular system.

Since the Rosenheim Advisory Group issued good practice guidelines to prevent the transmission of hepatitis B in 1972, new BBV's have emerged such as hepatitis C (HCV) and human immunodeficiency virus (HIV). This has since prompted further investigation into understanding such diseases in order to develop effective evidence based systems and protocols to reduce the transmission of all health care associated infections (HCAI) to patients and staff. As changes and development in dialysis technology have evolved so has the learning on disease. The Renal Association – Blood Borne Virus Guideline (2009) and the Department of Health Prevention Good Practice Guidelines for Renal Dialysis / Transplantation, Prevention and Control of Blood-borne Virus Infection (2002) have published recommendations on precautions to be taken by all renal units.

The Health Act 2006: Code of Practice for the Prevention and Control of Health Care Associated Infections requires effective systems and evidence based protocols to be embedded in everyday clinical practice to minimise the risk of health care associated infections (HCAI). The term HCAI, includes BBV infections as well as any other bacterial or viral infection and requires 100% compliance to preventative protocols, to ensure no patient or staff acquire such infections as a result of poor practice and lack of adherence to policies.

Reminder on Blood-Borne Viruses

Hepatitis B

Is an infectious liver disease. Entering via the blood stream, the hepatitis B virus attacks the liver. Once in the liver it reproduces releasing large volumes of the virus. In an attempt to destroy the virus, the body develops antibodies which result in the patient being known as a carrier, as they stay 'silently' infected for life. The incubation period can be between 45 – 180 days. Survival of the HBV outside the body on surfaces is known to be 7 days and longer in some studies, labelling it as a very high risk environmental disease. Hepatitis B vaccine will protect those who are negative for the disease, so long as they regain adequate levels of immunity (>10 – 100 mIU/ml). The level of immunity from vaccination is measured as HBs antibody titre levels. Hepatitis B surface antigen (HBsAg) is the test, which determines whether a person is negative, or not to the disease, however early in the infection this antigen may not be present. It may be that virology need look for core antigen rather than surface.

Hepatitis C

Is also an infectious liver disease which enters via the blood stream, attacking the liver. In the UK it is thought that around 200,000 people are affected but unaware. This is because it often lays dormant for decades, before erupting and producing symptoms. Detection of the disease is by looking for antibodies for HCV but can take up to 3 months from contracting the infection to being detected. This is because detection of this very changeable virus is difficult to confirm and can clear itself in 20-40% of people. Confirmation of earlier infectious episodes can only be verified by HCV RNA. A positive antibody and negative HCV RNA indicates infection but is not immunity to further infections. Unlike HBV, there is not a preventable vaccination available, this is because of its complex structure. However survival of the virus outside the body is only between 16 hours and 4 days.

HIV

HIV attacks the immune system, providing opportunist situations for infections to develop. Transmission is via the blood stream and other bodily fluids. Most people infected with HIV develop AIDS, due to their vulnerability to increased infections. HIV develops in four stages, with an incubation period of between 2-4 weeks, an acute infection stage of around 28 days, the third stage can last two weeks to twenty years, before progressing finally into AIDS. There is no protective immunisation against HIV or AIDS. The virus however does not survive outside the body, unlike other BBV's.
Universal precautions is the first line of defence against any of these conditions.

DETAILS OF GUIDELINE

The patient receiving haemodialysis is in an environment, which provides repeated opportunities for the transmission of infection of any kind from patient to patient, either directly or indirectly via contaminated dialysis equipment, consumables, devices, work surfaces, accidental bleeds and staff. All blood must be regarded as a potential risk of infection and strict cross infection precautions must be adhered to. Non-compliance to these protocols and polices will result in disciplinary actions.

Preventing the spread of BBV's within the haemodialysis environment is more than just complying to hygiene infection prevention. Being aware of all the patients virology status and knowledge of patient movement within the unit, means safe plans are to be arranged to minimise risk. Regular testing for hepatitis B (HBV), hepatitis C (HCV) and HIV will provide information, so the segregation of positive and negative patients can be followed. A patient could dialyse on twelve different machines in one month, providing the opportunity (if positive) to transfer a BBV to the 60 other patients that could be treated on that machine. (This is based on three shifts per day). Patient movement must be restricted to the same machine and station to be used by the same patient each time they attend, reducing any risk to only five other patients. Movement must be restricted to a maximum of three machines per patient use per month, any non-conformance will instigate a root cause analyse to determine why this breach has occurred. Documented evidence of in-between patient machine and station cleaning must be kept to ensure consistent hygiene policies are followed.

Patients returning from dialysing outside the UK and from areas regarded as high risk, must be informed before their departure that they will be nursed in segregation on their return and will be monitored closely for a minimum of three months. If they remain negative then they will return to dialysis within the main unit, but if sero-conversion takes place then they will continue to dialysis in a cohort or isolation.

Ensuring all patients are immunised and found to have adequate levels of protection against hepatitis B will help reduce risk further. However HCV and HIV still remain high risk.

Staff and any personnel handling blood or working in the environment have a duty and responsibility to ensure they also have adequate protection against HBV and that they wear the necessary personal protective equipment (PPE) at all times.

MONITORING TOOL

Records will be kept of all patients BBV status. Audits will ensure PPE is worn at all times and that guidelines and polices are followed and adhered to. Cleaning records of equipment will be kept for audit and checking purposes. All staff have a duty of responsibility to ensure they do not put patients or others at risk. Non-compliance will provoke an investigation and disciplinary action where the person will be judged as to their capability and whether they should be re-deployed to a lower risk environment.
The renal matron will be monitoring and ensuring compliance is followed.

STANDARDS	%	CLINICAL EXCEPTIONS
Complete compliance to all infection control measures.	100	None

OBJECTIVES OF THE GUIDELINE

The guideline will be divided into sections which are also the objectives:

1. Preventative Measures
2. Routine BBV Infection Testing
3. Surveillance programme for patients returning from Dialysing in High Risk Areas
4. Management of BBV Infected Patients
5. Actions to be taken as a result of a BBV Infection Outbreak

GUIDELINE STEPS

1. Preventative Measures

Immunisation against HBV is recommended for patients on dialysis. Evidence has found that patients with chronic kidney disease that are immunised early before they require dialysis or a transplant, have an improved chance of sero-conversion and protection (Beran 2008)

All patients must be regarded as potentially infectious, as protection is only available for HBV. A programme of surveillance of all BBV's for all patients will reduce the risk and unlikely spread of infection. However, because there is the possibility that a patient could unknowingly be positive, consent and counselling is required before sampling can be performed. Refusal to consent will result in the patient being cared for in isolation, from both negative and positive others. Any changes to a patients BBV status, must be reported to the renal matron and parent hospital Consultant.

All new patients to haemodialysis should be tested for:

New patients	Test
	Hepatitis B surface antigen (HBsAg) Hepatitis B core antibody (anti-HBc) Hepatitis C (HCV) HIV

The patient's BBV status must be known before they commence dialysis (and be taken within one month of starting). In the case where the patients status is unknown, the patient must be dialysed on a dedicated machine for the named patient only, until their status is known, in a segregated area. If negative, the patient can be dialysed in the main unit. If positive the patient will remain in isolation on the appropriate designated machine for that virus. The initial dedicated named machine cannot be used until appropriately decontaminated and the process recorded. In all cases the machine number must be recorded at each dialysis session.

Excellent communication between all staff caring for at risk patients is vital in ensuring further risk is reduced. The movement of patients between dialysis machines must be restricted to a maximum of three per month. When an alternative machine is used this must be recorded on the Machine Swap Log and where three or more machines are used during a one month period then a root cause analysis conducted.

2. Routine Blood Borne Infection Testing

Patients receiving maintenance haemodialysis should be tested routinely for hepatitis B surface antigen (HBsAg) and HCV antibody every three months. However, patients

identified as hepatitis B core antibody positive (an antibody to the hepatitis B core antigen) (abbreviated as HBcAb or anti-HBc) on initial screening must be tested monthly for HBsAg. Routine three monthly BBV testing will be undertaken in all other patients. Any changes in a patients status must be reported to the renal matron and parent hospital and an action plan initiated.

3. Surveillance programme for patients returning from Dialysing in High Risk Areas

Although such countries as Spain have a high prevalence of HCV, and the USA for all BBV's, because of their clear hygiene policies and regulated safe treated water for dialysis, these countries are regarded as low risk. However there are many countries which because of poor hygiene conditions and lack of regulation are regarded high risk of acquiring BBV infections. The Indian subcontinent, sub-Saharian Africa, Caribbean and south central America, Middle East, south east Asia and eastern Europe would be regarded as high risk countries. Patients should be advised and given information about the risk of BBV before going abroad. Testing for HBsAg, HCV and HIV antibody should occur before travelling.

Patients returning from dialysis abroad should be tested and found negative for HBsAg, HCV antibody and HCV RNA before dialysing in the main unit cohort. HIV is retested on a risk assessment basis. For those considered to be a potential risk of BBV, then increased surveillance should be initiated and the patient be dialysed on a dedicated named machine in a separate area for the period of time.

Increased surveillance	Intervals	Surveillance time
HBsAg	monthly	3 months (minimum)
HCV (antibody)	fortnightly	3 months (minimum)
HCV RNA	As required	Beginning and end of surveillance

After three months if all results are confirmed negative the patient can stop using the dedicated machine and return to main cohort of patients. If positive then the patient will remain segregated and further plans arranged on an individual basis.

4. Management of Blood-borne Virus Infected Patients

HBV
Patients infected with HBV must be segregated from non infected patients. This must be managed by using a single isolation room facility or a separate area designated for HBV infected patients. This area should not be used as a walk-though area or contain other shared equipment. A dedicated hepatitis B machine must be used for infected patients. The dedicated machine will be clearly labelled for the purpose. Only staff with adequate immunity and experience in caring for dialysis patients should treat HBV infected patients. Such staff should only care for infected patients and not mixtures of non and infected at the same time.

HCV and HIV
Patients infected with HCV or HIV are to be segregated by the use of designated areas separated from non-infected patients. There is no need for dedicated machine use for either HCV or HIV patients, so long as correct local policy decontamination and disinfection of all equipment and machinery is followed and documented. Again more experienced staff should care for patients with any BBV and should be assigned to only care for either infected or non-infected during their shift.

Patients with a BBV remain susceptible to other BBV infections. To avoid the risk of further infection, dialysis schedules are best planned so that patients with different infections are not dialysed together in the same shift, and are in a cohort from those that are negative.

5. Actions to be taken as a result of a BBV Infection Outbreak

Whenever a transmission of HBV, HCV or HIV infection is suspected within an area, immediate precautionary measures are to be taken to prevent further spread. Immediate arrangements should be made for the infected patient to be dialysed in a designated segregated area and should be cared for by experienced designated staff. A dedicated named machine will need to be identified and made available for that patients use only for the period of the surveillance.

When a previously unknown case of HBV infection is identified, weekly HBsAg testing should be initiated immediately for the expose cohort. (This is all the patients that have shared the same machines as the infected patient and on the same dialysis shift since the patients last negative result.)

Patients that do not have natural immunity or anti-HB titre levels less than or equal to 10mIU/ml should be included in the weekly HBsAg testing programme. Patiens with anti-HB levels between 10mIU/ml and 100mIU/ml should be given a booster dose of hepatitis B vaccine. Patients with natural immunity or who have had anti-HB levels of greater than 100mIU/ml in the previous 12 months need not be included in the enhance surveillance as they are regarded as not at risk.

In the case of HCV or HIV is found a PCR test should be taken on patients who have been exposed to the infection during the dialysis sessions (ie, shared the same machine or dialysis session with the infected patient).
Summary of actions for an outbreak

HBV	The exposed cohort should be identified and their immunisation status established. Those patients with anti-HB levels less than 10mIU/ml should be included in the enhanced surveillance programme and be tested weekly for HBsAg for 3 months after the last exposure to the index patient.
HCV	The exposed cohort should be tested for HCV RNA by PCR at fortnightly intervals until 3 months after the last exposure to the index patient.
HIV	A risk assessment should be undertaken. Consideration should be given to HIV RNA testing of the exposed cohort.

REFERENCES

Beran, J. Stage of chronic kidney disease predicts sero-conversion after hepatitis B immunisation, *American Journal of Kidney Disease; vol42, issue 6, pp1184-1192*

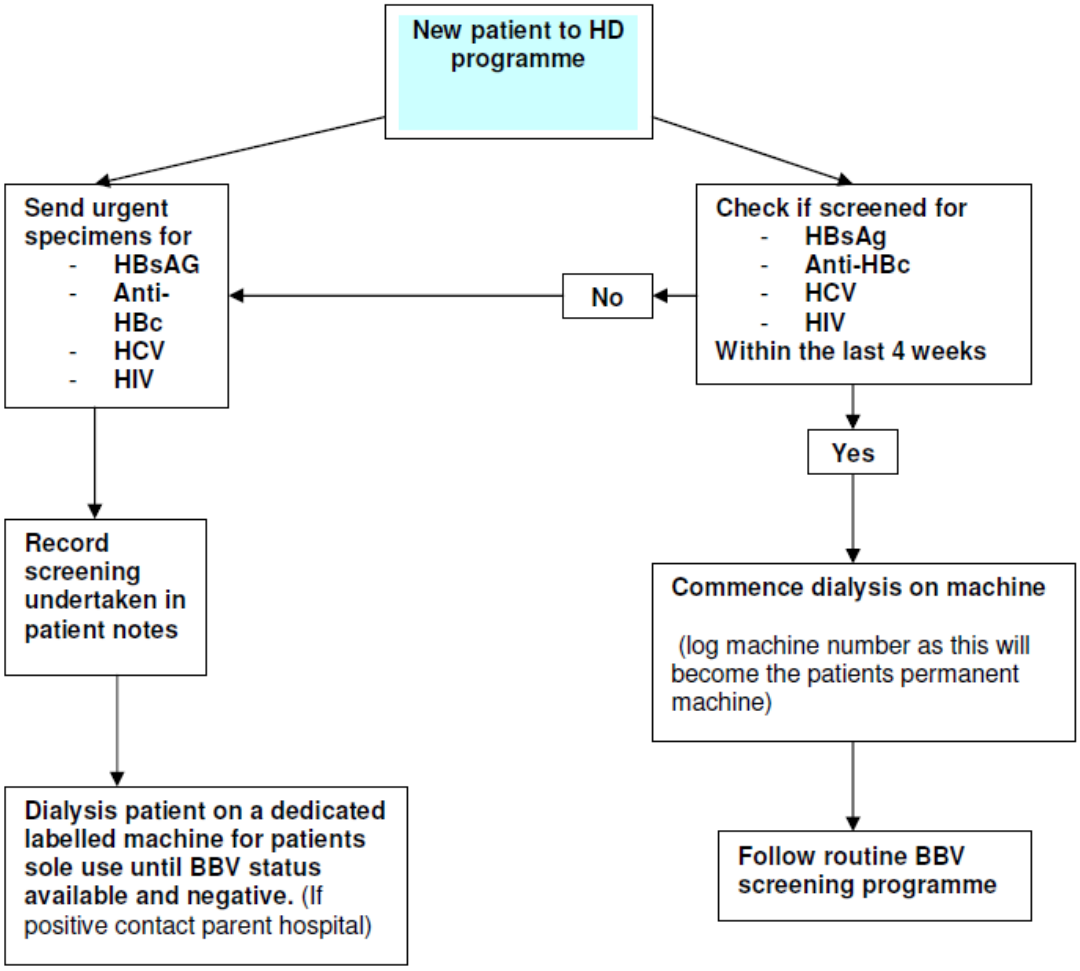
Department of Health (2002). *Good practice guidelines for renal dialysis/transplantation units – prevention and control of blood-borne virus infection.* London: DH 2002

Department of Health (2006). The Health Act 2006. *Code of practice for the prevention and control of health care associated infections.* London: DH 2006

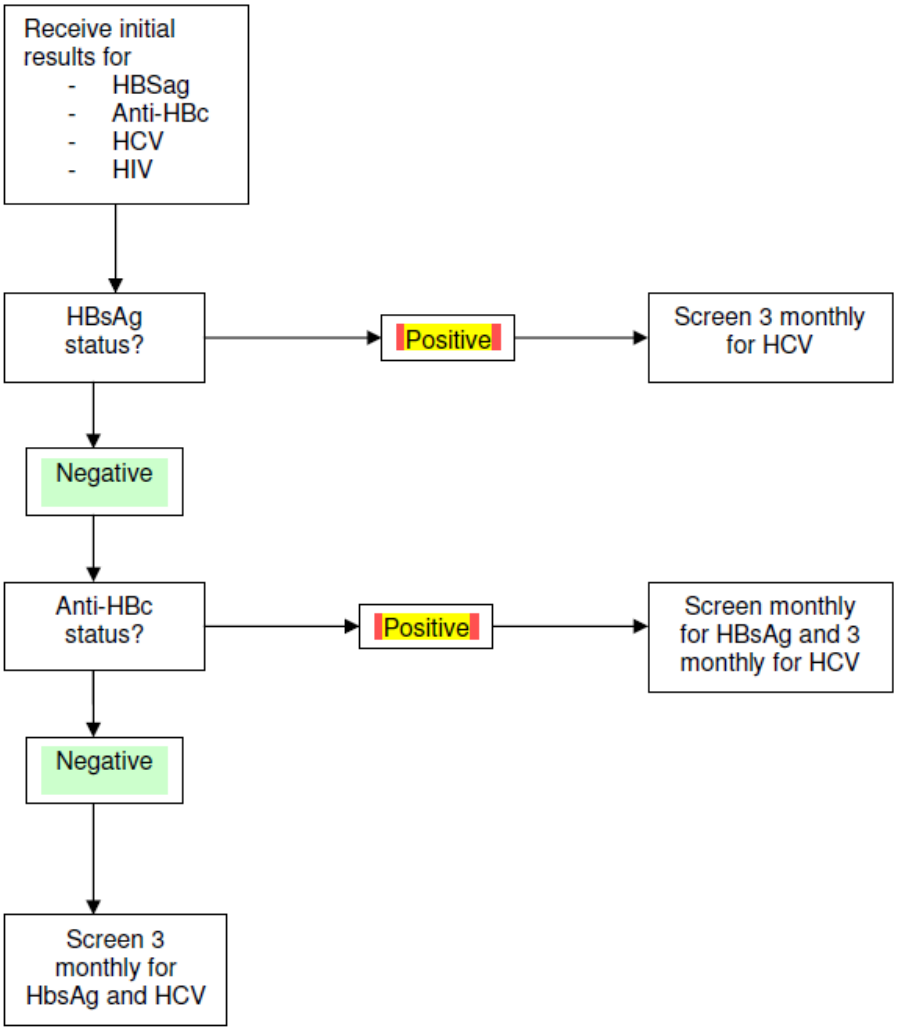
The Renal Association. *Blood-borne Virus Infections.* 2009

Appendices

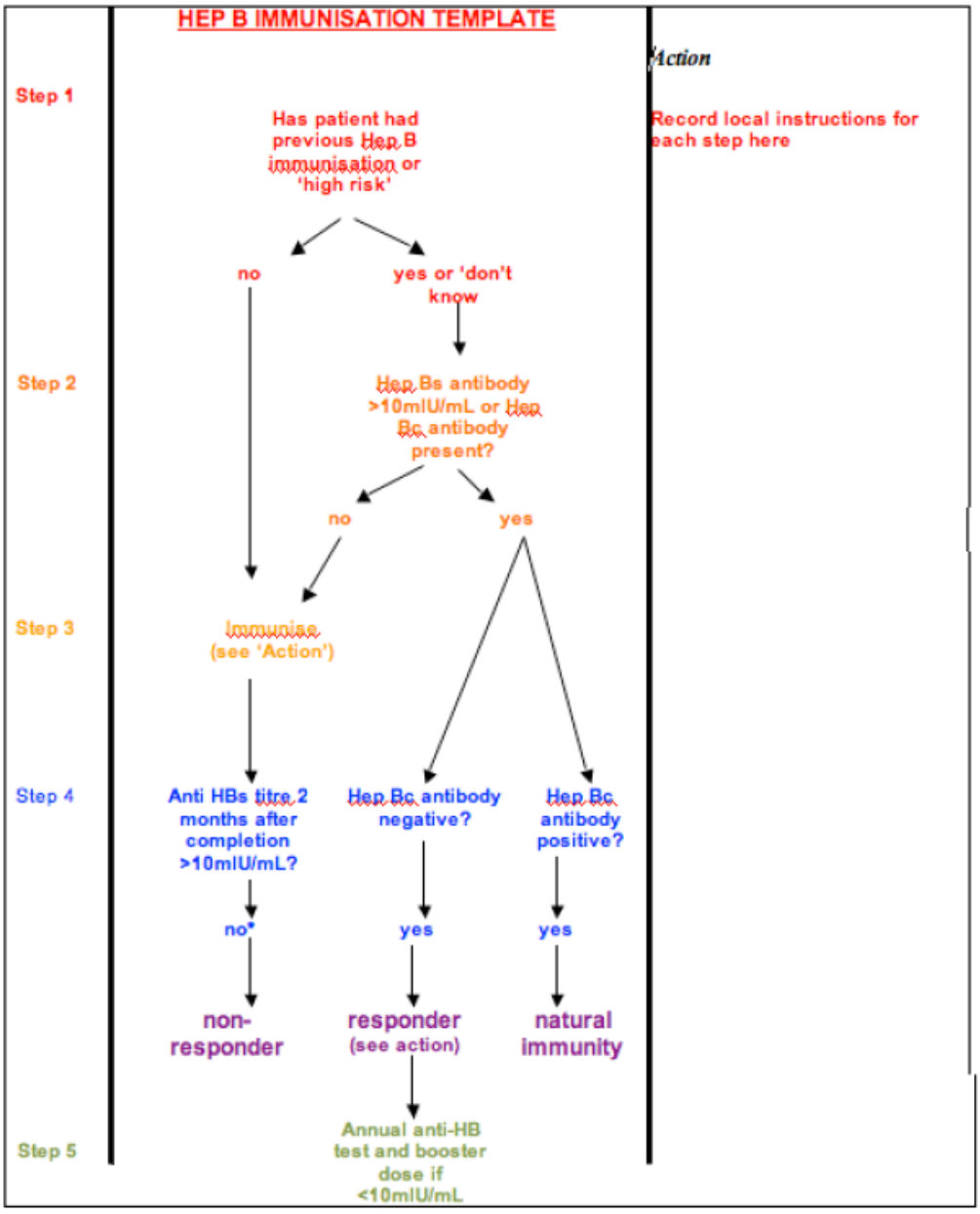
New patient commencing haemodialysis (HD)



Routine BBV Screening



HBV immunisation



CONTRIBUTION LIST

Key individuals involved in developing the document

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Circulated to the following CD's/Heads of dept for comments from their directorates / departments

Name	**Directorate / Department**

Circulated to the chair of the following committee's / groups for comments

Name	Committee / group

Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the Policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust		Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
Date assessment completed			

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:**			
What is the aim, purpose and/or intended outcomes of this Activity?				
Who will be affected by the development & implementation of this activity?	❑ ❑ ❑	Service User Patient Carers	❑ ❑ ❑	Staff Communities Other _____

	❑	Visitors	❑	
Is this:	❑ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.				
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)				
Summary of relevant findings				

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age				
Disability				
Gender Reassignment				
Marriage & Civil Partnerships				
Pregnancy & Maternity				
Race including Traveling Communities				
Religion & Belief				
Sex				

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation				
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)				
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the

diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.
1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	
2.	Does the implementation of this document require additional revenue	
3.	Does the implementation of this document require additional manpower	
4.	Does the implementation of this document release any manpower costs through a change in practice	
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.