Department of Health

Good Practice Guidelines for Renal Dialysis/Transplantation Units

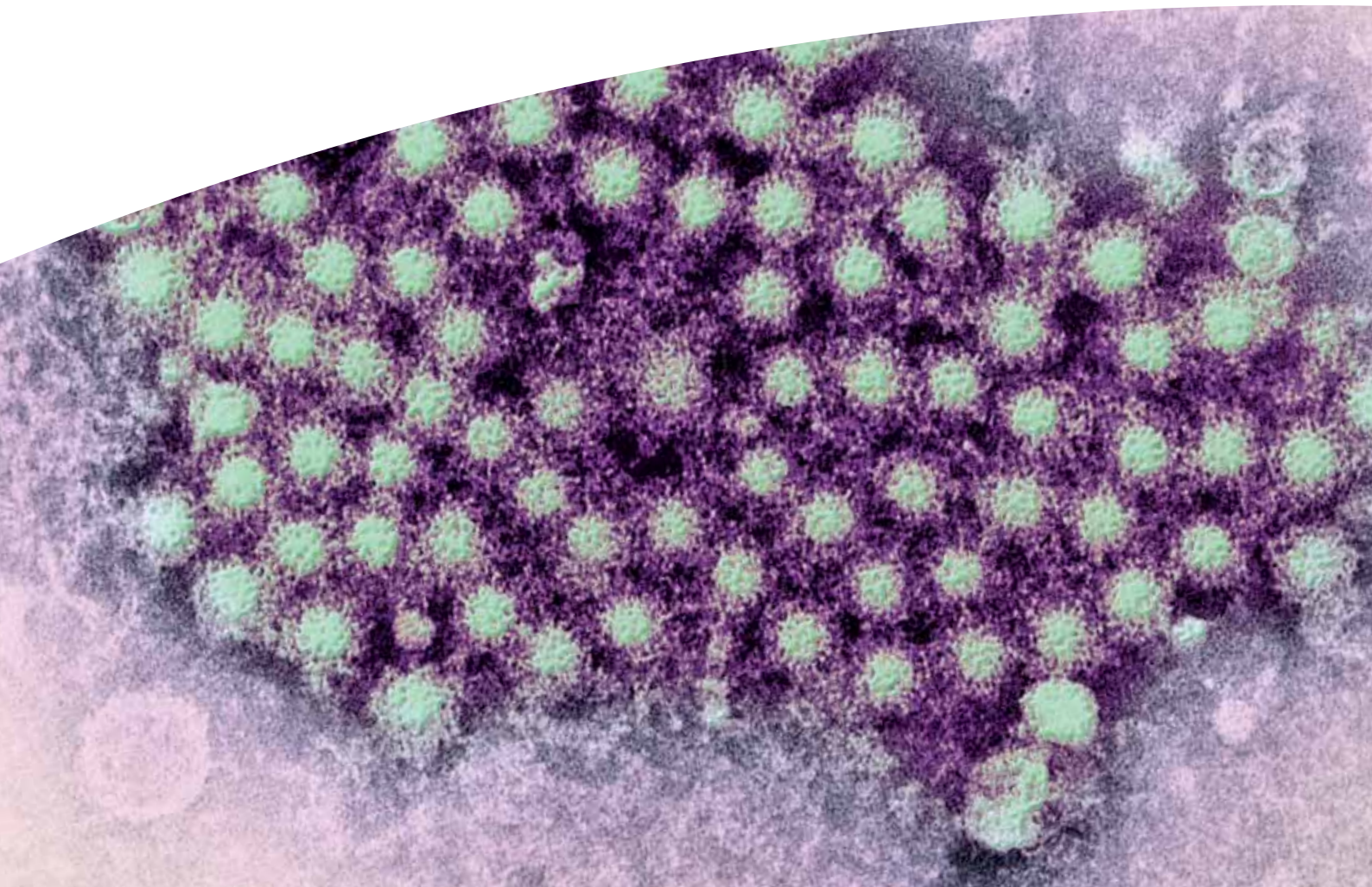
Prevention and Control of Blood-borne Virus Infection

Addendum

Guidelines for dialysis away from base (DAFB)

Recommendations of a working group convened by the Department of Health

October 2010



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The working group was set up to clarify good practice recommendations from the Department of Health's September 2002 guidance, *Good Practice Guidelines for Renal Dialysis/Transplantation Units: Prevention and Control of Blood-borne Virus Infection* on dialysing away from base and to produce a user-friendly pathway for renal units.

Preface

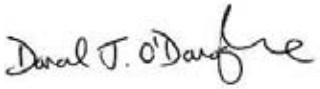
This addendum to the Department of Health's (DH's) *Good Practice Guidelines for Renal Dialysis/Transplantation Units* recognises that mobility and the opportunity to travel for business or personal and recreational purposes are key factors contributing to an enhanced quality of life for patients living with chronic kidney disease who require dialysis. The ability to travel within the UK and abroad is generally taken for granted by the majority of people, but people receiving dialysis face not only physical and psychological issues but also organisational and institutional barriers that make travel more difficult. *The National Service Framework for Renal Services*, Standard 1, states that 'all children, young people and adults with chronic kidney disease are to have ... an agreed care plan that supports them in managing their condition to achieve the best possible quality of life'. People receiving dialysis need to be able to fulfil professional and family commitments and to have opportunities for holidays and relaxation away from home if they are to live as full and healthy lives as possible.

This addendum has been produced as a framework for a safe and regulated approach to travel; it is not overly restrictive but provides a balance between an individual's need and wish to travel and the measures needed to protect them and other patients and staff in dialysis units from the risk of blood-borne virus infections. It also recognises that lifestyle factors posing a risk of blood-borne virus infection are not solely associated with travel and need to be taken into account in all patient care plans.

This addendum includes two algorithms: Algorithm 1 is for use in dialysis units with access to laboratories using standard testing methods and Algorithm 2 for laboratories with access to modern sensitive testing methods able to provide a quick turnaround of tests.

This addendum should help units to implement policies for dialysis away from base that impose as few restrictions on people receiving dialysis as are consistent with good clinical practice. They should provide protection for the travelling patients, other patients dialysed in the unit and the staff delivering the care.

Dr Donal O'Donoghue
National Clinical Director Kidney Care, DH



Professor Brian Duerden CBE
Inspector of Microbiology and Infection Control, DH

Polly Moseley
DH Renal Advisory Group, Patient

Algorithm 1

Dialysis away from base (DAFB) – Recommendations for immunisation against hepatitis B virus (HBV) and tests for HBV, hepatitis C virus (HCV) and human immunodeficiency virus (HIV)

Before DAFB in the UK

Confirm previous HBV immunisation or immunise as recommended by the Department of Health's (DH's) September 2002 guidance, *Good Practice Guidelines for Renal Dialysis/Transplantation Units: Prevention and Control of Blood-borne Virus Infection*.[1]

Before DAFB for foreign travel

Risk assessment to be undertaken to determine possible risks. Confirm previous hepatitis B (HBV) immunisation or immunise de novo. Also, test for hepatitis B surface antigen (HBsAg), HCV Ab and anti-HIV if required by overseas unit.

1 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005752

Algorithm for blood-borne virus (BBV) testing following dialysis away from base (DAFB)		
Low risk countries (e.g. UK, Europe,[2] US, Canada, Australia, New Zealand and Japan)	**Rest of the world** **(Intermediate risk e.g. South East Asia, South America, Middle East)**	**High risk countries (e.g. Indian sub-continent, parts of Africa)**
Continue regular testing for HBV/HCV in line with DH guidance for UK units, i.e. testing for HBsAg at least every three months and ideally monthly; testing for HCV Ab every three months; and testing for HIV if indicated by a risk assessment.	Undertake BBV risk assessment.[3] If dialysis abroad considered to have high risk features, move to high risk category. Screen for HBV/HCV on return and every two weeks for two months (the test for HCV should be a sensitive combined HCV Ab/Ag or HCV RNA). Only include HIV (Ag/Ab or HIV RNA) if risk assessment merits.	Test for HBV/HCV on return (the test for HCV should be a sensitive combined HCV Ab/Ag or HCV RNA). Segregate patient and isolate dialysis machine for two months.
Patient does not require segregation when dialysing.	Patient does not require segregation when dialysing once the initial 'on return' tests are known to be negative.	Screen for HBV/HCV every two weeks for two months. Only include HIV if risk assessment merits.
Review transplant status and agree on case-by-case basis on requirement for suspension from transplant list.	Patients who dialyse in intermediate risk countries should remain suspended from the transplant list until the initial serology results for HBsAg, HCV (Ag/Ab or HCV RNA) and HIV (Ag/Ab or HIV RNA) are found to be negative.	Patients who dialyse in high risk units should be suspended from the transplant list for two months and only reactivated when the two-month virology screening results are negative.

2 Local risk assessment may indicate that some European countries may be regarded as intermediate risk.

3 Local risk assessment for individual cases.

Algorithm 2 – ALTERNATIVE VERSION

For units with the diagnostic and organisational facility to implement this algorithm safely

Dialysis away from base (DAFB) – Recommendations for immunisation against hepatitis B virus (HBV) and tests for HBV, hepatitis C virus (HCV) and human immunodeficiency virus (HIV)

Sensitive testing methods

This shortened algorithm is applicable when dialysis units have close access to a virology diagnostic service equipped to provide a prompt turnaround of modern, sensitive testing methods and the dialysis unit itself can ensure rigorous adherence to the specific timing requirements of this algorithm. The safe implementation of the algorithm is entirely dependent on being able to pick up a new infection at an early stage (in effect, as soon as the virus appears in the peripheral blood) when the viral load is low and the risk of onward transmission is also low.

Before DAFB in the UK

Confirm previous HBV immunisation or immunise as recommended by the Department of Health's (DH's) September 2002 guidance, *Good Practice Guidelines for Renal Dialysis/Transplantation Units: Prevention and Control of Blood-borne Virus Infection*.

Before DAFB for foreign travel

Risk assessment to be undertaken. Confirm previous hepatitis B (HBV) immunisation or immunise de novo. Also, test for hepatitis B surface antigen (HBsAg), HCV Ab and anti-HIV if required by overseas unit.

Algorithm 2 – ALTERNATIVE VERSION

Alternative algorithm for blood borne virus (BBV) testing following dialysis away from base (DAFB) For units with the diagnostic and organisational facility to implement this algorithm safely (please see note above on sensitive testing methods)	
Low risk countries (e.g. UK, Europe,[4] US, Canada, Australia, New Zealand and Japan)	**Rest of the world**
Continue regular testing for HBV/HCV in line with DH guidance for UK units, i.e. testing for HBsAg at least every three months and ideally monthly; testing for HCV Ab every three months; and testing for HIV if indicated by a risk assessment.	Test for HBV/HCV on return (the test for HCV should be a sensitive combined HCV Ab/Ag or HCV RNA). Screen for HBV/HCV every week for one month. Only include HIV if risk assessment merits.
Patient does not require isolation/ segregation when dialysing.	Patient does not require segregation when dialysing and will only require segregation if BBV tests are positive.
Review transplant status and agree on case-by-case basis on requirement for suspension from transplant list.	Patients who dialyse in high risk units/ countries should be suspended from the transplant list for two months and only reactivated when the two-month virology screening results are negative.

Important actions before and after dialysing away from base

Importance of infection control practice

DH is aware of lapses in good infection control practice in the UK and elsewhere and it is important that the general principles for safe practice in DH guidance are adhered to. The Code of Practice[5] requires all health and social care organisations to implement appropriate policies for the prevention and control of blood-borne virus (BBV) infection.

4 Local risk assessment may indicate that some European countries may be regarded as intermediate risk.

5 *The Health and Social Care Act 2008, Code of Practice for health and adult social care on the prevention and control of infections and related guidance* (DH, 2009), www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110288

Recommendation – infection control practice

The evidence shows that lapses in good infection control can occur because of the relative rarity of BBV infections in dialysis units, and so there is merit in reinforcing important messages from time to time. There are practical advantages in adopting common infection control practices to prevent the transmission of all BBVs.

Adapted from *Good Practice Guidelines for Renal Dialysis/ Transplantation Units* (2002), Chapter 5.12

Immunisation against hepatitis B

Patients with renal failure remain potentially at risk of HBV infection because of their need for long-term dialysis.

Recommendation – Immunisation of patients with chronic renal failure

Immunisation against HBV is recommended for patients already on haemodialysis or renal transplantation programmes and for other patients with chronic renal failure as soon as it is anticipated they may require these interventions. Immunising all patients on a renal unit will help ensure that if an HBV outbreak occurs, the minimum number of infections will result, and that any breakthrough infections that do occur in immunised patients are unlikely to progress to the chronic carrier state. Use of higher doses of vaccine (e.g. 40 µg) should be considered in all of these patients.[6]

Adapted from *Good Practice Guidelines for Renal Dialysis/ Transplantation Units* (2002), Chapter 6.6

Local risk assessments

There is no national database to provide a definitive categorisation of all dialysis units worldwide. It should be a matter for local assessment between the clinician at the 'Home Unit (Base)' and the patient after dialysis abroad to determine the appropriate risk category.

The importance of local risk assessments on the likelihood of BBV exposure when a patient returns from dialysis abroad cannot be over-emphasised.

6 *Immunisation against infectious disease 2006 – The Green Book* (DH, 2006), p 165, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917

It is essential to have a discussion with the patient, on return from dialysis abroad, about lifestyle activities and the level of BBV safety precautions taken at the 'away' unit, which may have increased their risk of exposure to HBV and HCV transmission, and increase the precautions used accordingly.

HIV testing is recommended only when a risk assessment has identified a potential exposure to HIV.

Recommendation – Local risk assessments

Re-admitted patients who have been dialysed outside the UK or other low risk countries should be tested and found negative for HBsAg and HCV Ag/Ab or HCV RNA before being dialysed in the main unit. A risk assessment of potential BBV exposure should be carried out for all returning patients, and where possible exposure is considered likely, the patient's management should follow the algorithm for high risk countries.

This should include testing for HBsAg every two weeks for two months instead of three months' testing only if using modern sensitive test as indicated in algorithms above.

On return from dialysis abroad, a risk assessment of the likelihood of HIV infection should be conducted, and HIV testing carried out if indicated.

Adapted from *Good Practice Guidelines for Renal Dialysis/ Transplantation Units* (2002), Chapter 7.9 and 7.10

Some examples of important patient questions to include in local risk assessment on return from dialysis abroad:

- While abroad did you have any blood transfusions?
- While abroad did you have any surgery or dental treatment?
- While abroad were you ill, requiring hospital admission?

If so, please specify:

- Were any needles, dialysis lines or dialysers shared between you or any other patients?
- Do you undertake any high risk sexual activity?
- Do you inject any intravenous drugs into yourself?
- Do you have haemophilia?
- Did you have a transplant abroad?

Regular testing of patients for BBV infection

Although all patients should be considered as potentially infected, testing patients for the presence of BBVs is an important part of the strategy for preventing and controlling the spread of infection in renal units.

Recommendation – BBV surveillance policy: regular testing for infection

Patients who are being treated in dialysis units should be tested for HBsAg ideally monthly, but at least every three months. All patients should be tested for HCV antibody every three months. A decision on whether regular testing for HIV antibody is needed should be based on a risk assessment (e.g. presence of HIV cases on the unit or risky foreign travel).

Adapted from *Good Practice Guidelines for Renal Dialysis/ Transplantation Units* (2002), Chapter 7.11

Outbreak of infection

When a new case of BBV infection is detected, enhanced surveillance should be carried out.

Recommendation – Enhanced surveillance policy

Standard protocol for enhanced surveillance following a new case of BBV infection

HBV
The exposed cohort should be tested for HBsAg and those who have not demonstrated anti-HBs levels ≥ 100 mIU/ml in the preceding 12 months should be re-tested weekly for at least three months after the last exposure to the index case. For patients who have previously been immunised and shown to have responded, a booster dose of vaccine should be considered. In non-responders, or where status is unknown, HBIG and an accelerated course of vaccine should be considered.

HCV
The exposed cohort should be tested for HCV RNA by PCR or other molecular methods of similar sensitivity at two-weekly intervals until three months after the last exposure to the index case, particularly if the index case seroconverted while receiving dialysis on the unit (i.e. when (s)he would have had a high viral load during the acute phase of infection).

HIV
Undertake a risk analysis. If the index case seroconverted while receiving dialysis on the unit (i.e. when (s)he would have had a high viral load during the acute phase of infection), consider HIV RNA testing of the exposed cohort by PCR or other molecular tests of similar sensitivity at two-weekly intervals until three months after the last exposure.

Adapted from *Good Practice Guidelines for Renal Dialysis/ Transplantation Units* (2002), Chapter 7.14

Important

The BBV screening intervals should not be confused with the requirement for MRSA screening.

Management of BBV-infected patients

There have been documented cases worldwide of BBV outbreaks in renal units resulting from lapses in good practice. Therefore, units need to take adequate measures to ensure safety.

Recommendation – BBV segregation

Partitioning of segregated areas for BBV-infected patients can be achieved flexibly.

The guidance recommends that in renal units the separate areas for BBV-infected and uninfected patients should ideally be demarcated with clear boundaries, which may include permanent walls or glass partitions, or more adaptable arrangements such as tall, movable and washable screens.

However, because risks of transmission of HCV are lower than for HBV, it is felt that segregation by the use of designated areas separated from those used by uninfected patients should be sufficient for the control of HCV, providing scrupulous attention is paid to basic hygiene such as hand washing between patients.

Adapted from *Good Practice Guidelines for Renal Dialysis/ Transplantation Units* (2002), Chapter 9.12 and 9.5

Review of status on the transplant list when dialysing away from base

Patients who dialyse away from base should have their transplant list status reviewed before and after travelling.

The Kidney Advisory Group of UK Blood and Transplant has agreed the following:

Recommendation – Suspension from transplant list

Patients who are active on the transplant list and who dialyse outside the UK in other low risk countries should have their transplant status reviewed and any requirement for suspension from transplant list agreed on a case-by-case basis.

Patients who dialyse in intermediate risk countries should remain suspended from the transplant list until the initial serology results for HBsAg, HCV (Ag/Ab or HCV RNA) and HIV (Ag/Ab or HIV RNA) are found to be negative.

Patients who dialyse in high risk units should be suspended from the transplant list for two months and only reactivated when the two-month virology screening results are negative.

Working group members

Dr Donal O'Donoghue, Co-chair
National Clinical Director Kidney Care, DH

Professor Brian Duerden CBE, Co-chair
Inspector of Microbiology and Infection Control, DH

Bob Dunn OBE
Patient Advocate
National Kidney Federation
DH Renal Advisory Group

Professor John Feehally
Prof of Renal Medicine, University of Leicester
DH Renal Advisory Group

Dr Colin Geddes
Consultant Nephrologist
Western Infirmary, Glasgow
Renal Association

Professor Will Irving
Chair of DH Advisory Group on Hepatitis, DH

Breeda McManus
Renal Nurse Consultant
Barts and The London NHS Trust
DH Renal Advisory Group

Polly Moseley
DH Renal Advisory Group, Patient

Dr Fortune Ncube
Consultant Epidemiologist
Public Health Medicine, Blood-borne Viruses
Health Protection Agency

Gerry Robb
Blood-borne Viruses, DH Lead

Professor Richard Tedder
Head of BBV Laboratory
Health Protection Agency

Dr Charlie Tomson
Consultant Nephrologist
Southmead Hospital, Bristol
UK Renal Registry

Jennie Wilson
Nurse Consultant
Health Protection Agency

Dr Grahame Woods
Consultant Renal Physician
Salford Royal NHS Foundation Trust

Dr Tim Wreghitt OBE
Regional Microbiologist – East of England
Health Protection Agency

Secretariat
Monica Acheampong
Renal Policy Team, DH

References

Good Practice Guidelines for Renal Dialysis/Transplantation Units: Prevention and Control of Blood-borne Virus Infection, DH, September 2002

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